1.0 PRE - APPROVAL :

1.1 Prepared By :

Dept.	Name	Designation	Signature	Date
Quality Assurance	P. Vadivel	Sr. Executive QA	P. Vadivel	31/05/2021

1.2 Verified By:

Dept.	Name	Designation	Signature	Date
Head-Production	V. Dharabai	Sr. GM	31/05/21	31/05/21
Head-Quality Control	P. Vijayakumar	AGM	31/05/21	31/05/21

1.3 Approved By:

Dept.	Name	Designation	Signature	Date
Head-Quality Assurance	K. Chandrasekar	AGM -		01/06/21

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

4.1 TEST DATA FOR DRY MIXING STAGE: **B.No.: GD210601** **Mfg. Date: JUN-2021** **Exp. Date: MAY-2024**

FIRST BATCH **B. Size: 8.0L**

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS				
			Mixing time (10 minutes)				
			Sample Location	Lot-1		Lot-2	
				Ibuprofen (%)	Paracetamol (%)	Ibuprofen (%)	Paracetamol (%)
1	**Blend uniformity:** (Ibuprofen and Paracetamol)	Individual sample values between 85% to 115% of label claim & RSD: NMT 5 % Average value between 90% to 110%.	**TCL**	102.6	101.2	102.0%	101.0
			TC	102.5	102.5	102.3	100.9
			TCR	101.4	102.7	101.2	101.8
			MBL	100.7	100.0	101.7	100.3
			MBC	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

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS				
			Mixing time (10 minutes)				
			Sample Location	Lot-3		Lot-4	
				Ibuprofen (%)	Paracetamol (%)	Ibuprofen (%)	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%.	**TCL**	102.5	101.3	101.8	102.8
			TC	99.9	100.2	98.6	100.2
			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	100.5
			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

All the validation test results of Dry Mixing stage are found to be **satisfactory/not satisfactory.**

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4.2 TEST DATA FOR BLENDING STAGE:

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS		
			Mixing time (15 minutes)		
			Sample Location	Ibuprofen (%)	Paracetamol (%)
1	**Blend uniformity:** (Ibuprofen and Paracetamol)	Individual sample values between 85% to 115% of label claim & RSD: NMT 5 % Average value between 90% to 110%.	**TCL**	95.4	97.9
			TC	97.5	100.0
			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
			Composite	97.7	100.0

All the validation test results of Dry Mixing stage are found to be **satisfactory/not satisfactory.**

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4.3 TEST DATA FOR LUBRICATION STAGE:

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS		
			Mixing time (5 minutes)		
			Sample Location	Ibuprofen (%)	Paracetamol (%)
1	**Blend uniformity:** (Ibuprofen and Paracetamol)	Individual sample values between 85% to 115% of label claim & RSD: NMT 5 % Average value between 90% to 110%.	**TCL**	98.5	102.1
			TC	99.2	102.3
			TCR	99.2	100.3
			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 **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
FIRST BATCH	B. Size: 8.0L		

S.No	ON POOLED SAMPLE		
	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS
1	**Appearance** (pooled sample)	Light orange colour powder	Complies
2	**Bulk Density**	For information only	0.63g/ml
3	**Tapped Density**	For information only	0.77g/ml

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

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: _____ 22/07/2021
(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.

5.0 TEST DATA OF VALIDATION OF COMPRESSION PROCESS – FIRST BATCH

5.1 TEST DATA FOR COMPRESSION STAGE: | **B.No.: GD210601** | **Mfg. Date: JUN-2021** | **Exp. Date: MAY-2024**

CRITICAL PARAMETER-1:
COMPRESSION FORCE (HARDNESS -CHALLENGE) | **B. Size: 8.0L**

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS		
			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 ±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%

Comments: The above mentioned Minimum Compression force, Maximum and Standard force has been verified and found Complies with in the acceptance criteria.

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5.2 TEST DATA FOR COMPRESSION STAGE: (RPM -CHALLENGE)

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 ±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 Mentioned Low and High rpm has been verified and found Complies with in the acceptance Criteria.

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

5.3 TEST DATA FOR COMPRESSION STAGE: HOPPER LEVEL CHALLENGE

CRITICAL PARAMETER-3: HOPPER LEVEL CHALLENGE

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS		
			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 ±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%)

Comments: The above Mentioned Hopper level (Full, Half, Nearly empty) has been Verified and found Complies both in the acceptance Criteria.

