



PROCESS VALIDATION REPORT

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GENERIC NAME

IBUPROFEN AND PARACETAMOL TABLETS

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Doc No.: PVR/21/020

Ref. Protocol No.: PVP/21/020
Effective date: 200721

1.0 PRE - APPROVAL:

1.1 Prepared By:

Name	Docianation		
	Designation	Signature	Date
P-vadèves	Sr. Executive OA	P. valo	31/05/202
	Name - va dive	Designation	Signature Symptom

1.2 Verified By:

Dept.	Name	Designation	Signature	Date
Head-Production	V. Dharabal	Sr. Com	31/08/21	31/05/21
Head-Quality Control	4. N. Jagolamon	Hem	8 24 alos (21	31/05/21

1.3 Approved By:

Dept.	Name	D		
	rvarite	Designation	Signature	Date
Head-Quality Assurance	ri, chandrasekoo	AGM-	Muchoa	01/06/21



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2.0 INTRODUCTION:

This report summarizes the results of validation performed as per the Process Validation Protocol No. PVP/21/020.

3.0 REFERENCES:

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

4.0 TEST DATA FOR VALIDATION OF DRY MIXING -FIRST BATCH TEST DATA FOR DRY MIXING STAGE:

B.No.: GD210601 Mfg. Date: JUN-2021

Exp. Date: MAY-2024

FIRST BATCH

B. Size: 8.01

	11131	DATCH	B. Size: 8.UL					
			TEST RESULTS Mixing time (10 minutes)					
	MEASURED							
S.No	PARAMETERS	ACCEPTANCE CRITERIA		Lot	-1	Lot-2		
			Sample Location	Ibuprofen (%)	Paracetamol (%)	Ibuprofen (%)	Paracetamo	
1	Blend uniformity: (Ibuprofen and	Individual sample values	TCL	102.6	101.2	102.0%	101.0	
	Paracetamol)		TC	102.5	102.5	102.3	100.9	
			TCR	101.4	102.7	101.2	101.8	
	5070 to 11070.	50 70 10 110 70.	MBL	100.7	100.0	101.7	100.3	
			МВС	100.8	101.8	100.9	100.0	
				MBR	101.9	101.54	100.4	100.4
			BFL	101.4	101.4	101.7	102.1	
			BFC	98.7	101.3	102.4	99.9	
		BFR	100.7	100.0	102.3	100.7		
			Avg.	101.2	101.4	101.7	100.8	
			RSD	1.1	0.9	0.7	0.7	
	=		Composite	102.0	102.8	99.9	100.4	



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					TEST RESULTS					
S.No	MEASURED PARAMETERS	100	Mixing time (10 minutes)							
		ACCEPTANCE CRITERIA		Lot	-3	Lot-4				
			Sample Location	Ibuprofen (%)	Paracetamol (%)	Ibuprofen (%)	Paracetamo (%)			
	Blend uniformity: (Ibuprofen and	Individual sample values between 85% to 115% of	TCL	102.5	101.3	101.8	102.8			
	Paracetamol)	label claim & RSD: NMT 5 % Average value between	тс	99.9	100.2	98.6	100.2			
		90% to 110%.	TCR	101.2	102.9	98.7	100.6			
			MBL	102.6	102.7	99.2	99.5			
			MBC	100.8	100.9	99.9	100.7			
			MBR	99.6	101.5	99.2	101.2			
							BFL	99.1	101.3	98.4
				BFC	98.8	99.7	99.4	100.1		
					BFR	99.6	98.2	98.8	98.2	
			Avg.	100.5	101.0	99.3	100.4			
			RSD	1.4	1.4	1.0	1.2			
		Composite	101.9	104.8	99.9	103.1				
	validation test results	of Dry Mixing stage are found ory.	d to be	QA-Sign & Date:	P. Val - P.		1			



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	MEASURED	**		TEST RESULTS																	
S.No	PARAMETERS	ACCEPTANCE CRITERIA		Mixing time (15 minutes	5)																
			Sample Location	Ibuprofen (%)	Paracetamol (%)																
1	Blend uniformity:	Individual sample values	TCL	95.4	97.9																
	(Ibuprofen and Paracetamol)	between 85% to 115% of label claim & RSD: NMT 5	TC	97.5	100.0																
		% Average value between 90% to 110%.	TCR	96.7	98.7																
			MBL	96.0	98.2																
				MBC	95.7	95.3															
			MBR	96.1	98.3																
			BFL	98.5	107.4																
																			BFC	101.5	106.3
					BFR	94.0	100.4														
			DP	99.7	103.9																
			Avg.	97.1	100.6																
			RSD	2.3	3.9																
		ř ș	Composite	97.7	100.0																
	validation test results	of Dry Mixing stage are foun	d to be	-Sign & Date: P. Val 7 22/07/21	100.0																



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4.3 TEST DATA FOR LUBRICATION STAGE: **TEST RESULTS MEASURED** S.No **ACCEPTANCE CRITERIA** Mixing time (5 minutes) **PARAMETERS** Sample Location Ibuprofen (%) Paracetamol (%) 1 Blend uniformity: Individual sample values TCL 98.5 102.1 (Ibuprofen and between 85% to 115% of TC Paracetamol) 99.2 label claim & RSD: NMT 5 102.3 % Average value between TCR 99.2 100.3 90% to 110%. MBL 97.0 99.9 MBC 98.7 101.3 MBR 97.9 102.2 BFL 97.3 101.8 **BFC** 97.6 105.4 BFR 98.4 105.5 DP 98.6 100.2 Avg. 98.2 102.1 RSD 0.7 1.9 Composite 99.8 103.8 All the validation test results of Dry Mixing stage are found to be QA-Sign & Date: 7. 12/07/21 satisfactory/not satisfactory.



