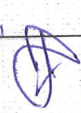
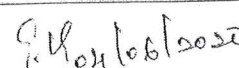
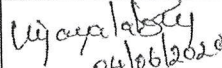
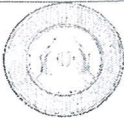
	Safetab Life Science				
	BATCH MANUFACTURING RECORD			Page 1 of 78	
Product:	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg. Date:	07/2020	Exp. Date:	06/2023

BATCH MANUFACTURING RECORD COVER SHEET:

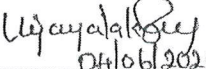
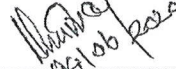
PRODUCT NAME	:	GLIDE M 60/850 TABLETS		
LABEL CLAIM	:	Each uncoated bilayered sustained release tablet contains: Gliclazide BP 60 mg Metformin Hydrochloride BP 850 mg (in sustained release form) Colour: Approved colours are used.		
Pack Size	:	TP: 3x10's blister pack		
Storage Condition	:	Store in a cool and dry place at a temperature not exceeding 30°C. Protect from light and moisture.		
SHELF LIFE	:	24 MONTHS		
CUSTOMER NAME	:	GENERIC		
EFFECTIVE BATCH NUMBER	:	GD200604	DATE:	04/06/20
MANUFACTURING LICENCE No.	:	PON/DRUGS/07 13 1906		
MFG. DATE:	:	07/2020	BMR. No	STBMR: 123/00
EXP. DATE:	:	06/2023	Supersedes BMR. No	Nil
BMR ISSUED BY/DATE (QA)	:	GIL 31/07/20		
BMR CHECKED & RECEIVED BY/DATE (PRODUCTION)	:	 31/08/20		
Allotted By: QA Executive Sign/Date:  31/07/20				
DATE OF COMMENCEMENT:		31/07/20	DATE OF COMPLETION: 31/08/2020	
This BMR contains 78 Pages + 15 Additional Pages				
Checked by Competent Staff Sign/Date:  31/08/20				

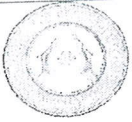
	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/06/2020	 04/06/2020	 04/06/2020	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page 2 of 78	
Product:	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg. Date:	07/2020	Exp. Date:	06/2023

1.0 LIST OF EQUIPMENTS:

S.No	Name of Equipment	Equipment ID No. to be used
1	Dispensing Booth	ST/SRDB/001
2	Balance -30 Kg Capacity	ST/SRWB/001
3	Balance -620 g Capacity	ST/SRWB/002
4	Balance -150 Kg Capacity	ST/WB/189
5	Balance -100 Kg Capacity	ST/PRWB/002
6	Balance - 220g Capacity	ST/WB/202
7	Vibro Sifter	ST/PRG/006
8	Rapid Mixer Granulator	ST/PRG/014
9	Fluid bed drier	ST/PRG/012
10	Multi mill	ST/PRG/009
11	Octagonal blender(2200L)	ST/PROB/001
12	Octagonal blender(600L)	ST/PRG/015
13	Compression Machine	ST/PRCM/001 or ST/PRCM/003 or ST/PRC/004
14	Disintegration Tester	ST/IPDT/002
15	Friability Test Apparatus	ST/IPF/001
16	Hardness Tester	ST/IPHT/004-02
17	Vernier Caliper	ST/IPV/005
18	IR moisture Balance	ST/IPMB/001

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/06/2020	 04/06/2020	 04/06/2020	

	Safetab Life Science				Page 3 of 78	
	BATCH MANUFACTURING RECORD					
Product:	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/RO	Supersedes MFC No:	NIL	
Batch No.:	GD200701	Mfg. Date:	07/2020	Exp. Date:	06/2023	

2.0 DISPENSING:

2.1 LINE CLEARANCE CHECKS:

S.No	CHECKS	Observation	
		store	IPQA
1	Ensure that all empty containers, labels, used Polybags, hand gloves of previous dispensed Product/ batch are removed from the area.	✓	✓
2	Ensure that all dispensed material of previous product / batch removed from the area.	✓	✓
3	Ensure that the previous batch BMR / documents are removed from the area.	✓	✓
4	Check the housekeeping general cleanliness of the floor, walls, ceiling, pass box, doors and door view panels of man and material entry of dispensing area is clean.	✓	✓
5	Check the cleanliness of the working table, cupboard, washing area and waste bin.	✓	✓
6	Check the cleanliness of the drain points.	✓	✓
7	Ensure that the dispensing booth is cleaned and it's status.	✓	✓
8	Check the cleanliness of the supply and return grill.	✓	✓
9	Check the cleanliness of side wall of the dispensing booth.	✓	✓
10	Check the differential pressure of pre filter, intermediate filter and hepa filter are within the limit	✓	✓
11	Check the cleanliness of the utility line (compressed air, First RO water and purified water).	✓	✓
12	Check the cleanliness of the SS side panel and SS Stool.	✓	✓
13	Ensure that the balances are cleaned and it's calibration status.	✓	✓
14	Check the status board of the area is updated.	✓	✓
15	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.	✓	✓
16	Check the differential pressure of the area should be within the limit.	✓	✓
17	Ensure that dispensing tools or accessories like scoops, spoons are cleaned and labeled with "Clean" label.	✓	✓
18	Check proper gowning procedure followed as per the SOP	✓	✓
19	Ensure the concurrent entries of log book.	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (store) sign/date: [Signature] 31/07/20

Verified by (IPQA) sign/date: [Signature] 31/07/20

Equipment	Dispensing Booth	Weighing Balance			AREA
Equipment. ID No.	ST/SRDB/001	ST/SRWB/001 (30.0 Kg)	ST/SRWB/002 (620.0g)	ST/WB/189 (150.0 Kg)	
Previous Product & Batch No.	K510f20m-94-52082004G (CONTINUED)				
Cleaned By	Raghu	Raghu	Raghu	Raghu	Raghu
Checked by Stores Sign/Date	S. V. 31/07/20	S. V. 31/07/20	S. V. 31/07/20	S. V. 31/07/20	S. V. 31/07/20
Counter checked by IPQA/Sign/Date	[Signature] 31/07/20	[Signature] 31/07/20	[Signature] 31/07/20	[Signature] 31/07/20	[Signature] 31/07/20

2.2 ENVIRONMENTAL CONDITIONS:

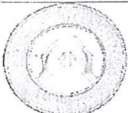
Area: Dispensing	Temperature: 23°C to 27°C	Observation	Stores Sign
		25.1°C	[Signature]
	Relative Humidity 45% to 55 %	Observation	Stores Sign
		53%	[Signature]

2.3 APPROVAL FOR DISPENSING BY IPQA: Sign: [Signature]

Date: 31/07/20

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	<u>[Signature]</u> 04/06/2020	<u>[Signature]</u> 04/06/2020	<u>[Signature]</u> 04/06/2020

CONTROLLED COPY

	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD				Page 4 of 78	
Product:	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	GD200701	Mfg. Date:	07/2020	Exp. Date:	06/2023	

2.4 INDENT OF ACTIVE PHARMACEUTICAL INGREDIENTS (METFORMIN HYDROCHLORIDE PART)

S.No	Name of the Ingredients	Material Code	Label claim per tablet in mg	Spec	Std Qty for 5.0L					Vendor
					Total Qty (Kg)	For LOT I	For LOT II	For LOT III	For LOT IV	
1	Metformin Hydrochloride	RMAM0030	850.000	BP	425.000	106.25	106.25	106.25	106.25	Aarti Drugs

2.4.1 INDENT OF EXCIPIENTS:

S.No	Name of the Ingredients	Material Code	Unit dose per tablet in mg	Spec	Std Qty for 5.0L (Kg)					Vendor
					Total Qty (Kg)	For LOT I	For LOT II	For LOT III	For LOT IV	
2	Hydroxy Propyl Methylcellulose K 100M Premium	RMEM0035	120.000	BP	60.000	15.000	15.000	15.000	15.000	DOW
3	Microcrystalline cellulose powder	RMEM0031	60.000	BP	30.000	7.500	7.500	7.500	7.500	Sigachi
4	Povidone K90	RMEP0045	45.000	BP	22.500	5.625	5.625	5.625	5.625	Haungshan Bonsun Pharmaceuticals
5	Isopropyl Alcohol	RMEI0010	88.000	BP	44.000	11.000	11.000	11.000	11.000	Deepak fertilizers
6	Purified water	RMEP0033	132.000	BP	66.000	16.500	16.500	16.500	16.500	Inhouse

Lubrication

7	Hydroxy Propyl Methylcellulose K 100M Premium	RMEM0035	100.000	BP	50.000	50.000				DOW
8	Magnesium stearate	RMEM0033	5.000	BP	2.500	2.500				Nitika

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	
Signature with Date	<i>S. P. H. 10/06/2020</i>	<i>Ujayaabhi 04/06/2020</i>	<i>10/06/2020</i>	

	Safetab Life Science		MASTER COPY		
	BATCH MANUFACTURING RECORD			Page 5 of 78	
Product:	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg. Date:	07/2020	Exp. Date:	06/2023

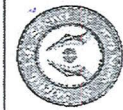
2.5 INDENT OF ACTIVE PHARMACEUTICAL INGREDIENTS (GLICLAZIDE PART)

S.No	Name of the Ingredients	Material Code	Label claim per tablet in mg	Overages %	Spec	Std. Qty. per batch (Kg)	Vendor
1	Gliclazide	RMAG0014	60.000	nil	BP	30.000	KIMIA

2.5.1 INDENT OF EXCIPIENTS:

S.No	Name of the Ingredients	Material Code	Unit dose per tablet in mg	Spec	Std. Qty. per batch (Kg)	Vendor
2	Dicalcium Phosphate	RMED0014	50.500	BP	25.250	India Phosphate
3	Methocel K 100 Premium LVCR	RMEM0036	40.000	BP	20.000	DOW
4	Iron oxide Red	RMEI0004	1.000	USP/NF	0.500	Neelikon
4	Povidone K30	RMEP0049	9.000	BP	4.500	Haungshan Bonsun Pharmaceuticals
5	Methylene dichloride	RMEM0029	100.000	BP	50.000	Chemplast
Blending and Lubrication						
6	Methocel K100 Premium	RMEM0035	10.000	BP	5.000	DOW
7	Colloidal silicone Dioxide	RMEC0017	2.000	BP	1.000	Wacker
8	Purified Talc	RMET0012	5.000	BP	2.500	Neelkanth
9	Magnesium stearate	RMEM0033	2.500	BP	1.250	Nitika

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/06/2020	 04/06/2020	 04/06/2020	



Safetab Life Science

BATCH MANUFACTURING RECORD

Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Product Code:	GD200701	Batch No.:	07/2020	Batch Size:	06/2023

2.6 DISPENSING OF RAW MATERIALS AGAINST RAW MATERIAL INDENT: (METFORMIN HYDROCHLORIDE PART)

Dispensing Started at Date: 31/07/20 Time: 11:45

S.No	Name of the Ingredients	LOT	Actual Qty. per batch (Kg)	A.R No:	Gross Weight (Kg)	Tare Weight (Kg)	Net Weight (Kg)	Weighted By Stores	Checked by stores	Checked by IPQA
1	Metformin Hydrochloride	I	*	MSP/2021/06/10/02/00152	28.100	3.100	25.000	10gms	10gms	10gms
				MSP/2021/06/10/02/00152	22.750	3.300	19.450	10gms	10gms	10gms
				MSP/2021/06/10/02/00268	28.100	3.100	25.000	10gms	10gms	10gms
				MSP/2021/06/10/02/00268	28.100	3.100	25.000	10gms	10gms	10gms
		II	*	MSP/2021/06/10/02/00268	12.916	0.100	12.816	10gms	10gms	10gms
				MSP/2021/06/10/02/00268	28.100	3.100	25.000	10gms	10gms	10gms
				MSP/2021/06/10/02/00268	28.100	3.100	25.000	10gms	10gms	10gms
				MSP/2021/06/10/02/00268	28.100	3.100	25.000	10gms	10gms	10gms
		III	*	MSP/2021/06/10/02/00268	7.366	0.100	7.266	10gms	10gms	10gms
				MSP/2021/06/10/02/00268	28.100	3.100	25.000	10gms	10gms	10gms
				MSP/2021/06/10/02/00268	28.100	3.100	25.000	10gms	10gms	10gms
				MSP/2021/06/10/02/00268	28.100	3.100	25.000	10gms	10gms	10gms
		IV	*	MSP/2021/06/10/02/00268	7.366	0.100	7.266	10gms	10gms	10gms
				MSP/2021/06/10/02/00268	28.100	3.100	25.000	10gms	10gms	10gms
				MSP/2021/06/10/02/00268	28.100	3.100	25.000	10gms	10gms	10gms
				MSP/2021/06/10/02/00268	28.100	3.100	25.000	10gms	10gms	10gms

Designation	Prepared by: QA Executive / Designer	Checked by: Production Head / Designer	Approved by: QA Head / Designer
Signature with Date	G.V. 04/10/2020	Vedapala Reddy 04/10/2020	04/10/2020

CONTROLLED COPY

		Safetab Life Science				MASTER COPY	
		BATCH MANUFACTURING RECORD					
Brand Name	GLIDE M 60/850 TABLETS		Product ID No.:	1014	Batch Size	5,00,000 Tablets	Page No.: 7 of 78
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg		MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	GD200701		Mfg.Date:	07/2020	Exp.Date:	06/2023	

S.No	Name of the Ingredients	LOT	Actual Qty. per batch (kg)	A.R No:	Gross Weight (Kg)	Tare Weight (Kg)	Net Weight (Kg)	Weighted By Stores	Checked by stores	Checked by IPQA
2	Hydroxy Propyl Methylcellulose K 100M Premium	I	15.000	M88/2021/06/06/00135	15.1024	0.100	15.000	15.000	15.000	15.000
		II	15.000	M88/2021/06/06/00135	15.100	0.100	15.000	15.000	15.000	15.000
		III	15.000	M88/2021/06/06/00135	15.100	0.100	15.000	15.000	15.000	15.000
		IV	15.000	M88/2021/06/06/00135	15.100	0.100	15.000	15.000	15.000	15.000
3	Microcrystalline cellulose powder	I	**	M88/2021/06/06/00008	6.5444	0.060	6.4844	6.4844	6.4844	6.4844
		II	**	M88/2021/06/06/00008	6.544	0.060	6.484	6.484	6.484	6.484
		III	**	M88/2021/06/06/00008	6.544	0.060	6.484	6.484	6.484	6.484
		IV	**	M88/2021/06/06/00008	6.544	0.060	6.484	6.484	6.484	6.484

Designation	Prepared by:	Checked by:	Approved By:
	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	G.R. 04/06/2020	Ujwala 04/06/2020	04/06/2020

CONTROLLED COPY



Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.: 8 of 78

Brand Name **GLIDE M 60/850 TABLETS**

Product ID No.: 1014

Batch Size 5,00,000 Tablets

Generic Name: Glliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg

MFC No: ST/MFC/130/R0

Supersedes MFC No: NTL

Batch No.: GD200701

Mfg.Date: 07/2020

Exp.Date: 06/2023

S.No	Name of the Ingredients	LOT	Actual Qty. per batch (Kg)	A.R No:	Gross Weight (Kg)	Tare Weight (Kg)	Net Weight (Kg)	Weighted By Stores	Checked by stores	Checked by IPOA
4	Povidone K90	I	5.625	MSR/2021/06/06/00058	5.685	0.060	5.625	MSR	MSR	MSR
		II	5.625	MSR/2021/06/06/00058	5.685	0.060	5.625	MSR	MSR	MSR
		III	5.625	MSR/2021/06/06/00058	5.685	0.060	5.625	MSR	MSR	MSR
		IV	5.625	MSR/2021/06/06/00058	5.685	0.060	5.625	MSR	MSR	MSR
5	Isopropyl Alcohol	I	11.000	MSR/2021/06/06/00110	13.000	2.000	11.000	MSR	MSR	MSR
		II	11.000	MSR/2021/06/06/00110	13.000	2.000	11.000	MSR	MSR	MSR
		III	11.000	MSR/2021/06/06/00110	13.000	2.000	11.000	MSR	MSR	MSR
		IV	11.000	MSR/2021/06/06/00110	13.000	2.000	11.000	MSR	MSR	MSR

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	G.V. 24/06/2020	MSR/2021/06/06/00110	MSR/2021/06/06/00110

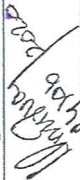
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		Safetab Life Science				
		BATCH MANUFACTURING RECORD				
Brand Name	GLIDE M 60/850 TABLETS		Product ID No.:	1014	Page No.:	9 of 78
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg		MFC NO:	ST/MFC/130/R0	Batch Size	5,00,000 Tablets
Batch No.:	GD200701		Mfg. Date:	07/2020	Supersedes MFC No:	NIL
					Exp. Date:	06/2023

S.No	Name of the Ingredients	Actual Qty. per batch(Kg)	A.R No:	Gross Weight (Kg)	Tare Weight(Kg)	Net Weight(Kg)	Welghed By Stores	Checked by stores	Checked by IPQA
6	Hydroxy Propyl Methy/Cellulose K 100M Premium	50.000	188/2021/06/06/00135	28.300	3.300	25.000	188	188	188
7	Magnesium stearate	2.500	188/2021/06/06/00135	28.300	3.300	25.000	188	188	188
			188/2021/06/06/00121	2.516	0.016	2.500	188	188	188

Dispensing Completed at Date 31/07/20 Time 12.45

[*,**refer calculation]

Designation	Prepared by:	Checked by:	Approved By:
	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	<u>9.18</u> <u>04/06/2020</u>	<u>04/06/2020</u>	 <u>04/06/2020</u>

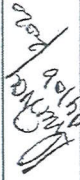
CONTROLLED COPY

		Safetab Life Science				
		BATCH MANUFACTURING RECORD				
Brand Name	GLIDE M 60/850 TABLETS		Product ID No.:	1014	Page No.:	10 of 78
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg		MFC NO:	ST/MFC/130/R0	Batch Size	5,00,000 Tablets
Batch No.:	GD200701	Mfg.Date:	07/2020	Supersededes MFC No:	NIL	
		Exp.Date:	06/2023			

2.7 DISPENSING OF RAW MATERIALS AGAINST RAW MATERIAL INDENT: (GLICLAZIDE PART)

Dispensing Started at Date 31/07/20 Time 12:46

S.No	Name of the Ingredients	Actual Qty. per batch (Kg)	A.R No:	Gross Weight (Kg)	Tare Weight (Kg)	Net Weight (Kg)	Weighted By Stores	Checked by stores	Checked by IPQA
1	Gliclazide	*	MSP/2021/06/06/00191	22.054	2.700	19.354	1935	Sgt.	✓
2	Dicalcium Phosphate	**	MSP/2021/06/06/00263	10.848	0.100	10.748	1074	Sgt.	✓
3	Methocel K100 Premium LVCR	20.000	MSP/2021/06/06/00131	10.100	0.100	10.000	1000	Sgt.	✓
4	Iron oxide Red	0.500	MSP/2021/06/06/00131	15.248	0.100	15.148	1514	Sgt.	✓
5	Povidone K30	4.500	MSP/2021/06/06/00134	23.300	3.300	20.000	2000	Sgt.	✓
6	Methylene dichloride	50.000	MSP/2021/06/06/00134	-	-	-	-	-	-
			MSP/1920/06/06/01048	0.508	0.008	0.500	500	Sgt.	✓
			MSP/1920/06/06/01050	4.560	0.060	4.500	4500	Sgt.	✓
			MSP/2021/06/06/00193	52.000	2.000	50.000	5000	Sgt.	✓

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	G. V. 10/06/2020	Ujwala 04/06/2020	 CONTROLLED COPY



Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.: 11 of 78

Brand Name GLIDE M 60/850 TABLETS

Product ID No.: 1014

Batch Size 5,00,000 Tablets

Generic Name: Glliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg

MFC NO: ST/MFC/130/R0

Supersedes MFC No: NIL

Batch No.: GD200701

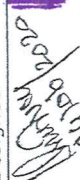
Mfg.Date: 07/2020

Exp.Date: 06/2023

S.No	Name of the Ingredients	Actual Qty. per batch(Kg)	A.R No:	Gross Weight (Kg)	Tare Weight(Kg)	Net Weight(Kg)	Weighted By Stores	Checked by stores	Checked by IPQA
7	Methocel K100 Premium	5.000	NRP/2021/06/106/00135	5.060	0.060	5.000	NRP	NRP	NRP
8	Colloidal silicone Dioxide	1.000	NRP/2021/06/106/00135	1.060	0.060	1.000	NRP	NRP	NRP
9	Purified Talc	2.500	NRP/2021/06/106/00130 NRP/2021/06/106/00214	1.016 1.516	0.016 0.016	1.000 1.500	NRP NRP	NRP NRP	NRP NRP
10	Magnesium stearate	1.250	NRP/2021/06/106/00121	1.266	0.016	1.250	NRP	NRP	NRP

Dispensing Completed at Date 31/07/20 Time 13.30

[*,**refer calculation]

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	G.V. 04/06/2020	Vijayabharathy 04/06/2020	 04/06/2020

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	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	12 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

3.0 CALCULATION:

3.1 Potency calculation for Metformin Hydrochloride :

S.No.	Q.C AR.No. for Metformin Hydrochloride	Expiry Date	Assay of Metformin Hydrochloride On dried basis	LOD %
1	msep/2021/QC/AR/00152	FEB/25	99.6	0.45
2	msep/2021/QC/AR/00268	MAY/25	99.3	0.26

The given quantity is based on 100% Assay on dried basis and without LOD.
Actual quantity to be added is calculated as:

$$\text{Actual qty. of Metformin Hcl} = \frac{850 \times 100 \times 100}{\% \text{ Assay of Metformin Hcl on dried basis} \times (100 - \% \text{ of LOD})} = \text{mg/tablet}$$

$$1) = \frac{8500000}{9915.18} = 857.271 \text{ mg/tablet}, 2) = \frac{8500000}{9904.182} = 858.223 \text{ mg/tablet}$$

$$= 44.450 \text{ Kgs (51850 nos)} + 384.613 \text{ Kgs (448150 nos)}$$

**Quantity of Microcrystalline Cellulose Powder varies based on Assay content of Metformin Hcl for keeping the core tablet weight constant.

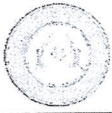
*Qty of Metformin Hcl to be added per batch	= 429.063 Kg's
Lot-I	= 107.266 Kg's
Lot-II	= 107.266 Kg's
Lot-III	= 107.266 Kg's
Lot-IV	= 107.266 Kg's

**Qty of Microcrystalline Cellulose Powder to be added per batch	= 25.937 Kg's
Lot-I	= 6.484 Kg's
Lot-II	= 6.484 Kg's
Lot-III	= 6.484 Kg's
Lot-IV	= 6.484 Kg's

Note: If the assay of Metformin Hcl is more than 100 %, calculation has to be done only for 100%

Calculation done by(store)/date: G.V. 31/07/20 checked by(production)/date: 31/07/20 Verified by(QA)/date: 31/07/20

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	
Signature with Date	<u>G.V. 04/06/2020</u>	<u>Udayakumar 04/06/2020</u>	<u>04/06/2020</u>	

	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD				Page No.:	13 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023	

3.2. Potency calculation for Gliclazide:

S.No.	Q.C AR.No. for Gliclazide	Expiry Date	Assay of Gliclazide	LOD%
1	mgp/2021/06/02/00191	APR/24	100.7	0.10
2	mgp/2021/06/02/00263	MAY/24	99.3	0.07

The given quantity is based on 100% Assay on dried basis and without LOD.
Actual quantity to be added is calculated as:

Actual qty. of Gliclazide = $\frac{60 \times 100 \times 100}{\% \text{ Assay of Gliclazide on dried basis} \times (100 - \% \text{ of LOD})}$ mg/tablet

$$1) = \frac{600000}{99.90} = 60.060 \text{ mg/tablet}, \quad 2) = \frac{600000}{99.23049} = 60.465 \text{ mg/tablet}$$

$$= 19.354 \text{ Kgs} \quad = 10.748 \text{ Kgs}$$

$$(322244 \text{ nos}) \quad + \quad (177756 \text{ nos})$$

Quantity of Dicalcium Phosphate varies based on Assay and LOD of Gliclazide for keeping the core tablet weight constant.

#Qty of Gliclazide = 30.102 Kg's

##Qty of Dicalcium Phosphate = 25.148 Kg's

Note: If the assay of Gliclazide is more than 100 %, calculation has to be done only for 100%.

Calculation done by(store)/date: G. U. S. checked by(production)/date: 31/07/20 Verified by(QA)/date: 31/07/20

	Prepared by:	Checked by:	Approved By:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	<u>G. U. S.</u> 31/07/2020	<u>M. J. S.</u> 31/07/2020	<u>M. J. S.</u> 31/07/2020

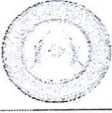
CONTROLLED COPY

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	14 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

4.0 VERIFICATION OF DISPENSED MATERIALS: (METFORMIN HYDROCHLORIDE PART)

S.No	Name of the Ingredients	Lot	Gross weight in Kg	A.R.No.	Checked by Production Sign/Date	Checked by IPQA Sign/Date
1	Metformin HCL	I	28.10	mfp/2021/2021/2021/00152	02/08/20	02/08/20
			28.75	mfp/2021/2021/2021/00152	02/08/20	02/08/20
			28.10	mfp/2021/2021/2021/00268	02/08/20	02/08/20
			28.10	mfp/2021/2021/2021/00268	02/08/20	02/08/20
			12.91	mfp/2021/2021/2021/00268	02/08/20	02/08/20
		II	7.366	mfp/2021/2021/2021/00268	02/08/20	02/08/20
			28.100	mfp/2021/2021/2021/00268	02/08/20	02/08/20
			28.100	mfp/2021/2021/2021/00268	02/08/20	02/08/20
			28.100	mfp/2021/2021/2021/00268	02/08/20	02/08/20
			28.100	mfp/2021/2021/2021/00268	02/08/20	02/08/20
		III	28.100	mfp/2021/2021/2021/00268	02/08/20	02/08/20
			28.100	mfp/2021/2021/2021/00268	02/08/20	02/08/20
			28.100	mfp/2021/2021/2021/00268	02/08/20	02/08/20
			28.100	mfp/2021/2021/2021/00268	02/08/20	02/08/20
			7.366	mfp/2021/2021/2021/00268	02/08/20	02/08/20
		IV	28.10	mfp/2021/2021/2021/00268	02/08/20	02/08/20
			28.10	mfp/2021/2021/2021/00268	02/08/20	02/08/20
			28.10	mfp/2021/2021/2021/00268	02/08/20	02/08/20
			28.10	mfp/2021/2021/2021/00268	02/08/20	02/08/20
			7.366	mfp/2021/2021/2021/00268	02/08/20	02/08/20
2	Hydroxy Propyl methylcellulose K100 Premium	I	15.10	mfp/2021/2021/2021/00136	02/08/20	02/08/20
			15.100	mfp/2021/2021/2021/00136	02/08/20	02/08/20
		II	15.10	mfp/2021/2021/2021/00136	02/08/20	02/08/20
			15.10	mfp/2021/2021/2021/00136	02/08/20	02/08/20
		III	15.10	mfp/2021/2021/2021/00136	02/08/20	02/08/20
			15.10	mfp/2021/2021/2021/00136	02/08/20	02/08/20
		IV	15.10	mfp/2021/2021/2021/00136	02/08/20	02/08/20
			15.10	mfp/2021/2021/2021/00136	02/08/20	02/08/20
3	Microcrystalline cellulose Powder	I	6.54	mfp/2021/2021/2021/00008	02/08/20	02/08/20
			6.53	mfp/2021/2021/2021/00008	02/08/20	02/08/20
		II	6.53	mfp/2021/2021/2021/00008	02/08/20	02/08/20
			6.53	mfp/2021/2021/2021/00008	02/08/20	02/08/20
		III	6.53	mfp/2021/2021/2021/00008	02/08/20	02/08/20
			6.53	mfp/2021/2021/2021/00008	02/08/20	02/08/20
		IV	6.53	mfp/2021/2021/2021/00008	02/08/20	02/08/20
			6.53	mfp/2021/2021/2021/00008	02/08/20	02/08/20

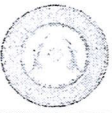
Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
Signature with Date	9.18 04/06/2020	04/06/2020	04/06/2020	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	15 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

S.No	Name of the Ingredients	Lot	Gross weight in Kg	A.R.No.	Checked by Production Sign/Date	Checked by IPQA Sign/Date
4	Povidone K90	I	5.68	mep/2021/aw/aw/00058	Kailash	Cholash
			NA	NA	NA	NA
		II	5.68	mep/2021/aw/aw/00058	Kailash	Kailash
			NA	NA	NA	NA
		III	5.68	mep/2021/aw/aw/00058	Kailash	Kailash
			NA	NA	NA	NA
		IV	5.68	mep/2021/aw/aw/00058	Kailash	Kailash
			NA	NA	NA	NA
5	Isopropyl Alcohol	I	13.00	mep/2021/aw/aw/00110	Kailash	Cholash
			NA	NA	NA	NA
		II	13.00	mep/2021/aw/aw/00110	Kailash	Kailash
			NA	NA	NA	NA
		III	13.00	mep/2021/aw/aw/00110	Kailash	Kailash
			NA	NA	NA	NA
		IV	13.00	mep/2021/aw/aw/00110	Kailash	NA
			NA	NA	NA	NA
6	Hydroxy Propyl methylcellulose K100 Premium		28.30	mep/2021/aw/aw/00135	Kailash	Kailash
			28.30	mep/2021/aw/aw/00135	Kailash	Kailash
			NA	NA	NA	NA
7	Magnesium stearate		1.2	NA	NA	NA
			2.51	mep/2021/aw/aw/00121	Kailash	Kailash
			NA	NA	NA	NA
8	Purified water		NA	NA	NA	NA

Note: Check the weight of the dispensed material, if found satisfactory, then proceeds to next stage, if any discrepancy inform to QA head for further instruction

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	S. V. 04/06/2020	Ujaya 04/06/2020	04/06/2020	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	16 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

4.1 VERIFICATION OF DISPENSED MATERIALS (GLICLAZIDE PART): Date: 01/08/20

S.No	Name of the Ingredients	Gross weight in Kg	A.R.No	Checked by Production Sign/Date	Checked by IPQA Sign/Date
1	Gliclazide	22.05	mSP/2021/QU/QU/00191	01/08/20	01/08/20
		10.85	mSP/2021/QU/QU/00263	01/08/20	01/08/20
2	Dicalcium Phosphate	10.10	mSP/2021/QU/QU/00131	01/08/20	01/08/20
		15.25	mSP/2021/QU/QU/00131	01/08/20	01/08/20
3	Methocel K100 LVCR	23.30	mSP/2021/QU/QU/00134	01/08/20	01/08/20
			N.D		NA
4	Iron oxide Red	0.51	mSP/1920/QU/QU/01048	01/08/20	01/08/20
			N.D		NA
5	Povidone K30	4.56	mSP/1920/QU/QU/01250	01/08/20	01/08/20
			N.D		NA
6	Methylene Dichloride	52.00	mSP/2021/QU/QU/00192	01/08/20	01/08/20
			N.D		NA
7	Methocel K100M Premium	5.06	mSP/2021/QU/QU/00135	01/08/20	01/08/20
			N.D		NA
8	Colloidal Silicon Dioxide	1.06	mSP/2021/QU/QU/00133	01/08/20	01/08/20
			N.D		NA
9	Purified Talc	1.01	mSP/2021/QU/QU/00130	01/08/20	01/08/20
		1.51	mSP/2021/QU/QU/00244	01/08/20	01/08/20
10	Magnesium Stearate	1.26	mSP/2021/QU/QU/00121	01/08/20	01/08/20
			N.D		NA

Note: Check the weight of the dispensed material, if found satisfactory, then proceeds to next stage, if any discrepancy inform to QA head for further instruction.

