



Safetab Life Science

PROCESS VALIDATION REPORT

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Doc No.: PVR /20/004

MASTER COPY

Ref. Protocol No.: PVP/20/004

Product

Gliclazide and Metformin Hydrochloride Sustained
Release Tablets 60/850mg

**PROCESS VALIDATION REPORT FOR
GLICLAZIDE AND METFORMIN
HYDROCHLORIDE SUSTAINED RELEASE
TABLETS 60/850MG**

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	PROCESS VALIDATION REPORT	Doc No.: PVR /20/004
Product	Gliclazide and Metformin Hydrochloride Sustained Release Tablets 60/850mg	Ref. Protocol No.: PVP/20/004

Product Name :Gliclazide and Metformin Hydrochloride Sustained Release Tablets 60/850mg			
Batch No :	GD200604	GD200701	GD210302
Batch Size :	500000	500000	500000
Mfg. Date :	06/2020	07/2020	03/2021
Expiry Date :	05/2023	06/2023	02/2024

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	PROCESS VALIDATION REPORT	Doc No.: PVR /20/004	
Product	Gliclazide and Metformin Hydrochloride Sustained Release Tablets 60/850mg		Ref. Protocol No.: PVP/20/004

1.0 INTRODUCTION:

This report summarizes the results of validation performed as per the Process Validation Protocol No. PVP/20/004.

2.0 REFERENCES:

The batches were manufactured and analysed as per Batch Manufacturing Record / Standard Operating Procedure.

3.0 VALIDATION:

3.1 VALIDATION OF DRY MIXING

DRY MIXING - BLEND UNIFORMITY OF GLICLAZIDE & METFORMIN HYDROCHLORIDE (Value in %)

Limits		GLICLAZIDE AND METFORMIN HYDROCHLORIDE (85.0% - 115.0%)														
Batch No.		GD200604					GD200701					GD210302				
		Mixing Time					Mixing Time					Mixing Time				
		10 mins	10 mins				10 mins	10 mins				10 mins	10 mins			
		Gliclazide	Metformin Hydrochloride				Gliclazide	Metformin Hydrochloride				Gliclazide	Metformin Hydrochloride			
			Lot-1	Lot-2	Lot-3	Lot-4		Lot-1	Lot-2	Lot-3	Lot-4		Lot-1	Lot-2	Lot-3	Lot-4
Sampling point	TL	93.1	100.4	100.8	99.8	98.5	93.4	100.4	100.6	100.5	101.3	99.0	101.8	102.7	102.0	102.2
	TR	91.6	101.8	99.6	98.5	99.6	92.3	100.5	100.8	101.1	99.7	99.9	102.2	102.4	102.8	104.9
	M	95.9	98.3	99.2	102.1	99.5	95.1	98.8	98.9	100.2	100.8	101.9	103.3	102.5	102.9	101.9
	BF	92.9	100.9	100.5	97.3	101.4	95.3	99.8	99.9	99.8	99.9	97.7	102.1	102.4	104.3	102.9
	BR	93.4	102.1	97.9	101.2	97.7	90.5	99.8	99.3	99.0	100.4	100.5	101.3	104.6	102.6	102.8
Composite		94.5	99.7	99.3	98.6	96.6	96.3	99.5	100.4	100.9	98.9	98.8	106.8	102.8	101.8	103.5
Minimum		91.6	98.3	97.9	97.3	97.7	92.3	98.8	98.9	99.8	99.7	97.7	101.3	102.4	101.8	101.9
Maximum		95.9	101.8	100.8	102.1	101.4	96.3	100.5	100.8	101.1	100.8	101.9	106.8	104.6	104.3	104.9
Mean		93.4	100.7	99.6	99.8	99.3	93.3	99.9	99.9	100.1	100.4	99.8	102.1	102.9	102.9	103.0
RSD (NMT 5%)		1.6	1.4	1.1	1.9	1.3	2.1	0.6	0.8	0.7	0.6	1.5	0.7	0.9	0.8	1.1

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3.2 VALIDATION OF BLENDING

BLENDING - BLEND UNIFORMITY OF GLICLAZIDE & METFORMIN HYDROCHLORIDE (Value in %)							
Limits		GLICLAZIDE & METFORMIN HYDROCHLORIDE (85.0% - 115.0%)					
Batch No.		GD200604		GD200701		GD210302	
		Mixing Time		Mixing Time		Mixing Time	
		10 mins	10 mins	10 mins	10 mins	10 mins	10 mins
		Gliclazide	Metformin Hydrochloride	Gliclazide	Metformin Hydrochloride	Gliclazide	Metformin Hydrochloride
Sampling point	TCL	91.4	97.7	86.7	94.0	98.7	93.4
	TC	86.7	100.7	87.3	95.6	98.2	95.1
	TCR	87.6	99.0	88.5	97.5	97.7	93.7
	BFL	91.9	94.9	86.3	92.4	96.5	93.9
	BFC	87.6	96.8	87.3	97.3	98.0	95.1
	BFR	92.3	95.1	90.4	98.4	97.4	92.8
	MBL	91.8	99.4	89.4	94.1	97.7	95.5
	MBC	89.6	98.1	87.7	94.4	98.7	94.7
	MBR	88.8	98.5	83.8	97.9	97.1	94.3
	DP	87.2	96.5	91.2	97.8	98.5	95.0
Composite		94.6	98.9	90.9	97.5	97.2	94.2
Minimum		86.7	95.1	83.8	92.4	96.5	92.8
Maximum		92.3	100.7	90.4	98.4	98.7	95.5
Mean		89.5	97.7	87.9	95.9	97.8	94.4
RSD (NMT 5%)		2.4	1.9	2.4	2.1	0.7	0.9

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3.3 VALIDATION OF LUBRICATION

LUBRICATION - BLEND UNIFORMITY OF GLICLAZIDE & METFORMIN HYDROCHLORIDE (Value in %)							
Limits		GLICLAZIDE & METFORMIN HYDROCHLORIDE (85.0% - 115.0%)					
Batch No.		GD200604		GD200701		GD210302	
		Mixing Time		Mixing Time		Mixing Time	
		3 mins	3 mins	3 mins	3 mins	3 mins	3 mins
		Gliclazide	Metformin Hydrochloride	Gliclazide	Metformin Hydrochloride	Gliclazide	Metformin Hydrochloride
Sampling point	TCL	97.5	101.6	98.2	100.8	104.6	99.9
	TC	98.2	100.5	103.3	101.3	102.6	90.8
	TCR	98.3	98.7	100.7	96.0	103.6	99.3
	BFL	100.0	98.7	98.2	100.5	102.1	102.0
	BFC	96.8	99.9	97.8	97.6	99.8	101.5
	BFR	99.0	95.5	98.5	100.4	99.9	90.8
	MBL	98.9	99.4	101.1	98.8	102.8	101.2
	MBC	97.3	97.4	96.1	101.0	101.0	99.5
	MBR	97.7	98.0	97.2	100.7	100.4	101.1
	DP	99.9	98.8	99.3	101.0	100.0	99.7
Composite		100.1	98.7	99.2	101.9	101.2	103.7
Minimum		97.3	97.4	96.1	96.0	99.8	90.8
Maximum		100.0	101.6	103.3	100.8	104.6	103.7
Mean		98.4	98.8	99.0	99.8	101.7	98.6
RSD (NMT 5%)		1.0	1.7	2.1	1.7	1.6	4.2