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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: 22/07/2021
(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.

6.0 TEST DATA FOR VALIDATION DRY MIXING STAGE – 2ND & 3RD BATCHES

6.1 TEST DATA FOR DRY MIXING STAGE: | **B.No.: GD210602** | **Mfg. Date: JUN-2021** | **Exp. Date: MAY-2024**

2ND BATCH | **B. Size: 8.0L**

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS – Mixing time (10 minutes)				
			Sample Location	Lot-1		Lot-2	
				Ibuprofen (%)	Paracetamol (%)	Ibuprofen (%)	Paracetamol (%)
1	**Blend uniformity:** (Ibuprofen and Paracetamol)	Individual sample values between 85% to 115% of label claim & RSD: NMT 5 % Average value between 90% to 110%.	**TCL**	98.36	101.6	92.4	105.2
			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
			MBC	98.7	102.6	91.6	106.7
			MBR	97.6	100.5	93.0	106.9
			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

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS				
			Mixing time (10 minutes)				
			Sample Location	Lot-3		Lot-4	
				Ibuprofen (%)	Paracetamol (%)	Ibuprofen (%)	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%.	**TCL**	90.5	103.6	97.1	98.3
			TC	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
			MBC	93.2	105.4	97.7	98.0
			MBR	90.6	103.1	96.4	99.1
			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

All the validation test results of Dry Mixing stage are found to be **satisfactory/not satisfactory.**

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6.2 TEST DATA FOR DRY MIXING STAGE:			B.No.: GD210603		Mfg. Date: JUN-2021		Exp. Date: MAY-2024
3RD BATCH			B. Size: 8.0L				
S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS				
			Mixing time (10 minutes)				
			Sample Location	Lot-1		Lot-2	
				Ibuprofen (%)	Paracetamol (%)	Ibuprofen (%)	Paracetamol (%)
1	**Blend uniformity:** (Ibuprofen and Paracetamol)	Individual sample values between 85% to 115% of label claim & RSD: NMT 5 % Average value between 90% to 110%.	**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
			MBC	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
			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
			Composite	97.4	99.9	97.8	97.6

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS				
			Mixing time (10 minutes)				
			Sample Location	Lot-3		Lot-4	
				Ibuprofen (%)	Paracetamol (%)	Ibuprofen (%)	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%.	**TCL**	100.1	100.9	101.4	100.2
			TC	96.3	98.3	99.2	98.2
			TCR	97.5	97.7	101.7	99.6
			MBL	95.3	97.6	100.0	98.6
			MBC	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

All the validation test results of Dry Mixing stage are found to be **satisfactory/not satisfactory.**

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6.3 TEST DATA FOR BLENDING STAGE: 2ND BATCH

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS		
			Mixing time (15 minutes)		
			Sample Location	Ibuprofen (%)	Paracetamol (%)
1	**Blend uniformity:** (Ibuprofen and Paracetamol)	Individual sample values between 85% to 115% of label claim & RSD: NMT 5 % Average value between 90% to 110%.	**TCL**	95.3	101.3
			TC	99.3	101.0
			TCR	97.0	99.6
			MBL	101.6	102.7
			MBC	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
			RSD	3.1	2.1
			Composite	100.0	100.0

All the validation test results of Dry Mixing stage are found to be **satisfactory/not satisfactory.**

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6.4 TEST DATA FOR BLENDING STAGE: 3RD BATCH

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS		
			Mixing time (15 minutes)		
			Sample Location	Ibuprofen (%)	Paracetamol (%)
1	**Blend uniformity:** (Ibuprofen and Paracetamol)	Individual sample values between 85% to 115% of label claim & RSD: NMT 5 % Average value between 90% to 110%.	**TCL**	100.8	103.5
			TC	98.6	101.6
			TCR	96.3	102.6
			MBL	98.3	101.3
			MBC	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

All the validation test results of Dry Mixing stage are found to be **satisfactory/not satisfactory.**

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6.5 TEST DATA FOR LUBRICATION STAGE: 2ND BATCH