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4.4 **TEST DATA FOR LUBRICATION STAGE:** B.No.: GD210601 Mfg. Date: JUN-2021 Exp. Date: MAY-2024 B. Size: 8.0L FIRST BATCH ON POOLED SAMPLE S.No **MEASURED PARAMETERS ACCEPTANCE CRITERIA TEST RESULTS** Appearance (pooled sample) 1 Light orange colour powder Complies **Bulk Density** 2 For information only 0.63g/ml **Tapped Density** 3 For information only 0.77g/ml

QA-Sign & Date:





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4.5 CONCLUSION ON VALIDATION OF DRY MIXING, BLENDING & LUBRICATION STAGE OF FIRST BATCH

- 1. All the validation test results of Dry Mixing stage of Ibuprofen and Paracetamol are found to be satisfactory/not satisfactory after 10 minutes mixing.
- 2. All the validation test results of Blending stage of Ibuprofen and Paracetamol are found to be **satisfactory/not satisfactory** after **15 minutes** mixing.
- 3. All the validation test results of Lubrication stage of Ibuprofen and Paracetamol are found to be satisfactory/not satisfactory after 5 minutes mixing.

Verify the following standard process meters during validation of next two batches of the product.

S.No	Process stage	Equipment	Fixed Standard (minutes)
1	Dry Mixing stage (Ibuprofen and Paracetamol)	Rapid Mixer granulator	10 minutes
2	Blending stage (Ibuprofen and Paracetamol)	Octagonal Blender	15 minutes
3	Lubrication stage (Ibuprofen and Paracetamol)	Octagonal Blender	5 minutes

Head-Quality Assurance:

(Sign & Date)

Note: If the test results are not found satisfactory raise unplanned deviation. Necessary corrective actions and preventive actions shall be taken before proceeding to validation of commercial batches.

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		COMPRESSION STAGE:	B.No.: GD210601	Mfg. Date: JUN-2021	Exp. Date: MAY-2024
	CRITICAL PARAMETER-1: COMPRESSION FORCE (HARDNESS -CHALLENGE)		B. Size: 8.0L	I	
				TEST RESULTS	
S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	Minimum compression force	Standard compression force	Maximum compression force
1.0	Appearance	Light orange coloured oval shape biconvex uncoated tablets with half break line on one side and plain on another side.	Complies	Complies	Complies
2.0	Average Weight	1040mg± 3.00% (1008.800mg-1071.200mg)	1039.12 mg	1038.20 mg	1036.20 mg
3.0	Uniformity of weight	Not more than 2 of the individual masses deviate from the average mass by more than $\pm 5\%$.	Complies	Complies	Complies
4.0	Thickness (Average 10 tablets)	7.90± 0.3mm (7.60 to 8.20 mm)	7.90mm	7.77mm	7.80mm
5.0	Hardness (Average 10 tablets)	160 N to 230 N * (To be monitored)	203.3N	201.6N	211.5N
6.0	Disintegration time	NMT 15 mins	01Minutes 24 seconds	01Minutes 49 seconds	02Minutes 17 seconds
7.0	Friability	Not more than 1.0% w/w	0.12%	0.11%	0.17%
Comm	ents: The above ment	Fored Minimum Compression Aaval Complies wo	o Aurce, Maximi	in and Standard	Horce has
ees	verified and	Aanal Complies wo	was in the ac	ceptance orsterla	,
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CRITICAL PARAMETER-2: COMPRESSION RATE (RPM -CHALLENGE)			TEST RESULTS		
S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	10RPM (Low)	35RPM (High)	
1.0	Appearance	Light orange coloured oval shape biconvex uncoated tablets with half break line on one side and plain on another side.	Complies	Complies	
2.0	Average Weight	1040mg± 3.00% (1008.800mg-1071.200mg)	1038.51mg	1036.41mg	
3.0	Uniformity of weight	Not more than 2 of the individual masses deviate from the average mass by more than $\pm 5\%$.	Complies	Complies	
4.0	Thickness (Average 10 tablets)	7.90± 0.3mm (7.60 to 8.20 mm)	7.77mm	7.76mm	
5.0	Hardness (Average 10 tablets)	160 N to 230 N * (To be monitored)	201.8N	203.0N	
6.0	Disintegration Time	NMT 15 mins	02Minutes 13 seconds	00Minutes 40 seconds	
7.0	Friability	Not more than 1.0% w/w	0.05%	0.10%	

Comments: The above Hentioned Low and High opm has been verified and found

Complies with in the adeptance criteria.