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>[Signature]</u> 04/06/2020	<u>[Signature]</u> 04/06/2020	<u>[Signature]</u> 04/06/2020	

	Safetab Life Science				CONTROLLED COPY	
	BATCH MANUFACTURING RECORD				Page No.:	17 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023	

5.0 GRANULATION (METFORMIN HCL PART):

5.1 LINE CLEARANCE CHECKS:

S.No	Check	Observation	
		Production	IPQA
1	Ensure that all empty containers, labels, used polybags, hand gloves of previous Product/ batch are removed from the area.	✓	✓
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.	✓	✓
3	Ensure that the previous batch BMR/documents are removed from the area.	✓	✓
4	Check the housekeeping general cleanliness of the floor, walls ceiling, tube light fixture, supply grills, riser grills, filters and electrical fixtures are clean.	✓	✓
5	Check the cleanliness of the doors, door view panel, SOP stand and compressed air filter outer surface.	✓	✓
6	Check for absence of previous batch/product from area below machine and inside the vessel.	✓	✓
7	Check whether the equipment body of Sifter, RMG, FBD and Multimill, Utensils are clean.	✓	✓
8	Ensure that the balances are cleaned and it's calibration status.	✓	✓
9	Check whether the Equipments/ Instruments to be used are within calibration/preventive maintenance due date.	✓	✓
10	Check the cleanliness of the utility line (compressed air, First RO water and purified water).	✓	✓
11	Check the cleanliness of the drain points.	✓	✓
12	Check the status board of the area is updated.	✓	✓
13	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.	✓	✓
14	Check the differential pressure of the area should be within the limit	✓	✓
15	Ensure the concurrent entries of log book.	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (Production) sign/date: *[Signature]* 02/06/20
Verified by (IPQA) sign/date: *[Signature]* 02/06/20

Equipment	Vibro sifter	Multimill	FBD	RMG	Balance
Equipment ID No:	ST/PRG/006	ST/PRG/010	ST/PRG/012	ST/PRG/014	ST/PRWB/002
Previous Product:	Glide m 60/850 (G)				
Batch No.	GD 200701				
Cleaned by:	Suresh				
Checked by:	Production:	IPQA:			

5.2 ENVIRONMENTAL CONDITIONS	Date: 02/06/20	Time: 06:05	Date:	Time:
	Observation	Production Sign	Observation	Production Sign
Temperature: 23°C to 27°C	24.5°C	✓		
Relative Humidity: 45% to 55 %	57 %	✓		

5.3 APPROVAL FOR SIFTING:

Production Sign/Date: *[Signature]* 02/06/20
IPQA Sign/Date: *[Signature]* 02/06/20

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	<i>[Signature]</i> 04/06/2020	<i>[Signature]</i> 04/06/2020	<i>[Signature]</i> 04/06/2020

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	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	18 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO.:	ST/MFC/130/R0	Supersedes MFC No.:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

5.4 SIFTING INSTRUCTIONS:

Date: 02/08/20

S. NO	PROCESS INSTRUCTIONS
1	Check the cleanliness of the Vibro Sifter.
2	Use hand gloves while handling the materials.
3	Carryout the sifting operation as per current version of SOP.
4	Check the integrity of sieve before and after sifting and record in the BMR.
5	Collect sifted materials in cleaned containers in polythene bag.

5.5 SIFTING RECORD (LOT-I):

S. No	Name of Ingredient	Mesh size of sieve	Integrity checked before use	Integrity checked after use	Checked By/Date
1	Metformin Hydrochloride	12#	OK/ Not OK	OK/ Not OK	02/08/20
2	Hydroxy Propyl Methyl Cellulose (Methocel K 100 Premium)	30#	OK/ Not OK	OK/ Not OK	02/08/20
3	Microcrystalline Cellulose Powder	30#	OK/ Not OK	OK/ Not OK	02/08/20

Note: If any discrepancy found, Initiate the deviation for corrective and preventive action and proceed to next step after QA approval.

5.6 MANUFACTURING PROCESS (LOT-I):

Step No.	Process Instructions	Date : 02/08/20		Done By	Checked by/Date
		Time			
		Started	Completed		
5.6.1	Sifting: Sift Metformin Hydrochloride through 12# (If required de-lump Metformin using co-mill or RMG) and HPMC K100 premium, Microcrystalline Cellulose powder through 30#, on a vibratory sifter.	06:15	06:30	Suresh	02/08/20
5.6.2	Binder preparation: Mix 11.000Kg of Isopropyl Alcohol and 16.500Kg of Purified Water.	06:20	06:25	Vignesh	02/08/20
	Filter the solution through 100# nylon cloth.	06:26	06:30	Vignesh	02/08/20
5.6.3	Dry mixing: Load the above sifted material of Step 5.6.1 into RMG	06:31	06:35	Suresh	02/08/20
	Mix for 10 minutes at slow speed of impeller.	06:36	06:46	Suresh	02/08/20
5.6.4	Granulation: Granulate the powder of Step 5.6.3 with binder solution of Step 5.6.2 by following steps	06:46	-	-	-

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	S.V. 04/06/2020	Udaya Lal 04/06/2020	04/06/2020	

	Safetab Life Science		MASTER COPY		
	BATCH MANUFACTURING RECORD		Page No.:	19 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO.:	ST/MFC/130/R0	Supersedes MFC No.:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

Step No.	Process Instructions	Date : 02/08/20		Done By	Checked by/Date
		Time			
		Started	Completed		
5.6.4	Binder addition: 2 minutes mixing –impellers slow/chopper off.	06:48	06:50	Sureeh	02/08/20
	Racking	06:51	06:52	Sureeh	02/08/20
	Mixing time: 1 minutes at slow impeller/chopper at fast speed.	06:53	06:54	Sureeh	02/08/20
	Racking	06:55	06:56	Sureeh	02/08/20
	Discharge the wet granules in FBD bowl for drying.	06:57	07:00	Sureeh	02/08/20

5.7 DRYING (LOT-I):

Step No	Instructions	Done by	Checked by/Date
1	Use hand gloves, nose mask while handling the materials.		
2	Check the cleanliness of the FBD.		
3	Carry out drying operation as per SOP.	Sureeh	02/08/20

5.7.1 DRYING AND SIZING DETAILS (LOT-I):

Step	Process	Start Time	End Time	Outlet Temperature	Done by	Checked by/date
1	Air dries the wet granules for 10 minutes with intermittent racking.	07:05	07:15	36°C	Sureeh	02/08/20
2	Steam Drying at 60°C ±5°C with intermittent racking at every 15mins until LOD reaches the limit 1.5% to 2.5%.	07:20	08:10	41°C	Sureeh	02/08/20
3	LOD (Limit: 1.5% to 2.5%): On IR moisture balance at 105°C (Auto mode).	Observed LOD: 2.46%			Sureeh	02/08/20
4	Pass the dried granules through mesh 20#.	08:15	08:30		Nigam	02/08/20
	Mesh integrity checks.	Before use	After use		Nigam	02/08/20
		OK/Not OK	OK/Not OK		Nigam	02/08/20
5	Mill the retained dried granules in 2.0 mm screen and pass through 20#.	08:31	08:45		Nigam	02/08/20
	Mesh integrity checks.	Before use	After use		Nigam	02/08/20
		OK/Not OK	OK/Not OK		Nigam	02/08/20

	Prepared by:	Checked by:	Approved By:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	G. P. 04/06/2020	Nigam 04/06/2020	Nigam 04/06/2020

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	Safetab Life Science			BATCH MANUFACTURING RECORD	
				Page No.:	20 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

5.8 DRIED GRANULES WEIGHT RECORD (LOT-I):

Container No	Gross weight (kg)	Tare weight (kg)	Net weight (kg)	Weighed By	Checked By/ Date
1	33.81	0.16	33.65	Q. Srinan	02/08/20
2	34.86	0.16	34.70	Q. Srinan	02/08/20
3	31.76	0.16	31.60	Q. Srinan	02/08/20
4	34.46	0.16	34.30	Q. Srinan	02/08/20
5			NA		
Total weight of dried granules (kg):			134.25		02/08/20

5.9 SIFTING RECORD (LOT-II):

S. No	Name of Ingredient	Mesh size of sieve	Integrity checked before use	Integrity checked after use	Checked By/Date
1	Metformin Hydrochloride	12#	OK/ Not OK	OK/ Not OK	02/08/20
2	Hydroxy Propyl Methyl Cellulose (Methocel K 100 Premium)	30#	OK/ Not OK	OK/ Not OK	02/08/20
3	Microcrystalline Cellulose Powder	30#	OK/ Not OK	OK/ Not OK	02/08/20

Note: If any discrepancy found, Initiate the deviation for corrective and preventive action and proceed to next step after QA approval.

5.10 MANUFACTURING PROCESS (LOT-II):

Step No.	Process Instructions	Date : 02/08/20		Done By	Checked by/Date
		Time			
		Started	Completed		
5.10.1	Sifting; Sift Metformin Hydrochloride through 12# (If required de-lump Metformin using co-mill or RMG) and HPMC K100 premium, Microcrystalline Cellulose powder through 30#, on a vibratory sifter.	06:45	07:00	Srinan	02/08/20
5.10.2	Binder preparation: Mix 11.000Kg of Isopropyl Alcohol and 16.500Kg of Purified Water.	06:50	06:55	Srinan	02/08/20
	Filter the solution through 100# nylon cloth.	06:56	07:00	Srinan	02/08/20
5.10.3	Dry mixing: Load the above sifted material of Step 5.10.1 into RMG	07:01	07:04	Srinan	02/08/20
	Mix for 10 minutes at slow speed of impeller.	07:05	07:15	Srinan	02/08/20
5.10.4	Granulation: Granulate the powder of Step 5.10.3 with binder solution of Step 5.10.2 by following steps	-	-	-	-

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	9.4/04/06/2020	Uyayalabey 04/06/2020	10/04/06/2020

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	Safetab Life Science			BATCH MANUFACTURING RECORD	
				Page No.:	21 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO.:	ST/MFC/130/R0	Supersedes MFC No.:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

Step No.	Process Instructions	Date : 02/08/20		Done By	Checked by/Date
		Time			
		Started	Completed		
5.10.4	Binder addition: 2 minutes mixing –impellers slow/chopper off.	07:15	07:17	Vijesh	02/08/20
	Racking	07:15	07:17		
		07:18	07:19	Vijesh	02/08/20
	Mixing time: 1 minutes at slow impeller/chopper at fast speed.	07:20	07:21	Vijesh	02/08/20
	Racking	07:22	07:23	Vijesh	02/08/20
	Discharge the wet granules in FBD bowl for drying.	07:24	07:26	Vijesh	02/08/20

5.11 DRYING (LOT-II):

Step No	Instructions	Done by	Checked by/Date
1	Use hand gloves, nose mask while handling the materials.		
2	Check the cleanliness of the FBD.		
3	Carry out drying operation as per SOP.	Suresh	02/08/20

5.11.1 DRYING AND SIZING DETAILS (LOT-II):

Step	Process	Start Time	End Time	Outlet Temperature	Done by	Checked by/date
1	Air dries the wet granules for 10 minutes with intermittent racking.	08:15	08:25	32°C	Suresh	02/08/20
2	Steam Drying at 60°C ±5°C with intermittent racking at every 15mins until LOD reaches the limit 1.5% to 2.5%.	08:30	09:15	45°C	Suresh	02/08/20
3	LOD (Limit: 1.5% to 2.5%): On IR moisture balance at 105°C (Auto mode).	Observed LOD: 2.30%			Suresh	02/08/20
4	Pass the dried granules through mesh 20#.	09:20	09:40		Shyam	02/08/20
	Mesh integrity checks.	Before use OK/ Not OK	After use OK/ Not OK		Shyam	02/08/20
5	Mill the retained dried granules in 2.0 mm screen and pass through 20#.	09:41	09:55		Shyam	02/08/20
	Mesh integrity checks.	Before use OK/ Not OK	After use OK/ Not OK		Shyam	02/08/20

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
Signature with Date	G. V. 04/06/2020	U. V. 04/06/2020	04/06/2020	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	22 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

5.12 DRIED GRANULES WEIGHT RECORD (LOT-II):

Container No	Gross weight (kg)	Tare weight (kg)	Net weight (kg)	Weighed By	Checked By/ Date
1	31.76	0.16	31.60	Nugeen	* 02/08/20
2	34.86	0.16	34.70	Nugeen	* 02/08/20
3	32.76	0.16	32.60	Nugeen	* 02/08/20
4	35.46	0.16	35.30	Nugeen	* 02/08/20
5					
Total weight of dried granules (kg):			134.20		

5.13 SIFTING RECORD (LOT-III):

S. No	Name of Ingredient	Mesh size of sieve	Integrity checked before use	Integrity checked after use	Checked By/Date
1	Metformin Hydrochloride	12#	OK/ Not OK	OK/ Not OK	* 02/08/20
2	Hydroxy Propyl Methyl Cellulose (Methocel K 100 Premium)	30#	OK/ Not OK	OK/ Not OK	* 02/08/20
3	Microcrystalline Cellulose Powder	30#	OK/ Not OK	OK/ Not OK	* 02/08/20

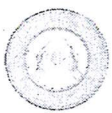
Note: If any discrepancy found, Initiate the deviation for corrective and preventive action and proceed to next step after QA approval.

5.14 MANUFACTURING PROCESS (LOT-III):

Step No.	Process Instructions	Date : 02/08/20		Done By	Checked by/Date
		Time			
		Started	Completed		
5.14.1	Sifting; Sift Metformin Hydrochloride through 12# (If required de-lump Metformin using co-mill or RMG) and HPMC K100 premium, Microcrystalline Cellulose powder through 30#, on a vibratory sifter.	07:30	07:45	Juvon	02/08/20
5.14.2	Binder preparation: Mix 11.000Kg of Isopropyl Alcohol and 16.500Kg of Purified Water.	07:40	07:45	Sureeh	02/08/20
	Filter the solution through 100# nylon cloth.	07:46	08:00	Sureeh	02/08/20
5.14.3	Dry mixing: Load the above sifted material of Step 5.14.1 into RMG	08:01	08:04	Sureeh	02/08/20
	Mix for 10 minutes at slow speed of impeller.	08:05	08:15	Sureeh	02/08/20
5.14.4	Granulation: Granulate the powder of Step 5.14.3 with binder solution of Step 5.14.2 by following steps	-	-	-	-

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	G.12 04/06/2020	W. Jayalakshy 04/06/2020	04/06/2020

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	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	23 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

Step No.	Process Instructions	Date : 02/08/20		Done By	Checked by/Date
		Time			
		Started	Completed		
5.14.4	Binder addition: 2 minutes mixing –impellers slow/chopper off.	08:16	08:18	Vuom	02/08/20
	Racking	08:19	08:20	Vuom	02/08/20
	Mixing time: 1 minutes at slow impeller/chopper at fast speed.	08:21	08:22	Vuom	02/08/20
	Racking	08:23	08:24	Vuom	02/08/20
	Discharge the wet granules in FBD bowl for drying.	08:25	08:30	Vuom	02/08/20

5.15 DRYING (LOT-III):

Step No	Instructions	Done by	Checked by/Date
1	Use hand gloves, nose mask while handling the materials.		
2	Check the cleanliness of the FBD.		
3	Carry out drying operation as per SOP.	Suregh	02/08/20

5.15.1 DRYING AND SIZING DETAILS (LOT-III):

Step	Process	Start Time	End Time	Outlet Temperature	Done by	Checked by/date
1	Air dries the wet granules for 10 minutes with intermittent racking.	09:20	09:30	36 L	Suregh	02/08/20
2	Steam Drying at 60° C±5°C with intermittent racking at every 15mins until LOD reaches the limit 1.5%to 2.5%.	09:40	10:15	41 L	Suregh	02/08/20
3	LOD (Limit: 1.5% to 2.5%): On IR moisture balance at 105°C (Auto mode).	Observed LOD: 2.36%			Sisran	02/08/20
4	Pass the dried granules through mesh 20#.	10:20	10:35		Sisran	02/08/20
	Mesh integrity checks.	Before use OK/ Not-OK	After use OK/ Not-OK		Sisran	02/08/20
5	Mill the retained dried granules in 2.0 mm screen and pass through 20#.	10:37	10:55		Sisran	02/08/20
	Mesh integrity checks.	Before use OK/ Not-OK	After use OK/ Not-OK		Sisran	02/08/20

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	9.12 04/06/2020	Wajayale 04/06/2020	11/06/2020	CONTROLLED COPY

	Safetab Life Science			CONTROLLED COPY	
	BATCH MANUFACTURING RECORD			Page No.:	24 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

5.16 DRIED GRANULES WEIGHT RECORD (LOT-III):

Container No	Gross weight (kg)	Tare weight (kg)	Net weight (kg)	Weighed By	Checked By/ Date
1	34.76	0.16	34.60	Suresh	02/08/20
2	31.86	0.16	31.70	Suresh	02/08/20
3	32.56	0.16	32.80	Suresh	02/08/20
4	35.36	0.16	35.20	Suresh	02/08/20
5					
Total weight of dried granules (kg):			134.30		02/08/20

5.17 SIFTING RECORD (LOT-IV):

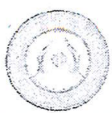
S. No	Name of Ingredient	Mesh size of sieve	Integrity checked before use	Integrity checked after use	Checked By/Date
1	Metformin Hydrochloride	12#	OK/ Not OK	OK/ Not OK	02/08/20
2	Hydroxy Propyl Methyl Cellulose (Methocel K 100 Premium)	30#	OK/ Not OK	OK/ Not OK	02/08/20
3	Microcrystalline Cellulose Powder	30#	OK/ Not OK	OK/ Not OK	02/08/20

Note: If any discrepancy found, Initiate the deviation for corrective and preventive action and proceed to next step after QA approval.

5.18 MANUFACTURING PROCESS (LOT-IV):

Step No.	Process Instructions	Date : 02/08/20		Done By	Checked by/Date
		Time			
		Started	Completed		
5.18.1	Sifting; Sift Metformin Hydrochloride through 12# (If required de-lump Metformin using co-mill or RMG) and HPMC K100 premium, Microcrystalline Cellulose powder through 30#, on a vibratory sifter.	08:30	08:45	Vinoth	02/08/20
5.18.2	Binder preparation: Mix 11.000Kg of Isopropyl Alcohol and 16.500Kg of Purified Water.	08:40	08:45	Vinoth	02/08/20
	Filter the solution through 100# nylon cloth.	08:47	08:55	Suresh	02/08/20
5.18.3	Dry mixing: Load the above sifted material of Step 5.18.1 into RMG	08:46	08:49	Suresh	02/08/20
	Mix for 10 minutes at slow speed of impeller.	08:50	09:00	Suresh	02/08/20
5.18.4	Granulation: Granulate the powder of Step 5.18.3 with binder solution of Step 5.18.2 by following steps	-	-	-	-

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
Signature with Date	G. U. 04/06/2020	Vijayalakshmi 04/06/2020	M. Suresh 04/06/2020	

	Safetab Life Science				
	BATCH MANUFACTURING RECORD			Page No.:	25 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC No.:	ST/MFC/130/R0	Supersedes MFC No.:	NIL
Batch No.:	GD200701	Mfg. Date:	07/2020	Exp. Date:	06/2023

Step No.	Process Instructions	Date : 02/08/20		Done By	Checked by/Date
		Time			
		Started	Completed		
5.18.4	Binder addition: 2 minutes mixing –impellers slow/chopper off.	09:05	09:07	Vijesh	02/08/20
	Racking	09:08	09:09	Vijesh	02/08/20
	Mixing time: 1 minutes at slow impeller/chopper at fast speed.	09:10	09:11	Vijesh	02/08/20
	Racking	09:12	09:13	Vijesh	02/08/20
	Discharge the wet granules in FBD bowl for drying.	09:14	09:18	Vijesh	02/08/20

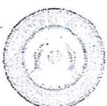
5.19 DRYING (LOT-IV):

Step No	Instructions	Done by	Checked by/Date
1	Use hand gloves, nose mask while handling the materials.		
2	Check the cleanliness of the FBD.		
3	Carry out drying operation as per SOP.	Vijesh	02/08/20

5.19.1 DRYING AND SIZING DETAILS (LOT-IV):

Step	Process	Start Time	End Time	Outlet Temperature	Done by	Checked by/date
1	Air dries the wet granules for 10 minutes with intermittent racking.	10:30	10:40	36°C	Vijesh	02/08/20
2	Steam Drying at 60°C ±5°C with intermittent racking at every 15mins until LOD reaches the limit 1.5% to 2.5%.	10:45	11:30	42°C	Vijesh	02/08/20
3	LOD (Limit: 1.5% to 2.5%): On IR moisture balance at 105°C (Auto mode).	Observed LOD: 2.40%			Vijesh	02/08/20
4	Pass the dried granules through mesh 20#.	11:35	11:50		Vijesh	02/08/20
	Mesh integrity checks.	Before use OK/Not OK	After use OK/Not OK		Vijesh	02/08/20
5	Mill the retained dried granules in 2.0 mm screen and pass through 20#.	11:55	12:05		Vijesh	02/08/20
	Mesh integrity checks.	Before use OK/Not OK	After use OK/Not OK		Vijesh	02/08/20

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	G. V. 04/06/2020	Vijayakumar 04/06/2020	Vijesh 04/06/2020	

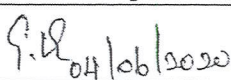
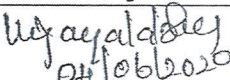
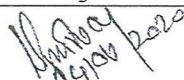
	Safetab Life Science			MASTER COPY	
				BATCH MANUFACTURING RECORD	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Page No.:	26 of 78
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

5.20 DRIED GRANULES WEIGHT RECORD (LOT-IV):

Container No	Gross weight (kg)	Tare weight (kg)	Net weight (kg)	Weighed By	Checked By/ Date
1	39.76	0.16	39.60	Suresh	* 02/08/20
2	32.76	0.16	32.60	Suresh	* 02/08/20
3	33.88	0.16	33.72	Suresh	* 02/08/20
4	28.51	0.16	28.35	Suresh	* 02/08/20
5					
Total weight of dried granules (kg):			134.25		

5.21 YIELD OF DRIED GRANULES:

1.0	Weight of total material added in granulation.	:	537.50	Kg
2.0	Weight of dried granules.	:	537.00	Kg
3.0	Yield (NLT 99.50%) {2.0 / 1.0 x 100}	:	99.90	%

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/06/2020	 04/06/2020	 04/06/2020	

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BATCH MANUFACTURING RECORD			Page No.:	27 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/RO	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

6.0 BLENDING AND LUBRICATION:

6.1 LINE CLEARANCE CHECKS:

Date: 03/08/20

S.No	Checks	Observation	
		production	IPQA
1	Ensure that all empty containers, used polybags, labels, hand gloves of previous Product/ batch are removed from the area.	✓	✓
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.	✓	✓
3	Ensure that the previous batch BMR / documents are removed from the area.	✓	✓
4	Check the housekeeping general cleanliness of the floor, walls ceiling, tube light fixture, supply grills, riser grills, filters and electrical fixtures are clean.	✓	✓
5	Check the cleanliness of the doors, door view panel and SOP stand.	✓	✓
6	Check the cleanliness of the utility line (compressed air, First RO water and purified water).	✓	✓
7	Check the cleanliness of the drain points.	✓	✓
8	Check for absence of previous batch/product from area below machine and inside machine by opening the guards of Octagonal blender.	✓	✓
9	Check whether the machine body and control panel of octagonal blender is clean.	✓	✓
10	Ensure that the balances are cleaned and it's calibration status.	✓	✓
11	Check whether the Equipments/ Instruments to be used are within calibration/preventive maintenance due date.	✓	✓
12	Check the status board of the area is updated with cleaned label.	✓	✓
13	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.	✓	✓
14	Check the differential pressure of the area should be within the limit.	✓	✓
15	Ensure the concurrent entries of log book.	✓	✓
16	Check the functioning and cleaning of return riser.	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (production) sign/date: *[Signature]* 03/08/20

Verified by (IPQA) sign/date: *[Signature]* 03/08/20

Equipment	Octagonal blender (2200L)	
Code No	ST/PROB/001	
Previous product	Litscold PLY. Tablets	
Batch No	GD 200705	
Cleaned by:	Ray's	
Checked by:	Production: <i>[Signature]</i> 03/08/20	IPQA: <i>[Signature]</i> 03/08/20

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<i>[Signature]</i> 04/06/2020	<i>[Signature]</i> 04/06/2020	<i>[Signature]</i> 04/06/2020	

	Safetab Life Science			03/08/20	
	BATCH MANUFACTURING RECORD			Page No.:	28 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

6.2 ENVIRONMENTAL CONDITIONS:	Date: 03/08/20	Time: 18:00	Date:	Time:
	Observation	Production Sign	Observation	Production Sign
Temperature: 23°C to 27°C	24.75			
Relative Humidity: 45% to 55 %	51%			
6.3 APPROVAL FOR BLENDING AND LUBRICATION:				
Production Sign/Date: 03/08/20		IPQA Sign/Date: 03/08/20		

6.4 BLENDING AND LUBRICATION INSTRUCTION:

Step No	Process Instructions	Date: 03/08/20		Done by	Checked by/date
		Time			
		Started	Completed		
1	Use hand gloves, nose mask while handling the materials.				
2	Operate the Octagonal Blender as per the current version of the SOP.				
3	Sift HPMC K 100 M premium through 40# Load the sifted dried granules of Lot-I, Lot-II, Lot III and Lot IV to the Octagonal blender.	18:10	18:25	Veeromai	03/08/20
4	Mix for 15 minutes.	18:30	18:45	Veeromai	03/08/20
5	Sift Magnesium Stearate through 60# and Distribute / sprinkle over the blended material.	18:47	18:58	Veeromai	03/08/20
6	Mix for 5 minutes.	19:05	19:10	Veeromai	03/08/20
7	Unload the final blend into suitable containers lined with double polythene bag with proper status label.	19:15	19:40	Veeromai	03/08/20
8	Record the weight in below table.				