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3.4 Description of Blend, Bulk density and Particle size analysis: Gliclazide part

Tests	Results		
Batch No.	GD200604	GD200701	GD210302
Description of blend	Red colour granular powder.	Red colour granular powder.	Red colour granular powder.
Bulk density Untapped	0.53g/ml	0.59g/ml	0.54g/ml
Tapped	0.59g/ml	0.67g/ml	0.61g/ml
Particle size distribution Retention on (20#,30#,40#,60# 80# & 100#)	(0.09%, 1.08%, 3.47%, 35.16%, 74.8%, 84.97%)	(3.42%, 7.03%, 8.84%, 17.16%, 33.57%, 45.66%)	(0.07%, 1.06%, 3.42%, 34.11%, 73.75%, 83.58%)
Particle size distribution passing on 100#	13.59%	58.46%	12.61%

3.5 Description of Blend, Bulk density and Particle size analysis: Metformin part

Tests	Results		
Batch No.	GD200604	GD200701	GD210302
Description of blend	White colour granular powder.	White colour granular powder.	White colour granular powder.
Bulk density Untapped	0.53g/ml	0.56g/ml	0.53g/ml
Tapped	0.67g/ml	0.63g/ml	0.63g/ml
Particle size distribution Retention on (20#,30#,40#,60# 80# & 100#)	(10.28%, 22.55%, 33.94%, 49.00%, 60.43%, 66.84%)	(8.35%, 18.13%, 27.89%, 41.36%, 53.49%, 61.44%)	(8.51%,20.20%, 34.44%, 49.36%, 62.13%, 68.73%)
Particle size distribution passing on 100#	30.70%	37.49%	29.17%

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4.0 VALIDATION OF COMPRESSION PROCESS (Batch No: GD200604):

4.1 INDIVIDUAL WEIGHT VARIATION, THICKNESS, HARDNESS AND FRIABILITY: (Batch No: GD200604):

(Batch No. GD20004):

Stage	MINIMUM COMPRESSION FORCE (LOW HARDNESS)									
Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides									
Group Weight of 20 tablets : 27.200g ± 3 % Limits : (26.384g to 28.016g) Avg Weight : 1360 mg ± 5% Limits : (1292.00mg – 1428.00mg) Uniformity of weight : Avg weight ± 5.0% (1292.00mg – 1428.00mg)										
Sample No.	1	2	3	4	5	6	7	8	9	10
Tablet wt in mg	1358	1365	1352	1359	1363	1368	1365	1364	1356	1352
Sample No.	11	12	13	14	15	16	17	18	19	20
Tablet wt in mg	1359	1367	1362	1360	1365	1356	1362	1368	1363	1366
	Thickness Limit: 7.10 ± 0.30mm (6.80mm -7.40mm)									
Sample No.	1	2	3	4	5	6	7	8	9	10
Thickness in mm	7.40	7.39	7.36	7.36	7.36	7.32	7.35	7.36	7.36	7.36
	Hardness limit: 250 N to 350 N									
Sample No.	1	2	3	4	5	6	7	8	9	10
Hardness in N	256	258	251	254	256	253	255	256	257	257
Friability in %	0.31					Limit : NMT 1.0 %				

Test	Limits	Results
Assay: 1. Gliclazide BP 60mg	90.0% to 110.0% of the labeled claim I.e. 54.0mg to 66.0mg	58.84mg (98.1%)
2. Metformin Hcl BP 850mg	90.0% to 110.0% of the labeled claim I.e. 765.0mg to 935.0mg	842.91mg (99.2%)
Dissolution: 1.Gliclazide: 2nd,5th&12th hr	Not more than 25.0% Between 30.0%-60.0% Not less than 70.0%	Min: 22.6% Max: 29.5% Avg: 26.1% Min: 41.3% Max: 52.9% Avg: 47.8% Min: 68.7% Max: 85.3% Avg: 79.6%
2. Metformin: 1st,3rd&10th hr	Between 20.0%-40.0% Between 45.0%-65.0% Not less than 85.0%	Min: 23.4% Max: 25.1% Avg: 24.1% Min: 46.6% Max: 47.7% Avg: 47.0% Min: 94.9% Max: 96.3% Avg: 95.6%

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4.2 INDIVIDUAL WEIGHT VARIATION, THICKNESS, HARDNESS AND FRIABILITY:
(Batch No: GD200604):

Stage	STANDARD COMPRESSION FORCE									
Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides									
Group Weight of 20 tablets : 27.200g ± 3 % Limits : (26.384g to 28.016g) Avg Weight : 1360 mg ± 5% Limits : (1292.500mg – 1428.000mg) Uniformity of weight : Avg weight ± 5.0% (1292.500mg – 1428.00mg)										
Sample No.	1	2	3	4	5	6	7	8	9	10
Tablet wt in mg	1362	1365	1354	1362	1360	1355	1359	1359	1362	1365
Sample No.	11	12	13	14	15	16	17	18	19	20
Tablet wt in mg	1367	1360	1359	1355	1357	1359	1360	1366	1365	1362
	Thickness Limit: 7.10 ± 0.30mm (6.80mm -7.40mm)									
Sample No.	1	2	3	4	5	6	7	8	9	10
Thickness in mm	7.14	7.10	7.10	7.12	7.08	7.08	7.10	7.12	7.09	7.05
	Hardness limit: 250 N to 350 N									
Sample No.	1	2	3	4	5	6	7	8	9	10
Hardness in N	289	295	296	290	301	304	295	291	305	303
Friability in %	0.10					Limit : NMT 1.0 %				

Test	Limits	Results
Assay: 1. Gliclazide BP 60mg	90.0% to 110.0% of the labeled claim I.e. 54.0mg to 66.0mg	58.28mg (97.1%)
2. Metformin Hcl BP 850mg	90.0% to 110.0% of the labeled claim I.e. 765.0mg to 935.0mg	849.96mg (100.0%)
Dissolution: 1. Gliclazide: 2nd, 5th & 12th hr	Not more than 25.0% Between 30.0%-60.0% Not less than 70.0%	Min: 18.9% Max: 21.9% Avg: 20.5% Min: 42.2% Max: 50.7% Avg: 47.2% Min: 73.6% Max: 83.7% Avg: 80.5%
2. Metformin: 1st, 3rd & 10th hr	Between 20.0%-40.0% Between 45.0%-65.0% Not less than 85.0%	Min: 24.4% Max: 26.1% Avg: 25.0% Min: 48.7% Max: 49.5% Avg: 49.2% Min: 97.4% Max: 99.4% Avg: 98.3%

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4.3 INDIVIDUAL WEIGHT VARIATION, THICKNESS, HARDNESS AND FRIABILITY:
(Batch No: GD200604):