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QA-Sign & Date: P. Valor 22/07/21

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CRITI	CAL PARAMETER-3: HOPPER LE	VEL CHALLENGE		TEST RESULTS	
S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	Full Hopper	Half-full Hopper	Nearly-empty Hopper
1.0	Appearance	Light orange coloured oval shape biconvex uncoated tablets with half break line on one side and plain on another side.	Complies	Complies	Complies
2.0	Average Weight	1040mg± 3.00% (1008.800mg-1071.200mg)	1040.75mg	1039.7mg	1038.25mg
3.0	Uniformity of weight	Not more than 2 of the individual masses deviate from the average mass by more than $\pm 5\%$.	Complies	Complies	Complies
4.0	Thickness (Average 10 tablets)	7.90± 0.3mm (7.60 to 8.20 mm)	7.77mm	7.78mm	7.78mm
5.0	Hardness (Average 10 tablets)	160 N to 230 N * (To be monitored)	201.9N	203.1N	199.6N
6.0	Disintegration Time	NMT 15 mins	01Minutes 20 seconds	01Minutes 17 seconds	02Minutes 05 seconds
7.0	Friability	Not more than 1.0% w/w	0.12%	0.14%	0.12%
8.0	Dissolution: i) Ibuprofen BP ii) Paracetamol BP	Not less than 80% of stated amount ibuprofen dissolved in 60 minutes. Not less than 80% of stated amount Paracetamol dissolved in 60 minutes	Min:100.4%, Max:102.3% Avg:101.5% Min:100.9%, Max:101.3% Avg:101.1%	Min:100.7%, Max:101.6% Avg:101.2% Min:100.7%, Max:101.6%, Avg:101.2%	Min:99.5%, Max:102.6% Avg:101.5% Min:100.5%, Max:102.6%, Avg:101.7%
9.0	Assay: i) Ibuprofen BP ii) Paracetamol BP	90.0% - 110.0% of the labeled claim 90.0% - 110.0% of the labeled claim	395.87mg (99.0%) 507.60mg (101.5%)	395.26mg (98.8%) 501.69mg (100.3%)	396.25mg (99.1%) 507.58mg (101.5%)

QA-Sign & Date: Q-Val



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5.4 CONCLUSION ON VALIDATION OF COMPRESSION PROCESS OF FIRST BATCH

All the validation test results of compression process are found to be satisfactory/not satisfactory during hardness challenge.

All the validation test results of compression process are found to be satisfactory/not satisfactory during rpm challenge.

All the validation test results of compression process are found to be satisfactory/not satisfactory during hopper level challenge.

Verify the quality attributes by applying the following optimum process parameters during validation of first three commercial batches of the product for compression stage.

Head-Quality Assurance:

(Sign & Date)

Note: If the test results are not found satisfactory raise unplanned deviation. Necessary corrective actions and preventive actions shall be taken as per SOP before proceeding to validation of commercial batches.

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6.1 TEST DATA FOR DRY MIXING STAGE:		B.No.: GD210602		Mfg. Date: JUN-20	021 Exp.	Date: MAY-2024	
	2 ^{NI}	BATCH	B. Size: 8.0L				
					TEST RESULTS	ebene Bish	e probable representation
	MEASURED			Mixin	ng time (10 minutes)		
S.No	PARAMETERS	ACCEPTANCE CRITERIA		Lo	ot-1		_ot-2
			Sample Location	Ibuprofen (%)	Paracetamol (%)	Ibuprofen (%)	Paracetamo (%)
1	Blend	niformity: between 85% to 115% of label claim & RSD: NMT 5	TCL	98.36	101.6	92.4	105.2
	(Ibuprofen and Paracetamol)		TC	99.4	103.6	93.2	109.1
			TCR	98.0	100.7	90.9	104.0
			MBL	97.2	102.7	90.8	105.0
			МВС	98.7	102.6	91.6	106.7
	2		MBR	97.6	100.5	93.0	106.9
	9		BFL	98.0	101.4	92.9	103.8
			BFC	99.3	101.0	91.3	106.6
			BFR	99.0	100.3	93.6	103.8
			Avg.	98.4	101.6	92.2	105.7
			RSD	0.7	1.11	1.14	1.6
			Composite	98.3	101.0	93.2	105.8



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		ACCEPTANCE CRITERIA		T	EST RESULTS			
	MEASURED		Mixing time (10 minutes)					
S.No	PARAMETERS			Lot	-3	Lot-4		
			Sample Location	Ibuprofen (%)	Paracetamol (%)	Ibuprofen (%)	Paracetamo (%)	
	Blend uniformity:	Individual sample values between 85% to 115% of	TCL	90.5	103.6	97.1	98.3	
	(Ibuprofen and Paracetamol)	label claim & RSD: NMT 5 % Average value between 90% to 110%.	тс	90.1	105.4	97.5	101.1	
			TCR	90.9	103.2	98.0	101.1	
			MBL	92.3	106.0	97.5	101.1	
			МВС	93.2	105.4	97.7	98.0	
			MBR	90.6	103.1	96.4	99.1	
2			BFL	92.5	103.7	98.4	101.8	
			BFC	93.4	106.8	95.0	100.8	
			BFR	92.2	105.9	96.6	100.4	
	-		Avg.	91.7	104.8	97.1	100.2	
			RSD	1.3	1.3	1.0	1.3	
			Composite	92.6	107.0	94.9	98.9	
	validation test resu actory/not satisfa	ilts of Dry Mixing stage are fou		QA-Sign & Date:	P. Val		•	