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	9.8 04/06/2020	Ujayaal 04/06/2020	04/06/2020	

	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD				Page No.:	29 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023	

6.5 WEIGHING OF FINAL BLEND:

Date: 03/08/20

Container No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by/date	Container No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by/date
✓ 1	47.29	2.50	44.79	Veeramani	03/08/20	31					
✓ 2	42.77	2.50	40.27	Veeramani	03/08/20	32					
✓ 3	41.94	2.50	39.44	Veeramani	03/08/20	33					
✓ 4	55.77	2.50	53.27	Veeramani	03/08/20	34					
✓ 5	36.80	2.50	34.30	Veeramani	03/08/20	35					
✓ 6	36.06	2.50	33.56	Veeramani	03/08/20	36					
✓ 7	50.15	2.50	47.65	Veeramani	03/08/20	37					
✓ 8	33.24	2.50	30.74	Veeramani	03/08/20	38					
✓ 9	45.09	2.50	42.59	Veeramani	03/08/20	39					
✓ 10	40.10	2.50	37.60	Veeramani	03/08/20	40					
✓ 11	46.60	2.50	44.10	Veeramani	03/08/20	41					
✓ 12	37.43	2.50	34.93	Veeramani	03/08/20	42					
✓ 13	38.00	2.50	35.50	Veeramani	03/08/20	43					
✓ 14	31.87	2.50	29.37	Veeramani	03/08/20	44					
✓ 15	43.39	2.50	40.89	Veeramani	03/08/20	45					
16						46					
17						47					
18						48					
19						49					
20						50					
21						51					
22						52					
23						53					
24						54					
25						55					
26						56					
27						57					
28						58					
29						59					
30						60					

Total weight of Lubricated granules:

589.00 kg

Intimate IPQA to draw the sample

Sample withdrawn by IPQA.

Production Sign: [Signature] Date: 03/08/20

IPQA Sign: [Signature] Date: 03/08/20

Send Test request form for testing lubricated granules to QC department.

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	<u>[Signature]</u> 04/06/2020	<u>[Signature]</u> 04/06/2020	<u>[Signature]</u> 04/06/2020

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	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD				Page No.:	30 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023	

7.0 RECONCILIATION:

1.0	Theoretical weight of blend	:	590.000 Kg
2.0	Actual weight of blend	:	589.00 Kg
3.0	Manufacturing Loss (1.0 – 6.0)	:	0.70 Kg
4.0	In-process samples	:	
	A IPQA Samples	:	0. – Kg
	B QC Samples	:	0.05 Kg
	C Validation Samples	:	0.25 Kg
5.0	Total samples: (A + B + C)	:	0.30 Kg
6.0	Total: (2.0+5.0)	:	589.30 Kg
7.0	% Yield = $\frac{6.0}{1.0} \times 100$ (Limit- NLT 99.00%)*	:	99.88 %
If yield is out of limit, raise deviation and inform to QA. After QA, investigation and approval proceed to the next stage.			

*Tentative limit

Total rejects destroyed: 0.70 Kg. Done by Production sign/Date: 02/08/20 Checked by IPQA sign/Date: 03/08/20

(Rejected materials should be destroyed in the presence of QA)

Yield reconciliation done by Production sign/Date: 03/08/20 Checked by IPQA sign/Date: 03/08/20

7.1 BLENDED GRANULES RELEASED FOR COMPRESSION:

Reconciliation checked and blended granules released for compression.

Checked by Competent Staff Sign/Date: 07/08/20

Verified by IPQA sign/Date: 07/08/20

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	S. V. 04/06/2020	W. J. 04/06/2020	W. J. 04/06/2020

CONTROLLED COPY

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	31 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/RO	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

8.0 GRANULATION (GLICLAZIDE PART):

8.1 LINE CLEARANCE CHECKS:

S.No	Check	Observation	
		Production	IPQA
1	Ensure that all empty containers, labels, used polybags, hand gloves of previous Product/ batch are removed from the area.	✓	✓
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.	✓	✓
3	Ensure that the previous batch BMR/documents are removed from the area.	✓	✓
4	Check the housekeeping general cleanliness of the floor, walls ceiling, tube light fixture, supply grills, riser grills, filters and electrical fixtures are clean.	✓	✓
5	Check the cleanliness of the doors, door view panel, SOP stand and compressed air filter outer surface.	✓	✓
6	Check for absence of previous batch/product from area below machine and inside the vessel.	✓	✓
7	Check whether the equipment body of Sifter, RMG, FBD and Multimill, Utensils are clean.	✓	✓
8	Ensure that the balances are cleaned and it's calibration status.	✓	✓
9	Check whether the Equipments/ Instruments to be used are within calibration/preventive maintenance due date.	✓	✓
10	Check the cleanliness of the utility line (compressed air, First RO water and purified water).	✓	✓
11	Check the cleanliness of the drain points.	✓	✓
12	Check the status board of the area is updated.	✓	✓
13	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.	✓	✓
14	Check the differential pressure of the area should be within the limit	✓	✓
15	Ensure the concurrent entries of log book.	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (Production) sign/date: Suresh 01/08/20

Verified by (IPQA) sign/date: MB 01/08/20

Equipment	Sifter	Multi mill	RMG	FBD	Balance	AREA
Equipment ID No:	ST/PRG/006	ST/PRG/010	ST/PRG/014	ST/PRG/012	ST/PRWB/001	
Previous Product:	<u>Litacold Flu Tab</u>					
Batch No.	<u>GD 200701</u>					
Cleaned by:	<u>Suresh</u>	<u>Suresh</u>	<u>Suresh</u>	<u>Suresh</u>	<u>Anbu</u>	<u>Anbu</u>
Checked by	Production Sign: <u>Suresh</u> IPQA Sign: <u>MB</u>					

8.2 ENVIRONMENTAL CONDITIONS

		Date: <u>01/08/20</u>	Time: <u>12:30</u>	Date:	Time:
		Observation	Production Sign	Observation	Production Sign
Area: Granulation	Temperature: 23°C to 27°C	<u>23.2°C</u>	<u>S</u>	<u>N.A</u>	
	Relative Humidity: 45% to 55 %	<u>54%</u>	<u>S</u>		

8.3 APPROVAL FOR GRANULATION:

Production Sign/Date: <u>Suresh 01/08/20</u>	IPQA Sign/Date: <u>MB 01/08/20</u>
--	------------------------------------

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>Suresh 01/08/2020</u>	<u>W. Suresh 01/08/2020</u>	<u>MB 01/08/2020</u>	CONTROLLED COPY

	Safetab Life Science			BATCH MANUFACTURING RECORD	
				Page No.:	32 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

8.4 SIFTING INSTRUCTIONS:

Date: 01/08/20

S. NO	PROCESS INSTRUCTIONS
1	Check the cleanliness of the Vibro Sifter.
2	Use hand gloves while handling the materials.
3	Carryout the sifting operation as per current version of SOP.
4	Check the integrity of sieve before and after sifting and record in the BMR.
5	Collect sifted materials in cleaned containers in polythene bag.

8.5 SIFTING RECORD:

S. No	Name of Ingredient	Size of sieve	Integrity checked before use*	Integrity checked after use*	Done by	Checked By/date
1	Gliclazide	40#	OK/ Not OK	OK/ Not OK	Suresh	01/08/20
2	Dicalcium Phosphate Anhydrous Granular (A-Tab)	40#	OK/ Not OK	OK/ Not OK	Suresh	01/08/20
3	Hydroxypropyl Methylcellulose Methocel K100 Premium LVCR	40#	OK/ Not OK	OK/ Not OK	Suresh	01/08/20
4	Iron Oxide Red Lake	80#	OK/ Not OK	OK/ Not OK	Suresh	01/08/20
6	Methocel K 100M Premium Hydroxypropyl Methylcellulose	40#	OK/ Not OK	OK/ Not OK	Praveen	01/08/20
7	Colloidal silicon dioxide	40#	OK/ Not OK	OK/ Not OK	Praveen	01/08/20
8	Purified Talc	40#	OK/ Not OK	OK/ Not OK	Praveen	01/08/20
9	Magnesium stearate	60#	OK/ Not OK	OK/ Not OK	Praveen	01/08/20

Note: If any discrepancy found, Initiate the deviation for corrective and preventive action and proceed to next step after QA approval.

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	G. R. 04/06/2020	04/06/2020	04/06/2020	

	Safetab Life Science			MASTER COPY	
				BATCH MANUFACTURING RECORD	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Page No.:	33 of 78
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Batch Size	5,00,000 Tablets
Batch No.:	GD200701	Mfg.Date:	07/2020	Supersedes MFC No:	NIL
			Exp.Date:	06/2023	

8.6 MANUFACTURING PROCESS:

Step No	Process Instructions	Date : 01/08/20		Done By	Checked by/Date
		Time			
		Started	Completed		
8.6.1	Sifting Co -sift Gliclazide, Dicalcium phosphate and Methocel K 100 Premium LVCR through 40# and Iron oxide red through 80#.	12:35	13:10	Suresh	01/08/20
8.6.2	Dry mixing: Load the above sifted material of step 8.6.1 into RMG.	13:12	13:16	Suresh	01/08/20
	Mix for 10 minutes at fast speed impeller and chopper ON at slow/fast speed.	13:20	13:30	Suresh	01/08/20
8.6.3	Binder preparation: Add 4.50 kg Povidone K30 in 50.00 kg Methylene Dichloride and mix well to get a clear solution.	13:40	14:00	Vignesh	01/08/20
8.6.4	Granulation: (Wet mixing) Granulate the blend of Step 8.6.2 with binder solution of Step 8.6.3 by following steps	14:02	14:04	Santhosh	01/08/20
	Binder addition: 1-2 minutes mixing at fast impeller speed and chopper at slow/fast speed.	14:06	14:08	Santhosh	01/08/20
	Racking.	14:09	14:11	Santhosh	01/08/20
	(If required add additional quantity of Methylene dichloride and mix for 1minutes to get the uniform granules.)	NA	NA	NA	NA
	Kneading:	14:12	14:13	Santhosh	01/08/20
	Mixing: 1-2 minutes mixing at fast speed impeller and chopper at slow/fast speed.	14:14	14:15	Santhosh	01/08/20
	Discharge the wet granules in FBD bowl for drying.	14:18	14:22	Santhosh	01/08/20

8.7 DRYING:

Step No	Instructions
1	Use hand gloves, nose mask while handling the materials.
2	Check the cleanliness of the FBD.
3	Carry out drying operation as per SOP.

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	G.V.R 04/06/2020	Vijayabharathi 04/06/2020	18/06/2020	

	Safetab Life Science		MASTER COPY		
	BATCH MANUFACTURING RECORD		Page No.:	34 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

8.7.1 DRYING AND SIZING DETAILS:

Step	Process	Start Time	End Time	Done by	Checked by/date
1	Load the Wet granules into FBD bowl and air drying for 10 mins & steam drying at 60° C±5°C with intermittent racking at 10-15 minutes to achieve LOD limit 0.5%-1.5%.	14:25	15:00	Unoth	R 01/08/20
3	LOD%: limit 0.5%-1.5%.	Observed LOD%: 1.42%			
4	Sift the dried granules through 30#.	15:10	15:40	Sathya	R 01/08/20
5	Mesh integrity checks.	Before use	After use	Sathya	R 01/08/20
		OK/ Not OK	OK/ Not OK		
6	Mill the retained granules through 1.5mm screen and pass through 30#.	15:50	16:15	Praveen	R 01/08/20
7	Screen integrity checks.	Before use	After use	Praveen	R 01/08/20
		OK/ Not OK	OK/ Not OK		

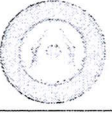
8.8 DRIED GRANULES WEIGHT RECORD:

Container No	Gross weight (kg)	Tare weight (kg)	Net weight (kg)	Weighed By	Checked By/ Date
1	33.31	0.16	33.15	Praveen	R 01/08/20
2	19.20	0.16	19.04	Praveen	R 01/08/20
3	27.37	0.16	27.21	Praveen	R 01/08/20
4	1				
5					
6					
7					
Total weight of dried granules:			79.60 kg		R 01/08/20

8.9 YIELD OF DRIED GRANULES:

1.0	Weight of total material added in granulation	:	80.250	Kg
2.0	Weight of dried granules	:	79.60	Kg
3.0	Yield (NLT 97.50 %) {2.0 / 1.0 x 100}	:	99.20	%

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	S. U 04/06/2020	Vijayalakshmi 04/06/2020	M. S. 04/06/2020	CONTROLLED COPY

	Safetab Life Science			MASTER COPY	
				BATCH MANUFACTURING RECORD	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Page No.:	35 of 78
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

9.0 BLENDING AND LUBRICATION:

9.1 LINE CLEARANCE CHECKS:

S.No	Checks	Observation	
		Production	IPQA
1	Ensure that all empty containers, used polybags, labels, hand gloves of previous Product/ batch are removed from the area.	✓	✓
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.	✓	✓
3	Ensure that the previous batch BMR / documents are removed from the area.	✓	✓
4	Check the housekeeping general cleanliness of the floor, walls ceiling, tube light fixture, supply grills, riser grills, filters and electrical fixtures are clean.	✓	✓
5	Check the cleanliness of the doors, door view panel and SOP stand.	✓	✓
6	Check the cleanliness of the utility line (compressed air, First RO water and purified water).	✓	✓
7	Check the cleanliness of the drain points.	✓	✓
8	Check for absence of previous batch/product from area below machine and inside machine by opening the guards of Octagonal blender.	✓	✓
9	Check whether the machine body and control panel of octagonal blender is clean.	✓	✓
10	Ensure that the balances are cleaned and it's calibration status.	✓	✓
11	Check whether the Equipments/ Instruments to be used are within calibration/preventive maintenance due date.	✓	✓
12	Check the status board of the area is updated with cleaned label.	✓	✓
13	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.	✓	✓
14	Check the differential pressure of the area should be within the limit.	✓	✓
15	Ensure the concurrent entries of log book.	✓	✓
16	Check the functioning and cleaning of return riser.	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (Production) sign/date: *[Signature]* 01/08/20

Verified by (IPQA) sign/date: *[Signature]* 01/08/20

Equipment	Octagonal blender(600L)	AREA
Code No.	SJ/PRG/015	
Previous product		
Batch No	CINOD-T S2011607	

9.2 ENVIRONMENTAL CONDITIONS:

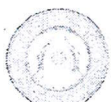
		Date: 01/08/20	Time: 16:30	Date:	Time
		Observation	Production Sign	Observation	Production Sign
Area: Blending	Temperature: 23°C to 27°C	21.2°C	✓	✓	✓
	Relative Humidity: 45% to 55 %	53%	✓	✓	✓

9.3 APPROVAL FOR BLENDING AND LUBRICATION:

Production Sign/Date: *[Signature]* 01/08/20

IPQA Sign/Date: *[Signature]* 01/08/20

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	
Signature with Date	<i>[Signature]</i> 04/06/2020	<i>[Signature]</i> 04/06/2020	<i>[Signature]</i> 04/06/2020	

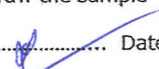
	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	36 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

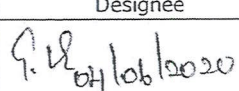
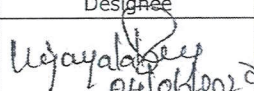
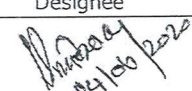
9.4 BLENDING AND LUBRICATION INSTRUCTION:

Step No.	Process Instructions	Date: 01/08/20		Done by	Checked by/Date
		Time			
		Started	Completed		
1	Use hand gloves, nose mask while handling the materials.				
2	Operate the Octagonal Blender (600L) as per the current version of the SOP.				
3	Sift Methocel K100M Premium through 40# and Geometrically mix Methocel K100M Premium with half quantity of dried granules and load into octagonal blender along with remaining quantity of dried granules.	16:35	16:50	mohandas	01/08/20
4	Mix for 5 minutes.	16:52	16:57	mohandas	01/08/20
5	Co-sift Colloidal silicone dioxide and Purified Talc through 40#.	16:58	17:02	mohandas	01/08/20
6	Load the above sifted materials into octagonal blender and mix for 10minutes.	17:04	17:14	mohandas	01/08/20
7	Sift Magnesium Stearate through 60# and distribute / sprinkle over the blended material.	17:15	17:18	mohandas	01/08/20
8	Mix for 3 minutes.	17:20	17:23	mohandas	01/08/20
9	Unload the final blend into suitable containers lined with double polythene bag container with proper label.	17:24	17:35	mohandas	01/08/20
10	Record the weight in below mentioned table.	17:36	17:46	mohandas	01/08/20

9.5 WEIGHING OF FINAL BLEND:

Date: 01/08/20

Container No	Gross weight (kg)	Tare weight (kg)	Net weight (kg)	Weighed by	Checked by/Date
1	31.19	2.50	28.69	mohandas	01/08/20
2	33.23	2.50	30.73	mohandas	01/08/20
3	32.08	2.50	29.58	mohandas	01/08/20
4					
5					
6					
7					
8					
9					
10					
Total weight of blend:			89.00 kg		
Intimate IPQA to draw the sample			Sample withdrawn by IPQA		
Production Sign:  Date: 01/08/20			IPQA Sign:  Date: 01/08/20		
Send Test request form for testing lubricated granules to QC department.					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	 04/06/2020	 04/06/2020	 04/06/2020

CONTROLLED COPY

	Safetab Life Science		MASTER COPY		
			BATCH MANUFACTURING RECORD		
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Page No.:	37 of 78
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Batch Size	5,00,000 Tablets
Batch No.:	GD200701	Mfg.Date:	07/2020	Supersedes MFC No:	NIL
				Exp.Date:	06/2023

10.0 RECONCILIATION:

1.0	Theoretical weight of blend	:	90.000 Kg
2.0	Actual weight of blend	:	89.00 Kg
3.0	Manufacturing Loss (1.0 – 6.0)	:	0.89 Kg
4.0	In-process samples		
	A IPQA Samples	:	— Kg
	B QC Samples	:	0.05 Kg
	C Validation Samples	:	0.06 Kg
5.0	Total samples: (A + B + C)	:	0.11 Kg
6.0	Total: (5.0+2.0)	:	89.11 Kg
7.0	% Yield = $\frac{6.0}{1.0} \times 100$ (Limit- NLT 97.00%)*	:	99.01 %

If yield is out of limit, raise deviation and inform to QA. After QA, investigation and approval proceed to the next stage.

*Tentative limit.

Total rejects destroyed: 0.89 Kg. Done by Production sign/Date: *[Signature]* 01/08/20 Checked by IPQA sign/Date: *[Signature]* 01/08/20
 (Rejected materials should be destroyed in the presence of QA)
 Yield reconciliation done by Production sign/Date: *[Signature]* 01/08/20 Checked by IPQA sign/Date: *[Signature]* 01/08/20

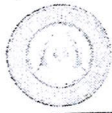
10.1 BLENDED GRANULES RELEASED FOR COMPRESSION:

Reconciliation checked and blended granules are released for compression.

Checked by Competent Staff Sign/Date: *[Signature]* 01/08/20

IPQA sign/Date: *[Signature]* 01/08/20

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<i>[Signature]</i> 04/06/2020	<i>[Signature]</i> 04/06/2020	<i>[Signature]</i> 04/06/2020	CONTROLLED COPY

	Safetab Life Science		MASTER COPY		
	BATCH MANUFACTURING RECORD		Page No.:	38 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.0 COMPRESSION:

11.1 LINE CLEARANCE CHECKS:

S.No	Checks	Observation	
		production	IPQA
1	Ensure that all empty containers, used polybags, labels, hand gloves of previous Product/ batch are removed from the area.	✓	✓
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.	✓	✓
3	Ensure that the previous batch BMR / documents are removed from the area.	✓	✓
4	Check the housekeeping general cleanliness of the floor, walls, ceiling, tube light fixture, supply grills, riser grills, filters and electrical fixtures are clean.	✓	✓
5	Check the cleanliness of the doors, door view panel and compressed air filter outer surface.	✓	✓
6	Check whether the machine body and machine parts like hoppers, feed frame, discharge chute and ejection chute and control panel are clean.	✓	✓
7	Check whether the dust collector main body and hosepipe of the dust collector is clean.	✓	✓
8	Ensure that the balances are cleaned and it's calibration status.	✓	✓
9	Check whether the Equipments/ Instruments to be used are within calibration/preventive maintenance due date.	✓	✓
10	Check the status board of the area is updated with cleaned label.	✓	✓
11	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.	✓	✓
12	Check the differential pressure of the area should be within the limit.	✓	✓
13	Ensure the concurrent entries of log book.	✓	✓
14	Check the Release Status of product Lubricated blend.	✓	✓
15	Check the calibration status of related IPQA Equipment like hardness tester, Vernier Caliper, DT apparatus, Friability etc.	✓	✓
16	Check the functioning and cleaning of return riser.	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (production) sign/date: S. Pi 07/08/20

Verified by (IPQA) sign/date: [Signature] 07/08/20

Equipment	Double Rotary/Single Rotary Compression Machine	Balance	Area
Equipment ID No.:	ST/PRCM/001 or ST/PRCM/003 or ST/PRC/004	ST/WB/202	
Previous product:	F lupi 200 - P		
Batch No.	S2095801H		

11.2 ENVIRONMENTAL CONDITIONS:

	Date: 07/08/20		Date: 08/08/20	
	Observation	Production Sign	Observation	Production sign
Temperature: 23°C to 27°C	24.25	S. Pi	24.1°C	R. R.
Relative Humidity: 45% to 55 %	53%	S. Pi	58%	R. R.

11.3 APPROVAL FOR COMPRESSION:

Production sign/Date: S. Pi 07/08/20 IPQA sign/Date: [Signature] 07/08/20

	Prepared by:	Checked by:	Approved By:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	<u>G. H. 04/06/2020</u>	<u>[Signature] 07/08/2020</u>	<u>[Signature] 07/08/2020</u>

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	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	39 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

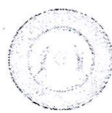
11.4 PROCESS INSTRUCTIONS:

S. No	Process Instructions	Start Time	End Time	Done By	Checked by/date
1	Check the cleanliness of area and equipment.				
2	Ensure that the correct punch sets are issued as per the Punch issue record and ensure the cleanliness and verification of the punch and dies. Checked by/date(production): <u>S. Pi 07/08/20</u> verified by/date(IPQA): <u>S. Pi 07/08/20</u>				
3	Set the 27- station Double Rotary Compression Machine with Upper Punch : 22.00 x 9.50 mm Caplet shape with breakline. Lower punch : 22.00 x 9.50 mm Caplet shape biconcave and plain. Dies : 22.00 x 9.50 mm Caplet shape.	17:45	18:45	Mahindran	S. Pi 07/08/20
4	Transfer the blend to compression cubicle. Load the granules of Metformin Hcl in one hopper and Gliclazide in other hopper of the compression machine.	18:50	19:05	Mahindran	S. Pi 07/08/20
5	Operate the Double Rotary Compression machine as per the current version of the SOP and reject tablets of the first three round which shall be destroyed as per SOP.	19:15	19:25	Mahindran	S. Pi 07/08/20
6	Check the initial tablet for all the parameters as described below and set the machine accordingly.	20:00	20:10	Mahindran	S. Pi 07/08/20
7	Collect the compressed tablets in polythene bag lined and labeled cleaned containers.	20:16	21:20	Dyppan	S. Pi 07/08/20
8	Check and record the weight of the compressed tablets.				

11.5 COMPRESSION SPECIFICATION/PARAMETERS:

S. No	Parameter	Limits	No. of tablets to be checked	Frequency	
				Production	IPQA
1	Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides.	20	Every 30 min	Every 1 hrs
2	Average weight	1360 mg $\pm$ 5% (1292.00mg - 1428.000mg)	20	Every 30 min	Every 1 hrs
3	Weight of 20 tablets	27.200g $\pm$ 3 % (26.384g to 28.016g)	20	Every 30 min	Every 1 hrs
4	Uniformity of weight	$\pm$ 5% of actual average weight	20	Every 1 hrs	Every 2 hrs
5	Uniformity weight checks for individual layer	Metformin - 1180mg $\pm$ 3% (Limit: 1144.600mg - 1215.400mg) Gliclazide- 180mg $\pm$ 3% (Limit: 174.600mg - 185.400mg)	20	Every 2 hrs	Every 2 hrs
6	Hardness	(250N-350N) (To be monitored)	5	Every 30 min	Every 1 hrs
7	Thickness	7.10 $\pm$ 0.30mm (6.80mm -7.40mm) (To be monitored)	5	Every 30 min	Every 1 hrs
8	Friability	NMT 1.0 %w/w	20	Every 1 hrs	Every 2 hrs
9	Machine rpm	12 - 18 rpm	NA	Every 1 hrs	Every 2 hrs

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>S. Pi 04/06/2020</u>	<u>Wijayalakshmi 04/06/2020</u>	<u>Mahindran 04/06/2020</u>	

	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD				Page No.:	40 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023	

11.5.1 MACHINE SETTING FOR COMPRESSION: (UNIFORMITY OF WEIGHT AND THICKNESS)

Sr. No.	Weight			Thickness	Sr. No.	Weight			Thickness
	Tablet wt.	Metformin Hcl part	Gliclazide Part			Tablet wt.	Metformin Hcl part	Gliclazide Part	
1	1360	1180	180	6.85	16	1364	1184	180	6.79
2	1341	1162	179	6.87	17	1373	1192	181	6.76
3	1352	1170	182	6.85	18	1374	1194	180	6.84
4	1355	1175	180	6.87	19	1358	1179	179	6.89
5	1367	1185	182	6.86	20	1362	1182	180	6.81
6	1373	1190	183	6.80	21	1358	1178	181	6.82
7	1374	1192	182	6.76	22	1366	1186	180	6.85
8	1341	1161	180	6.79	23	1369	1190	179	6.86
9	1370	1192	178	6.81	24	1348	1168	180	6.84
10	1357	1178	179	6.84	25	1353	1170	183	6.76
11	1360	1180	180	6.85	26	1360	1182	178	6.79
12	1364	1182	182	6.87	27	1365	1186	179	6.81
13	1360	1180	180	6.89					
14	1364	1185	179	6.86					
15	1360	1180	180	6.80					

Parameters	Instrument used	Observations		Limits
		Min	Max	
Uniformity of weight	Balance	1341	1374	±5% of actual average weight
Group weight of 20 tablets	Balance	27.204 gm		27.200g ± 3 % (26.384g to 28.016g)
Average weight	Balance	1360 mg		1360.000 mg ± 5% (1292.000mg - 1428.000mg)
Uniformity weight checks for individual layer	Balance	1154	1201	Metformin - 1180mg ± 3% (Limit: 1144.600mg - 1215.400mg)
		178	183	Gliclazide - 180.000mg ± 3% (Limit: 174.600mg - 185.400mg)
Hardness	Hardness tester	298 N		(250N-350N) (To be monitored)
Thickness	Vernier	6.85 mm		7.10 ± 0.30mm (6.80 - 7.40) (To be monitored)
Friability	Friabilator	0.15%		NMT 1.0 %
Appearance	visual	Complies		Red / white colored, Capsule shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides.