Stage	MAXIMUM COMPRESSION FORCE (HIGH HARDNESS)									
Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides									
Group Weight of 20 tablets : 27.200g ± 3 % Limits : (26.384g to 28.016g) Avg Weight : 1360 mg ± 5% Limits : (1292.500mg – 1428.000mg) Uniformity of weight : Avg weight ± 5.0% (1292.500mg – 1428.00mg)										
Sample No.	1	2	3	4	5	6	7	8	9	10
Tablet wt in mg	1355	1352	1358	1354	1360	1362	1365	1358	1359	1360
Sample No.	11	12	13	14	15	16	17	18	19	20
Tablet wt in mg	1365	1362	1357	1358	1360	1365	1364	1359	1355	1354
	Thickness Limit: 7.10 ± 0.30mm (6.80mm -7.40mm)									
Sample No.	1	2	3	4	5	6	7	8	9	10
Thickness in mm	6.84	6.86	6.85	6.88	6.87	6.85	6.84	6.88	6.82	6.89
	Hardness limit: 250 N to 350 N									
Sample No.	1	2	3	4	5	6	7	8	9	10
Hardness in N	349	343	345	344	347	343	342	342	342	346
Friability in %	0.05					Limit : NMT 1.0 %				

Test	Limits	Results
Assay: 1. Gliclazide BP 60mg	90.0% to 110.0% of the labeled claim I.e. 54.0mg to 66.0mg	62.67mg (104.5%)
2. Metformin Hcl BP 850mg	90.0% to 110.0% of the labeled claim I.e. 765.0mg to 935.0mg	843.40mg (99.2%)
Dissolution: 1. Gliclazide: 2nd, 5th & 12th hr	Not more than 25.0%	Min: 15.2% Max: 24.3% Avg: 18.5%
	Between 30.0%-60.0%	Min: 38.3% Max: 56.2% Avg: 45.2%
	Not less than 70.0%	Min: 70.4% Max: 91.0% Avg: 80.0%
2. Metformin: 1st, 3rd & 10th hr	Between 20.0%-40.0%	Min: 24.1% Max: 25.1% Avg: 24.5%
	Between 45.0%-65.0%	Min: 47.8% Max: 49.4% Avg: 48.2%
	Not less than 85.0%	Min: 91.6% Max: 93.3% Avg: 92.4%

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4.4 INDIVIDUAL WEIGHT VARIATION, THICKNESS, HARDNESS AND FRIABILITY:
(Batch No: GD200604):

Stage	Minimum RPM (12 RPM)									
Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides									
Group Weight of 20 tablets : 27.200g ± 3 % Limits : (26.384g to 28.016g) Avg Weight : 1360 mg ± 5% Limits : (1292.500mg – 1428.000mg) Uniformity of weight : Avg weight ± 5.0% (1292.500mg – 1428.00mg)										
Sample No.	1	2	3	4	5	6	7	8	9	10
Tablet wt in mg	1364	1360	1364	1362	1365	1361	1364	1362	1360	1362
Sample No.	11	12	13	14	15	16	17	18	19	20
Tablet wt in mg	1365	1361	1364	1367	1362	1370	1361	1365	1360	1369
	Thickness Limit: 7.10 ± 0.30mm (6.80mm -7.40mm)									
Sample No.	1	2	3	4	5	6	7	8	9	10
Thickness in mm	6.83	6.83	6.83	6.85	6.83	6.84	6.84	6.81	6.82	6.83
	Hardness limit: 250 N to 350 N									
Sample No.	1	2	3	4	5	6	7	8	9	10
Hardness in N	344	343	344	347	341	341	345	347	341	346
Friability in %	0.03					Limit : NMT 1.0 %				

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4.5 INDIVIDUAL WEIGHT VARIATION, THICKNESS, HARDNESS AND FRIABILITY:
(Batch No: GD200604):

(Batch No. 3120001)

Stage	MAXIMUM RPM (20 RPM)									
Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides									
Group Weight of 20 tablets : 27.200g ± 3 % Limits : (26.384g to 28.016g) Avg Weight : 1360 mg ± 5% Limits : (1292.500mg – 1428.000mg) Uniformity of weight : Avg weight ± 5.0% (1292.500mg – 1428.00mg)										
Sample No.	1	2	3	4	5	6	7	8	9	10
Tablet wt in mg	1358	1362	1360	1364	1360	1356	1362	1360	1362	1350
Sample No.	11	12	13	14	15	16	17	18	19	20
Tablet wt in mg	1355	1358	1362	1360	1362	1369	1360	1362	1365	1360
	Thickness Limit: 7.10 ± 0.30mm (6.80mm -7.40mm)									
Sample No.	1	2	3	4	5	6	7	8	9	10
Thickness in mm	7.15	7.21	7.17	7.13	7.12	7.17	7.15	7.16	7.14	7.17
	Hardness limit: 250 N to 350 N									
Sample No.	1	2	3	4	5	6	7	8	9	10
Hardness in N	325	310	323	328	328	323	326	323	322	325
Friability in %	0.04					Limit : NMT 1.0 %				

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4.6 INDIVIDUAL WEIGHT VARIATION, THICKNESS, HARDNESS AND FRIABILITY:
(Batch No: GD200604):

Stage	Top Hopper Level									
Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides									
Group Weight of 20 tablets : 27.200g ± 3 % Limits : (26.384g to 28.016g) Avg Weight : 1360 mg ± 5% Limits : (1292.500mg – 1428.000mg) Uniformity of weight : Avg weight ± 5.0% (1292.500mg – 1428.00mg)										
Sample No.	1	2	3	4	5	6	7	8	9	10
Tablet wt in mg	1364	1355	1362	1369	1362	1360	1362	1360	1358	1355
Sample No.	11	12	13	14	15	16	17	18	19	20
Tablet wt in mg	1360	1362	1369	1362	1369	1362	1358	1360	1352	1358
	Thickness Limit: 7.10 ± 0.30mm (6.80mm -7.40mm)									
Sample No.	1	2	3	4	5	6	7	8	9	10
Thickness in mm	7.01	6.98	7.03	6.99	7.03	7.04	7.01	7.05	7.09	7.11
	Hardness limit: 250 N to 350 N									
Sample No.	1	2	3	4	5	6	7	8	9	10
Hardness in N	278	265	262	269	275	281	277	275	281	277
Friability in %	0.16					Limit : NMT 1.0 %				

Test	Limits	Results
Assay: 1. Gliclazide BP 60mg	90.0% to 110.0% of the labeled claim I.e. 54.0mg to 66.0mg	57.40mg (95.7%)
2. Metformin Hcl BP 850mg	90.0% to 110.0% of the labeled claim I.e. 765.0mg to 935.0mg	835.36mg (98.3%)
Dissolution: 1. Gliclazide: 2nd, 5th & 12th hr	Not more than 25.0%	Min: 22.1% Max: 25.2% Avg: 23.4%
	Between 30.0%-60.0%	Min: 43.9% Max: 53.4% Avg: 47.9%
	Not less than 70.0%	Min: 73.5% Max: 87.8% Avg: 81.9%
	Between 20.0%-40.0%	Min: 25.7% Max: 26.7% Avg: 26.1%
2. Metformin: 1st, 3rd & 10th hr	Between 45.0%-65.0%	Min: 47.8% Max: 49.0% Avg: 48.4%
	Not less than 85.0%	Min: 96.0% Max: 96.9% Avg: 96.6%

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4.7 INDIVIDUAL WEIGHT VARIATION, THICKNESS, HARDNESS AND FRIABILITY:
(Batch No: GD200604):