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	6.2 TEST DATA	FOR DRY MIXING STAGE:	B.No.: GD210603		Mfg. Date: JUN-20	21 Exp. [Date: MAY-2024								
	3 RD B	ATCH	B. Size: 8.0L				Company of the second of the s								
				性表。如于生物的。	TEST RESULTS										
				Mixin	g time (10 minutes)										
S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA		Lot	Hi.	Lo	ot-2								
		,	Sample Location	Ibuprofen (%)	Paracetamol (%)	Ibuprofen (%)	Paracetamo (%)								
1	Blend uniformity: (Ibuprofen and Paracetamol)	profen and between 85% to 115% of	TCL	99.5	99.6	99.2	99.5								
			TC	100.3	98.8	99.9	102.3								
			TCR	100.8	98.2	98.3	101.2								
			MBL	99.4	98.9	95.2	94.8								
			МВС	103.2	101.8	99.6	99.1								
			MBR	97.7	98.8	98.4	99.5								
			BFL	98.4	111.6	97.0	97.2								
	2	(2) (3)	BFC	98.8	98.7	98.4	97.6								
											BFR	97.6	98.7	98.6	98.6
			Avg.	99.5	100.6	98.3	98.9								
			RSD	1.7	4.2	1.4	2.2								
		v	Composite	97.4	99.9	97.8	97.6								



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	MEASURED PARAMETERS	ACCEPTANCE CRITERIA		T	TEST RESULTS			
			Mixing time (10 minutes)					
S.No				Lot	-3	Lot-4		
		**	Sample Location	Ibuprofen (%)	Paracetamol (%)	Ibuprofen (%)	Paracetamo (%)	
	Blend uniformity:	Individual sample values between 85% to 115% of	TCL	100.1	100.9	101.4	100.2	
	(Ibuprofen and Paracetamol)	label claim & RSD: NMT 5 % Average value between	тс	96.3	98.3	99.2	98.2	
		90% to 110%.	TCR	97.5	97.7	101.7	99.6	
			MBL	95.3	97.6	100.0	98.6	
			МВС	97.5	98.1	98.6	97.2	
			MBR	97.9	98.4	98.4	98.6	
			BFL	97.6	98.1	99.2	100.1	
			BFC	100.4	104.4	98.4	99.6	
			BFR	100.1	99.8	99.6	99.9	
			Avg.	98.1	99.3	99.6	99.1	
			RSD	1.8	2.2	1.2	1.0	
			Composite	100.8	101.0	100.1	99.2	
	validation test resu actory/not satisfa	lts of Dry Mixing stage are foun		QA-Sign & Date: 🗸	P. Val 0			



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	MEAGUEE	ACCEPTANCE CRITERIA		TEST RESULTS		
S.No	MEASURED PARAMETERS		Mixing time (15 minutes)			
			Sample Location	Ibuprofen (%)	Paracetamol (%)	
1	Blend uniformity:		TCL	95.3	101.3	
	Paracetamol) label claim & RSD: N	between 85% to 115% of label claim & RSD: NMT 5	TC	99.3	101.0	
		% Average value between	TCR	97.0	99.6	
			MBL	101.6	102.7	
			МВС	94.7	97.5	
			MBR	99.4	102.9	
			BFL	104.8	102.3	
			BFC	98.8	104.8	
			BFR	99.4	104.4	
			DP	102.0	102.2	
			Avg.	99.2	101.9	
		x	RSD	3.1	2.1	
			Composite	100.0	100.0	

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		ACCEPTANCE CRITERIA		TEST RESULTS	
S.No	MEASURED PARAMETERS			Mixing time (15 minute	es)
			Sample Location	Ibuprofen (%)	Paracetamol (%)
1	Blend uniformity: (Ibuprofen and	Individual sample values	TCL	100.8	103.5
	Paracetamol)	between 85% to 115% of label claim & RSD: NMT 5	TC	98.6	101.6
	% Average value betwee 90% to 110%.	% Average value between	TCR	96.3	102.6
			MBL	98.3	101.3
			МВС	97.2	99.7
			MBR	91.9	94.2
			BFL	98.3	104.1
			BFC	103.1	107.1
			BFR	96.8	101.2
			DP	96.6	100.7
			Avg.	97.8	101.6
			RSD	3.0	3.2
			Composite	98.3	99.1
	validation test results actory/not satisfact	s of Dry Mixing stage are foun	d to be	QA-Sign & Date: 22/07/2	