Initial M/C set up checked by (Production): S.Pi Date: 07/08/20 Verified by (IPQA): J.R. Date: 07/08/20

Initial Setting tablets Destroyed by: Sign: S.Pi Date: 07/08/20

Initial setting tablets destruction checked by IPQA: Sign: J.R. Date: 07/08/20

Designation	Prepared by:	Checked by:	Approved By:
	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	S.Pi 04/06/2020	Udaya 04/06/2020	J.R. 04/06/2020

CONTROLLED COPY

	Safetab Life Science		BATCH MANUFACTURING RECORD		Page No.:	41 of 78
	Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	GD200701	Mfg. Date:	07/2020	Exp. Date:	06/2023	

11.6 IN-PROCESS CHECKS: (EVERY 30 MINUTES) BY PRODUCTION:

S.Pi
07/08/20

DATE	TIME	Group Wt: 27.200g ± 3 % (26.384g to 28.016g) Avg. Wt: 1360.000 mg ± 5% (1292.000mg - 1428.000mg)		HARDNESS (250N-350N) (To be monitored)	THICKNESS 7.10 ± 0.30mm (6.80mm - 7.40mm) (To be monitored)	APPEARANCE Red / white colored, Capsule shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides.	Done by Production
		Weight of 20 Tab (g)	Avg. Weight (mg)				
07/08/20	20:20	27.206	1360	295	6.85	Complies	S.Pi
07/08/20	20:56	27.244	1362	308	6.89	Complies	S.Pi
07/08/20	21:20	27.208	1360	296	6.82	Complies	S.Pi
MIC Stopped at 21:50 due to shift closed							
08/08/20	06:55	27.263	1363	299	6.81	Complies	R.ey
08/08/20	07:35	27.185	1359	302	6.83	Complies	R.ey
08/08/20	08:05	27.247	1362	289	6.85	Complies	R.ey
08/08/20	08:40	27.229	1361	295	6.84	Complies	R.ey
MIC Stopped at 08:45 to 09:00 due to Break fast							
08/08/20	09:15	27.301	1365	289	6.82	Complies	R.ey
08/08/20	09:45	27.243	1362	292	6.80	Complies	R.ey
08/08/20	10:20	27.287	1364	285	6.83	Complies	R.ey
08/08/20	10:50	27.205	1360	299	6.85	Complies	R.ey
MIC Stopped at 11:00 to 11:10 due to Tea Break							
08/08/20	11:20	27.245	1362	289	6.81	Complies	R.ey
08/08/20	11:55	27.204	1360	295	6.83	Complies	R.ey
08/08/20	12:30	27.168	1358	290	6.85	Complies	R.ey
08/08/20	13:05	27.265	1363	298	6.84	Complies	R.ey
08/08/20	13:40	27.225	1361	287	6.81	Complies	R.ey
08/08/20	14:15	27.240	1362	206	6.80	Complies	S.Pi
08/08/20	14:45	27.209	1360	296	6.82	Complies	S.Pi
08/08/20	15:15	27.186	1359	299	6.80	Complies	S.Pi
08/08/20	15:45	27.220	1361	304	6.82	Complies	S.Pi
MIC Stopped at 16:00 to 16:10 due to Tea break							
08/08/20	16:15	27.200	1360	297	6.85	Complies	S.Pi
08/08/20	16:45	27.260	1363	304	6.88	Complies	S.Pi

*If appearance are satisfactory document as complies.

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	
Signature with Date	G.18 04/06/2020	Ujjayal 04/06/2020	11/06/2020	

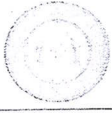
		Safetab Life Science		MASTER COPY	
BATCH MANUFACTURING RECORD					
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Page No.:	42 of 78
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO.:	ST/MFC/130/R0	Batch Size	5,00,000 Tablets
Batch No.:	GD200701	Mfg. Date:	07/2020	Supersedes MFC No.:	NIL
			Exp. Date:	06/2023	

11.6-A IN-PROCESS CHECKS: (EVERY 30 MINUTES) BY PRODUCTION:

DATE	TIME	Group Wt: 27.200g $\pm$ 3 % (26.384g to 28.016g) Avg. Wt: 1360.000 mg $\pm$ 5% (1292.000mg - 1428.000mg)		HARDNESS (250N-350N) (To be monitored)	THICKNESS 7.10 $\pm$ 0.30mm (6.80mm - 7.40mm) (To be monitored)	APPEARANCE Red / white colored, Capsule shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides.	Done by Production
		Weight of 20 Tab (g)	Avg. Weight (mg)				
08/08/20	17:15	27.208	1362	298	6.84	Complies	S. Pi
08/08/20	17:45	27.200	1360	295	6.85	Complies	S. Pi
08/08/20	18:15	27.220	1361	300	6.88	Complies	S. Pi
08/08/20	18:45	27.240	1362	305	6.85	Complies	S. Pi
08/08/20	19:15	27.260	1363	310	6.85	Complies	S. Pi
M/C Stopped at 19:30 to 20:00 due to Dinner Break							
08/08/20	20:05	27.204	1360	295	6.80	Complies	S. Pi
08/08/20	20:35	27.224	1361	298	6.82	Complies	S. Pi
08/08/20	21:05	27.246	1362	300	6.84	Complies	S. Pi
M/C Stopped at 21:40 due to Shift closed							
08/08/20	06:30	27.200	1360	298	6.84	Complies	S. Pi
08/08/20	07:00	27.220	1361	295	6.84	Complies	S. Pi
08/08/20	07:30	27.208	1362	298	6.84	Complies	S. Pi
08/08/20	08:06	27.198	1355	295	6.84	Complies	S. Pi
08/08/20	08:30	27.20	1360	298	6.84	Complies	S. Pi
M/C Stopped at 08:45 to 09:00 due to Break Fast							
08/08/20	09:15	27.199	1359	290	6.84	Complies	S. Pi
08/08/20	09:45	27.1200	1360	290	6.84	Complies	S. Pi
08/08/20	10:15	27.260	1363	290	6.84	Complies	S. Pi
08/08/20	10:45	27.200	1360	295	6.84	Complies	S. Pi
M/C Stopped at 11:00 due to Reg Break							
08/08/20	11:30	27.198	1359	298	6.84	Complies	S. Pi
08/08/20	12:06	27.200	1360	290	6.84	Complies	S. Pi
08/08/20	12:30	27.240	1362	290	6.84	Complies	S. Pi
08/08/20	13:00	27.240	1362	295	6.84	Complies	S. Pi
08/08/20	13:30	27.240	1362	295	6.84	Complies	S. Pi

*If appearance are satisfactory document as complies.

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	
Signature with Date	G. P. 04/06/2020	W. P. 04/06/2020	M. P. 04/06/2020	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	43 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.6-B IN-PROCESS CHECKS: (EVERY 30 MINUTES) BY PRODUCTION:

DATE	TIME	Group Wt: 27.200g $\pm$ 3 % (26.384g to 28.016g)		HARDNESS (250N-350N) (To be monitored)	THICKNESS 7.10 $\pm$ 0.30mm (6.80mm - 7.40mm) (To be monitored)	APPEARANCE Red / white colored, Capsule shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides.	Done by Production
		Avg. Wt: 1360.000 mg $\pm$ 5% (1292.000mg – 1428.000mg)					
MIC Stopped at 13:45 due to shift closed							
10/08/20	07:30	27.228	1361	299	6.90	Complies	R.ey
10/08/20	07:55	27.147	1357	282	6.88	Complies	R.ey
10/08/20	08:25	27.223	1361	285	6.91	Complies	R.ey
MIC Stopped at 08:45 to 09:00 due to Break fast							
10/08/20	09:10	27.329	1366	290	6.93	Complies	R.ey
10/08/20	09:45	27.301	1365	307	6.85	Complies	R.ey
10/08/20	10:20	27.224	1361	287	6.84	Complies	R.ey
10/08/20	10:55	27.265	1363	305	6.88	Complies	R.ey
MIC Stopped at 11:00 to 11:10 due to tea Break							
10/08/20	11:20	27.283	1364	289	6.91	Complies	R.ey
10/08/20	11:50	27.205	1360	294	6.83	Complies	R.ey
10/08/20	12:25	27.183	1359	297	6.81	Complies	R.ey
10/08/20	13:00	27.247	1362	295	6.87	Complies	R.ey
10/08/20	13:25	27.284	1364	294	6.85	Complies	R.ey
10/08/20	14:10	27.223	1361	286	6.91	Complies	R.ey
10/08/20	14:45	27.283	1364	286	6.93	Complies	R.ey
10/08/20	15:15	27.261	1363	296	6.81	Complies	R.ey
10/08/20	15:45	27.265	1363	290	6.84	Complies	R.ey
MIC Stopped at 16:00 to 16:10 due to tea Break							
10/08/20	16:20	27.184	1359	286	6.80	Complies	R.ey
10/08/20	17:05	27.222	1361	291	6.84	Complies	R.ey
10/08/20	17:35	27.167	1358	291	6.83	Complies	R.ey
10/08/20	18:05	27.147	1357	287	6.81	Complies	R.ey
10/08/20	18:35	27.262	1363	300	6.85	Complies	R.ey
10/08/20	19:05	27.225	1361	284	6.97	Complies	R.ey

*If appearance are satisfactory document as complies.

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	
Signature with Date	G. R. 04/06/2020	Ujaya Babu 04/06/2020	M. R. 04/06/2020	

Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.:

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Brand Name

GLIDE M 60/850 TABLETS

Product ID
No.:

1014

Batch Size

5,00,000 Tablets

Generic Name:

Gliclazide and Metformin Hydrochloride
sustained release Tablets 60/850mg

MFC NO:

ST/MFC/130/R0

Supersedes
MFC No:

NTU

Batch No.:

GD200701

Mfg. Date:

07/2020

Exp.Date:

06/2023

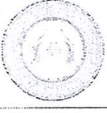
11.6-C IN-PROCESS CHECKS: (EVERY 30 MINUTES) BY PRODUCTION:

DATE	TIME	Group Wt: 27.200g $\pm$ 3 % (26.384g to 28.016g)		HARDNESS (250N-350N) (To be monitored)	THICKNESS 7.10 $\pm$ 0.30mm (6.80mm - 7.40mm) (To be monitored)	APPEARANCE Red / white colored, Capsule shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides.	Done by Production
		Avg. Wt: 1360.000 mg $\pm$ 5% (1292.000mg - 1428.000mg)					
		Weight of 20 Tab (g)	Avg. Weight (mg)				
MIC Stopped at 19:30 due to 20:00 due to dinner Break							
10/08/20	20:20	27.224	1361	283	6.90	Complies	
10/08/20	20:55	27.263	1363	290	6.85	Complies	
MIC Stopped at 21:20 due to Batch Completed							
10/08/20							

*If appearance are satisfactory document as complies.

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	9.18 04/06/2020	Udaya Lakshmi 04/06/2020	10/06/2020	

CONTROLLED COPY

	Safetab Life Science				
	BATCH MANUFACTURING RECORD			Page No.:	45 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.7 IN-PROCESS CHECKS: (EVERY 1 HOUR) BY IPQA:

DATE	TIME	Group Wt: 27.200g $\pm$ 3 % (26.384g to 28.016g) Avg. Wt: 1360.000 mg $\pm$ 5% (1292.000mg - 1428.000mg)		HARDNESS (250N-350N) (To be monitored)	THICKNESS 7.10 $\pm$ 0.30mm (6.80mm - 7.40mm) (To be monitored)	APPEARANCE Red / white colored, Capsule shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides.	Done by IPQA
		Weight of 20 Tab (g)	Avg. Weight (mg)				
07/08/20	20:40	27.226	1361	301	6.89	Complies	JKR
07/08/20	21:40	27.207	1360	298	6.88	Complies	JKR
		- M/c stopped at 21:50 due to shift closed -					
08/08/20	07:15	27.216	1360	314	6.84	Complies	Oh
08/08/20	08:15	27.243	1362	306	6.85	Complies	Oh
		- M/c stopped at 08:45 to 09:00 for breakfast -					
08/08/20	09:20	27.218	1360	298	6.82	Complies	Oh
08/08/20	10:26	27.226	1361	316	6.86	Complies	Oh
		- M/c stopped at 11:00 to 11:10 for tea break -					
08/08/20	11:30	27.216	1360	318	6.85	Complies	Oh
08/08/20	12:36	27.232	1361	322	6.84	Complies	Oh
08/08/20	13:30	27.226	1361	297	6.86	Complies	Oh
08/08/20	14:36	27.216	1360	280	6.89	Complies	JKR
08/08/20	15:30	27.248	1362	290	6.91	Complies	JKR
		- M/c stopped at 16:00 to 16:10 due to tea break -					
08/08/20	16:35	27.209	1360	287	6.87	Complies	JKR
08/08/20	17:35	27.232	1361	290	6.90	Complies	JKR
08/08/20	18:27	27.209	1360	288	6.93	Complies	JKR
		- M/c stopped at 19:30 to 20:00 due to dinner -					
08/08/20	20:20	27.287	1361	292	6.90	Complies	JKR
08/08/20	21:20	27.187	1329	287	6.89	Complies	JKR
		- M/c stopped at 21:40 due to shift closed -					
09/08/20	06:45	27.243	1362	278	6.86	Complies	Oh
09/08/20	07:48	27.228	1361	284	6.84	Complies	Oh
		- M/c stopped at 08:45 to 09:00 for breakfast -					
09/08/20	09:18	27.211	1360	291	6.86	Complies	Oh

*If appearance are satisfactory document as complies.

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/06/2020	 04/06/2020	 04/06/2020	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	46 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.7-A IN-PROCESS CHECKS: (EVERY 1 HOUR) BY IPQA:

DATE	TIME	Group Wt: 27.200g $\pm$ 3 % (26.384g to 28.016g) Avg. Wt: 1360.000 mg $\pm$ 5% (1292.000mg - 1428.000mg)		HARDNESS (250N-350N) (To be monitored)	THICKNESS 7.10 $\pm$ 0.30mm (6.80mm - 7.40mm) (To be monitored)	APPEARANCE Red / white colored, Capsule shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides.	Done by IPQA
		Weight of 20 Tab (g)	Avg. Weight (mg)				
09/08/20	10:15	27.228	1361	298	6.89	Complies	Ch
	- M/c	Stopped at 10:00 to 11:00 for tea break					
09/08/20	11:20	27.218	1360	302	6.86	Complies	Ch
09/08/20	12:26	27.246	1362	289	6.87	Complies	Ch
09/08/20	13:20	27.206	1360	302	6.85	Complies	Ch
	- M/c	Stopped at 13:45 due to shift closed					
10/08/20	07:45	27.231	1361	300	6.88	Complies	JR
	- M/c	Stopped at 08:45 to 09:00 due to breakfast					
10/08/20	09:20	27.208	1360	296	6.82	Complies	JR
10/08/20	10:25	27.236	1361	287	6.80	Complies	JR
	- M/c	Stopped at 11:00 to 11:10 due to tea break					
10/08/20	11:30	27.216	1360	294	6.83	Complies	JR
10/08/20	12:36	27.247	1362	290	6.87	Complies	JR
10/08/20	13:30	27.212	1360	298	6.90	Complies	JR
10/08/20	14:36	27.246	1362	282	6.84	Complies	NR
10/08/20	15:35	27.211	1360	287	6.82	Complies	NR
	- M/c	Stopped at 16:00 to 16:10 due to tea break					
10/08/20	16:40	27.204	1362	278	6.80	Complies	NR
10/08/20	17:42	27.224	1361	275	6.84	Complies	NR
10/08/20	18:45	27.247	1362	280	6.82	Complies	NR
	- M/c	Stopped at 19:30 to 20:00 due to dinner break					
10/08/20	20:30	27.214	1360	284	6.83	Complies	NR
	- M/c	Stopped at 21:20 due to Batch Completed					
		10/08/20					

*If appearance are satisfactory document as complies.

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	
Signature with Date	G. L. 04/06/2020	Ujaya 04/06/2020	04/06/2020	

	Safetab Life Science		MASTER COPY		
			BATCH MANUFACTURING RECORD		
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Page No.:	47 of 78
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.8 IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

Date: 07/08/20		Time: 20:25	
Weight of 20 tablets: 27.180 gm			
1	1.348	8	1.368
2	1.370	9	1.365
3	1.372	10	1.347
4	1.365	11	1.349
5	1.360	12	1.351
6	1.362	13	1.352
7	1.365	14	1.370
Limit: 5% of actual average weight, (1292.000 - 1428.000 mg)		M/C Speed: 12 RPM	
Min. weight: 1.347 g		99.11 %	
Average weight of 20 Tablets: 1.359 g		Max. weight: 1.372 g	
Friability: 0.15 %		NMT 1.0 %	
Done by: S. Di (Production)			
Date: 07/08/20		Time: 21:30	
Weight of 20 tablets: 27.186 gm			
1	1.346	8	1.345
2	1.348	9	1.348
3	1.345	10	1.350
4	1.347	11	1.351
5	1.320	12	1.373
6	1.322	13	1.370
7	1.323	14	1.372
Limit: 5% of actual average weight, (1292.000 - 1428.000 mg)		M/C Speed: 12 RPM	
Min. weight: 1.345 g		99.96 %	
Average weight of 20 Tablets: 1.359 g		Max. weight: 1.373 g	
Friability: 0.15 %		NMT 1.0 %	
Done by: S. Di (Production)			
Date: 08/07/20		Time: 07:15	
Weight of 20 tablets: 27.224 g			
1	1.359	8	1.365
2	1.368	9	1.360
3	1.361	10	1.359
4	1.367	11	1.357
5	1.359	12	1.365
6	1.355	13	1.361
7	1.363	14	1.364
Limit: 5% of actual average weight, (1292.000 - 1428.000 mg)		M/C Speed: 12 RPM	
Min. weight: 1.355 g		99.55 %	
Average weight of 20 Tablets: 1.361 g		Max. weight: 1.367 g	
Friability: 0.15 %		NMT 1.0 %	
Done by: R. ey (Production)			

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	G. R. 04/06/2020	Udaya Babu 04/06/2020	R. ey 04/06/2020

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	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	48 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.8-A IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

Date: <u>08/08/20</u> Time: <u>08:35</u>					
Weight of 20 tablets: <u>27.224 g</u>					
1	<u>1.362</u>	8	<u>1.369</u>	15	<u>1.369</u>
2	<u>1.359</u>	9	<u>1.359</u>	16	<u>1.365</u>
3	<u>1.354</u>	10	<u>1.361</u>	17	<u>1.353</u>
4	<u>1.367</u>	11	<u>1.364</u>	18	<u>1.359</u>
5	<u>1.365</u>	12	<u>1.355</u>	19	<u>1.362</u>
6	<u>1.360</u>	13	<u>1.359</u>	20	<u>1.364</u>
7	<u>1.353</u>	14	<u>1.364</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: <u>12</u> RPM	
Min. weight <u>1.353</u> g		<u>99.41</u> %		Max. weight <u>1.369</u> g <u>100.58</u> %	
Average weight of 20 Tablets: <u>1.361</u> g					
Friability: <u>0.12%</u>		NMT 1.0 %			
Done by: <u>P. Ruy</u> (Production)					
Date: <u>08/08/20</u> Time: <u>09:35</u>					
Weight of 20 tablets: <u>27.198 g</u>					
1	<u>1.359</u>	8	<u>1.355</u>	15	<u>1.368</u>
2	<u>1.365</u>	9	<u>1.367</u>	16	<u>1.350</u>
3	<u>1.366</u>	10	<u>1.365</u>	17	<u>1.359</u>
4	<u>1.357</u>	11	<u>1.360</u>	18	<u>1.362</u>
5	<u>1.368</u>	12	<u>1.351</u>	19	<u>1.365</u>
6	<u>1.369</u>	13	<u>1.359</u>	20	<u>1.361</u>
7	<u>1.359</u>	14	<u>1.361</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: <u>12</u> RPM	
Min. weight <u>1.350</u> g		<u>99.33</u> %		Max. weight <u>1.369</u> g <u>100.73</u> %	
Average weight of 20 Tablets: <u>1.359</u> g					
Friability: <u>0.12%</u>		NMT 1.0 %			
Done by: <u>P. Ruy</u> (Production)					
Date: <u>08/08/20</u> Time: <u>09:40</u>					
Weight of 20 tablets: <u>27.203 g</u>					
1	<u>1.362</u>	8	<u>1.368</u>	15	<u>1.359</u>
2	<u>1.365</u>	9	<u>1.358</u>	16	<u>1.368</u>
3	<u>1.359</u>	10	<u>1.360</u>	17	<u>1.365</u>
4	<u>1.352</u>	11	<u>1.368</u>	18	<u>1.360</u>
5	<u>1.358</u>	12	<u>1.362</u>	19	<u>1.359</u>
6	<u>1.365</u>	13	<u>1.352</u>	20	<u>1.365</u>
7	<u>1.362</u>	14	<u>1.355</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: <u>12</u> RPM	
Min. weight <u>1.352</u> g		<u>99.41</u> %		Max. weight <u>1.368</u> g <u>100.58</u> %	
Average weight of 20 Tablets: <u>1.360</u> g					
Friability: <u>0.12%</u>		NMT 1.0 %			
Done by: <u>P. Ruy</u> (Production)					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
Signature with Date	<u>G. L</u> 04/06/2020	<u>U. Ruy</u> 04/06/2020	<u>P. Ruy</u> 04/06/2020	

	Safetab Life Science			BATCH MANUFACTURING RECORD	
				Page No.:	49 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.8-B IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION

W.R. R.ey 08/08/20

Date: 08/08/20 Time: 10:40

Weight of 20 tablets: 27.2158

1	1.355	8	1.352	15	1.367
2	1.357	9	1.368	16	1.357
3	1.362	10	1.362	17	1.352
4	1.368	11	1.369	18	1.359
5	1.362	12	1.358	19	1.362
6	1.365	13	1.360	20	1.368
7	1.358	14	1.364		

Limit: 5% of actual average weight, (1292.000 – 1428.000 mg) M/C Speed: 12 RPM

Min. weight: 1.352 g 99.41 % Max. weight: 1.369 g 100.66 %

Average weight of 20 Tablets: 1.360 g

Friability: 0.12% NMT 1.0 %

Done by: R.ey (Production)

Date: 08/08/20 Time: 12:50

Weight of 20 tablets: 27.2188

1	1.362	8	1.355	15	1.359
2	1.359	9	1.364	16	1.367
3	1.351	10	1.370	17	1.360
4	1.365	11	1.365	18	1.362
5	1.370	12	1.359	19	1.355
6	1.359	13	1.362	20	1.364
7	1.365	14	1.351		

Limit: 5% of actual average weight, (1292.000 – 1428.000 mg) M/C Speed: 12 RPM

Min. weight: 1.351 g 99.33 % Max. weight: 1.370 g 100.73 %

Average weight of 20 Tablets: 1.360 g

Friability: 0.12% NMT 1.0 %

Done by: R.ey (Production)

Date: 08/08/20 Time: 13:52

Weight of 20 tablets: 27.240 gm

1	1.354	8	1.358	15	1.370
2	1.360	9	1.360	16	1.371
3	1.362	10	1.362	17	1.370
4	1.364	11	1.354	18	1.354
5	1.370	12	1.358	19	1.358
6	1.371	13	1.360	20	1.359
7	1.356	14	1.362		

Limit: 5% of actual average weight, (1292.000 – 1428.000 mg) M/C Speed: 12 RPM

Min. weight: 1.354 g 99.41 % Max. weight: 1.371 g 100.66 %

Average weight of 20 Tablets: 1.362 g

Friability: 0.12% NMT 1.0 %

Done by: R.ey (Production)

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	<u>G. R.</u> 04/06/2020	<u>W. R. R.ey</u> 04/06/2020	<u>W. R. R.ey</u> 04/06/2020

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	Safetab Life Science			BATCH MANUFACTURING RECORD		Page No.:	50 of 78
	Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL		
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023		

11.8-C IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION

Date: <u>08/08/20</u>		Time: <u>14:56</u>			
Weight of 20 tablets: <u>27.224 gm</u>					
1	<u>1.354</u>	8	<u>1.354</u>	15	<u>1.371</u>
2	<u>1.355</u>	9	<u>1.356</u>	16	<u>1.370</u>
3	<u>1.360</u>	10	<u>1.360</u>	17	<u>1.365</u>
4	<u>1.362</u>	11	<u>1.361</u>	18	<u>1.368</u>
5	<u>1.360</u>	12	<u>1.362</u>	19	<u>1.365</u>
6	<u>1.352</u>	13	<u>1.360</u>	20	<u>1.362</u>
7	<u>1.355</u>	14	<u>1.352</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: <u>12</u> RPM	
Min. weight: <u>1.352</u> g		<u>99.33</u> %		Max. weight <u>1.371</u> g <u>100.69</u> %	
Average weight of 20 Tablets: <u>1.361</u> g					
Friability: <u>0.13%</u>		NMT 1.0 %			
Done by: <u>S. Pi</u> (Production)					
Date: <u>08/08/20</u>		Time: <u>15:58</u>			
Weight of 20 tablets: <u>27.240 gm</u>					
1	<u>1.355</u>	8	<u>1.370</u>	15	<u>1.356</u>
2	<u>1.360</u>	9	<u>1.370</u>	16	<u>1.358</u>
3	<u>1.370</u>	10	<u>1.365</u>	17	<u>1.360</u>
4	<u>1.357</u>	11	<u>1.368</u>	18	<u>1.361</u>
5	<u>1.370</u>	12	<u>1.370</u>	19	<u>1.354</u>
6	<u>1.365</u>	13	<u>1.365</u>	20	<u>1.370</u>
7	<u>1.368</u>	14	<u>1.368</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: <u>12</u> RPM	
Min. weight: <u>1.354</u> g		<u>99.41</u> %		Max. weight <u>1.370</u> g <u>100.58</u> %	
Average weight of 20 Tablets: <u>1.362</u> g					
Friability: <u>0.13%</u>		NMT 1.0 %			
Done by: <u>S. Pi</u> (Production)					
Date: <u>08/08/20</u>		Time: <u>16:55</u>			
Weight of 20 tablets: <u>27.260 gm</u>					
1	<u>1.258</u>	8	<u>1.370</u>	15	<u>1.370</u>
2	<u>1.370</u>	9	<u>1.371</u>	16	<u>1.371</u>
3	<u>1.371</u>	10	<u>1.358</u>	17	<u>1.359</u>
4	<u>1.365</u>	11	<u>1.360</u>	18	<u>1.365</u>
5	<u>1.368</u>	12	<u>1.362</u>	19	<u>1.368</u>
6	<u>1.359</u>	13	<u>1.365</u>	20	<u>1.371</u>
7	<u>1.356</u>	14	<u>1.368</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: <u>12</u> RPM	
Min. weight: <u>1.356</u> g		<u>99.48</u> %		Max. weight <u>1.371</u> g <u>100.58</u> %	
Average weight of 20 Tablets: <u>1.363</u> g					
Friability: <u>0.12%</u>		NMT 1.0 %			
Done by: <u>S. Pi</u> (Production)					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
Signature with Date	<u>G. R.</u> <u>04/06/2020</u>	<u>W. Jayalakshy</u> <u>04/06/2020</u>	<u>M. S. Srinivas</u> <u>04/06/2020</u>	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	51 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.8-D IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION

Date: <u>08/08/20</u> Time: <u>17:55</u>					
Weight of 20 tablets: <u>27.250 gm</u>					
1	<u>1.356</u>	8	<u>1.360</u>	15	<u>1.368</u>
2	<u>1.358</u>	9	<u>1.362</u>	16	<u>1.370</u>
3	<u>1.360</u>	10	<u>1.360</u>	17	<u>1.358</u>
4	<u>1.362</u>	11	<u>1.355</u>	18	<u>1.365</u>
5	<u>1.356</u>	12	<u>1.358</u>	19	<u>1.368</u>
6	<u>1.358</u>	13	<u>1.362</u>	20	<u>1.370</u>
7	<u>1.362</u>	14	<u>1.370</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M/C Speed: <u>12</u> RPM	
Min. weight: <u>1.355</u> g		<u>99.48</u> %		Max. weight: <u>1.370</u> g	
Average weight of 20 Tablets: <u>1.362</u> g				<u>100.58</u> %	
Friability: <u>0.14%</u>		NMT 1.0 %			
Done by: <u>S. Pi</u> (Production)					
Date: <u>08/08/20</u> Time: <u>18:55</u>					
Weight of 20 tablets: <u>27.290 gm</u>					
1	<u>1.358</u>	8	<u>1.358</u>	15	<u>1.370</u>
2	<u>1.365</u>	9	<u>1.360</u>	16	<u>1.368</u>
3	<u>1.368</u>	10	<u>1.365</u>	17	<u>1.370</u>
4	<u>1.370</u>	11	<u>1.368</u>	18	<u>1.368</u>
5	<u>1.359</u>	12	<u>1.370</u>	19	<u>1.370</u>
6	<u>1.361</u>	13	<u>1.371</u>	20	<u>1.371</u>
7	<u>1.364</u>	14	<u>1.358</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M/C Speed: <u>12</u> RPM	
Min. weight: <u>1.358</u> g		<u>99.05</u> %		Max. weight: <u>1.371</u> g	
Average weight of 20 Tablets: <u>1.364</u> g				<u>100.51</u> %	
Friability: <u>0.12%</u>		NMT 1.0 %			
Done by: <u>S. Pi</u> (Production)					
Date: <u>08/08/20</u> Time: <u>20:10</u>					
Weight of 20 tablets: <u>27.240 gm</u>					
1	<u>1.356</u>	8	<u>1.354</u>	15	<u>1.364</u>
2	<u>1.370</u>	9	<u>1.358</u>	16	<u>1.368</u>
3	<u>1.369</u>	10	<u>1.354</u>	17	<u>1.365</u>
4	<u>1.370</u>	11	<u>1.356</u>	18	<u>1.368</u>
5	<u>1.356</u>	12	<u>1.356</u>	19	<u>1.370</u>
6	<u>1.358</u>	13	<u>1.360</u>	20	<u>1.370</u>
7	<u>1.356</u>	14	<u>1.362</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M/C Speed: <u>12</u> RPM	
Min. weight: <u>1.354</u> g		<u>99.41</u> %		Max. weight: <u>1.370</u> g	
Average weight of 20 Tablets: <u>1.362</u> g				<u>100.58</u> %	
Friability: <u>0.12%</u>		NMT 1.0 %			
Done by: <u>S. Pi</u> (Production)					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY.
Signature with Date	<u>9/8</u> <u>04/06/2020</u>	<u>Ugayalabey</u> <u>04/06/2020</u>	<u>Manoj</u> <u>04/06/2020</u>	

	Safetab Life Science		MASTER COPY		
	BATCH MANUFACTURING RECORD		Page No.:	52 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.8-E IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION

Date: <u>08/08/20</u> Time: <u>21:15</u>					
Weight of 20 tablets: <u>27.260 gm</u>					
1	1.356	8	1.356	15	1.356
2	1.358	9	1.358	16	1.357
3	1.360	10	1.360	17	1.358
4	1.362	11	1.362	18	1.365
5	1.370	12	1.370	19	1.371
6	1.371	13	1.371	20	1.368
7	1.356	14	1.370		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M/C Speed: <u>12</u> RPM	
Min. weight <u>1.355</u> g		<u>99.41</u> %		Max. weight <u>1.371</u> g <u>100.58</u> %	
Average weight of 20 Tablets: <u>1.363</u> g					
Friability: <u>0.12%</u>		NMT 1.0 %			
Done by: <u>S.P.</u> (Production)					
Date: <u>09/08/20</u> Time: <u>06:40</u>					
Weight of 20 tablets: <u>27.240 gm</u>					
1	1.360	8	1.359	15	1.360
2	1.358	9	1.360	16	1.358
3	1.361	10	1.360	17	1.359
4	1.360	11	1.360	18	1.360
5	1.360	12	1.359	19	1.358
6	1.360	13	1.360	20	1.360
7		14			
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M/C Speed: <u>12</u> RPM	
Min. weight <u>1.352</u> g		<u>99.70</u> %		Max. weight <u>1.364</u> g <u>100.14</u> %	
Average weight of 20 Tablets: <u>1.362</u> g					
Friability: <u>0.14%</u>		NMT 1.0 %			
Done by: <u>*</u> (Production)					
Date: <u>09/08/20</u> Time: <u>07:45</u>					
Weight of 20 tablets: <u>27.220 gm</u>					
1	1.361	8	1.360	15	1.362
2	1.358	9	1.362	16	1.361
3	1.364	10	1.362	17	1.361
4	1.362	11	1.362	18	1.362
5	1.354	12	1.360	19	1.361
6	1.368	13	1.361	20	1.361
7	1.363	14	1.361		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M/C Speed: <u>12</u> RPM	
Min. weight <u>1.354</u> g		<u>99.48</u> %		Max. weight <u>1.368</u> g <u>100.9</u> %	
Average weight of 20 Tablets: <u>1.361</u> g					
Friability: <u>0.14%</u>		NMT 1.0 %			
Done by: <u>*</u> (Production)					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
Signature with Date	<u>G.P.</u> <u>04/06/2020</u>	<u>Udaya Lakshmi</u> <u>04/06/2020</u>	<u>M. S. S.</u> <u>04/06/2020</u>	

	Safetab Life Science		MASTER COPY		
			BATCH MANUFACTURING RECORD		
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Page No.:	53 of 78
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.8-F IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION

Date: <u>09/08/20</u> Time: <u>08:45</u>					
Weight of 20 tablets: <u>27.240</u>					
1	<u>1.361</u>	8	<u>1.360</u>	15	<u>1.362</u>
2	<u>1.359</u>	9	<u>1.362</u>	16	<u>1.364</u>
3	<u>1.360</u>	10	<u>1.361</u>	17	<u>1.364</u>
4	<u>1.370</u>	11	<u>1.362</u>	18	<u>1.362</u>
5	<u>1.352</u>	12	<u>1.362</u>	19	<u>1.362</u>
6	<u>1.360</u>	13	<u>1.361</u>	20	<u>1.362</u>
7		14	<u>1.362</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M/C Speed: <u>12</u> RPM	
Min. weight: <u>1.352</u> g		<u>99.26</u> %		Max. weight: <u>1.368</u> g <u>100.44</u> %	
Average weight of 20 Tablets: <u>1.362</u> g					
Friability: <u>0.12%</u>		NMT 1.0 %			
Done by: <u>[Signature]</u> (Production)					
Date: <u>09/08/20</u> Time: <u>10:48</u>					
Weight of 20 tablets: <u>27.280</u>					
1	<u>1.365</u>	8	<u>1.361</u>	15	<u>1.366</u>
2	<u>1.366</u>	9	<u>1.364</u>	16	<u>1.364</u>
3	<u>1.364</u>	10	<u>1.362</u>	17	<u>1.354</u>
4	<u>1.362</u>	11	<u>1.364</u>	18	<u>1.360</u>
5	<u>1.361</u>	12	<u>1.362</u>	19	<u>1.361</u>
6	<u>1.362</u>	13	<u>1.361</u>	20	<u>1.375</u>
7		14	<u>1.364</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M/C Speed: <u>12</u> RPM	
Min. weight: <u>1.354</u> g		<u>99.26</u> %		Max. weight: <u>1.375</u> g <u>100.81</u> %	
Average weight of 20 Tablets: <u>1.364</u> g					
Friability: <u>0.12%</u>		NMT 1.0 %			
Done by: <u>[Signature]</u> (Production)					
Date: <u>09/08/20</u> Time: <u>10:45</u>					
Weight of 20 tablets: <u>27.300</u>					
1	<u>1.364</u>	8	<u>1.369</u>	15	<u>1.375</u>
2	<u>1.362</u>	9	<u>1.370</u>	16	<u>1.360</u>
3	<u>1.364</u>	10	<u>1.375</u>	17	<u>1.378</u>
4	<u>1.362</u>	11	<u>1.365</u>	18	<u>1.360</u>
5	<u>1.364</u>	12	<u>1.378</u>	19	<u>1.360</u>
6	<u>1.362</u>	13	<u>1.365</u>	20	<u>1.354</u>
7	<u>1.354</u>	14			
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M/C Speed: <u>12</u> RPM	
Min. weight: <u>1.354</u> g		<u>99.19</u> %		Max. weight: <u>1.375</u> g <u>100.73</u> %	
Average weight of 20 Tablets: <u>1.365</u> g					
Friability: <u>0.11%</u>		NMT 1.0 %			
Done by: <u>[Signature]</u> (Production)					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
Signature with Date	<u>[Signature]</u> 09/08/2020	<u>[Signature]</u> 09/08/2020	<u>[Signature]</u> 09/08/2020	

	Safetab Life Science		A		
	BATCH MANUFACTURING RECORD		Page No.:	53 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC No.:	ST/MFC/130/R0	Supersedes MFC No.:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.8-F IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION

Date: 09/08/20 Time: 11:40					
Weight of 20 tablets: 27.248 gm					
1	1.356	8	1.360	15	1.370
2	1.358	9	1.362	16	1.370
3	1.360	10	1.360	17	1.358
4	1.362	11	1.358	18	1.365
5	1.356	12	1.360	19	1.368
6	1.358	13	1.358	20	1.370
7	1.362	14	1.362		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: 12 RPM	
Min. weight: 1.355 g		99.8 %		Max. weight: 1.370 g	
Average weight of 20 Tablets: 1.362 g				100.58 %	
Friability: 0.14 %		NMT 1.0 %			
Done by: (Production)					
Date: 09/08/20 Time: 12:48					
Weight of 20 tablets: 27.286 gm					
1	1.365	8	1.358	15	1.370
2	1.358	9	1.360	16	1.368
3	1.368	10	1.365	17	1.370
4	1.370	11	1.368	18	1.368
5	1.358	12	1.370	19	1.370
6	1.361	13	1.371	20	1.371
7	1.364	14	1.358		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: 12 RPM	
Min. weight: 1.358 g		99.05 %		Max. weight: 1.371 g	
Average weight of 20 Tablets: 1.364 g				100.57 %	
Friability: 0.12 %		NMT 1.0 %			
Done by: (Production)					
Date: 09/08/20 Time: 13:46					
Weight of 20 tablets: 27.228 gm					
1	1.361	8	1.363	15	1.360
2	1.358	9	1.368	16	1.364
3	1.364	10	1.355	17	1.358
4	1.362	11	1.354	18	1.362
5	1.354	12	1.356	19	1.365
6	1.360	13	1.358	20	1.368
7	1.365	14	1.358		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: 12 RPM	
Min. weight: 1.354 g		99.48 %		Max. weight: 1.368 g	
Average weight of 20 Tablets: 1.361 g				100.57 %	
Friability: 0.12 %		NMT 1.0 %			
Done by: (Production)					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	G. B. 04/06/2020	Ujaya Lal 04/06/2020	04/06/2020

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	Safetab Life Science		B		
	BATCH MANUFACTURING RECORD		Page No.:	53 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.8-F IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION

Date: <u>10/08/20</u> Time: <u>07:36</u>					
Weight of 20 tablets: <u>27.224 g</u>					
1	<u>1.362</u>	8	<u>1.359</u>	15	<u>1.362</u>
2	<u>1.354</u>	9	<u>1.357</u>	16	<u>1.358</u>
3	<u>1.357</u>	10	<u>1.363</u>	17	<u>1.355</u>
4	<u>1.365</u>	11	<u>1.365</u>	18	<u>1.362</u>
5	<u>1.361</u>	12	<u>1.360</u>	19	<u>1.361</u>
6	<u>1.366</u>	13	<u>1.359</u>	20	<u>1.359</u>
7	<u>1.355</u>	14	<u>1.367</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: <u>12</u> RPM	
Min. weight: <u>1.355</u> g		<u>99.55</u> %		Max. weight <u>1.367</u> g <u>100.44</u> %	
Average weight of 20 Tablets: <u>1.361</u> g					
Friability : <u>0.13%</u>		NMT 1.0 %			
Done by: <u>R. E. V.</u> (Production)					
Date: <u>10/08/20</u> Time: <u>08:35</u>					
Weight of 20 tablets: <u>27.197 g</u>					
1	<u>1.359</u>	8	<u>1.360</u>	15	<u>1.353</u>
2	<u>1.354</u>	9	<u>1.365</u>	16	<u>1.364</u>
3	<u>1.358</u>	10	<u>1.359</u>	17	<u>1.362</u>
4	<u>1.362</u>	11	<u>1.354</u>	18	<u>1.359</u>
5	<u>1.366</u>	12	<u>1.362</u>	19	<u>1.362</u>
6	<u>1.365</u>	13	<u>1.366</u>	20	<u>1.366</u>
7	<u>1.353</u>	14	<u>1.359</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: <u>12</u> RPM	
Min. weight: <u>1.353</u> g		<u>99.55</u> %		Max. weight <u>1.366</u> g <u>100.96</u> %	
Average weight of 20 Tablets: <u>1.359</u> g					
Friability : <u>0.12%</u>		NMT 1.0 %			
Done by: <u>R. E. V.</u> (Production)					
Date: <u>10/08/20</u> Time: <u>09:38</u>					
Weight of 20 tablets: <u>27.224 g</u>					
1	<u>1.356</u>	8	<u>1.365</u>	15	<u>1.367</u>
2	<u>1.367</u>	9	<u>1.356</u>	16	<u>1.359</u>
3	<u>1.359</u>	10	<u>1.355</u>	17	<u>1.364</u>
4	<u>1.360</u>	11	<u>1.360</u>	18	<u>1.366</u>
5	<u>1.358</u>	12	<u>1.357</u>	19	<u>1.361</u>
6	<u>1.364</u>	13	<u>1.364</u>	20	<u>1.359</u>
7	<u>1.361</u>	14	<u>1.360</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: <u>12</u> RPM	
Min. weight: <u>1.355</u> g		<u>99.55</u> %		Max. weight <u>1.367</u> g <u>100.44</u> %	
Average weight of 20 Tablets: <u>1.361</u> g					
Friability : <u>0.12%</u>		NMT 1.0 %			
Done by: <u>R. E. V.</u> (Production)					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
Signature with Date	<u>G. R.</u> 04/06/2020	<u>Ujaya Lakshmi</u> 04/06/2020	<u>[Signature]</u> 04/06/2020	

	Safetab Life Science		MASTER COPY		
	BATCH MANUFACTURING RECORD		Page No.:	53 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.8-F IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION

Date: <u>10/08/20</u> Time: <u>10:48</u>					
Weight of 20 tablets: <u>27.218 g</u>					
1	1.364	8	1.365	15	1.368
2	1.360	9	1.359	16	1.359
3	1.359	10	1.353	17	1.358
4	1.355	11	1.365	18	1.364
5	1.361	12	1.368	19	1.366
6	1.353	13	1.361	20	1.361
7	1.362	14	1.364		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg) M /C Speed: <u>12</u> RPM					
Min. weight: <u>1.353</u> g		<u>99.48</u> %		Max. weight: <u>1.368</u> g <u>100.51</u> %	
Average weight of 20 Tablets: <u>1.360</u> g					
Friability: <u>0.12%</u>		NMT 1.0 %			
Done by: <u>R.ey</u> (Production)					
Date: <u>10/08/20</u> Time: <u>11:58</u>					
Weight of 20 tablets: <u>27.213 g</u>					
1	1.362	8	1.364	15	1.362
2	1.359	9	1.361	16	1.354
3	1.355	10	1.367	17	1.359
4	1.364	11	1.354	18	1.362
5	1.367	12	1.359	19	1.365
6	1.359	13	1.361	20	1.367
7	1.354	14	1.365		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg) M /C Speed: <u>12</u> RPM					
Min. weight: <u>1.354</u> g		<u>99.55</u> %		Max. weight: <u>1.367</u> g <u>100.51</u> %	
Average weight of 20 Tablets: <u>1.360</u> g					
Friability: <u>0.12%</u>		NMT 1.0 %			
Done by: <u>R.ey</u> (Production)					
Date: <u>10/08/20</u> Time: <u>13:10</u>					
Weight of 20 tablets: <u>27.207 g</u>					
1	1.359	8	1.353	15	1.367
2	1.357	9	1.359	16	1.365
3	1.362	10	1.362	17	1.359
4	1.365	11	1.365	18	1.362
5	1.360	12	1.367	19	1.353
6	1.353	13	1.360	20	1.359
7	1.367	14	1.353		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg) M /C Speed: <u>12</u> RPM					
Min. weight: <u>1.353</u> g		<u>99.48</u> %		Max. weight: <u>1.367</u> g <u>100.51</u> %	
Average weight of 20 Tablets: <u>1.360</u> g					
Friability: <u>0.12%</u>		NMT 1.0 %			
Done by: <u>R.ey</u> (Production)					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	<u>G.ey</u> 04/06/2020	<u>Ujaya Lakshmi</u> 04/06/2020	<u>Ujaya Lakshmi</u> 04/06/2020

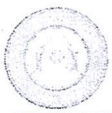
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	Safetab Life Science		MASTER COPY D		
	BATCH MANUFACTURING RECORD		Page No.:	53 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.8-F IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION

Date: <u>10/08/20</u> Time: <u>14:15</u>					
Weight of 20 tablets: <u>27.246 gm</u>					
1	<u>1.363</u>	8	<u>1.361</u>	15	<u>1.361</u>
2	<u>1.358</u>	9	<u>1.360</u>	16	<u>1.364</u>
3	<u>1.361</u>	10	<u>1.364</u>	17	<u>1.369</u>
4	<u>1.360</u>	11	<u>1.361</u>	18	<u>1.356</u>
5	<u>1.357</u>	12	<u>1.366</u>	19	<u>1.360</u>
6	<u>1.355</u>	13	<u>1.363</u>	20	<u>1.364</u>
7	<u>1.361</u>	14	<u>1.368</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: <u>12</u> RPM	
Min. weight: <u>1.355</u> g		<u>99.48</u> %		Max. weight: <u>1.369</u> g <u>100.57</u> %	
Average weight of 20 Tablets: <u>1.362</u> g					
Friability: <u>0.14</u> %		NMT 1.0 %			
Done by: <u>[Signature]</u> (Production)					
Date: <u>10/08/20</u> Time: <u>15:20</u>					
Weight of 20 tablets: <u>27.214 gm</u>					
1	<u>1.361</u>	8	<u>1.367</u>	15	<u>1.361</u>
2	<u>1.360</u>	9	<u>1.365</u>	16	<u>1.358</u>
3	<u>1.364</u>	10	<u>1.361</u>	17	<u>1.364</u>
4	<u>1.358</u>	11	<u>1.360</u>	18	<u>1.360</u>
5	<u>1.354</u>	12	<u>1.362</u>	19	<u>1.364</u>
6	<u>1.360</u>	13	<u>1.357</u>	20	<u>1.366</u>
7	<u>1.362</u>	14	<u>1.360</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: <u>12</u> RPM	
Min. weight: <u>1.354</u> g		<u>99.58</u> %		Max. weight: <u>1.367</u> g <u>100.57</u> %	
Average weight of 20 Tablets: <u>1.360</u> g					
Friability: <u>0.187</u> %		NMT 1.0 %			
Done by: <u>[Signature]</u> (Production)					
Date: <u>10/08/20</u> Time: <u>16:26</u>					
Weight of 20 tablets: <u>27.181 gm</u>					
1	<u>1.357</u>	8	<u>1.358</u>	15	<u>1.361</u>
2	<u>1.355</u>	9	<u>1.361</u>	16	<u>1.357</u>
3	<u>1.360</u>	10	<u>1.354</u>	17	<u>1.361</u>
4	<u>1.354</u>	11	<u>1.361</u>	18	<u>1.361</u>
5	<u>1.361</u>	12	<u>1.364</u>	19	<u>1.363</u>
6	<u>1.361</u>	13	<u>1.361</u>	20	<u>1.364</u>
7	<u>1.360</u>	14	<u>1.364</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: <u>12</u> RPM	
Min. weight: <u>1.354</u> g		<u>99.63</u> %		Max. weight: <u>1.364</u> g <u>100.36</u> %	
Average weight of 20 Tablets: <u>1.359</u> g					
Friability: <u>0.137</u> %		NMT 1.0 %			
Done by: <u>[Signature]</u> (Production)					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
Signature with Date	<u>G. R. 04/06/2020</u>	<u>Ujaya Lakshmi 04/06/2020</u>	<u>[Signature] 04/06/2020</u>	

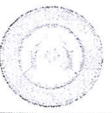
	Safetab Life Science		MASTER COPY E		
	BATCH MANUFACTURING RECORD		Page No.:	53 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC No:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg. Date:	07/2020	Exp. Date:	06/2023

11.8-F IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION

Date: <u>10/08/20</u> Time: <u>17:25</u>					
Weight of 20 tablets: <u>27.224 gm</u>					
1	<u>1.361</u>	8	<u>1.364</u>	15	<u>1.358</u>
2	<u>1.364</u>	9	<u>1.360</u>	16	<u>1.355</u>
3	<u>1.356</u>	10	<u>1.364</u>	17	<u>1.360</u>
4	<u>1.360</u>	11	<u>1.367</u>	18	<u>1.361</u>
5	<u>1.361</u>	12	<u>1.360</u>	19	<u>1.364</u>
6	<u>1.359</u>	13	<u>1.361</u>	20	<u>1.361</u>
7	<u>1.365</u>	14	<u>1.364</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: <u>12</u> RPM	
Min. weight: <u>1.355</u> g		<u>99.55</u> %		Max. weight <u>1.367</u> g <u>100.44</u> %	
Average weight of 20 Tablets: <u>1.361</u> g					
Friability: <u>0.147</u>		NMT 1.0 %			
Done by: <u>[Signature]</u> (Production)					
Date: <u>10/08/20</u> Time: <u>18:30</u>					
Weight of 20 tablets: <u>27.219 gm</u>					
1	<u>1.360</u>	8	<u>1.364</u>	15	<u>1.367</u>
2	<u>1.364</u>	9	<u>1.361</u>	16	<u>1.360</u>
3	<u>1.356</u>	10	<u>1.363</u>	17	<u>1.361</u>
4	<u>1.359</u>	11	<u>1.364</u>	18	<u>1.364</u>
5	<u>1.356</u>	12	<u>1.361</u>	19	<u>1.354</u>
6	<u>1.357</u>	13	<u>1.364</u>	20	<u>1.356</u>
7	<u>1.365</u>	14	<u>1.360</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: <u>12</u> RPM	
Min. weight: <u>1.354</u> g		<u>99.58</u> %		Max. weight <u>1.367</u> g <u>100.51</u> %	
Average weight of 20 Tablets: <u>1.360</u> g					
Friability: <u>0.117</u>		NMT 1.0 %			
Done by: <u>[Signature]</u> (Production)					
Date: <u>10/08/20</u> Time: <u>19:25</u>					
Weight of 20 tablets: <u>27.194 gm</u>					
1	<u>1.364</u>	8	<u>1.364</u>	15	<u>1.365</u>
2	<u>1.354</u>	9	<u>1.366</u>	16	<u>1.360</u>
3	<u>1.359</u>	10	<u>1.365</u>	17	<u>1.361</u>
4	<u>1.355</u>	11	<u>1.361</u>	18	<u>1.357</u>
5	<u>1.361</u>	12	<u>1.364</u>	19	<u>1.355</u>
6	<u>1.364</u>	13	<u>1.361</u>	20	<u>1.360</u>
7	<u>1.363</u>	14	<u>1.364</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: <u>12</u> RPM	
Min. weight: <u>1.354</u> g		<u>99.63</u> %		Max. weight <u>1.365</u> g <u>100.44</u> %	
Average weight of 20 Tablets: <u>1.359</u> g					
Friability: <u>0.187</u>		NMT 1.0 %			
Done by: <u>[Signature]</u> (Production)					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	<u>G. R. 04/06/2020</u>	<u>Ujaya Lakshmi 04/06/2020</u>	<u>[Signature] 04/06/2020</u>

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			F		
BATCH MANUFACTURING RECORD			Page No.:	53 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.8-F IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION

Date: 10/08/20		Time: 20:30	
Weight of 20 tablets: 27.157 gm			
1	1.364	8	1.361
2	1.360	9	1.364
3	1.365	10	1.365
4	1.360	11	1.357
5	1.359	12	1.360
6	1.361	13	1.357
7	1.364	14	1.364
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M /C Speed: 12 RPM	
Min. weight: 1.350 g		99.48 %	
Average weight of 20 Tablets: 1.357 g		Max. weight: 1.365 g	
Friability: 0.157		NMT 1.0 %	
Done by: (Production)			
Date:		Time:	
Weight of 20 tablets:			
1		8	
2		9	
3		10	
4		11	
5		12	
6		13	
7		14	
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M /C Speed:RPM	
Min. weight:g		%	
Average weight of 20 Tablets:g		Max. weight:g	
Friability:		NMT 1.0 %	
Done by: (Production)			
Date:		Time:	
Weight of 20 tablets:			
1		8	
2		9	
3		10	
4		11	
5		12	
6		13	
7		14	
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M /C Speed:RPM	
Min. weight:g		%	
Average weight of 20 Tablets:g		Max. weight:g	
Friability:		NMT 1.0 %	
Done by: (Production)			

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	9.18 04/06/2020	Ujaya Lakshmi 04/06/2020	10/08/20

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	Safetab Life Science		MASTER COPY		
	BATCH MANUFACTURING RECORD		Page No.:	54 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.9 IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR-BY IPQA

Date: <u>07/08/20</u> Time: <u>20:45</u>					
Weight of 20 tablets: <u>27.2318</u>					
1	<u>1.362</u>	8	<u>1.357</u>	15	<u>1.364</u>
2	<u>1.360</u>	9	<u>1.352</u>	16	<u>1.369</u>
3	<u>1.352</u>	10	<u>1.364</u>	17	<u>1.370</u>
4	<u>1.360</u>	11	<u>1.357</u>	18	<u>1.368</u>
5	<u>1.370</u>	12	<u>1.365</u>	19	<u>1.364</u>
6	<u>1.368</u>	13	<u>1.370</u>	20	<u>1.361</u>
7	<u>1.363</u>	14	<u>1.368</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: <u>12</u> RPM	
Min. weight <u>1.352</u> g		<u>98.49</u> %		Max. weight <u>1.370</u> g <u>100.78</u> %	
Average weight of 20 Tablets: <u>1.361</u> g					
Friability: <u>0.12</u> %		NMT 1.0 %			
Done by: <u>[Signature]</u> (IPQA)					
Date: <u>07/08/20</u> Time: <u>07:30</u>					
Weight of 20 tablets: <u>27.2198</u>					
1	<u>1.369</u>	8	<u>1.370</u>	15	<u>1.370</u>
2	<u>1.359</u>	9	<u>1.366</u>	16	<u>1.369</u>
3	<u>1.362</u>	10	<u>1.365</u>	17	<u>1.357</u>
4	<u>1.353</u>	11	<u>1.359</u>	18	<u>1.350</u>
5	<u>1.369</u>	12	<u>1.358</u>	19	<u>1.369</u>
6	<u>1.366</u>	13	<u>1.359</u>	20	<u>1.366</u>
7	<u>1.361</u>	14	<u>1.366</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: <u>12</u> RPM	
Min. weight <u>1.350</u> g		<u>99.26</u> %		Max. weight <u>1.370</u> g <u>100.74</u> %	
Average weight of 20 Tablets: <u>1.360</u> g					
Friability: <u>0.13</u> %		NMT 1.0 %			
Done by: <u>[Signature]</u> (IPQA)					
Date: <u>08/08/20</u> Time: <u>09:30</u>					
Weight of 20 tablets: <u>27.2498</u>					
1	<u>1.369</u>	8	<u>1.356</u>	15	<u>1.372</u>
2	<u>1.368</u>	9	<u>1.362</u>	16	<u>1.368</u>
3	<u>1.356</u>	10	<u>1.366</u>	17	<u>1.363</u>
4	<u>1.360</u>	11	<u>1.372</u>	18	<u>1.352</u>
5	<u>1.363</u>	12	<u>1.357</u>	19	<u>1.363</u>
6	<u>1.371</u>	13	<u>1.360</u>	20	<u>1.367</u>
7	<u>1.370</u>	14	<u>1.363</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: <u>12</u> RPM	
Min. weight <u>1.352</u> g		<u>99.26</u> %		Max. weight <u>1.372</u> g <u>100.74</u> %	
Average weight of 20 Tablets: <u>1.362</u> g					
Friability: <u>0.14</u> %		NMT 1.0 %			
Done by: <u>[Signature]</u> (IPQA)					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
Signature with Date	<u>[Signature]</u> 04/06/2020	<u>[Signature]</u> 04/06/2020	<u>[Signature]</u> 04/06/2020	