Stage	Middle Hopper Level									
Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides									
Group Weight of 20 tablets : 27.200g ± 3 % Limits : (26.384g to 28.016g) Avg Weight : 1360 mg ± 5% Limits : (1292.500mg – 1428.000mg) Uniformity of weight : Avg weight ± 5.0% (1292.500mg – 1428.000mg)										
Sample No.	1	2	3	4	5	6	7	8	9	10
Tablet wt in mg	1362	1365	1360	1363	1370	1371	1360	1366	1362	1361
Sample No.	11	12	13	14	15	16	17	18	19	20
Tablet wt in mg	1349	1363	1362	1365	1368	1364	1361	1369	1362	1360
	Thickness Limit: 7.10 ± 0.30mm (6.80mm -7.40mm)									
Sample No.	1	2	3	4	5	6	7	8	9	10
Thickness in mm	7.02	6.98	7.00	7.00	7.00	7.01	7.03	6.99	6.99	7.02
	Hardness limit: 250 N to 350 N									
Sample No.	1	2	3	4	5	6	7	8	9	10
Hardness in N	264	256	269	267	268	262	265	267	269	258
Friability in %	0.14					Limit : NMT 1.0 %				

Test	Limits	Results
Assay:		
1. Gliclazide BP 60mg	90.0% to 110.0% of the labeled claim I.e. 54.0mg to 66.0mg	57.14mg (95.2%)
2. Metformin Hcl BP 850mg	90.0% to 110.0% of the labeled claim I.e. 765.0mg to 935.0mg	848.91mg (99.9%)
Dissolution:		
1. Gliclazide: 2 nd , 5 th & 12 th hr	Not more than 25.0% Between 30.0%-60.0% Not less than 70.0%	Min: 16.3% Max: 19.8% Avg: 17.6% Min: 41.2% Max: 49.9% Avg: 45.6% Min: 70.9% Max: 86.2% Avg: 82.1%
2. Metformin: 1 st , 3 rd & 10 th hr	Between 20.0%-40.0% Between 45.0%-65.0% Not less than 85.0%	Min: 25.2% Max: 25.7% Avg: 25.6% Min: 49.0% Max: 50.0% Avg: 49.5% Min: 97.0% Max: 98.5% Avg: 97.6%

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Product	Gliclazide and Metformin Hydrochloride Sustained Release Tablets 60/850mg	Ref. Protocol No.: PVP/20/004

4.8 INDIVIDUAL WEIGHT VARIATION, THICKNESS, HARDNESS AND FRIABILITY:
(Batch No: GD200604):

Stage	Bottom Hopper Level									
Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides									
Group Weight of 20 tablets : 27.200g ± 3 % Limits : (26.384g to 28.016g) Avg Weight : 1360 mg ± 5% Limits : (1292.500mg – 1428.000mg) Uniformity of weight : Avg weight ± 5.0% (1292.500mg – 1428.000mg)										
Sample No.	1	2	3	4	5	6	7	8	9	10
Tablet wt in mg	1355	1360	1363	1362	1358	1371	1359	1364	1362	1360
Sample No.	11	12	13	14	15	16	17	18	19	20
Tablet wt in mg	1350	1361	1364	1368	1363	1360	1358	1355	1359	1364
	Thickness Limit: 7.10 ± 0.30mm (6.80mm -7.40mm)									
Sample No.	1	2	3	4	5	6	7	8	9	10
Thickness in mm	6.92	6.95	6.96	6.95	6.97	6.93	6.98	6.94	6.94	6.93
	Hardness limit: 250 N to 350 N									
Sample No.	1	2	3	4	5	6	7	8	9	10
Hardness in N	348	343	341	349	344	344	346	347	342	341
Friability in %	0.06					Limit : NMT 1.0 %				

Test	Limits	Results
Assay: 1. Gliclazide BP 60mg	90.0% to 110.0% of the labeled claim I.e. 54.0mg to 66.0mg	56.53mg (94.2%)
2. Metformin Hcl BP 850mg	90.0% to 110.0% of the labeled claim I.e. 765.0mg to 935.0mg	845.61mg (99.5%)
Dissolution: 1. Gliclazide: 2nd, 5th & 12th hr	Not more than 25.0%	Min: 14.0% Max: 23.6% Avg: 17.6%
	Between 30.0%-60.0%	Min: 34.7% Max: 48.8% Avg: 41.0%
	Not less than 70.0%	Min: 65.8% Max: 81.2% Avg: 73.7%
	Between 20.0%-40.0%	Min: 25.0% Max: 26.8% Avg: 26.2%
2. Metformin: 1st, 3rd & 10th hr	Between 45.0%-65.0%	Min: 48.3% Max: 50.0% Avg: 49.1%
	Not less than 85.0%	Min: 94.0% Max: 98.3% Avg: 96.4%

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	PROCESS VALIDATION REPORT	Doc No.: PVR /20/004
Product	Gliclazide and Metformin Hydrochloride Sustained Release Tablets 60/850mg	Ref. Protocol No.: PVP/20/004

4.9 INDIVIDUAL WEIGHT VARIATION, THICKNESS, HARDNESS AND FRIABILITY:
(Batch No: GD200604):

Stage	composite									
Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides									
Group Weight of 20 tablets : 27.200g ± 3 % Limits : (26.384g to 28.016g) Avg Weight : 1360 mg ± 5% Limits : (1292.500mg – 1428.000mg) Uniformity of weight : Avg weight ± 5.0% (1292.500mg – 1428.000mg)										
Sample No.	1	2	3	4	5	6	7	8	9	10
Tablet wt in mg	1361	1360	1357	1359	1365	1360	1364	1357	1359	1362
Sample No.	11	12	13	14	15	16	17	18	19	20
Tablet wt in mg	1360	1353	1361	1365	1364	1361	1368	1360	1358	1361
	Thickness Limit: 7.10 ± 0.30mm (6.80mm -7.40mm)									
Sample No.	1	2	3	4	5	6	7	8	9	10
Thickness in mm	7.12	6.89	7.02	6.99	7.16	7.01	6.86	7.14	7.21	7.25
	Hardness limit: 250 N to 350 N									
Sample No.	1	2	3	4	5	6	7	8	9	10
Hardness in N	260	341	268	268	260	267	342	262	270	273
Friability in %	0.12					Limit : NMT 1.0 %				

Test	Limits	Results
Assay: 1. Gliclazide BP 60mg 2. Metformin Hcl BP 850mg	90.0% to 110.0% of the labeled claim I.e. 54.0mg to 66.0mg	58.02mg (96.7%)
	90.0% to 110.0% of the labeled claim I.e. 765.0mg to 935.0mg	836.89mg (98.5%)
Dissolution: 1. Gliclazide: 2nd, 5th & 12th hr 2. Metformin: 1st, 3rd & 10th hr	Not more than 25.0% Between 30.0%-60.0% Not less than 70.0%	Min: 18.1% Max: 23.3% Avg: 20.7% Min: 43.6% Max: 52.8% Avg: 48.1% Min: 80.4% Max: 89.2% Avg: 85.3%
	Between 20.0%-40.0% Between 45.0%-65.0% Not less than 85.0%	Min: 25.1% Max: 26.1% Avg: 25.7% Min: 48.7% Max: 49.9% Avg: 49.6% Min: 98.4% Max: 102.5% Avg: 100.1%