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MEASURED PARAMETERS	ACCEPTANCE CRITERIA	Mixing time (5 minutes)				
		Sample Location	Ibuprofen (%)	Paracetamol (%)		
		TCL	100.4	99.8		
Paracetamol)	label claim & RSD: NMT 5	TC	98.5	100.4		
	% Average value between	TCR	96.6	101.8		
	MBI MBG MBF BFL BFC BFR	MBL	99.0	96.8		
		МВС	99.9	100.0		
		MBR	99.7	100.4		
		BFL	98.4	103.3		
		BFC	98.3	100.5		
		BFR	100.6	99.8		
		DP	99.5	101.8		
		Avg.	99.1	100.5		
				RSD	1.2	1.6
		Composite	101.0	103.7		
SCHOOL STANDARD STANDARD	Blend uniformity: (Ibuprofen and Paracetamol)	Blend uniformity: (Ibuprofen and Paracetamol) Individual sample values between 85% to 115% of label claim & RSD: NMT 5% Average value between 90% to 110%.	Blend uniformity: (Ibuprofen and Paracetamol) ACCEPTANCE CRITERIA Sample Location Individual sample values between 85% to 115% of label claim & RSD: NMT 5 % Average value between 90% to 110%. TC TCR MBL MBC MBR BFL BFC BFR DP Avg. RSD	ACCEPTANCE CRITERIA Sample Location Ibuprofen (%)		

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		ACCEPTANCE CRITERIA		TEST RESULTS			
S.No	MEASURED PARAMETERS			Mixing time (5 minutes)			
			Sample Location	Ibuprofen (%)	Paracetamol (%)		
1	Blend uniformity: (Ibuprofen and	Individual sample values	TCL	99.1	93.2		
	Paracetamol)	between 85% to 115% of label claim & RSD: NMT 5	TC	100.4	99.9		
		% Average value between 90% to 110%.	TCR	99.5	99.2		
			MBL	99.6	99.1		
			МВС	98.5	101.5		
			MBR	97.7	100.1		
			BFL	96.5	97.9		
			BFC	97.0	98.2		
			BFR	96.7	99.3		
			DP	97.4	97.9		
			Avg.	98.2	98.6		
			RSD 1.4			1.4	2.2
			Composite	97.6	98.3		
all the	validation test results	s of Dry Mixing stage are found cory.	to be	QA-Sign & Date: Rval			

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6.7 **TEST DATA FOR LUBRICATION STAGE:** B.No.: GD210602 Mfg. Date: JUN-2021 Exp. Date: MAY-2024 **B. Size: 8.0L** 2ND BATCH ON POOLED SAMPLE S.No **MEASURED PARAMETERS ACCEPTANCE CRITERIA TEST RESULTS** Appearance (pooled sample) Light orange colour powder 1 Complies 2 **Bulk Density** For information only 0.59g/ml 3 **Tapped Density** For information only 0.77g/ml g. 101 P QA-Sign & Date:



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	6.8 TEST DATA FOR LUBR	ICATION STAGE :	B.No.: GD210603	Mfg. Date: JUN-202	Exp. Date: MAY-2024	
	3 RD BATCH		B. Size: 8.0L			
S.No	ON POOLED SAMPLE					
	MEASURED PARAMETERS		ACCEPTANCE CRITER	IA	TEST RESULTS	
1	Appearance (pooled sample)	Light orange colour po	owder		Complies	
2	Bulk Density	For information only			0.59g/ml	
3	Tapped Density	For information only			0.77g/ml	





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6.9 CONCLUSION ON VALIDATION OF DRY MIXING, BLENDING & LUBRICATION STAGE OF 1ST, 2ND & 3RD BATCHES

S.No	Observation	1 st Batch No.: GD210601	2 nd Batch No.: GD210602	3 rd Batch No.: GD210603
1.	All the validation test results of Dry Mixing stage of Ibuprofen and Paracetamol are found to be satisfactory after 10 minutes mixing.	Complies/Does not comply	Complies/Does not comply	Complies/Does not comply
2.	All the validation test results of Blending stage of Ibuprofen and Paracetamol are found to be satisfactory after 10 minutes mixing.	Complies/Does not comply	Complies/Does not comply	Complies/Does not comply
3.	All the validation test results of Lubrication stage of Ibuprofen and Paracetamol are found to be satisfactory after 10 minutes mixing.	Complies/Does not comply	Complies/Does not comply	Complies/Does not comply

Head-Quality Assurance:_

(Sign & Date)

Note: If the test results are not found satisfactory raise unplanned deviation. Necessary corrective actions and preventive actions shall be taken before proceeding to validation of commercial batches.