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS		
			Mixing time (5 minutes)		
			Sample Location	Ibuprofen (%)	Paracetamol (%)
1	**Blend uniformity:** (Ibuprofen and Paracetamol)	Individual sample values between 85% to 115% of label claim & RSD: NMT 5 % Average value between 90% to 110%.	**TCL**	100.4	99.8
			TC	98.5	100.4
			TCR	96.6	101.8
			MBL	99.0	96.8
			MBC	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

All the validation test results of Dry Mixing stage are found to be **satisfactory/not satisfactory.**

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

6.6 TEST DATA FOR LUBRICATION STAGE: 3RD BATCH

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS		
			Mixing time (5 minutes)		
			Sample Location	Ibuprofen (%)	Paracetamol (%)
1	**Blend uniformity:** (Ibuprofen and Paracetamol)	Individual sample values between 85% to 115% of label claim & RSD: NMT 5 % Average value between 90% to 110%.	**TCL**	99.1	93.2
			TC	100.4	99.9
			TCR	99.5	99.2
			MBL	99.6	99.1
			MBC	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	2.2
			Composite	97.6	98.3

All the validation test results of Dry Mixing stage are found to be **satisfactory/not satisfactory.**

QA-Sign & Date: Rval 28/07/21

6.7 TEST DATA FOR LUBRICATION STAGE :	B.No.: GD210602	Mfg. Date: JUN-2021	Exp. Date: MAY-2024
2ND BATCH	B. Size: 8.0L		

S.No	ON POOLED SAMPLE		
	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS
1	**Appearance** (pooled sample)	Light orange colour powder	Complies
2	**Bulk Density**	For information only	0.59g/ml
3	**Tapped Density**	For information only	0.77g/ml

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

6.8 TEST DATA FOR LUBRICATION STAGE :	B.No.: GD210603	Mfg. Date: JUN-2021	Exp. Date: MAY-2024
3RD BATCH	B. Size: 8.0L		

S.No	ON POOLED SAMPLE		
	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS
1	**Appearance** (pooled sample)	Light orange colour powder	Complies
2	**Bulk Density**	For information only	0.59g/ml
3	**Tapped Density**	For information only	0.77g/ml

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

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

S.No	Observation	1st Batch No.: GD210601	2nd Batch No.: GD210602	3rd 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: _____ 22/07/2021
(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.

7.0 TEST DATA OF VALIDATION OF COMPRESSION PROCESS – 2ND BATCH

7.1 TEST DATA FOR COMPRESSION STAGE: | **B.No.: GD210602** | **Mfg. Date: JUN-2021** | **Exp. Date: MAY-2024**

CRITICAL PARAMETER-1: COMPRESSION FORCE (HARDNESS -CHALLENGE) | **B. Size: 8.0L**

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS		
			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%

Comments: The above Mentioned Minimum, Standard, Maximum Compression force has been verified and found complies with in the acceptance criteria.

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

7.2 TEST DATA FOR COMPRESSION STAGE: (RPM -CHALLENGE)

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)	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 ±5%.	Complies	Complies
4.0	**Thickness** (Average 10 tablets)	7.90± 0.3mm (7.60 to 8.20 mm)	7.78mm	7.76mm
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%

Comments: The above Mentioned low and High Rpm has been verified and found Complies with in the acceptance Criteria.

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

7.3 TEST DATA FOR COMPRESSION STAGE: HOPPER LEVEL CHALLENGE

CRITICAL PARAMETER-3: HOPPER LEVEL 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 ±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
6.0	**Disintegration Time**	NMT 15 mins	01Minutes 50 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 (Full, Half, Nearly empty) has been Verified and found Complies with in the acceptance criteria.

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

8.0 TEST DATA OF VALIDATION OF COMPRESSION PROCESS – 3RD BATCH

8.1 TEST DATA FOR COMPRESSION STAGE: | **B.No.: GD210603** | **Mfg. Date: JUN-2021** | **Exp. Date: MAY-2024**

CRITICAL PARAMETER-1:
COMPRESSION FORCE (HARDNESS -CHALLENGE) | **B. Size: 8.0L**

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS		
			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%

Comments: The above Mentioned Minimum, Standard, Maximum Compression force has been verified and found Complies with the acceptance criteria.