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	PROCESS VALIDATION REPORT	Doc No.: PVR /20/004
Product	Gliclazide and Metformin Hydrochloride Sustained Release Tablets 60/850mg	Ref. Protocol No.: PVP/20/004

5.0 VALIDATION OF COMPRESSION PROCESS (Batch No: GD200701):

5.1 INDIVIDUAL WEIGHT VARIATION, THICKNESS, HARDNESS AND FRIABILITY:

(Batch No: GD200701):

Stage	MINIMUM COMPRESSION FORCE (LOW HARDNESS)									
Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides									
Group Weight of 20 tablets : 27.200g ± 3 % Limits : (26.384g to 28.016g) Avg Weight : 1360 mg ± 5% Limits : (1292.500mg – 1428.000mg) Uniformity of weight : Avg weight ± 5.0% (1292.500mg – 1428.000mg)										
Sample No.	1	2	3	4	5	6	7	8	9	10
Tablet wt in mg	1362	1360	1352	1360	1370	1368	1363	1357	1352	1364
Sample No.	11	12	13	14	15	16	17	18	19	20
Tablet wt in mg	1357	1365	1370	1368	1364	1369	1370	1368	1364	1361
	Thickness Limit: 7.10 ± 0.30mm (6.80mm -7.40mm)									
Sample No.	1	2	3	4	5	6	7	8	9	10
Thickness in mm	7.38	7.38	7.36	7.34	7.38	7.35	7.34	7.39	7.31	7.32
	Hardness limit: 250 N to 350 N									
Sample No.	1	2	3	4	5	6	7	8	9	10
Hardness in N	257	256	251	253	255	255	256	258	260	260
Friability in %	0.31					Limit : NMT 1.0 %				

Test	Limits	Results
Assay:		
1. Gliclazide BP 60mg	90.0% to 110.0% of the labeled claim I.e. 54.0mg to 66.0mg	58.50mg (97.5%)
2. Metformin Hcl BP 850mg	90.0% to 110.0% of the labeled claim I.e. 765.0mg to 935.0mg	856.80mg (100.8%)
Dissolution:		
1. Gliclazide: 2 nd , 5 th & 12 th hr	Not more than 25.0%	Min: 21.0% Max: 23.2% Avg: 22.1%
	Between 30.0%-60.0%	Min: 46.9% Max: 56.2% Avg: 52.3%
	Not less than 70.0%	Min: 78.8% Max: 93.6% Avg: 84.9%
2. Metformin: 1 st , 3 rd & 10 th hr	Between 20.0%-40.0%	Min: 25.5% Max: 28.2% Avg: 26.4%
	Between 45.0%-65.0%	Min: 48.1% Max: 52.7% Avg: 49.8%
	Not less than 85.0%	Min: 95.5% Max: 97.8% Avg: 96.6%

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Product	Gliclazide and Metformin Hydrochloride Sustained Release Tablets 60/850mg	Ref. Protocol No.: PVP/20/004

5.2 INDIVIDUAL WEIGHT VARIATION, THICKNESS, HARDNESS AND FRIABILITY:
(Batch No: GD200701):

Stage	MAXIMUM COMPRESSION FORCE (HIGH HARDNESS)									
Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides									
Group Weight of 20 tablets : 27.200g ± 3 % Limits : (26.384g to 28.016g) Avg Weight : 1360 mg ± 5% Limits : (1292.500mg – 1428.000mg) Uniformity of weight : Avg weight ± 5.0% (1292.500mg – 1428.000mg)										
Sample No.	1	2	3	4	5	6	7	8	9	10
Tablet wt in mg	1362	1354	1367	1369	1362	1360	1359	1354	1362	1360
Sample No.	11	12	13	14	15	16	17	18	19	20
Tablet wt in mg	1368	1369	1360	1354	1362	1367	1360	1359	1357	1362
	Thickness Limit: 7.10 ± 0.30mm (6.80mm -7.40mm)									
Sample No.	1	2	3	4	5	6	7	8	9	10
Thickness in mm	6.88	6.85	6.88	6.86	6.89	6.90	6.86	6.85	6.86	6.84
	Hardness limit: 250 N to 350 N									
Sample No.	1	2	3	4	5	6	7	8	9	10
Hardness in N	345	345	343	341	345	340	341	346	344	345
Friability in %	0.06					Limit : NMT 1.0 %				

Test	Limits	Results
Assay: 1. Gliclazide BP 60mg	90.0% to 110.0% of the labeled claim I.e. 54.0mg to 66.0mg	59.08mg (98.5%)
2. Metformin Hcl BP 850mg	90.0% to 110.0% of the labeled claim I.e. 765.0mg to 935.0mg	854.76mg (100.6%)
Dissolution: 1. Gliclazide: 2nd, 5th & 12th hr	Not more than 25.0%	Min: 16.0% Max: 18.9% Avg: 17.1%
	Between 30.0%-60.0%	Min: 39.7% Max: 51.5% Avg: 46.1%
	Not less than 70.0%	Min: 77.1% Max: 91.8% Avg: 85.1%
	Between 20.0%-40.0%	Min: 24.9% Max: 25.8% Avg: 25.4%
2. Metformin: 1st, 3rd & 10th hr	Between 45.0%-65.0%	Min: 48.9% Max: 50.8% Avg: 49.8%
	Not less than 85.0%	Min: 96.9% Max: 99.1% Avg: 97.8%

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5.3 INDIVIDUAL WEIGHT VARIATION, THICKNESS, HARDNESS AND FRIABILITY:
(Batch No: GD200701):

Stage	Minimum RPM (12 RPM)									
Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides									
Group Weight of 20 tablets : 27.200g ± 3 % Limits : (26.384g to 28.016g) Avg Weight : 1360 mg ± 5% Limits : (1292.500mg – 1428.000mg) Uniformity of weight : Avg weight ± 5.0% (1292.500mg – 1428.000mg)										
Sample No.	1	2	3	4	5	6	7	8	9	10
Tablet wt in mg	1364	1360	1350	1367	1362	1358	1350	1367	1362	1350
Sample No.	11	12	13	14	15	16	17	18	19	20
Tablet wt in mg	1367	1362	1360	1352	1358	1351	1367	1360	1362	1360
	Thickness Limit: 7.10 ± 0.30mm (6.80mm -7.40mm)									
Sample No.	1	2	3	4	5	6	7	8	9	10
Thickness in mm	6.90	6.88	6.91	6.93	6.85	6.84	6.88	6.91	6.83	6.81
	Hardness limit: 250 N to 350 N									
Sample No.	1	2	3	4	5	6	7	8	9	10
Hardness in N	299	282	285	290	307	287	305	288	294	297
Friability in %	0.12					Limit : NMT 1.0 %				

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5.4 INDIVIDUAL WEIGHT VARIATION, THICKNESS, HARDNESS AND FRIABILITY:
(Batch No: GD200701):