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	7.1 TEST DATA FOR	COMPRESSION STAGE:	B.No.: GD210602	Mfg. Date: JUN-2021	Exp. Date: MAY-2024
	CAL PARAMETER-1: RESSION FORCE (HARDNE	SS -CHALLENGE)	B. Size: 8.0L		
				TEST RESULTS	
S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	Minimum compression force	Standard compression force	Maximum compression force
1.0	Appearance	Light orange coloured oval shape biconvex uncoated tablets with half break line on one side and plain on another side.	Complies	Complies	Complies
2.0	Average Weight	1040mg± 3.00% (1008.800mg-1071.200mg)	1052.00 mg	1038.00 mg	1037.00 mg
3.0	Uniformity of weight	Not more than 2 of the individual masses deviate from the average mass by more than ±5%.	Complies	Complies	Complies
4.0	Thickness (Average 10 tablets)	7.90± 0.3mm (7.60 to 8.20 mm)	7.72mm	7.80mm	7.65mm
5.0	Hardness (Average 10 tablets)	160 N to 230 N * (To be monitored)	196.80N	223.80N	221.00N
6.0	Disintegration time	NMT 15 mins	02 Minutes 17 seconds	01 Minutes 26 seconds	02 Minutes 29 seconds
7.0	Friability	Not more than 1.0% w/w	0.18%	0.16%	0.12%
Comm	nents: The choice	Mentioned Minimum , Sten	unixon, broad	m compression	Lorce has
beec	weakfied and	Aand complies and	rain the o	icceptance ext	erva

(D)

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QA-Sign & Date: 8 Not 121

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CRITI	CAL PARAMETER-2: COMPRE	SSION RATE (RPM -CHALLENGE)	TEST RESULTS		
S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	10RPM (Low)	35RPM (High)	
1.0	Appearance	Light orange coloured oval shape biconvex uncoated tablets with half break line on one side and plain on another side.	Complies	Complies	
2.0	Average Weight	1040mg± 3.00% (1008.800mg-1071.200mg)	1045.00mg	1041.00mg	
3.0	Uniformity of weight	Not more than 2 of the individual masses deviate from the average mass by more than $\pm 5\%$.	Complies	Complies	
4.0	Thickness (Average 10 tablets)	7.90± 0.3mm (7.60 to 8.20 mm)	.90± 0.3mm (7.60 to 8.20 mm) 7.78mm		
5.0	Hardness (Average 10 tablets)	160 N to 230 N * (To be monitored)	233.50N	224.30N	
6.0	Disintegration Time	NMT 15 mins	01 Minutes 48 seconds	01 Minutes 55 seconds	
7.0	Friability	Not more than 1.0% w/w	0.12%	0.14%	
Comm	nents: The above	Monotoned tow and High with in the acceptance	Ren has been	verified	

(D)

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CRITI	CAL PARAMETER-3: HOPPER LE	VEL CHALLENGE		TEST RESULTS	
S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	Full Hopper	Half-full Hopper	Nearly-empty Hopper
1.0	Appearance	Light orange coloured oval shape biconvex uncoated tablets with half break line on one side and plain on another side.	Complies	Complies	Complies
2.0	Average Weight	1040mg± 3.00% (1008.800mg-1071.200mg)	1038.00mg	1042.00mg	1039.00mg
3.0	Uniformity of weight	Not more than 2 of the individual masses deviate from the average mass by more than $\pm 5\%$.	Complies	Complies	Complies
4.0	Thickness (Average 10 tablets)	7.90± 0.3mm (7.60 to 8.20 mm)	7.73mm	7.74mm	7.74mm
5.0	Hardness (Average 10 tablets)	160 N to 230 N * (To be monitored)	231.29N	225.04N	232.58N
			01Minutes 50		AND TRANSPORT IN CONTRACT
6.0 D	Disintegration Time	NMT 15 mins	seconds	01Minutes 51seconds	01Minutes 54 seconds
7.0	Friability	Not more than 1.0% w/w	0.16%	0.13%	0.11%

Comments: The above Mentioned Hopper level (ful, Houly, Nearly empty) has been verified and fund complies with in the acceptance extresion.

QA-Sign & Date:

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	8.1 TEST DATA FO	R COMPRESSION STAGE:	B.No.: GD210603	Mfg. Date: JUN-2021	Exp. Date: MAY-2024	
	CAL PARAMETER-1: RESSION FORCE (HARDN	ESS -CHALLENGE)	B. Size: 8.0L			
				TEST RESULTS		
S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	Minimum compression force	Standard compression force	Maximum compression force	
1.0	Appearance	Light orange coloured oval shape biconvex uncoated tablets with half break line on one side and plain on another side.	Complies	Complies	Complies	
2.0	Average Weight	1040mg± 3.00% (1008.800mg-1071.200mg) 1042.00mg	1043.00mg	1037.0mg		
3.0	Uniformity of weight	Not more than 2 of the individual masses deviate from the average mass by more than ±5%.	Complies	Complies	Complies	
4.0	Thickness (Average 10 tablets)	7.90± 0.3mm (7.60 to 8.20 mm)	7.73mm	7.86mm	7.68mm	
5.0	Hardness (Average 10 tablets)	160 N to 230 N * (To be monitored)	236.1N	237.3N	237.0N	
6.0	Disintegration time	NMT 15 mins	02Minutes 17 seconds	03Minutes 19 seconds	02Minutes 14 seconds	
7.0	Friability	Not more than 1.0% w/w	0.18%	0.13%	0.15%	
Comm	ients: The choose	vosified and found (m, stolenderd	, Maximum	Compress as	

QA-Sign & Date:

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CRITI	CAL PARAMETER-2: COMPRESS	ION RATE (RPM -CHALLENGE)	TEST RESULTS		
S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	10RPM (Low)	35RPM (High)	
1.0	Appearance	Light orange coloured oval shape biconvex uncoated tablets with half break line on one side and plain on another side.	Complies	Complies	
2.0	Average Weight	1040mg± 3.00% (1008.800mg-1071.200mg)	1045.0mg	1041.0mg	
3.0	Uniformity of weight	Not more than 2 of the individual masses deviate from the average mass by more than $\pm 5\%$.	Complies	Complies	
4.0	Thickness (Average 10 tablets)	7.90± 0.3mm (7.60 to 8.20 mm)	7.75mm	7.76mm	
5.0	Hardness (Average 10 tablets)	160 N to 230 N * (To be monitored)	233.5N	224.3N	
6.0	Disintegration Time	NMT 15 mins	01Minutes 48 seconds	01Minutes 55 seconds	
7.0	Friability	Not more than 1.0% w/w	0.12%	0.14%	

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CKIII	CAL PARAMETER-3: HOPPER LE	VEL CHALLENGE	TEST RESULTS			
S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	Full Hopper	Half-full Hopper	Nearly-empty Hopper	
1.0	Appearance	Light orange coloured oval shape biconvex uncoated tablets with half break line on one side and plain on another side.	Complies	Complies	Complies	
2.0	Average Weight	1040mg± 3.00% (1008.800mg-1071.200mg)	1039.99mg	1040.05mg	1041.97mg	
3.0	Uniformity of weight	Not more than 2 of the individual masses deviate from the average mass by more than $\pm 5\%$.	Complies	Complies	Complies	
4.0	Thickness (Average 10 tablets)	7.90± 0.3mm (7.60 to 8.20 mm)	7.78mm	7.75mm	7.78mm	
5.0	Hardness (Average 10 tablets)	160 N to 230 N * (To be monitored)	229.83N	236.45N	231.93N	
6.0	Disintegration Time	NMT 15 mins	02Minutes 11 seconds	02Minutes 20 seconds	02Minutes 26 seconds	
7.0	Friability	Not more than 1.0% w/w	0.15%	0.11%	0.20%	
Comm	ents: The Copone Ma	entioned atopper level (Fall, Ho	ey, Noarry 7	sulph) pa	s heer	
rens	fied and stoud	comples with in the	acceptance	exteria.		



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8.4 CONCLUSION ON VALIDATION OF **COMPRESSION PROCESS OF COMMERCIAL BATCHES**

S.No	Observation	1 st Batch No.: GD210601	2 nd Batch No.: GD210602	3 rd Batch No.: GD210603
1.	All the validation test results of compression process are found to be satisfactory during hardness challenge.	Complies/Does not comply	Complies/Does not comply	Complies/Does not comply
2.	All the validation test results of compression process are found to be satisfactory during rpm challenge.	Complies/Does not comply	Complies/Does not comply	Complies/Does not comply
3.	All the validation test results of compression process are found to be satisfactory during hopper level challenge.	Complies/Does not comply	Complies/Does not comply	Complies/Does not comply

Overall Remarks on Validation of Compression Process: (Mention details of Deviations/Non-Conformance/Abnormalities if any)

(Sign & Date)

Head-Quality Assurance:

Note: If the test results are not found satisfactory, raise unplanned deviation. Necessary corrective actions and preventive actions shall be taken as per SOP. Repeat the complete process validation on next 3 consecutive batches.



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	9.1 TEST DATA FOR	UN COATED STAGE: 1 ST BATCH	B.No: GD210601	Mfg. Date: J	UN-2021	Exp. Date: MAY-2024
CRITI	CAL PARAMETER		B. Size: 8.0L			•
S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA		TES	T RESULTS	
1.0	Appearance	Light orange coloured oval shape bid line on one side and plain on anothe		with half break	Complies	
2.0	Average Weight	1040mg± 3.00% (1008.800mg-1071.200mg)			1029.9mg	
3.0	Uniformity of weight	Not more than 2 of the individual material by more than $\pm 5\%$.	asses deviate from the a	verage mass	Complies	
4.0	Thickness (Average 10 tablets)	Accordance in the Chemical Section of the Chemical Sec		7.76mm		
5.0	Disintegration time	NMT 15 mins		01 Minutes 57 seconds		
6.0	Friability	Not more than 1.0% w/w	2		0.11%	
7.0	Hardness	160 N to 230 N * (To be monitored)		0	237.40N	
8.0	Dissolution: i) Ibuprofen BP	Not less than 80% of stated amount	ibuprofen dissolved in 6	0 minutes.	Min:100.4%,Max:103.2%,Avg:103	
	ii) Paracetamol BP	Not less than 80% of stated amount	Paracetamol dissolved i	n 60 minutes	Min:100.79	%,Max:102.6%,Avg:101.6
9.0	Assay: i) Ibuprofen BP	90.0% - 110.0% of the labeled claim	n		391.35mg	• Control Control Control
	ii) Paracetamol BP	90.0% - 110.0% of the labeled claim		504.34mg	(100.9%)	
10.0	Related Substances: Single Maximum unknown impurity	Not more than 0.20%			0.04%	
	Total impurities	Not more than 0.50%			0.07%	
		entioned Parameters, As	say, D 18806M2	ian, Relai	red 2	ubstances, has b
rest	feel and found	Complies with in the	e alceptance	criper	भेद .	