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	BATCH MANUFACTURING RECORD			Page No.:	55 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.9-A IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR BY IPQA

Date: <u>08/08/20</u> Time: <u>11:136</u>					
Weight of 20 tablets: <u>27.269g</u>					
1	<u>1.361</u>	8	<u>1.370</u>	15	<u>1.368</u>
2	<u>1.359</u>	9	<u>1.368</u>	16	<u>1.371</u>
3	<u>1.360</u>	10	<u>1.357</u>	17	<u>1.373</u>
4	<u>1.367</u>	11	<u>1.366</u>	18	<u>1.367</u>
5	<u>1.362</u>	12	<u>1.353</u>	19	<u>1.354</u>
6	<u>1.359</u>	13	<u>1.362</u>	20	<u>1.353</u>
7	<u>1.373</u>	14	<u>1.364</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M / C Speed: <u>12</u> RPM	
Min. weight: <u>1.353</u> g		<u>99.26</u> %		Max. weight: <u>1.373</u> g <u>100.79</u> %	
Average weight of 20 Tablets: <u>1.363</u> g					
Friability: <u>0.13 %</u>		NMT 1.0 %			
Done by: <u>Oh</u> (IPQA)					
Date: <u>08/08/20</u> Time: <u>13:136</u>					
Weight of 20 tablets: <u>27.227g</u>					
1	<u>1.366</u>	8	<u>1.362</u>	15	<u>1.370</u>
2	<u>1.362</u>	9	<u>1.366</u>	16	<u>1.364</u>
3	<u>1.357</u>	10	<u>1.365</u>	17	<u>1.365</u>
4	<u>1.369</u>	11	<u>1.358</u>	18	<u>1.360</u>
5	<u>1.364</u>	12	<u>1.352</u>	19	<u>1.352</u>
6	<u>1.360</u>	13	<u>1.366</u>	20	<u>1.358</u>
7	<u>1.359</u>	14	<u>1.362</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M / C Speed: <u>12</u> RPM	
Min. weight: <u>1.352</u> g		<u>99.33</u> %		Max. weight: <u>1.370</u> g <u>100.67</u> %	
Average weight of 20 Tablets: <u>1.361</u> g					
Friability: <u>0.14 %</u>		NMT 1.0 %			
Done by: <u>Oh</u> (IPQA)					
Date: <u>08/08/20</u> Time: <u>15:26</u>					
Weight of 20 tablets: <u>27.249g</u>					
1	<u>1.362</u>	8	<u>1.354</u>	15	<u>1.362</u>
2	<u>1.354</u>	9	<u>1.362</u>	16	<u>1.367</u>
3	<u>1.367</u>	10	<u>1.360</u>	17	<u>1.360</u>
4	<u>1.369</u>	11	<u>1.365</u>	18	<u>1.359</u>
5	<u>1.362</u>	12	<u>1.369</u>	19	<u>1.357</u>
6	<u>1.360</u>	13	<u>1.360</u>	20	<u>1.362</u>
7	<u>1.359</u>	14	<u>1.354</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M / C Speed: <u>12</u> RPM	
Min. weight: <u>1.354</u> g		<u>98.82</u> %		Max. weight: <u>1.369</u> g <u>100.64</u> %	
Average weight of 20 Tablets: <u>1.362</u> g					
Friability: <u>0.15 %</u>		NMT 1.0 %			
Done by: <u>JP</u> (IPQA)					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
Signature with Date	<u>P. H. 04/06/2020</u>	<u>Ugaya/04/06/2020</u>	<u>04/06/2020</u>	

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				BATCH MANUFACTURING RECORD	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Page No.:	56 of 78
Generic Name:	Glucilazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.9-B IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR BY IPQA

Date: 08/08/20 Time: 17:29					
Weight of 20 tablets: 27.216g					
1	1.360	8	1.365	15	1.362
2	1.359	9	1.360	16	1.360
3	1.353	10	1.353	17	1.359
4	1.368	11	1.362	18	1.353
5	1.364	12	1.368	19	1.362
6	1.353	13	1.360	20	1.368
7	1.362	14	1.357		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M / C Speed: 12 RPM	
Min. weight: 1.352 g		98.43 %		Max. weight: 1.368 g	
Average weight of 20 Tablets: 1.361 g					
Friability: 0.13 %		NMT 1.0 %			
Done by: J.P.R. (IPQA)					
Date: 08/08/20 Time: 20:15					
Weight of 20 tablets:					
1	1.364	8	1.367	15	1.358
2	1.360	9	1.362	16	1.351
3	1.350	10	1.350	17	1.367
4	1.367	11	1.367	18	1.360
5	1.362	12	1.362	19	1.362
6	1.358	13	1.360	20	1.360
7	1.350	14	1.352		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M / C Speed: 12 RPM	
Min. weight: 1.350 g		98.64 %		Max. weight: 1.367 g	
Average weight of 20 Tablets: 1.361 g					
Friability: 0.15 %		NMT 1.0 %			
Done by: J.P.R. (IPQA)					
Date: 09/08/20 Time: 07:00					
Weight of 20 tablets: 27.248g					
1	1.363	8	1.354	15	1.370
2	1.357	9	1.366	16	1.362
3	1.365	10	1.359	17	1.358
4	1.370	11	1.362	18	1.354
5	1.366	12	1.365	19	1.367
6	1.362	13	1.360	20	1.370
7	1.358	14	1.366		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M / C Speed: 12 RPM	
Min. weight: 1.354 g		99.41 %		Max. weight: 1.370 g	
Average weight of 20 Tablets: 1.362 g					
Friability: 0.14 %		NMT 1.0 %			
Done by: Oly (IPQA)					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	G. P. 04/06/2020	Ujaya 04/06/2020	M. S. 04/06/2020

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	BATCH MANUFACTURING RECORD		Page No.:	57 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.9-C IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR BY IPQA

Date: <u>09/08/20</u> Time: <u>09:15</u>					
Weight of 20 tablets: <u>27.206g</u>					
1	1.356	8	1.357	15	1.364
2	1.362	9	1.360	16	1.366
3	1.365	10	1.370	17	1.370
4	1.358	11	1.366	18	1.361
5	1.352	12	1.361	19	1.363
6	1.363	13	1.357	20	1.362
7	1.365	14	1.350		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M / C Speed: <u>12</u> RPM	
Min. weight: <u>1.350</u> g		<u>99.26</u> %		Max. weight: <u>1.370</u> g <u>100.74</u> %	
Average weight of 20 Tablets: <u>1.360</u> g					
Friability: <u>0.14</u> %		NMT 1.0 %			
Done by: <u>Oh</u> (IPQA)					
Date: <u>09/08/20</u> Time: <u>11:20</u>					
Weight of 20 tablets: <u>27.228g</u>					
1	1.357	8	1.358	15	1.352
2	1.362	9	1.360	16	1.358
3	1.366	10	1.365	17	1.363
4	1.358	11	1.358	18	1.365
5	1.361	12	1.361	19	1.355
6	1.366	13	1.370	20	1.355
7	1.370	14	1.366		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M / C Speed: <u>12</u> RPM	
Min. weight: <u>1.352</u> g		<u>99.53</u> %		Max. weight: <u>1.370</u> g <u>100.67</u> %	
Average weight of 20 Tablets: <u>1.361</u> g					
Friability: <u>0.13</u> %		NMT 1.0 %			
Done by: <u>Oh</u> (IPQA)					
Date: <u>09/08/20</u> Time: <u>13:20</u>					
Weight of 20 tablets: <u>27.644g</u>					
1	1.357	8	1.365	15	1.373
2	1.364	9	1.358	16	1.370
3	1.366	10	1.366	17	1.366
4	1.360	11	1.373	18	1.361
5	1.358	12	1.370	19	1.357
6	1.367	13	1.351	20	1.354
7	1.370	14	1.358		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M / C Speed: <u>12</u> RPM	
Min. weight: <u>1.351</u> g		<u>99.19</u> %		Max. weight: <u>1.373</u> g <u>100.81</u> %	
Average weight of 20 Tablets: <u>1.362</u> g					
Friability: <u>0.14</u> %		NMT 1.0 %			
Done by: <u>Oh</u> (IPQA)					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	<u>S. R. 04/06/2020</u>	<u>Udayakumar 04/06/2020</u>	<u>04/06/2020</u>

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	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	58 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.9-D IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR BY IPQA

Date: <u>10/08/20</u> Time: <u>07:50</u>					
Weight of 20 tablets: <u>27.216 g</u>					
1	<u>1.364</u>	8	<u>1.365</u>	15	<u>1.364</u>
2	<u>1.360</u>	9	<u>1.364</u>	16	<u>1.360</u>
3	<u>1.352</u>	10	<u>1.367</u>	17	<u>1.358</u>
4	<u>1.368</u>	11	<u>1.360</u>	18	<u>1.355</u>
5	<u>1.360</u>	12	<u>1.352</u>	19	<u>1.357</u>
6	<u>1.352</u>	13	<u>1.359</u>	20	<u>1.360</u>
7	<u>1.362</u>	14	<u>1.361</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: <u>12</u> RPM	
Min. weight: <u>1.352</u> g		<u>98.62</u> %		Max. weight: <u>1.368</u> g	
Average weight of 20 Tablets: <u>1.360</u> g				<u>100.78</u> %	
Friability: <u>0.14</u> %		NMT 1.0 %			
Done by: <u>J.P.</u> (IPQA)					
Date: <u>10/08/20</u> Time: <u>09:55</u>					
Weight of 20 tablets: <u>27.208 g</u>					
1	<u>1.357</u>	8	<u>1.369</u>	15	<u>1.360</u>
2	<u>1.351</u>	9	<u>1.351</u>	16	<u>1.364</u>
3	<u>1.363</u>	10	<u>1.364</u>	17	<u>1.358</u>
4	<u>1.369</u>	11	<u>1.361</u>	18	<u>1.362</u>
5	<u>1.362</u>	12	<u>1.360</u>	19	<u>1.367</u>
6	<u>1.365</u>	13	<u>1.357</u>	20	<u>1.360</u>
7	<u>1.360</u>	14	<u>1.365</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: <u>12</u> RPM	
Min. weight: <u>1.351</u> g		<u>98.92</u> %		Max. weight: <u>1.369</u> g	
Average weight of 20 Tablets: <u>1.360</u> g				<u>100.78</u> %	
Friability: <u>0.16</u> %		NMT 1.0 %			
Done by: <u>J.P.</u> (IPQA)					
Date: <u>10/08/20</u> Time: <u>12:00</u>					
Weight of 20 tablets: <u>27.210 g</u>					
1	<u>1.362</u>	8	<u>1.365</u>	15	<u>1.367</u>
2	<u>1.360</u>	9	<u>1.364</u>	16	<u>1.360</u>
3	<u>1.358</u>	10	<u>1.363</u>	17	<u>1.359</u>
4	<u>1.352</u>	11	<u>1.360</u>	18	<u>1.354</u>
5	<u>1.367</u>	12	<u>1.352</u>	19	<u>1.360</u>
6	<u>1.361</u>	13	<u>1.359</u>	20	<u>1.358</u>
7	<u>1.360</u>	14	<u>1.361</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: <u>12</u> RPM	
Min. weight: <u>1.352</u> g		<u>98.62</u> %		Max. weight: <u>1.367</u> g	
Average weight of 20 Tablets: <u>1.360</u> g				<u>100.64</u> %	
Friability: <u>0.14</u> %		NMT 1.0 %			
Done by: <u>J.P.</u> (IPQA)					

	Prepared by:	Checked by:	Approved By:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	<u>G.P.</u> 04/06/2020	<u>Udaya Lakshmi</u> 04/06/2020	<u>M. Srinivas</u> 04/06/2020

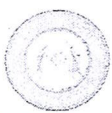
CONTROLLED COPY

	Safetab Life Science		A		
	BATCH MANUFACTURING RECORD		Page No.:	58 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.9-D IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR BY IPQA

Date: <u>10/08/20</u> Time: <u>14:08</u>					
Weight of 20 tablets: <u>27.208g</u>					
1	1.360	8	1.358	15	1.364
2	1.362	9	1.365	16	1.365
3	1.357	10	1.368	17	1.360
4	1.352	11	1.352	18	1.353
5	1.357	12	1.366	19	1.357
6	1.364	13	1.367	20	1.364
7	1.370	14	1.370		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: <u>12</u> RPM	
Min. weight: <u>1.352</u> g		<u>99.33</u> %		Max. weight <u>1.370</u> g <u>100.66</u> %	
Average weight of 20 Tablets: <u>1.361</u> g					
Friability : <u>0.13%</u>		NMT 1.0 %			
Done by: <u>HB</u> (IPQA)					
Date: <u>10/08/20</u> Time: <u>16:20</u>					
Weight of 20 tablets: <u>27.115g</u>					
1	1.359	8	1.360	15	1.365
2	1.361	9	1.359	16	1.366
3	1.367	10	1.350	17	1.367
4	1.362	11	1.357	18	1.358
5	1.351	12	1.361	19	1.362
6	1.354	13	1.365	20	1.367
7	1.360	14	1.350		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: <u>12</u> RPM	
Min. weight: <u>1.350</u> g		<u>99.41</u> %		Max. weight <u>1.367</u> g <u>100.66</u> %	
Average weight of 20 Tablets: <u>1.358</u> g					
Friability : <u>0.12%</u>		NMT 1.0 %			
Done by: <u>HB</u> (IPQA)					
Date: <u>10/08/20</u> Time: <u>18:23</u>					
Weight of 20 tablets: <u>27.211g</u>					
1	1.361	8	1.358	15	1.360
2	1.362	9	1.355	16	1.364
3	1.352	10	1.360	17	1.360
4	1.359	11	1.372	18	1.367
5	1.366	12	1.358	19	1.352
6	1.366	13	1.364	20	1.364
7	1.359	14	1.359		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: <u>12</u> RPM	
Min. weight: <u>1.352</u> g		<u>99.41</u> %		Max. weight <u>1.372</u> g <u>100.88</u> %	
Average weight of 20 Tablets: <u>1.360</u> g					
Friability : <u>0.14%</u>		NMT 1.0 %			
Done by: <u>HB</u> (IPQA)					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
Signature with Date	<u>9.18</u> 04/06/2020	<u>C. Jayalakshy</u> 04/06/2020	<u>M. S. S. S.</u> 04/06/2020	

	Safetab Life Science		MASTER COPY B		
	BATCH MANUFACTURING RECORD		Page No.:	58 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO.:	ST/MFC/130/R0	Supersedes MFC No.:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.9-D IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR BY IPQA

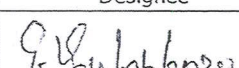
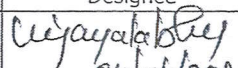
Date: <u>10/08/20</u> Time: <u>20:20</u>					
Weight of 20 tablets: <u>27.2478</u>					
1	<u>1.360</u>	8	<u>1.365</u>	15	<u>1.368</u>
2	<u>1.357</u>	9	<u>1.367</u>	16	<u>1.374</u>
3	<u>1.361</u>	10	<u>1.360</u>	17	<u>1.353</u>
4	<u>1.364</u>	11	<u>1.367</u>	18	<u>1.366</u>
5	<u>1.353</u>	12	<u>1.376</u>	19	<u>1.377</u>
6	<u>1.356</u>	13	<u>1.366</u>	20	<u>1.364</u>
7	<u>1.358</u>	14	<u>1.360</u>		
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: <u>12</u> RPM	
Min. weight: <u>1.353</u> g		<u>99.33</u> %		Max. weight <u>1.373</u> g <u>100.80</u> %	
Average weight of 20 Tablets: <u>1.362</u> g					
Friability : <u>0.137</u>		NMT 1.0 %			
Done by: <u>MB</u> (IPQA)					
Date: Time:					
Weight of 20 tablets:					
1		8		15	
2		9		16	
3		10		17	
4		11		18	
5		12		19	
6		13		20	
7		14			
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: RPM	
Min. weight: g		 %		Max. weight g %	
Average weight of 20 Tablets: g					
Friability :		NMT 1.0 %			
Done by: (IPQA)					
Date: Time:					
Weight of 20 tablets:					
1		8		15	
2		9		16	
3		10		17	
4		11		18	
5		12		19	
6		13		20	
7		14			
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)				M /C Speed: RPM	
Min. weight: g		 %		Max. weight g %	
Average weight of 20 Tablets: g					
Friability :		NMT 1.0 %			
Done by: (IPQA)					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
Signature with Date	<u>9.18</u> 04/06/2020	<u>Chayalab</u> 04/06/2020	<u>Manoj</u> 04/06/2020	

	Safetab Life Science		MASTER COPY		
			BATCH MANUFACTURING RECORD		
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Page No.:	59 of 78
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.10 IN PROCESS CHECK FREQUENCY FOR INDIVIDUAL LAYER: EVERY 2 HOUR BY PRODUCTION:

Date: 07/08/20 Time: 20:30					Done by: S. Ti (Production)						
WHITE PART [METFORMIN HCL] Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg] 23.520g					COLOUR PART [GLICLAZIDE] Limit: 180.000 ± 3% [174.600mg - 185.400mg] 3.610g						
1	1.169	8	1.172	15	1.169	1	0.179	8	0.182	15	0.178
2	1.180	9	1.180	16	1.170	2	0.181	9	0.180	16	0.179
3	1.182	10	1.182	17	1.172	3	0.180	10	0.183	17	0.180
4	1.190	11	1.180	18	1.175	4	0.181	11	0.178	18	0.182
5	1.190	12	1.165	19	1.180	5	0.182	12	0.180	19	0.180
6	1.165	13	1.190	20	1.182	6	0.178	13	0.182	20	0.183
7	1.168	14	1.168			7	0.183	14	0.180		
Min. weight: 1.162 g 98.80% Max. weight: 1.191 g 101.28% Average weight of 20 Tablets: 1.176 g					Min. weight: 0.178 g 98.88% Max. weight: 0.183 g 101.66% Average weight of 20 Tablets: 0.180 g						
Date: 08/08/20 Time: 07:25					Done by: R. Ti (Production)						
WHITE PART [METFORMIN HCL] 23.618g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.592g Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.179	8	1.175	15	1.172	1	0.181	8	0.177	15	0.178
2	1.182	9	1.177	16	1.182	2	0.179	9	0.180	16	0.180
3	1.175	10	1.189	17	1.189	3	0.181	10	0.182	17	0.182
4	1.185	11	1.183	18	1.174	4	0.182	11	0.179	18	0.181
5	1.177	12	1.174	19	1.185	5	0.177	12	0.182	19	0.179
6	1.185	13	1.185	20	1.179	6	0.180	13	0.180	20	0.177
7	1.189	14	1.180			7	0.181	14	0.179		
Min. weight: 1.172 g 99.32% Max. weight: 1.189 g 100.76% Average weight of 20 Tablets: 1.180 g					Min. weight: 0.177 g 98.88% Max. weight: 0.182 g 101.67% Average weight of 20 Tablets: 0.179 g						
Date: 08/08/20 Time: 09:40					Done by: R. Ti (Production)						
WHITE PART [METFORMIN HCL] 23.625g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.601g Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.179	8	1.174	15	1.178	1	0.177	8	0.177	15	0.179
2	1.175	9	1.183	16	1.173	2	0.181	9	0.184	16	0.184
3	1.181	10	1.185	17	1.183	3	0.184	10	0.180	17	0.179
4	1.185	11	1.180	18	1.189	4	0.179	11	0.179	18	0.181
5	1.183	12	1.182	19	1.181	5	0.176	12	0.176	19	0.183
6	1.173	13	1.175	20	1.174	6	0.181	13	0.181	20	0.181
7	1.189	14	1.181			7	0.184	14	0.184		
Min. weight: 1.173 g 99.32% Max. weight: 1.189 g 100.67% Average weight of 20 Tablets: 1.181 g					Min. weight: 0.176 g 99.77% Max. weight: 0.184 g 102.22% Average weight of 20 Tablets: 0.180 g						

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	 04/06/2020	 04/06/2020	 04/06/2020

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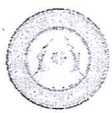
	Safetab Life Science		MASTER COPY		
			BATCH MANUFACTURING RECORD		
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Page No.:	60 of 78
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.10- A IN PROCESS CHECK FREQUENCY FOR INDIVIDUAL LAYER: EVERY 2 HOUR BY PRODUCTION:

Date: 08/08/20 Time: 11:50						Done by: R. E. (Production)					
WHITE PART [METFORMIN HCL] 23.548g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] 3.605g Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.182	8	1.170	15	1.183	1	0.181	8	0.182	15	0.179
2	1.179	9	1.178	16	1.173	2	0.179	9	0.180	16	0.182
3	1.175	10	1.175	17	1.178	3	0.181	10	0.178	17	0.181
4	1.183	11	1.184	18	1.181	4	0.180	11	0.179	18	0.181
5	1.180	12	1.183	19	1.174	5	0.178	12	0.181	19	0.179
6	1.189	13	1.189	20	1.183	6	0.181	13	0.182	20	0.178
7	1.183	14	1.180			7	0.178	14	0.180		
Min. weight: 1.170 g 99.23% Max. weight: 1.189 g 100.84% Average weight of 20 Tablets: 1.179 g						Min. weight: 0.178 g 98.88% Max. weight: 0.182 g 101.11% Average weight of 20 Tablets: 0.180 g					
Date: 08/08/20 Time: 13:55						Done by: R. E. (Production)					
WHITE PART [METFORMIN HCL] 23.540 gm Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] 3.620 gm Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.168	8	1.168	15	1.169	1	0.182	8	0.183	15	0.179
2	1.170	9	1.169	16	1.170	2	0.179	9	0.182	16	0.182
3	1.172	10	1.165	17	1.172	3	0.178	10	0.180	17	0.183
4	1.180	11	1.170	18	1.189	4	0.180	11	0.179	18	0.179
5	1.189	12	1.172	19	1.165	5	0.182	12	0.182	19	0.182
6	1.184	13	1.168	20	1.169	6	0.182	13	0.183	20	0.180
7	1.182	14	1.180			7	0.180	14	0.180		
Min. weight: 1.165 g 98.98% Max. weight: 1.189 g 101.01% Average weight of 20 Tablets: 1.172 g						Min. weight: 0.179 g 98.89% Max. weight: 0.183 g 101.0% Average weight of 20 Tablets: 0.181 g					
Date: 08/08/20 Time: 15:05						Done by: S. P. (Production)					
WHITE PART [METFORMIN HCL] 23.540 gm Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] 3.604 gm Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.168	8	1.178	15	1.165	1	0.178	8	0.178	15	0.179
2	1.170	9	1.165	16	1.168	2	0.180	9	0.180	16	0.180
3	1.190	10	1.169	17	1.174	3	0.182	10	0.181	17	0.183
4	1.168	11	1.170	18	1.176	4	0.180	11	0.178	18	0.178
5	1.167	12	1.172	19	1.180	5	0.182	12	0.180	19	0.183
6	1.168	13	1.175	20	1.182	6	0.180	13	0.182	20	0.179
7	1.175	14	1.178			7	0.183	14	0.180		
Min. weight: 1.164 g 98.89% Max. weight: 1.190 g 101.04% Average weight of 20 Tablets: 1.172 g						Min. weight: 0.178 g 98.88% Max. weight: 0.183 g 101.06% Average weight of 20 Tablets: 0.180 g					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	G. V. 04/06/2020	U. V. 04/06/2020	M. V. 04/06/2020

CONTROLLED COPY

	Safetab Life Science			MASTER COPY	
				BATCH MANUFACTURING RECORD	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Page No.:	61 of 78
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.10-B IN PROCESS CHECK FREQUENCY FOR INDIVIDUAL LAYER: EVERY 2 HOUR BY PRODUCTION:

Date: 08/08/20 Time: 18:00						Done by: S. P. (Production)					
WHITE PART [METFORMIN HCL] 23.560 gm Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] 3.620 gm Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.169	8	1.185	15	1.165	1	0.179	8	0.180	15	0.179
2	1.175	9	1.169	16	1.170	2	0.182	9	0.179	16	0.179
3	1.178	10	1.175	17	1.182	3	0.180	10	0.181	17	0.181
4	1.184	11	1.178	18	1.180	4	0.182	11	0.183	18	0.183
5	1.188	12	1.180	19	1.167	5	0.183	12	0.179	19	0.180
6	1.189	13	1.182	20	1.186	6	0.179	13	0.183	20	0.179
7	1.169	14	1.189			7	0.182	14	0.180		
Min. weight: 1.167 g 99.06 % Max. weight: 1.189 g 100.93 % Average weight of 20 Tablets: 1.178 g						Min. weight: 0.179 g 98.89 % Max. weight: 0.183 g 101.10 % Average weight of 20 Tablets: 0.181 g					
Date: 08/08/20 Time: 20:15						Done by: S. P. (Production)					
WHITE PART [METFORMIN HCL] 23.520 gm Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] 3.620 gm Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.165	8	1.165	15	1.180	1	0.179	8	0.179	15	0.180
2	1.168	9	1.168	16	1.165	2	0.182	9	0.182	16	0.181
3	1.180	10	1.170	17	1.166	3	0.180	10	0.180	17	0.180
4	1.168	11	1.172	18	1.167	4	0.183	11	0.180	18	0.179
5	1.180	12	1.185	19	1.165	5	0.179	12	0.183	19	0.182
6	1.182	13	1.187	20	1.168	6	0.180	13	0.179	20	0.180
7	1.187	14	1.165			7	0.182	14	0.179		
Min. weight: 1.165 g 99.06 % Max. weight: 1.187 g 100.93 % Average weight of 20 Tablets: 1.176 g						Min. weight: 0.179 g 98.89 % Max. weight: 0.183 g 101.10 % Average weight of 20 Tablets: 0.181 g					
Date: 09/08/20 Time: 08:50						Done by: X (Production)					
WHITE PART [METFORMIN HCL] 23.560 gm Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] 3.620 gm Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.165	8	1.180	15	1.184	1	0.184	8	0.180	15	0.181
2	1.161	9	1.179	16	1.180	2	0.180	9	0.184	16	0.180
3	1.160	10	1.175	17	1.180	3	0.177	10	0.181	17	0.180
4	1.160	11	1.187	18	1.184	4	0.180	11	0.180	18	0.181
5	1.170	12	1.190	19	1.180	5	0.184	12	0.180	19	0.181
6	1.180	13	1.180	20	1.180	6	0.184	13	0.180	20	0.184
7	1.160	14	1.184			7	0.180	14	0.181		
Min. weight: 1.165 g 98.89 % Max. weight: 1.190 g 101.65 % Average weight of 20 Tablets: 1.178 g						Min. weight: 0.177 g 97.79 % Max. weight: 0.184 g 101.65 % Average weight of 20 Tablets: 0.181 g					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	S. P. 04/06/2020	Ujjayalaxmi 04/06/2020	M. S. 04/06/2020

CONTROLLED COPY

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	62 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.10-C IN PROCESS CHECK FREQUENCY FOR INDIVIDUAL LAYER: EVERY 2 HOUR BY PRODUCTION:

Date: 09/08/20 Time: 08:50 23.640						Done by: * (Production) 3.620					
WHITE PART [METFORMIN HCL] Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.181	8	1.176	15	1.180	1	0.181	8	0.180	15	0.181
2	1.180	9	1.180	16	1.179	2	0.180	9	0.180	16	0.181
3	1.190	10	1.180	17	1.180	3	0.176	10	0.181	17	0.180
4	1.178	11	1.180	18	1.176	4	0.181	11	0.186	18	0.180
5	1.180	12	1.180	19	1.180	5	0.181	12	0.181	19	0.180
6	1.180	13	1.181	20	1.180	6	0.181	13	0.180	20	0.181
7	1.190	14	1.180			7	0.184	14	0.180		
Min. weight: 1.176 g 99.49 % Max. weight: 1.190 g 100.67 % Average weight of 20 Tablets: 1.182 g						Min. weight: 0.176 g 97.23 % Max. weight: 0.186 g 102.76 % Average weight of 20 Tablets: 0.181 g					
Date: 09/08/20 Time: 10:50 23.660						Done by: * (Production) 3.640					
WHITE PART [METFORMIN HCL] Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.176	8	1.180	15	1.180	1	0.176	8	0.181	15	0.182
2	1.180	9	1.180	16	1.179	2	0.181	9	0.181	16	0.181
3	1.181	10	1.180	17	1.180	3	0.182	10	0.184	17	0.183
4	1.189	11	1.180	18	1.180	4	0.184	11	0.181	18	0.181
5	1.180	12	1.179	19	1.180	5	0.181	12	0.182	19	0.182
6	1.180	13	1.180	20	1.180	6	0.184	13	0.181	20	0.181
7	1.179	14	1.180			7	0.182	14	0.181		
Min. weight: 1.176 g 99.40 % Max. weight: 1.189 g 100.50 % Average weight of 20 Tablets: 1.183 g						Min. weight: 0.176 g 96.70 % Max. weight: 0.184 g 101.09 % Average weight of 20 Tablets: 0.182 g					
Date: 09/08/20 Time: 12:56 23.660						Done by: * (Production) 3.64					
WHITE PART [METFORMIN HCL] Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.174	8	1.180	15	1.182	1	0.181	8	0.184	15	0.181
2	1.181	9	1.186	16	1.183	2	0.180	9	0.185	16	0.181
3	1.180	10	1.184	17	1.182	3	0.180	10	0.181	17	0.182
4	1.182	11	1.182	18	1.182	4	0.176	11	0.181	18	0.181
5	1.183	12	1.182	19	1.182	5	0.181	12	0.181	19	0.181
6	1.182	13	1.182	20	1.183	6	0.180	13	0.181	20	0.182
7	1.189	14	1.182			7	0.181	14	0.182		
Min. weight: 1.174 g 99.23 % Max. weight: 1.189 g 100.50 % Average weight of 20 Tablets: 1.183 g						Min. weight: 0.176 g 96.70 % Max. weight: 0.184 g 101.09 % Average weight of 20 Tablets: 0.182 g					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	9.18 04/06/2020	Wipaya/abley 04/06/2020	04/06/2020

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	Safetab Life Science			MASTER COPY A	
	BATCH MANUFACTURING RECORD			Page No.:	62 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

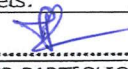
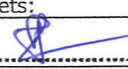
11.10-C IN PROCESS CHECK FREQUENCY FOR INDIVIDUAL LAYER: EVERY 2 HOUR BY PRODUCTION:

Date: 10/08/20 Time: 07:14.5					Done by: P. Anj (Production)						
WHITE PART [METFORMIN HCL] 23.607g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.601g Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.184	8	1.173	15	1.173	1	0.181	8	0.183	15	0.181
2	1.177	9	1.181	16	1.181	2	0.177	9	0.177	16	0.179
3	1.179	10	1.179	17	1.185	3	0.181	10	0.181	17	0.180
4	1.183	11	1.175	18	1.174	4	0.179	11	0.180	18	0.179
5	1.187	12	1.180	19	1.179	5	0.181	12	0.179	19	0.183
6	1.180	13	1.187	20	1.184	6	0.183	13	0.177	20	0.181
7	1.182	14	1.179			7	0.177	14	0.183		
Min. weight: 1.173 g 99.40 % Max. weight: 1.187 g 100.59 % Average weight of 20 Tablets: 1.180 g					Min. weight: 0.177 g 98.33 % Max. weight: 0.183 g 101.66 % Average weight of 20 Tablets: 0.180 g						
Date: 10/08/20 Time: 09:55					Done by: P. Anj (Production)						
WHITE PART [METFORMIN HCL] 23.625g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.593g Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.179	8	1.187	15	1.187	1	0.182	8	0.182	15	0.178
2	1.182	9	1.185	16	1.175	2	0.178	9	0.177	16	0.179
3	1.187	10	1.179	17	1.179	3	0.181	10	0.179	17	0.181
4	1.180	11	1.181	18	1.182	4	0.180	11	0.182	18	0.177
5	1.176	12	1.187	19	1.182	5	0.182	12	0.181	19	0.182
6	1.183	13	1.180	20	1.179	6	0.177	13	0.180	20	0.180
7	1.175	14	1.175			7	0.181	14	0.177		
Min. weight: 1.175 g 99.49 % Max. weight: 1.187 g 100.59 % Average weight of 20 Tablets: 1.181 g					Min. weight: 0.177 g 98.85 % Max. weight: 0.182 g 101.66 % Average weight of 20 Tablets: 0.179 g						
Date: 10/08/20 Time: 12:10					Done by: P. Anj (Production)						
WHITE PART [METFORMIN HCL] 23.617g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.615g Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.181	8	1.174	15	1.180	1	0.181	8	0.178	15	0.183
2	1.180	9	1.181	16	1.174	2	0.178	9	0.181	16	0.181
3	1.175	10	1.176	17	1.179	3	0.181	10	0.180	17	0.180
4	1.179	11	1.179	18	1.182	4	0.180	11	0.183	18	0.178
5	1.182	12	1.183	19	1.187	5	0.178	12	0.179	19	0.179
6	1.183	13	1.187	20	1.180	6	0.183	13	0.178	20	0.183
7	1.187	14	1.185			7	0.180	14	0.181		
Min. weight: 1.174 g 99.40 % Max. weight: 1.187 g 100.59 % Average weight of 20 Tablets: 1.180 g					Min. weight: 0.178 g 98.85 % Max. weight: 0.183 g 101.66 % Average weight of 20 Tablets: 0.180 g						

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	
Signature with Date	G. R. 04/06/2020	W. S. 04/06/2020	M. S. 04/06/2020	

	Safetab Life Science		MASTER B		
	BATCH MANUFACTURING RECORD		Page No.:	62 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.10-C IN PROCESS CHECK FREQUENCY FOR INDIVIDUAL LAYER: EVERY 2 HOUR BY PRODUCTION:

Date: 10/08/20 Time: 14:15					Done by:  (Production)						
WHITE PART [METFORMIN HCL] 23.6148 gm Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.586 gm Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.184	8	1.178	15	1.181	1	0.176	8	0.181	15	0.176
2	1.178	9	1.180	16	1.184	2	0.175	9	0.180	16	0.180
3	1.180	10	1.175	17	1.186	3	0.180	10	0.181	17	0.181
4	1.182	11	1.181	18	1.184	4	0.179	11	0.176	18	0.178
5	1.180	12	1.180	19	1.178	5	0.181	12	0.175	19	0.181
6	1.186	13	1.176	20	1.175	6	0.180	13	0.178	20	0.180
7	1.176	14	1.176			7	0.183	14	0.180		
Min. weight: 1.175 g 99.57 % Max. weight: 1.186 g 100.50 % Average weight of 20 Tablets: 1.180 g					Min. weight: 0.175 g 97.76 % Max. weight: 0.183 g 102.23 % Average weight of 20 Tablets: 0.179 g						
Date: 10/08/20 Time: 16:20					Done by:  (Production)						
WHITE PART [METFORMIN HCL] 23.6018 gm Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.586 gm Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.179	8	1.180	15	1.186	1	0.181	8	0.183	15	0.180
2	1.176	9	1.176	16	1.182	2	0.180	9	0.180	16	0.176
3	1.186	10	1.175	17	1.176	3	0.176	10	0.178	17	0.178
4	1.183	11	1.174	18	1.185	4	0.180	11	0.179	18	0.180
5	1.187	12	1.180	19	1.180	5	0.181	12	0.181	19	0.176
6	1.176	13	1.181	20	1.186	6	0.179	13	0.180	20	0.176
7	1.175	14	1.184			7	0.181	14	0.181		
Min. weight: 1.174 g 99.49 % Max. weight: 1.186 g 100.50 % Average weight of 20 Tablets: 1.180 g					Min. weight: 0.176 g 98.32 % Max. weight: 0.183 g 102.23 % Average weight of 20 Tablets: 0.179 g						
Date: 10/08/20 Time: 18:25					Done by:  (Production)						
WHITE PART [METFORMIN HCL] 23.5948 gm Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.604 gm Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.181	8	1.176	15	1.175	1	0.183	8	0.180	15	0.178
2	1.184	9	1.179	16	1.180	2	0.180	9	0.176	16	0.178
3	1.176	10	1.180	17	1.178	3	0.181	10	0.181	17	0.180
4	1.179	11	1.176	18	1.184	4	0.180	11	0.181	18	0.177
5	1.181	12	1.181	19	1.182	5	0.176	12	0.184	19	0.180
6	1.180	13	1.180	20	1.180	6	0.181	13	0.180	20	0.176
7	1.184	14	1.176			7	0.178	14	0.180		
Min. weight: 1.175 g 99.66 % Max. weight: 1.184 g 100.42 % Average weight of 20 Tablets: 1.179 g					Min. weight: 0.176 g 97.77 % Max. weight: 0.184 g 102.23 % Average weight of 20 Tablets: 0.180 g						

Prepared by:	Checked by:	Approved By:	
QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	Signature with Date	Signature with Date	
G. P. 04/06/2020	W. P. 04/06/2020	M. P. 04/06/2020	

	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD				Page No.:	62 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023	

11.10-C IN PROCESS CHECK FREQUENCY FOR INDIVIDUAL LAYER: EVERY 2 HOUR BY PRODUCTION:

Date: 06/08/20 Time: 20:30						Done by: [Signature] (Production)					
WHITE PART [METFORMIN HCL] 23.6158m Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] 3.5868m Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.181	8	1.187	15	1.184	1	0.178	8	0.180	15	0.181
2	1.176	9	1.180	16	1.186	2	0.181	9	0.176	16	0.183
3	1.179	10	1.181	17	1.180	3	0.180	10	0.180	17	0.180
4	1.175	11	1.176	18	1.181	4	0.176	11	0.181	18	0.176
5	1.180	12	1.176	19	1.176	5	0.180	12	0.176	19	0.175
6	1.184	13	1.174	20	1.175	6	0.175	13	0.180	20	0.179
7	1.181	14	1.180			7	0.177	14	0.176		
Min. weight: 1.174 g 99.49 % Max. weight: 1.187 g 100.59 % Average weight of 20 Tablets: 1.180 g						Min. weight: 0.175 g 97.76 % Max. weight: 0.183 g 102.23 % Average weight of 20 Tablets: 0.179 g					
Date: Time:						Done by: (Production)					
WHITE PART [METFORMIN HCL] Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1		8		15		1		8		15	
2		9		16		2		9		16	
3		10		17		3		10		17	
4		11		18		4		11		18	
5		12		19		5		12		19	
6		13		20		6		13		20	
7		14				7		14			
Min. weight: g % Max. weight: g % Average weight of 20 Tablets: g						Min. weight: g % Max. weight: g % Average weight of 20 Tablets: g					
Date: Time:						Done by: (Production)					
WHITE PART [METFORMIN HCL] Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1		8		15		1		8		15	
2		9		16		2		9		16	
3		10		17		3		10		17	
4		11		18		4		11		18	
5		12		19		5		12		19	
6		13		20		6		13		20	
7		14				7		14			
Min. weight: g % Max. weight: g % Average weight of 20 Tablets: g						Min. weight: g % Max. weight: g % Average weight of 20 Tablets: g					
Date: Time:						Done by: (Production)					
WHITE PART [METFORMIN HCL] Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1		8		15		1		8		15	
2		9		16		2		9		16	
3		10		17		3		10		17	
4		11		18		4		11		18	
5		12		19		5		12		19	
6		13		20		6		13		20	
7		14				7		14			
Min. weight: g % Max. weight: g % Average weight of 20 Tablets: g						Min. weight: g % Max. weight: g % Average weight of 20 Tablets: g					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
Signature with Date	G. P. 04/06/2020	Wijaya 04/06/2020	[Signature] 04/06/2020	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	63 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Glizalide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.11 IN PROCESS CHECK FREQUENCY FOR INDIVIDUAL LAYER: EVERY 2 HOUR BY IPQA:

Date: 07/08/20 Time: 20:50					Done by: <u>IPQA</u> (IPQA)						
WHITE PART [METFORMIN HCL] 23.580g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.612g Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.176	8	1.186	15	1.179	1	0.179	8	0.186	15	0.183
2	1.180	9	1.179	16	1.182	2	0.182	9	0.180	16	0.180
3	1.186	10	1.186	17	1.186	3	0.180	10	0.178	17	0.174
4	1.178	11	1.180	18	1.180	4	0.174	11	0.179	18	0.182
5	1.181	12	1.185	19	1.178	5	0.182	12	0.186	19	0.186
6	1.180	13	1.178	20	1.172	6	0.180	13	0.180	20	0.179
7	1.177	14	1.174			7	0.174	14	0.178		
Min. weight 1.172 g 98.08% Max. weight 1.186 g 100.84% Average weight of 20 Tablets: 1.179 g					Min. weight 0.174 g 98.64% Max. weight 0.186 g 100.72% Average weight of 20 Tablets: 0.180 g						
Date: 09/08/20 Time: 07:10					Done by: <u>Oh</u> (IPQA)						
WHITE PART [METFORMIN HCL] 23.609g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.609g Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.176	8	1.173	15	1.177	1	0.182	8	0.185	15	0.175
2	1.182	9	1.175	16	1.179	2	0.179	9	0.176	16	0.177
3	1.174	10	1.181	17	1.180	3	0.180	10	0.179	17	0.180
4	1.183	11	1.180	18	1.171	4	0.183	11	0.180	18	0.183
5	1.185	12	1.189	19	1.174	5	0.177	12	0.185	19	0.180
6	1.180	13	1.186	20	1.177	6	0.180	13	0.181	20	0.176
7	1.176	14	1.182			7	0.182	14	0.179		
Min. weight 1.171 g 99.25% Max. weight 1.189 g 100.77% Average weight of 20 Tablets: 1.180 g					Min. weight 0.175 g 97.22% Max. weight 0.185 g 102.78% Average weight of 20 Tablets: 0.180 g						
Date: 08/08/20 Time: 09:10					Done by: <u>Oh</u> (IPQA)						
WHITE PART [METFORMIN HCL] 23.627g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.627g Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.176	8	1.183	15	1.172	1	0.179	8	0.185	15	0.185
2	1.179	9	1.180	16	1.181	2	0.181	9	0.182	16	0.181
3	1.183	10	1.186	17	1.183	3	0.183	10	0.176	17	0.176
4	1.180	11	1.181	18	1.186	4	0.177	11	0.180	18	0.179
5	1.183	12	1.190	19	1.190	5	0.180	12	0.177	19	0.181
6	1.181	13	1.187	20	1.173	6	0.182	13	0.183	20	0.183
7	1.172	14	1.179			7	0.183	14	0.180		
Min. weight 1.172 g 99.25% Max. weight 1.190 g 100.73% Average weight of 20 Tablets: 1.181 g					Min. weight 0.176 g 97.23% Max. weight 0.185 g 102.73% Average weight of 20 Tablets: 0.181 g						

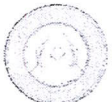
Prepared by:	Checked by:	Approved By:	
Designation	Designation	Designation	
Signature with Date	Signature with Date	Signature with Date	
G. U 04/06/2020	Ujwal B. 04/06/2020	M. U. 04/06/2020	

	Safetab Life Science			MASTER COPY	
				BATCH MANUFACTURING RECORD	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Page No.:	64 of 78
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/RO	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.11-A IN PROCESS CHECK FREQUENCY FOR INDIVIDUAL LAYER: EVERY 2 HOUR BY IPQA:

Date: 08/08/20 Time: 11:40					Done by: Oh (IPQA)						
WHITE PART [METFORMIN HCL] 23.664g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.608g Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.177	8	1.184	15	1.190	1	0.179	8	0.181	15	0.184
2	1.183	9	1.181	16	1.193	2	0.182	9	0.184	16	0.182
3	1.186	10	1.186	17	1.178	3	0.180	10	0.178	17	0.178
4	1.179	11	1.179	18	1.187	4	0.178	11	0.176	18	0.176
5	1.177	12	1.173	19	1.173	5	0.181	12	0.181	19	0.179
6	1.182	13	1.180	20	1.177	6	0.180	13	0.182	20	0.180
7	1.191	14	1.192			7	0.183	14	0.180		
Min. weight: 1.173 g 99.15% Max. weight: 1.193 g 100.85% Average weight of 20 Tablets: 1.183 g					Min. weight: 0.176 g 97.77% Max. weight: 0.184 g 102.23% Average weight of 20 Tablets: 0.180 g						
Date: 08/08/20 Time: 13:42					Done by: Oh (IPQA)						
WHITE PART [METFORMIN HCL] 23.644g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.611g Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.176	8	1.180	15	1.186	1	0.179	8	0.184	15	0.184
2	1.181	9	1.183	16	1.181	2	0.181	9	0.176	16	0.179
3	1.186	10	1.172	17	1.172	3	0.180	10	0.178	17	0.180
4	1.185	11	1.191	18	1.187	4	0.183	11	0.180	18	0.182
5	1.192	12	1.184	19	1.191	5	0.178	12	0.183	19	0.179
6	1.190	13	1.185	20	1.180	6	0.183	13	0.182	20	0.180
7	1.178	14	1.192			7	0.182	14	0.180		
Min. weight: 1.172 g 99.15% Max. weight: 1.192 g 100.85% Average weight of 20 Tablets: 1.182 g					Min. weight: 0.176 g 97.77% Max. weight: 0.184 g 102.23% Average weight of 20 Tablets: 0.180 g						
Date: 08/08/20 Time: 15:45					Done by: J.R. (IPQA)						
WHITE PART [METFORMIN HCL] 23.607g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.608g Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.179	8	1.173	15	1.185	1	0.179	8	0.180	15	0.183
2	1.182	9	1.186	16	1.180	2	0.182	9	0.177	16	0.180
3	1.180	10	1.180	17	1.173	3	0.174	10	0.174	17	0.179
4	1.173	11	1.178	18	1.177	4	0.182	11	0.183	18	0.185
5	1.177	12	1.173	19	1.182	5	0.177	12	0.186	19	0.180
6	1.185	13	1.186	20	1.180	6	0.183	13	0.180	20	0.177
7	1.180	14	1.179			7	0.186	14	0.178		
Min. weight: 1.173 g 98.64% Max. weight: 1.186 g 100.85% Average weight of 20 Tablets: 1.180 g					Min. weight: 0.174 g 98.47% Max. weight: 0.186 g 100.68% Average weight of 20 Tablets: 0.180 g						

Prepared by:	Checked by:	Approved By:	
QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date: G.V. 04/06/2020	Signature with Date: Vijayabharathi 04/06/2020	Signature with Date: M. Anand 04/06/2020	

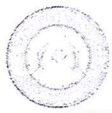
	Safetab Life Science		MASTER COPY		
			BATCH MANUFACTURING RECORD		
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Page No.:	65 of 78
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.11-B IN PROCESS CHECK FREQUENCY FOR INDIVIDUAL LAYER: EVERY 2 HOUR BY IPQA:

Date: 08/08/20 Time: 17:47						Done by: JKR (IPQA) 3.612					
WHITE PART [METFORMIN HCL] 23.613g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.179	8	1.183	15	1.183	1	0.182	8	0.179	15	0.187
2	1.182	9	1.185	16	1.179	2	0.179	9	0.176	16	0.182
3	1.180	10	1.180	17	1.178	3	0.180	10	0.178	17	0.177
4	1.185	11	1.187	18	1.180	4	0.183	11	0.183	18	0.180
5	1.182	12	1.182	19	1.182	5	0.185	12	0.180	19	0.182
6	1.178	13	1.179	20	1.183	6	0.181	13	0.183	20	0.180
7	1.178	14	1.181			7	0.179	14	0.186		
Min. weight: 1.174 g 98.64% Max. weight: 1.187 g 100.76% Average weight of 20 Tablets: 1.180 g						Min. weight: 0.174 g 98.72% Max. weight: 0.187 g 100.68% Average weight of 20 Tablets: 0.180 g					
Date: 08/08/20 Time: 20:20						Done by: JKR (IPQA) 3.602g					
WHITE PART [METFORMIN HCL] 23.608g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.182	8	1.177	15	1.187	1	0.181	8	0.173	15	0.176
2	1.177	9	1.180	16	1.178	2	0.179	9	0.180	16	0.173
3	1.180	10	1.181	17	1.183	3	0.180	10	0.182	17	0.180
4	1.184	11	1.185	18	1.173	4	0.187	11	0.183	18	0.182
5	1.182	12	1.176	19	1.181	5	0.183	12	0.176	19	0.187
6	1.185	13	1.181	20	1.180	6	0.178	13	0.180	20	0.181
7	1.180	14	1.182			7	0.180	14	0.187		
Min. weight: 1.173 g 98.48% Max. weight: 1.187 g 100.72% Average weight of 20 Tablets: 1.180 g						Min. weight: 0.173 g 98.47% Max. weight: 0.187 g 100.68% Average weight of 20 Tablets: 0.180 g					
Date: 09/08/20 Time: 07:10						Done by: QA (IPQA) 3.626g					
WHITE PART [METFORMIN HCL] 23.611g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.182	8	1.177	15	1.179	1	0.181	8	0.183	15	0.180
2	1.176	9	1.180	16	1.180	2	0.178	9	0.178	16	0.176
3	1.177	10	1.182	17	1.181	3	0.180	10	0.176	17	0.178
4	1.180	11	1.188	18	1.185	4	0.183	11	0.180	18	0.180
5	1.183	12	1.181	19	1.172	5	0.177	12	0.182	19	0.181
6	1.185	13	1.177	20	1.176	6	0.180	13	0.181	20	0.183
7	1.186	14	1.172			7	0.182	14	0.185		
Min. weight: 1.172 g 99.52% Max. weight: 1.188 g 100.68% Average weight of 20 Tablets: 1.180 g						Min. weight: 0.176 g 97.23% Max. weight: 0.185 g 102.77% Average weight of 20 Tablets: 0.181 g					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	G. R. 04/06/2020	W. J. 04/06/2020	M. J. 04/06/2020

CONTROLLED COPY

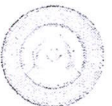
	Safetab Life Science		MASTER COPY A		
	BATCH MANUFACTURING RECORD		Page No.:	65 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.11-B IN PROCESS CHECK FREQUENCY FOR INDIVIDUAL LAYER: EVERY 2 HOUR BY IPQA:

Date: 09/08/20 Time: 09:20						Done by: <u>Ch</u> (IPQA)					
WHITE PART [METFORMIN HCL] 23.626g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] 3.608g Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.176	8	1.177	15	1.181	1	0.182	8	0.176	15	0.177
2	1.182	9	1.180	16	1.180	2	0.179	9	0.179	16	0.180
3	1.180	10	1.178	17	1.185	3	0.180	10	0.180	17	0.182
4	1.178	11	1.176	18	1.178	4	0.182	11	0.181	18	0.180
5	1.182	12	1.182	19	1.173	5	0.183	12	0.183	19	0.176
6	1.185	13	1.180	20	1.180	6	0.180	13	0.180	20	0.182
7	1.180	14	1.173			7	0.184	14	0.184		
Min. weight: 1.173 g 99.49% Max. weight: 1.185 g 100.51% Average weight of 20 Tablets: 1.179 g						Min. weight: 0.176 g 97.77% Max. weight: 0.184 g 102.23% Average weight of 20 Tablets: 0.180 g					
Date: 09/08/20 Time: 11:26						Done by: <u>Ch</u> (IPQA)					
WHITE PART [METFORMIN HCL] 23.646g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] 3.611g Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.181	8	1.172	15	1.179	1	0.182	8	0.179	15	0.183
2	1.180	9	1.186	16	1.180	2	0.178	9	0.181	16	0.182
3	1.186	10	1.183	17	1.183	3	0.180	10	0.183	17	0.180
4	1.178	11	1.192	18	1.189	4	0.181	11	0.182	18	0.184
5	1.191	12	1.183	19	1.192	5	0.183	12	0.178	19	0.179
6	1.183	13	1.181	20	1.174	6	0.180	13	0.176	20	0.178
7	1.177	14	1.172			7	0.176	14	0.180		
Min. weight: 1.172 g 99.15% Max. weight: 1.192 g 100.85% Average weight of 20 Tablets: 1.182 g						Min. weight: 0.176 g 97.77% Max. weight: 0.184 g 102.23% Average weight of 20 Tablets: 0.180 g					
Date: 09/08/20 Time: 13:26						Done by: <u>Ch</u> (IPQA)					
WHITE PART [METFORMIN HCL] 23.643g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] 3.629g Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.182	8	1.173	15	1.183	1	0.180	8	0.177	15	0.180
2	1.181	9	1.176	16	1.176	2	0.178	9	0.180	16	0.182
3	1.178	10	1.182	17	1.173	3	0.182	10	0.182	17	0.178
4	1.180	11	1.180	18	1.180	4	0.180	11	0.184	18	0.180
5	1.186	12	1.187	19	1.185	5	0.184	12	0.180	19	0.182
6	1.178	13	1.185	20	1.175	6	0.183	13	0.179	20	0.177
7	1.180	14	1.191			7	0.179	14	0.177		
Min. weight: 1.173 g 99.23% Max. weight: 1.191 g 100.77% Average weight of 20 Tablets: 1.182 g						Min. weight: 0.177 g 97.77% Max. weight: 0.184 g 102.21% Average weight of 20 Tablets: 0.181 g					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	<u>S. R. 04/06/2020</u>	<u>Ujaya B. 04/06/2020</u>	<u>M. 04/06/2020</u>

CONTROLLED COPY

	Safetab Life Science		BATCH MANUFACTURING RECORD		Page No.:	65 of 78
			Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023	

11.11-B IN PROCESS CHECK FREQUENCY FOR INDIVIDUAL LAYER: EVERY 2 HOUR BY IPQA:

Date: 10/8/20 Time: 07:55				Done by: JPR (IPQA)							
WHITE PART [METFORMIN HCL] 23.628g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]				COLOUR PART [GLICLAZIDE] 2.616g Limit: 180.000 ± 3% [174.600mg - 185.400mg]							
1	1.179	8	1.174	15	1.186	1	0.178	8	0.186	15	0.186
2	1.182	9	1.187	16	1.180	2	0.182	9	0.180	16	0.180
3	1.180	10	1.179	17	1.183	3	0.180	10	0.174	17	0.177
4	1.177	11	1.183	18	1.178	4	0.174	11	0.182	18	0.174
5	1.174	12	1.180	19	1.185	5	0.183	12	0.180	19	0.185
6	1.186	13	1.174	20	1.180	6	0.180	13	0.178	20	0.180
7	1.180	14	1.178			7	0.178	14	0.177		
Min. weight: 1.174 g 98.42% Max. weight: 1.187 g 100.78% Average weight of 20 Tablets: 1.181 g				Min. weight: 0.174 g 98.67% Max. weight: 0.186 g 100.86% Average weight of 20 Tablets: 0.180 g							
Date: 10/8/20 Time: 10:00				Done by: JPR (IPQA)							
WHITE PART [METFORMIN HCL] 23.612g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]				COLOUR PART [GLICLAZIDE] 3.609g Limit: 180.000 ± 3% [174.600mg - 185.400mg]							
1	1.177	8	1.180	15	1.186	1	0.177	8	0.173	15	0.186
2	1.182	9	1.179	16	1.180	2	0.182	9	0.184	16	0.180
3	1.180	10	1.176	17	1.179	3	0.180	10	0.180	17	0.178
4	1.187	11	1.182	18	1.184	4	0.186	11	0.179	18	0.182
5	1.173	12	1.187	19	1.180	5	0.173	12	0.183	19	0.180
6	1.178	13	1.180	20	1.178	6	0.185	13	0.180	20	0.176
7	1.187	14	1.178			7	0.180	14	0.173		
Min. weight: 1.173 g 98.48% Max. weight: 1.187 g 100.62% Average weight of 20 Tablets: 1.180 g				Min. weight: 0.173 g 98.64% Max. weight: 0.186 g 100.86% Average weight of 20 Tablets: 0.180 g							
Date: 10/8/20 Time: 12:08				Done by: JPR (IPQA)							
WHITE PART [METFORMIN HCL] 23.616g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]				COLOUR PART [GLICLAZIDE] 3.616g Limit: 180.000 ± 3% [174.600mg - 185.400mg]							
1	1.177	8	1.179	15	1.173	1	0.178	8	0.187	15	0.174
2	1.182	9	1.185	16	1.187	2	0.182	9	0.180	16	0.186
3	1.180	10	1.180	17	1.174	3	0.180	10	0.178	17	0.180
4	1.173	11	1.187	18	1.182	4	0.174	11	0.174	18	0.179
5	1.187	12	1.178	19	1.180	5	0.187	12	0.185	19	0.177
6	1.180	13	1.182	20	1.179	6	0.180	13	0.180	20	0.185
7	1.173	14	1.180			7	0.174	14	0.179		
Min. weight: 1.173 g 98.62% Max. weight: 1.187 g 100.74% Average weight of 20 Tablets: 1.180 g				Min. weight: 0.174 g 98.64% Max. weight: 0.187 g 100.78% Average weight of 20 Tablets: 0.180 g							

Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date: S. R. 04/06/2020	Signature with Date: [Signature] 04/06/2020	Signature with Date: [Signature] 04/06/2020	

	Safetab Life Science		Page No.: 65 of 78		
			BATCH MANUFACTURING RECORD		
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

11.11-B IN PROCESS CHECK FREQUENCY FOR INDIVIDUAL LAYER: EVERY 2 HOUR BY IPQA:

Date: 10/08/20 Time: 14:25						Done by: [Signature] (IPQA)					
WHITE PART [METFORMIN HCL] 23.625g						COLOUR PART [GLICLAZIDE] 3.607g					
Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.182	8	1.179	15	1.185	1	0.182	8	0.179	15	0.182
2	1.180	9	1.182	16	1.180	2	0.177	9	0.180	16	0.180
3	1.188	10	1.180	17	1.188	3	0.185	10	0.178	17	0.177
4	1.179	11	1.188	18	1.180	4	0.180	11	0.176	18	0.180
5	1.185	12	1.184	19	1.179	5	0.178	12	0.181	19	0.175
6	1.180	13	1.178	20	1.182	6	0.181	13	0.180	20	0.182
7	1.174	14	1.180			7	0.180	14	0.185		
Min. weight: 1.174 g 99.40% Max. weight: 1.188 g 100.59% Average weight of 20 Tablets: 1.181 g						Min. weight: 0.176 g 97.77% Max. weight: 0.185 g 102.77% Average weight of 20 Tablets: 0.180 g					
Date: 10/08/20 Time: 16:30						Done by: [Signature] (IPQA)					
WHITE PART [METFORMIN HCL] 23.591g						COLOUR PART [GLICLAZIDE] 3.626g					
Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.182	8	1.182	15	1.181	1	0.180	8	0.182	15	0.181
2	1.175	9	1.179	16	1.183	2	0.178	9	0.185	16	0.180
3	1.172	10	1.181	17	1.180	3	0.180	10	0.177	17	0.184
4	1.181	11	1.178	18	1.187	4	0.182	11	0.178	18	0.180
5	1.184	12	1.172	19	1.180	5	0.185	12	0.181	19	0.175
6	1.180	13	1.180	20	1.179	6	0.178	13	0.182	20	0.182
7	1.187	14	1.182			7	0.180	14	0.179		
Min. weight: 1.172 g 99.40% Max. weight: 1.187 g 100.67% Average weight of 20 Tablets: 1.179 g						Min. weight: 0.177 g 97.77% Max. weight: 0.185 g 102.20% Average weight of 20 Tablets: 0.181 g					
Date: 10/08/20 Time: 18:32						Done by: [Signature] (IPQA)					
WHITE PART [METFORMIN HCL] 23.634g						COLOUR PART [GLICLAZIDE] 3.593g					
Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.182	8	1.180	15	1.182	1	0.180	8	0.180	15	0.175
2	1.178	9	1.175	16	1.181	2	0.180	9	0.178	16	0.180
3	1.174	10	1.179	17	1.190	3	0.178	10	0.181	17	0.180
4	1.176	11	1.174	18	1.187	4	0.175	11	0.180	18	0.176
5	1.188	12	1.182	19	1.180	5	0.180	12	0.184	19	0.181
6	1.190	13	1.180	20	1.178	6	0.184	13	0.179	20	0.179
7	1.181	14	1.184			7	0.179	14	0.180		
Min. weight: 1.174 g 99.40% Max. weight: 1.190 g 100.76% Average weight of 20 Tablets: 1.181 g						Min. weight: 0.175 g 97.76% Max. weight: 0.184 g 102.77% Average weight of 20 Tablets: 0.179 g					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	[Signature] 04/06/2020	[Signature] 04/06/2020	[Signature] 04/06/2020

CONTROLLED COPY

		Safetab Life Science		MASTER COPY D	
		BATCH MANUFACTURING RECORD			
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Page No.:	65 of 78
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Batch Size	5,00,000 Tablets
Batch No.:	GD200701	Mfg. Date:	07/2020	Supersedes MFC No:	NIL
			Exp. Date:	06/2023	

11.11-B IN PROCESS CHECK FREQUENCY FOR INDIVIDUAL LAYER: EVERY 2 HOUR BY IPQA:

Date: <u>10/08/20</u> Time: <u>20:40</u>										Done by: <u>IPQA</u> (IPQA)									
WHITE PART [METFORMIN HCL] Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]										COLOUR PART [GLICLAZIDE] Limit: 180.000 ± 3% [174.600mg - 185.400mg]									
1	1.180	8	1.172	15	1.178	1	0.180	8	0.178	15	0.178								
2	1.178	9	1.180	16	1.181	2	0.178	9	0.180	16	0.180								
3	1.176	10	1.178	17	1.177	3	0.180	10	0.179	17	0.179								
4	1.180	11	1.182	18	1.185	4	0.176	11	0.180	18	0.180								
5	1.172	12	1.186	19	1.178	5	0.180	12	0.179	19	0.184								
6	1.180	13	1.180	20	1.180	6	0.184	13	0.184	20	0.180								
7	1.186	14	1.178			7	0.180	14	0.180										
Min. weight: <u>1.172</u> g Max. weight: <u>1.186</u> g Average weight of 20 Tablets: <u>1.179</u> g					Min. weight: <u>0.176</u> g Max. weight: <u>0.184</u> g Average weight of 20 Tablets: <u>0.180</u> g					Min. weight: <u>0.177</u> g Max. weight: <u>0.184</u> g Average weight of 20 Tablets: <u>0.180</u> g									
Date: <u>10/08/20</u> Time: <u>20:40</u>										Done by: <u>IPQA</u> (IPQA)									
WHITE PART [METFORMIN HCL] Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]										COLOUR PART [GLICLAZIDE] Limit: 180.000 ± 3% [174.600mg - 185.400mg]									
1		8		15		1		8		15									
2		9		16		2		9		16									
3		10		17		3		10		17									
4		11		18		4		11		18									
5		12		19		5		12		19									
6		13		20		6		13		20									
7		14				7		14											
Min. weight: <u>1.172</u> g Max. weight: <u>1.186</u> g Average weight of 20 Tablets: <u>1.179</u> g					Min. weight: <u>0.176</u> g Max. weight: <u>0.184</u> g Average weight of 20 Tablets: <u>0.180</u> g					Min. weight: <u>0.177</u> g Max. weight: <u>0.184</u> g Average weight of 20 Tablets: <u>0.180</u> g									
Date: <u>10/08/20</u> Time: <u>20:40</u>										Done by: <u>IPQA</u> (IPQA)									
WHITE PART [METFORMIN HCL] Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]										COLOUR PART [GLICLAZIDE] Limit: 180.000 ± 3% [174.600mg - 185.400mg]									
1		8		15		1		8		15									
2		9		16		2		9		16									
3		10		17		3		10		17									
4		11		18		4		11		18									
5		12		19		5		12		19									
6		13		20		6		13		20									
7		14				7		14											
Min. weight: <u>1.172</u> g Max. weight: <u>1.186</u> g Average weight of 20 Tablets: <u>1.179</u> g					Min. weight: <u>0.176</u> g Max. weight: <u>0.184</u> g Average weight of 20 Tablets: <u>0.180</u> g					Min. weight: <u>0.177</u> g Max. weight: <u>0.184</u> g Average weight of 20 Tablets: <u>0.180</u> g									

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	<u>S. R. 04/06/2020</u>	<u>U. S. 04/06/2020</u>	<u>10/06/2020</u>

CONTROLLED COPY

	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD				Page No.:	66 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023	

11.12 WEIGHING RECORD OF COMPRESSED TABLETS:-

Container No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by/date	Container No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by/date
1	18.26	1.80	16.46	Immanu	P. R. 01/08/20	31	18.25	1.80	16.45	Immanu	P. R. 01/08/20
2	18.03	1.80	16.23	Immanu	P. R. 01/08/20	32	19.28		17.48		
3	17.00	1.80	15.20	Immanu	P. R. 01/08/20	33					
4	18.63	1.80	16.23	Immanu	P. R. 01/08/20	34					
5	18.23	1.80	16.43	Immanu	P. R. 01/08/20	35					
6	17.96	1.80	16.16	Immanu	P. R. 01/08/20	36					
7	33.73	2.50	31.23	Immanu	P. R. 01/08/20	37					
8	32.79	2.50	30.29	Immanu	P. R. 01/08/20	38					
9	33.87	2.50	31.37	Immanu	P. R. 01/08/20	39					
10	31.49	2.50	28.99	Maharaju	P. R. 01/08/20	40					
11	38.22	2.50	30.72	Maharaju	P. R. 01/08/20	41					
12	30.22	2.50	27.72	Maharaju	P. R. 01/08/20	42					
13	18.40	1.80	16.60	Vijayan	P. R. 01/08/20	43					
14	18.24	1.80	16.44	Vijayan	P. R. 01/08/20	44					
15	17.56	1.80	15.76	Vijayan	P. R. 01/08/20	45					
16	18.04	1.80	16.24	Vijayan	P. R. 01/08/20	46					
17	17.89	1.80	16.09	Vijayan	P. R. 01/08/20	47					
18	17.96	1.80	16.16	Vijayan	P. R. 01/08/20	48					
19	18.12	1.80	16.32	Vijayan	P. R. 01/08/20	49					
20	18.33	1.80	16.53	Vijayan	P. R. 01/08/20	50					
21	37.40	2.50	34.90	Maharaju	P. R. 01/08/20	51					
22	34.90	2.50	32.40	Maharaju	P. R. 01/08/20	52					
23	31.25	2.50	28.75	Maharaju	P. R. 01/08/20	53					
24	29.88	2.50	27.38	Maharaju	P. R. 01/08/20	54					
25	17.80	1.80	16.00	Immanu	P. R. 01/08/20	55					
26	18.58	1.80	16.78	Immanu	P. R. 01/08/20	56					
27	18.70	1.80	16.90	Immanu	P. R. 01/08/20	57					
28	18.32	1.80	16.52	Immanu	P. R. 01/08/20	58					
29	19.72	1.80	17.92	Immanu	P. R. 01/08/20	59					
30	18.20	1.80	16.40	Immanu	P. R. 01/08/20	60					
Total weight of compressed tablets:							647.54648.57 kg				

Intimate IPQA to draw the sample.	Sample withdrawn by IPQA.
Production Sign: <i>[Signature]</i> Date: 10/08/20	IPQA Sign: <i>[Signature]</i> Date: 10/08/20
Send Test Request Form for analysis of compressed tablets to QC department.	

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	<i>[Signature]</i> 9.8.04/06/2020	<i>[Signature]</i> 04/06/2020	<i>[Signature]</i> 04/06/2020

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	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	67 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

12.0 RECONCILIATION:

1.0	Theoretical weight of Compressed tablets	:	680.00 Kg	500000 No's
2.0	Actual weight of Compressed tablets	:	648.57 Kg	4,76,889
3.0	Manufacturing Loss (1.0 - 6.0)	:	27.75 Kg	20,404
4.0	In-process samples			
	A IPQA Samples	:	2.47 Kg	1,820
	B QC Samples	:	0.13 Kg	120
	C Validation Samples	:	1.08 Kg	800
5.0	Total samples: (A + B + C)	:	3.68 Kg	2,720
6.0	Total: (5.0 + 2.0)	:	652.25 Kg	4,79,593
7.0	% Yield = $\frac{6.0}{1.0} \times 100$ Limit: NLT 95.00%*	:	95.91	%
If yield is out of limit raise deviation and inform to QA. After QA investigation and approval proceed to the next stage.				

*Tentative limit

Total rejects destroyed: 27.75 Kg. by Production sign/Date: 21/08/2020 Checked By IPQA sign/Date: 10/08/2020

(Rejected materials should be destroyed in the presence of IPQA.)

Yield reconciliation done by Production sign/Date: 21/08/2020 Checked By IPQA sign/Date: 10/08/2020

12.1 COMPRESSED TABLETS RELEASED FOR INSPECTION:

Checked by Production Sign/Date: 21/08/2020

IPQA sign/Date: 30/08/2020

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	9.18 04/06/2020	Ujaya 04/06/2020	04/06/2020	CONTROLLED COPY

	Safetab Life Science		MASTER COPY		
	BATCH MANUFACTURING RECORD		Page No.:	68 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg. Date:	07/2020	Exp. Date:	06/2023

13.0 TABLET INSPECTION:

13.1 LINE CLEARANCE CHECKS:

S.No	Checks	Observation	
		Production	IPQA
1	Check whether empty containers, polythene bags and documents of previous batch/product are removed from the area.	✓	✓
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.	✓	✓
3	Check the absence of tablets of previous batch/product in the container and surrounding area.	✓	✓
4	Check whether the area (floor, wall, ceiling, door, windows) are clean.	✓	✓
5	Check whether the tubelight fixture, supply grills, riser grills, filters and electrical fixtures are clean.	✓	✓
6	Check whether the daily records are updated and signed.	✓	✓
7	Check the environmental condition and record in BMR	✓	✓
8	Check whether area and equipment status board is updated.	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (Production) sign/date: *[Signature]* 30/08/2020

Verified by (IPQA) sign/date: *[Signature]* 30/08/2020

13.2 ENVIRONMENTAL CONDITIONS		Date: 30/08/2020		Date: 31/08/2020	
Refer Current version of SOP	Temperature: 23°C to 27°C Relative Humidity: 45% to 55 %	Observation	Production Sign	Observation	Production Sign
		24.5	<i>[Signature]</i>	24.5	<i>[Signature]</i>
		53%	<i>[Signature]</i>	54%	<i>[Signature]</i>

13.3 APPROVAL FOR INSPECTION:

Production Sign./Date: *[Signature]* 30/08/2020

Line clearance IPQA Sign./Date: *[Signature]* 30/08/2020

S. No	Process Instructions
1	Carry out visual inspection of tablets on tablet manual inspection area.
2	Collect inspected tablets in containers lined with polythene bags. Weigh the containers and record the weight.
3	Intimate In-process Quality Assurance.

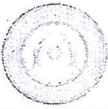
13.4 TABLETS VISUAL INSPECTION RECORD:

Types of rejection: broken tablets, damage edges, capping, sticking, foreign particle and for other rejections.

Date	Container No		Time		Total Quantity Rejected	Tablets Inspection Done by/Date	Checked by/Date
	From	To	Started	Completed			
30/08/2020	01	04	20:35	22:00	0.17 kg	Mayavathi, Swathy	<i>[Signature]</i> 30/08/2020
31/08/2020	05	31	06:05	11:00	0.40 kg	Hanjula, Malli, Habathi, Chitra	<i>[Signature]</i> 31/08/2020
					NA		<i>[Signature]</i> 31/08/2020

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	<i>[Signature]</i> 04/06/2020	<i>[Signature]</i> 04/06/2020	<i>[Signature]</i> 04/06/2020

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	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	69 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg. Date:	07/2020	Exp. Date:	06/2023

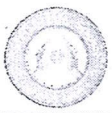
13.5 WEIGHING RECORD OF INSPECTED TABLETS:

Date: 30/08/2022

Container No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by/date	Container No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by/date
1	18.20	1.80	16.40	Puthalika	(Signature)	31	18.32	1.80	16.52	Gopi	(Signature)
2	18.00	1.80	16.20	Puthalika	(Signature)	32					
3	16.99	1.80	15.19	Puthalika	(Signature)	33					
4	18.60	1.80	16.80	Puthalika	(Signature)	34					
5	18.20	1.80	16.40	Gopi	(Signature)	35					
6	17.92	1.80	16.12	Gopi	(Signature)	36					
7	33.70	2.50	31.20	Gopi	(Signature)	37					
8	32.70	2.50	30.20	Gopi	(Signature)	38					
9	33.85	2.50	31.35	Gopi	(Signature)	39					
10	31.45	2.50	28.95	Gopi	(Signature)	40					
11	33.21	2.50	30.71	Gopi	(Signature)	41					
12	30.20	2.50	27.70	Gopi	(Signature)	42					
13	18.39	1.80	16.59	Gopi	(Signature)	43					
14	18.23	1.80	16.43	Gopi	(Signature)	44					
15	17.55	1.80	15.75	Gopi	(Signature)	45					
16	18.02	1.80	16.22	Gopi	(Signature)	46					
17	17.82	1.80	16.02	Gopi	(Signature)	47					
18	17.95	1.80	16.15	Gopi	(Signature)	48					
19	18.11	1.80	16.31	Gopi	(Signature)	49					
20	18.32	1.80	16.52	Gopi	(Signature)	50					
21	37.39	2.50	34.89	Gopi	(Signature)	51					
22	38.89	2.50	36.39	Gopi	(Signature)	52					
23	31.24	2.50	28.74	Gopi	(Signature)	53					
24	29.87	2.50	27.37	Gopi	(Signature)	54					
25	17.78	1.80	15.98	Gopi	(Signature)	55					
26	18.56	1.80	16.76	Gopi	(Signature)	56					
27	18.67	1.80	16.87	Gopi	(Signature)	57					
28	18.30	1.80	16.50	Gopi	(Signature)	58					
29	19.71	1.80	17.91	Gopi	(Signature)	59					
30	18.18	1.80	16.38	Gopi	(Signature)	60					
Total weight of inspected tablets:							648.00		kg		

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	G. V. 04/06/2020	Udaya 04/06/2020	(Signature) 04/06/2020

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	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	70 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg. Date:	07/2020	Exp. Date:	06/2023

14.0 RECONCILIATION: (INSPECTION OF TABLETS)

1.0	Theoretical weight of tablets	:	680.00 kg	500000 No's
2.0	Tablets transferred for Inspection	:	648.57 kg	476889 No's
3.0	Rejected tablets	:	0.57 kg	419 No's
4.0	Total weight of good tablets	:	648.00 kg	476471 No's
5.0	% Yield = $\frac{4.0}{1.0} \times 100$ (Limit- NLT 94.0%)*	:	95.29	%

If yield is out of limit, raise deviation and inform to QA. After QA, investigation and approval proceed to the next stage.

*Tentative limit

Total rejects destroyed: 0.57 Kg by Production/Date: 31/08/2020 Checked by IPQA/Date: 31/08/2020

(Rejected materials should be destroyed in the presence of QA)

Yield reconciliation done by Production/Date: 31/08/2020 Checked by IPQA/Date: 31/08/2020

14.1 RELEASE FOR PACKING

Compressed tablet report checked and released for packing

Checked by Competent Staff Sign/Date: 31/08/2020 IPQA Sign/Date: 31/08/2020

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	9.14/04/06/2020	Ujaya/04/06/2020	10/06/2020	

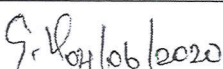
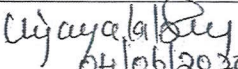
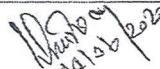
	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	71 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

15.0 PROCESS HISTORY

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<i>G. D.</i> 04/06/2020	<i>Ujaya...</i> 04/06/2020	<i>...</i> 04/06/2020	

	Safetab Life Science			MASTER COPY	
BATCH MANUFACTURING RECORD				Page No.:	72 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

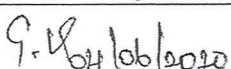
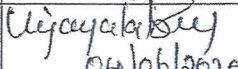
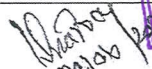
16.0 Following the BMR records in additional attached.		Checked by Production Head	Reviewed by QA Head
1	Raw Materials dispensed labels	/	/
2	Granulation stage analytical report	/	/
3	Compression stage analytical report	/	/
Note: Tick mark (✓) if Complies and (X) if Does not comply.			
This Batch Manufacturing reviewed on date..... 31/08/2020		Production Head sign/date.....  31/08/20	
This Batch Manufacturing Record received, reviewed and batch is released for packing on date..... 31/08/2020		Reviewed by QA Head.....  31/08/20	

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/06/2020	 04/06/2020	 04/06/2020	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	73 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

17.0 ABBREVIATIONS

S.No.	Short Form	Abbreviation	S.No.	Short Form	Abbreviation
1	BP	British Pharmacopeia	19	A.R.No.	Analytical Report Number
2	API	Active Pharmaceutical Ingredients	20	IPQA	In Process Quality Assurance
3	BMR	Batch Manufacturing Record	21	L	Lakhs
4	MFG	Manufacturing	22	TRF	Test Request Form
5	EXP	Expiry	23	RMG	Rapid Mixer Granulator
6	QA	Quality Assurance	24	FBD	Fluid Bed Drier
7	Kg	Kilogram	25	SOP	Standard Operating Procedure
8	g	Gram	26	mm	Millimeter
9	lts	Liters	27	NLT	Not Less Than
10	Min	Minutes	28	NMT	Not More Than
11	Hrs	Hours	29	Tab	Tablet
12	M/C	Machine	30	RHS	Right Hand Side
13	Prod	Production	31	LHS	Left Hand Side
14	B.No	Batch number	32	Std	Standard
15	mg	Milligram	33	Avg	Average
16	Qty	Quantity	34	rpm	Rotation Per Minute
17	QC	Quality Control	35	No's	Numbers
18	LOD	Loss On Drying	36	Sign	Signature

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/06/2020	 04/06/2020	 04/06/2020	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	74 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO.:	ST/MFC/130/R0	Supersedes MFC No.:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

BMR COPY/QUALITY CONTROL COPY

18.0 TEST REQUEST FORM FOR LUBRICATED GRANULES [METFORMIN HYDROCHLORIDE PART]

From: Manufacturing Department		To: Q.A. Department	
To be filled by production		To be filled by IPQA	
Date of Mfg: <u>07/2020</u> Date of exp: <u>06/2023</u>		Quantity Sampled: <u>50 gms.</u>	
Test Request for: <u>Content</u>		Sampled by: <u>JR</u> on date: <u>04/08/20</u>	
TRF raised by: <u>[Signature]</u> on date: <u>03/08/20</u>		No. of containers: <u>15</u>	
To be filled by QC		Sample received by: <u>[Signature]</u> on date: <u>04/08/20</u>	
TRF received on: <u>04/08/20</u>			
Sample tested on: <u>05/08/20</u>			
Test Results		Limits	
Each 1180mg of granule containing metformin Hcl - 826.10mg (97.2%)			
Analytical Reference no.: <u>GH100519/2020</u> Analysed By: <u>[Signature]</u> on: <u>06/08/20</u>		Space for QC Approval (Stamping and Signing) <u>[Signature]</u> <u>06/08/20</u> Sign: _____ Date: _____	

	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
Designation				
Signature with Date	<u>[Signature]</u> <u>04/06/2020</u>	<u>[Signature]</u> <u>04/06/2020</u>	<u>[Signature]</u> <u>04/06/2020</u>	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	75 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

BMR COPY/QUALITY CONTROL COPY

19.0 TEST REQUEST FORM FOR LUBRICATED GRANULES [GLICLAZIDE PART]

From: Manufacturing Department	To: Q.A. Department
To be filled by production	To be filled by IPQA
Date of Mfg.: 07/2020 Date of exp: 06/2023	Quantity Sampled: 50g
Test Request for: content	Sampled by: Chandra on date: 01/08/20
TRF raised by: [Signature] on date: 01/08/20	No. of containers: 3
	Sample received by: [Signature] on date: 02/08/20
To be filled by QC	
TRF received on: 02/08/20	
Sample tested on: 05/08/20	
Test Results	Limits
Each 180mg of granule containing Gliclazide - 57.71mg (96.2%)	
Analytical Reference no.: G11100511/2020 Analysed By: [Signature] on: 06/08/20	Space for QC Approval (Stamping and Signing)  Sign: [Signature] Date: 06/08/20

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	
Signature with Date	S. V. 04/06/2020	Vijayalakshmi 04/06/2020	[Signature] 04/06/2020	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	76 of 78
'Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

BMR COPY/QUALITY CONTROL COPY

20.0 TEST REQUEST FORM FOR COMPRESSED TABLETS

From: Manufacturing Department	To: Q.A. Department
To be filled by production Date of Mfg.: 07/2020 Date of exp: 06/2023 Test Request for: Content TRF raised by: [Signature] on date: 10/08/2020	To be filled by IPQA Quantity Sampled: 100 tablets Sampled by: [Signature] on date: 10/08/2020 No. of containers: 30 Sample received by: [Signature] on date: 10/08/2020
To be filled by QC TRF received on: 10/08/2020 Sample tested on: 10/08/2020	
Test Results	Limits
Each bilayer uncoated tablet contains: Gliclazide: Assay: 57.52 mg (95.9%) Disso: I st Hr: 17.1% 26.2% (20.0%) (Lt NMT 25%) II nd Hr: 46.1% 59.7% (50.2%) (Lt = 30-60%) XII th Hr: 84.7% 110% (91.1%) (Lt - NLT 70%) Metformin Hcl: Assay: 857.72 mg (100.9%) (Lt - 20-40%) Disso: I st Hr: 24.5% 25.6% (25.1%) (Lt - 45-65%) III rd Hr: 49.2% 51.2% (49.8%) (Lt - NLT 85%) X Hr: 96.6% 99.7% (98.2%)	
Analytical Reference no.: SFA/H/00759/200 Analysed By: [Signature] on: 20/08/2020	Space for QC Approval (Stamping and Signing) APPROVED Sign: [Signature] Date: 20/08/20

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	[Signature] 10/06/2020	[Signature] 04/06/2020	[Signature] 09/06/2020	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	77 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023

21.0 BATCH MANUFACTURING RECORD REVIEW CHECK LIST		
S.No. No.	CHECK POINTS	Status
1	The entire Page no: <u>01</u> to <u>78</u> are available, verified and found correct.	Yes / No
2	Batch numbers available in all pages verified and are correct.	Yes / No
3	Manufacturing and expiry is correctly allotted verified.	Yes / No
4	Dispensing carried out on calibrated balance verified.	Yes / No
5	Dispensing Cards attached.	Yes / No
6	Line clearance is taken prior to all dispensing and manufacturing activities.	Yes / No
7	Dispensing is carried out as per indent of raw materials are correct.	Yes / No
8	Environmental conditions comply during all the manufacturing steps.	Yes / No
9	All wrong entries if any have been strike out and signed and verified.	Yes / No
10	Actual equipment used is as specified and verified.	Yes / No
11	Dry mixing, compression and coating reconciliation is filled and variance is within acceptance limit.	Yes / No
12	If any deviation and change control raised related to this batch attached with Batch record.	Yes / No / NA
Note:	If any abnormalities noticed during batch manufacturing record review it should be brought to the notice of QA Head.	

Batch Manufacturing Record reviewed by IPQA Sign/Date: 31/08/2020

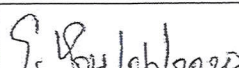
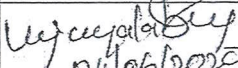
QA Head Sign/Date: 31/08/2020

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>9.18/04/06/2020</u>	<u>Wajayal Ray</u> <u>04/06/2020</u>	<u>QA Head</u> <u>04/06/2020</u>	

	Safetab Life Science				CONTROLLED COPY	
	BATCH MANUFACTURING RECORD				Page No.:	78 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	GD200701	Mfg.Date:	07/2020	Exp.Date:	06/2023	

22.0 REVISION HISTORY:

Revision No.	Date of Revision	Changes Made	Effective Date
00	--	1.0 New product introduced, refer change control no. ST/CC/20/21.	04/06/20

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/06/2020	 04/06/2020	 04/06/2020	