Stage	Maximum RPM (20 RPM)									
Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides									
Group Weight of 20 tablets : 27.200g ± 3 % Limits : (26.384g to 28.016g) Avg Weight : 1360 mg ± 5% Limits : (1292.500mg – 1428.000mg) Uniformity of weight : Avg weight ± 5.0% (1292.500mg – 1428.000mg)										
Sample No.	1	2	3	4	5	6	7	8	9	10
Tablet wt in mg	1355	1357	1362	1368	1362	1365	1358	1352	1368	1362
Sample No.	11	12	13	14	15	16	17	18	19	20
Tablet wt in mg	1369	1358	1360	1364	1367	1357	1352	1359	1362	1368
	Thickness Limit: 7.10 ± 0.30mm (6.80mm -7.40mm)									
Sample No.	1	2	3	4	5	6	7	8	9	10
Thickness in mm	7.09	7.05	7.10	7.12	7.04	7.15	7.16	7.04	7.09	7.09
	Hardness limit: 250 N to 350 N									
Sample No.	1	2	3	4	5	6	7	8	9	10
Hardness in N	265	268	269	270	272	265	268	268	270	271
Friability in %	0.15					Limit : NMT 1.0 %				

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5.5 INDIVIDUAL WEIGHT VARIATION, THICKNESS, HARDNESS AND FRIABILITY:
(Batch No: GD200701):

Stage	Bottom Hopper Level									
Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides									
Group Weight of 20 tablets : 27.200g ± 3 % Limits : (26.384g to 28.016g) Avg Weight : 1360 mg ± 5% Limits : (1292.500mg – 1428.000mg) Uniformity of weight : Avg weight ± 5.0% (1292.500mg – 1428.000mg)										
Sample No.	1	2	3	4	5	6	7	8	9	10
Tablet wt in mg	1361	1358	1364	1362	1354	1368	1363	1360	1362	1362
Sample No.	11	12	13	14	15	16	17	18	19	20
Tablet wt in mg	1362	1360	1361	1361	1362	1361	1365	1367	1369	1365
	Thickness Limit: 7.10 ± 0.30mm (6.80mm -7.40mm)									
Sample No.	1	2	3	4	5	6	7	8	9	10
Thickness in mm	6.89	6.86	6.84	6.85	6.89	6.90	6.91	6.89	6.85	6.89
	Hardness limit: 250 N to 350 N									
Sample No.	1	2	3	4	5	6	7	8	9	10
Hardness in N	301	298	314	306	298	316	318	322	297	280
Friability in %	0.14					Limit : NMT 1.0 %				

Test	Limits	Results
Assay:		
1. Gliclazide BP 60mg	90.0% to 110.0% of the labeled claim I.e. 54.0mg to 66.0mg	56.27mg (93.8%)
2. Metformin Hcl BP 850mg	90.0% to 110.0% of the labeled claim I.e. 765.0mg to 935.0mg	851.29mg (100.2%)
Dissolution:		
1. Gliclazide: 2nd, 5th & 12th hr	Not more than 25.0% Between 30.0%-60.0% Not less than 70.0%	Min: 18.5% Max: 20.7% Avg: 19.9% Min: 43.7% Max: 53.4% Avg: 49.2% Min: 76.0% Max: 88.5% Avg: 82.2%
2. Metformin: 1st, 3rd & 10th hr	Between 20.0%-40.0% Between 45.0%-65.0% Not less than 85.0%	Min: 24.7% Max: 27.4% Avg: 25.7% Min: 48.4% Max: 50.8% Avg: 49.3% Min: 96.3% Max: 97.8% Avg: 97.3%

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5.8 INDIVIDUAL WEIGHT VARIATION, THICKNESS, HARDNESS AND FRIABILITY:
(Batch No: GD200701):

Stage	composite									
Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides									
Group Weight of 20 tablets : 27.200g ± 3 % Limits : (26.384g to 28.016g) Avg Weight : 1360 mg ± 5% Limits : (1292.500mg – 1428.000mg) Uniformity of weight : Avg weight ± 5.0% (1292.500mg – 1428.000mg)										
Sample No.	1	2	3	4	5	6	7	8	9	10
Tablet wt in mg	1362	1359	1358	1360	1364	1365	1361	1354	1360	1362
Sample No.	11	12	13	14	15	16	17	18	19	20
Tablet wt in mg	1366	1359	1369	1364	1361	1363	1369	1364	1359	1362
	Thickness Limit: 7.10 ± 0.30mm (6.80mm -7.40mm)									
Sample No.	1	2	3	4	5	6	7	8	9	10
Thickness in mm	7.11	6.90	7.12	6.99	7.14	7.11	6.96	7.15	7.11	7.15
	Hardness limit: 250 N to 350 N									
Sample No.	1	2	3	4	5	6	7	8	9	10
Hardness in N	260	341	265	268	260	261	342	262	270	273
Friability in %	0.16					Limit : NMT 1.0 %				

Test	Limits	Results
Assay: 1. Gliclazide BP 60mg	90.0% to 110.0% of the labeled claim I.e. 54.0mg to 66.0mg	57.52mg (95.9%)
2. Metformin Hcl BP 850mg	90.0% to 110.0% of the labeled claim I.e. 765.0mg to 935.0mg	857.72mg (100.9%)
Dissolution: 1.Gliclazide: 2nd,5th&12th	Not more than 25.0%	Min: 17.1% Max: 24.2% Avg: 20.0%
	Between 30.0%-60.0%	Min: 46.1% Max: 59.7% Avg: 50.2%
	Not less than 70.0%	Min: 84.7% Max: 110.0% Avg: 91.1%
	Between 20.0%-40.0%	Min: 24.5% Max: 25.6% Avg: 25.1%
2. Metformin: 1st,3rd& 10th hr	Between 45.0%-65.0%	Min: 49.2% Max: 51.2% Avg: 49.8%
	Not less than 85.0%	Min: 96.6% Max: 99.7% Avg: 98.2%

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6.0 VALIDATION OF COMPRESSION PROCESS (Batch No: GD210302):

6.1 INDIVIDUAL WEIGHT VARIATION, THICKNESS, HARDNESS AND FRIABILITY: (Batch No: GD210302):

Stage	MINIMUM COMPRESSION FORCE (LOW HARDNESS)									
Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides									
Group Weight of 20 tablets : 27.200g ± 3 % Limits : (26.384g to 28.016g) Avg Weight : 1360 mg ± 5% Limits : (1292.500mg – 1428.000mg) Uniformity of weight : Avg weight ± 5.0% (1292.500mg – 1428.000mg)										
Sample No.	1	2	3	4	5	6	7	8	9	10
Tablet wt in mg	1360	1359	1353	1368	1364	1353	1362	1365	1360	1353
Sample No.	11	12	13	14	15	16	17	18	19	20
Tablet wt in mg	1362	1368	1360	1357	1362	1360	1359	1353	1362	1368
	Thickness Limit: 7.10 ± 0.30mm (6.80mm -7.40mm)									
Sample No.	1	2	3	4	5	6	7	8	9	10
Thickness in mm	7.32	7.35	7.37	7.31	7.31	7.35	7.34	7.36	7.34	7.38
	Hardness limit: 250 N to 350 N									
Sample No.	1	2	3	4	5	6	7	8	9	10
Hardness in N	244	248	241	244	246	243	245	246	247	247
Friability in %	0.38					Limit : NMT 1.0 %				