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		UN COATED STAGE: 2 ND BATCH	B.No: GD210602	Mfg. Date: J	JN-2021	Exp. Date: MAY-2024
CRITI	CAL PARAMETER		B. Size: 8.0L			
S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA		TES	T RESULTS	3
1.0	Appearance	Light orange coloured oval shape bid line on one side and plain on anothe		with half break	Complies	
2.0	Average Weight	1040mg± 3.00% (1008.800mg-1071.200mg)			1041.5mg	
3.0	Uniformity of weight	Not more than 2 of the individual m by more than ±5%.	asses deviate from the a	verage mass	Complies	
4.0	Thickness (Average 10 tablets)	7.90± 0.3mm (7.60 to 8.20 mm)			7.78mm	
5.0	Disintegration time	NMT 15 mins	NMT 15 mins 0		01 Minutes 35seconds	
6.0	Friability	Not more than 1.0% w/w		0.11%		
7.0	Hardness	160 N to 230 N * (To be monitored)			219.12N	
8.0	Dissolution: i) Ibuprofen BP	Not less than 80% of stated amount	: ibuprofen dissolved in 6	0 minutes.	Min:99.0%	o,Max:101.1%,Avg:99.9%
	ii) Paracetamol BP	Not less than 80% of stated amount	Paracetamol dissolved i	n 60 minutes	Min:99.9%	,Max:102.7%,Avg:101.0%
9.0	Assay: i) Ibuprofen BP	90.0% - 110.0% of the labeled clair	n		402.05mg	(100.5%)
	ii) Paracetamol BP	90.0% - 110.0% of the labeled claim			515.62mg	(103.1%)
10.0	Related Substances: Single Maximum unknown impurity	Not more than 0.20%			0.04%	
	Total impurities	Not more than 0.50%			0.05%	
Comm	ients: The above Me	entioned Parameters, A	185cy, D 1850PW	sos, Rel	shed	Bulystances.
tos d	seen verified a	entioned Parameters, F	who in The	- accept	are	substances.
	In & Date : P . 10 2 2 10 1 1			1		

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		UN COATED STAGE: 3 RD BATCH	B.No: GD210603	Mfg. Date: J	UN-2021	Exp. Date: MAY-2024
CRITI	CAL PARAMETER	Y	B. Size: 8.0L			
S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS			
1.0	Appearance	Light orange coloured oval shape bid break line on one side and plain on a		s with half	Complies	
2.0	Average Weight	1040mg± 3.00% (1008.800mg-1071.200mg)			1040.7mg	
3.0	Uniformity of weight	Not more than 2 of the individual may by more than ±5%.	asses deviate from the	average mass	Complies	
4.0	Thickness (Average 10 tablets)	7.90± 0.3mm (7.60 to 8.20 mm)			7.71mm	
5.0	Disintegration time	NMT 15 mins	NMT 15 mins		01 Minutes 39 seconds	
6.0	Friability	Not more than 1.0% w/w		0.16%		
7.0	Hardness	160 N to 230 N * (To be monitored)			249.11N	
8.0	Dissolution: i) Ibuprofen BP	Not less than 80% of stated amount ibuprofen dissolved in 60 minutes.		Min:98.5%	,Max:102.0%,Avg:99.9%	
	ii) Paracetamol BP	Not less than 80% of stated amount minutes	Paracetamol dissolved	in 60	Min:100.39	%,Max:101.8%,Avg:101.1%
9.0	Assay: i) Ibuprofen BP	90.0% - 110.0% of the labeled clain	n		396.39mg	
	ii) Paracetamol BP	90.0% - 110.0% of the labeled claim			499.76mg	(100.0%)
10.0	Related Substances: Single Maximum unknown impurity	Not more than 0.20%			0.04%	
	Total impurities	Not more than 0.50%			0.07%	
Comm	ents: The above P	renovered Parametels 1	Assey , D18	solution,	Relate	d Substances
ras '	heer verified	send found complete	s wire in	tre ac	centanie	cosoda
	n & Date : P. Valago	1/2/				



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EVALUATION OF RESULTS, CONCLUSION AND RECOMMENDATIONS: analytisd 23/07/2 NA **Head-Quality Assurance:** (Sign & Date)

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11.0 POST APPROVAL:

10.1 Compiled By:

Dept.	Name	Designation	Signature	Date
Quality Assurance	P. Vadirel	Sr. Executive GA	Prati	24/107/2

10.2 Verified By:

Dept.	Name	Designation	Signature	Date
Head-Production	V. Dharabal	81. Cm	A	24/07/21
Head-Quality Control	47-Vijayekimos	AEM.	Aur	24/07/21

10.3 Approved By:

Dept.	Name	Designation	Signature	Date
Head-Quality Assurance	19. Chandrasekae	AGM	Dungan	26/07/21