Test	Limits	Results
Dissolution: 1. Gliclazide: 2nd, 5th & 12th hr	Not more than 25.0%	Min: 18.6% Max: 24.5% Avg: 22.6%
	Between 30.0%-60.0%	Min: 45.5% Max: 59.2% Avg: 55.3%
	Not less than 70.0%	Min: 86.5% Max: 99.6% Avg: 91.2%
	Between 20.0%-40.0%	Min: 24.6% Max: 26.6% Avg: 25.7%
2. Metformin: 1st, 3rd & 10th hr	Between 45.0%-65.0%	Min: 50.6% Max: 59.2% Avg: 54.9%
	Not less than 85.0%	Min: 97.5% Max: 100.5% Avg: 98.8%

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6.2 INDIVIDUAL WEIGHT VARIATION, THICKNESS, HARDNESS AND FRIABILITY:
(Batch No: GD210302):

Stage	MAXIMUM COMPRESSION FORCE (HIGH HARDNESS)									
Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides									
Group Weight of 20 tablets : 27.200g ± 3 % Limits : (26.384g to 28.016g) Avg Weight : 1360 mg ± 5% Limits : (1292.500mg – 1428.000mg) Uniformity of weight : Avg weight ± 5.0% (1292.500mg – 1428.000mg)										
Sample No.	1	2	3	4	5	6	7	8	9	10
Tablet wt in mg	1357	1351	1363	1369	1362	1365	1360	1369	1351	1364
Sample No.	11	12	13	14	15	16	17	18	19	20
Tablet wt in mg	1361	1360	1357	1365	1360	1364	1358	1362	1367	1360
	Thickness Limit: 7.10 ± 0.30mm (6.80mm -7.40mm)									
Sample No.	1	2	3	4	5	6	7	8	9	10
Thickness in mm	6.85	6.84	6.86	6.89	6.89	6.92	6.91	6.85	6.84	6.89
	Hardness limit: 250 N to 350 N									
Sample No.	1	2	3	4	5	6	7	8	9	10
Hardness in N	340	340	340	339	339	335	335	340	340	339
Friability in %	0.08					Limit : NMT 1.0 %				

Test	Limits	Results
Dissolution: 1. Gliclazide: 2nd, 5th & 12th hr	Not more than 25.0%	Min: 17.1% Max: 24.7% Avg: 21.5%
	Between 30.0%-60.0%	Min: 44.6% Max: 59.7% Avg: 53.8%
	Not less than 70.0%	Min: 73.8% Max: 90.5% Avg: 83.3%
2. Metformin: 1st, 3rd & 10th hr	Between 20.0%-40.0%	Min: 25.4% Max: 26.7% Avg: 25.8%
	Between 45.0%-65.0%	Min: 48.2% Max: 49.1% Avg: 48.8%
	Not less than 85.0%	Min: 95.2% Max: 98.3% Avg: 96.7%

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6.3 INDIVIDUAL WEIGHT VARIATION, THICKNESS, HARDNESS AND FRIABILITY:
(Batch No: GD210302):

Stage	Minimum RPM (12 RPM)									
Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides									
Group Weight of 20 tablets : 27.200g ± 3 % Limits : (26.384g to 28.016g) Avg Weight : 1360 mg ± 5% Limits : (1292.500mg – 1428.000mg) Uniformity of weight : Avg weight ± 5.0% (1292.500mg – 1428.000mg)										
Sample No.	1	2	3	4	5	6	7	8	9	10
Tablet wt in mg	1360	1362	1357	1352	1357	1364	1370	1358	1365	1368
Sample No.	11	12	13	14	15	16	17	18	19	20
Tablet wt in mg	1352	1366	1367	1370	1364	1365	1360	1353	1357	1364
	Thickness Limit: 7.10 ± 0.30mm (6.80mm -7.40mm)									
Sample No.	1	2	3	4	5	6	7	8	9	10
Thickness in mm	6.99	6.90	6.95	6.99	6.99	6.95	6.97	6.93	6.93	6.91
	Hardness limit: 250 N to 350 N									
Sample No.	1	2	3	4	5	6	7	8	9	10
Hardness in N	295	299	295	296	301	297	300	295	296	295
Friability in %	0.10					Limit : NMT 1.0 %				

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6.4 INDIVIDUAL WEIGHT VARIATION, THICKNESS, HARDNESS AND FRIABILITY:
(Batch No: GD210302):

Stage	Maximum RPM (20 RPM)									
Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides									
Group Weight of 20 tablets : 27.200g ± 3 % Limits : (26.384g to 28.016g) Avg Weight : 1360 mg ± 5% Limits : (1292.500mg – 1428.000mg) Uniformity of weight : Avg weight ± 5.0% (1292.500mg – 1428.000mg)										
Sample No.	1	2	3	4	5	6	7	8	9	10
Tablet wt in mg	1361	1362	1352	1359	1364	1360	1359	1358	1355	1360
Sample No.	11	12	13	14	15	16	17	18	19	20
Tablet wt in mg	1372	1358	1364	1359	1360	1364	1360	1367	1352	1364
	Thickness Limit: 7.10 ± 0.30mm (6.80mm -7.40mm)									
Sample No.	1	2	3	4	5	6	7	8	9	10
Thickness in mm	7.10	7.15	7.11	7.10	7.14	7.12	7.15	7.04	7.09	7.15
	Hardness limit: 250 N to 350 N									
Sample No.	1	2	3	4	5	6	7	8	9	10
Hardness in N	270	268	269	270	267	269	268	268	270	268
Friability in %	0.09					Limit : NMT 1.0 %				

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6.5 INDIVIDUAL WEIGHT VARIATION, THICKNESS, HARDNESS AND FRIABILITY:
(Batch No: GD210302):

Stage	Bottom Hopper Level									
Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides									
Group Weight of 20 tablets : 27.200g ± 3 % Limits : (26.384g to 28.016g) Avg Weight : 1360 mg ± 5% Limits : (1292.500mg – 1428.000mg) Uniformity of weight : Avg weight ± 5.0% (1292.500mg – 1428.000mg)										
Sample No.	1	2	3	4	5	6	7	8	9	10
Tablet wt in mg	1360	1357	1361	1364	1353	1356	1358	1365	1367	1360
Sample No.	11	12	13	14	15	16	17	18	19	20
Tablet wt in mg	1367	1370	1366	1360	1368	1354	1353	1360	1357	1364
	Thickness Limit: 7.10 ± 0.30mm (6.80mm -7.40mm)									
Sample No.	1	2	3	4	5	6	7	8	9	10
Thickness in mm	7.10	7.02	7.13	6.99	7.04	7.10	7.13	7.10	6.97	7.18
	Hardness limit: 250 N to 350 N									
Sample No.	1	2	3	4	5	6	7	8	9	10
Hardness in N	278	287	280	289	276	281	280	279	292	290
Friability in %	0.12					Limit : NMT 1.0 %				

Test	Limits	Results
Assay: 1. Gliclazide BP 60mg	90.0% to 110.0% of the labeled claim I.e. 54.0mg to 66.0mg	57.14mg (95.2%)
2. Metformin Hcl BP 850mg	90.0% to 110.0% of the labeled claim I.e. 765.0mg to 935.0mg	848.91mg (99.9%)
Dissolution: 1. Gliclazide: 2nd, 5th & 12th	Not more than 25.0% Between 30.0%-60.0% Not less than 70.0%	Min: 16.3% Max: 19.8% Avg: 17.6% Min: 41.2% Max: 49.9% Avg: 45.6% Min: 74.9% Max: 86.2% Avg: 82.1%
2. Metformin: 1st, 3rd & 10th hr	Between 20.0%-40.0% Between 45.0%-65.0% Not less than 85.0%	Min: 25.2% Max: 25.7% Avg: 25.6% Min: 49.0% Max: 50.0% Avg: 49.5% Min: 97.0% Max: 98.5% Avg: 97.6%

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6.6 INDIVIDUAL WEIGHT VARIATION, THICKNESS, HARDNESS AND FRIABILITY:
(Batch No: GD210302):

Stage	composite									
Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides									
Group Weight of 20 tablets : 27.200g ± 3 % Limits : (26.384g to 28.016g) Avg Weight : 1360 mg ± 5% Limits : (1292.500mg – 1428.000mg) Uniformity of weight : Avg weight ± 5.0% (1292.500mg – 1428.000mg)										
Sample No.	1	2	3	4	5	6	7	8	9	10
Tablet wt in mg	1357	1362	1365	1361	1362	1359	1363	1367	1365	1368
Sample No.	11	12	13	14	15	16	17	18	19	20
Tablet wt in mg	1359	1361	1365	1362	1364	1365	1361	1357	1362	1365
	Thickness Limit: 7.10 ± 0.30mm (6.80mm -7.40mm)									
Sample No.	1	2	3	4	5	6	7	8	9	10
Thickness in mm	7.12	7.10	7.13	7.15	7.07	7.18	7.16	7.13	7.12	7.10
	Hardness limit: 250 N to 350 N									
Sample No.	1	2	3	4	5	6	7	8	9	10
Hardness in N	286	282	280	278	274	281	275	269	274	270
Friability in %	0.11					Limit : NMT 1.0 %				

Test	Limits	Results
Assay: 1. Gliclazide BP 60mg	90.0% to 110.0% of the labeled claim I.e. 54.0mg to 66.0mg	58.98mg (98.3%)
2. Metformin Hcl BP 850mg	90.0% to 110.0% of the labeled claim I.e. 765.0mg to 935.0mg	850.21mg (100.0%)
Dissolution: 1.Gliclazide: 2nd,5th&12th	Not more than 25.0%	Min: 19.5% Max: 22.5% Avg: 20.8%
	Between 30.0%-60.0%	Min: 42.4% Max: 55.5% Avg: 49.5%
	Not less than 70.0%	Min: 83.5% Max: 92.4% Avg: 87.9%
	Between 20.0%-40.0%	Min: 25.1% Max: 26.1% Avg: 25.7%
2. Metformin: 1st,3rd&10th hr	Between 45.0%-65.0%	Min: 48.7% Max: 49.9% Avg: 49.6%
	Not less than 85.0%	Min: 98.4% Max: 102.5% Avg: 100.1%

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7.0 FINISH PRODUCT PROCESS PARAMETERS:

Stage	INITIAL									
Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides									
Group Weight of 20 tablets : 27.200g ± 3 % Limits : (26.384g to 28.016g) Avg Weight : 1360 mg ± 5% Limits : (1292.500mg – 1428.000mg) Uniformity of weight : Avg weight ± 5.0% (1292.500mg – 1428.000mg)										
Sample No.	1	2	3	4	5	6	7	8	9	10
Tablet wt in mg	1362	1365	1354	1362	1360	1355	1359	1359	1362	1365
Sample No.	11	12	13	14	15	16	17	18	19	20
Tablet wt in mg	1367	1360	1359	1355	1357	1359	1360	1366	1365	1362

Stage	MIDDLE									
Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides									
Group Weight of 20 tablets : 27.200g ± 3 % Limits : (26.384g to 28.016g) Avg Weight : 1360 mg ± 5% Limits : (1292.500mg – 1428.000mg) Uniformity of weight : Avg weight ± 5.0% (1292.500mg – 1428.000mg)										
Sample No.	1	2	3	4	5	6	7	8	9	10
Tablet wt in mg	1354	1365	1370	1371	1368	1356	1357	1364	1350	1352
Sample No.	11	12	13	14	15	16	17	18	19	20
Tablet wt in mg	1354	1356	1365	1364	1.362	1.350	1352	1368	1354	1357

Stage	FINAL									
Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides									
Group Weight of 20 tablets : 27.200g ± 3 % Limits : (26.384g to 28.016g) Avg Weight : 1360 mg ± 5% Limits : (1292.500mg – 1428.000mg) Uniformity of weight : Avg weight ± 5.0% (1292.500mg – 1428.000mg)										
Sample No.	1	2	3	4	5	6	7	8	9	10
Tablet wt in mg	1362	1367	1358	1354	1361	1369	1357	1362	1359	1354
Sample No.	11	12	13	14	15	16	17	18	19	20
Tablet wt in mg	1367	1365	1354	1369	1354	1359	1364	1368	1362	1367

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8.0 FINISHED PRODUCT (Composite Sample):

S. No.	Test	Limits	Results		
			GD200604	GD200701	GD210302
1	Description:	White and reddish coloured, bilayered, bilayered red convex, uncoated tablet with break line on reddish layer and plain on white layer	Complies	Complies	Complies
2	Average net Weight of tablet:	1360 mg $\pm$ 5% (1292.5mg – 1428.0mg)	1362.5	1362.5	1366.2
3	Uniformity of fill weight:	Not more than 2 of the individual masses deviate from the average mass by more than 5% and none deviates by more than 10%.	(-) 1.01% (+) 1.90%	(-) 0.57% (+) 1.22%	(-) 0.44% (+) 1.37%
4	Microbiological Parameters: 1. Total viable aerobic count a. Total aerobic microbial count b. Total yeast and mould count 2. Pseudomonas aeruginosa 3. Salmonella Species 4. Escherichia coli 5. Staphylococcus aureus	Not more than 1000 cfu/g Not more than 100 cfu/g Should be absent/g Should be absent/10g Should be absent/g Should be absent/g	40 cfu/g Found absent Found absent Found absent Found absent Found absent	60 cfu/g Found absent Found absent Found absent Found absent Found absent	10 cfu/g Found absent Found absent Found absent Found absent Found absent

9.0 YIELD DETAILS

Stage	Limit	Observed Yield		
		GD200604	GD200701	GD210302
Lubricated granules Metformin	NLT 99.00%	99.71	99.88	99.46
Lubricated granules Gliclazide	NLT 97.00%	99.52	99.01	97.33
Compression	NLT 95.00%(Tentative)	95.36	95.91	94.14
Packing	NLT 93.00% (Tentative)	93.97	94.85	92.78

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10.0 OUT OF SPECIFICATION IF ANY:

Nil

11.0 DEVIATIONS IF ANY:

Nil

12.0 CONCLUSION:

Based on the validation study, all parameters and analytical results found complies with pre-defined validation parameter.

The overall validation study found satisfactory.

13.0 APPROVAL

JOB TITLE	PREPARED BY	REVIEWED BY		APPROVED BY
NAME	P. Vadivel	V. Dhorabai	M. V. Jayalaxman	K. Chandrasekar
DESIGNATION	Sr. Executive QA	Sr. Qm	AGM-QC	AGM-QA
SIGNATURE	P. vadivel	V. D	M. V. Jayalaxman	K. Chandrasekar
DATE	26/04/2021	26/04/21	27/04/21	28/04/2021