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

8.2 TEST DATA FOR COMPRESSION STAGE: (RPM -CHALLENGE)

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)	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 ±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%

Comments: The above Mentioned Low and High RPM has been Verified and found Complies with in the acceptance criteria.

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

8.3 TEST DATA FOR COMPRESSION STAGE: HOPPER LEVEL CHALLENGE

CRITICAL PARAMETER-3: HOPPER LEVEL 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 ±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%

Comments: The above Mentioned Hopper level (Full, Half, Nearly empty) has been verified and found complies with in the acceptance criteria.

QA-Sign & Date: 22/07/21

8.4 CONCLUSION ON VALIDATION OF COMPRESSION PROCESS OF COMMERCIAL BATCHES

S.No	Observation	1st Batch No.: GD210601	2nd Batch No.: GD210602	3rd 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)

QA: P. Val 22/07/21
(Sign & Date)

Head-Quality Assurance: 22/07/2021
(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. Repeat the complete process validation on next 3 consecutive batches.

9.0 TEST DATA OF VALIDATION OF UN COATED TABLET (COMPOSITE SAMPLE) – 1ST,2ND & 3RD BATCHES

9.1 TEST DATA FOR UN COATED STAGE: 1ST BATCH | **B.No: GD210601** | **Mfg. Date: JUN-2021** | **Exp. Date: MAY-2024**

CRITICAL PARAMETER | **B. Size: 8.0L**

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS
1.0	**Appearance**	Light orange coloured oval shape biconvex uncoated tablets with half break line on one side and plain on another side.	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 masses deviate from the average mass by more than ±5%.	Complies
4.0	**Thickness** (Average 10 tablets)	7.90± 0.3mm (7.60 to 8.20 mm)	7.76mm
5.0	**Disintegration time**	NMT 15 mins	01 Minutes 57 seconds
6.0	**Friability**	Not more than 1.0% w/w	0.11%
7.0	**Hardness**	160 N to 230 N * (To be monitored)	237.40N
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:103.2%,Avg:101.6% Min:100.7%,Max:102.6%,Avg:101.6%
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	391.35mg (97.8%) 504.34mg (100.9%)
10.0	**Related Substances:** Single Maximum unknown impurity Total impurities	Not more than 0.20% Not more than 0.50%	0.04% 0.07%

Comments: The above Mentioned Parameters, Assay, Dissolution, Related Substances. has been verified and Found Complies with as the acceptance criteria.

QA-Sign & Date : P. Vad 23/07/21

9.2 TEST DATA FOR UN COATED STAGE: 2ND BATCH			B.No: GD210602	Mfg. Date: JUN-2021	Exp. Date: MAY-2024
CRITICAL PARAMETER			**B. Size: 8.0L**		
S.No	**MEASURED PARAMETERS**	**ACCEPTANCE CRITERIA**	**TEST RESULTS**		
1.0	**Appearance**	Light orange coloured oval shape biconvex uncoated tablets with half break line on one side and plain on another side.	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 masses deviate from the average mass by more than ±5%.	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	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 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:99.0%,Max:101.1%,Avg:99.9% Min:99.9%,Max:102.7%,Avg:101.0%		
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	402.05mg (100.5%) 515.62mg (103.1%)		
10.0	**Related Substances:** Single Maximum unknown impurity Total impurities	Not more than 0.20% Not more than 0.50%	0.04% 0.05%		

Comments: The above Mentioned Parameters, Assay, Dissolution, Related Substances, has been verified and found Complies were in the acceptance criteria.

QA-Sign & Date : P. Rai 23/07/21

9.3 TEST DATA FOR UN COATED STAGE: 3RD BATCH			B.No: GD210603	Mfg. Date: JUN-2021	Exp. Date: MAY-2024
CRITICAL PARAMETER			**B. Size: 8.0L**		
S.No	**MEASURED PARAMETERS**	**ACCEPTANCE CRITERIA**	**TEST RESULTS**		
1.0	**Appearance**	Light orange coloured oval shape biconvex uncoated tablets with half break line on one side and plain on another side.	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 masses deviate from the average mass by more than ±5%.	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	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 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:98.5%,Max:102.0%,Avg:99.9% Min:100.3%,Max:101.8%,Avg:101.1%		
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	396.39mg (99.1%) 499.76mg (100.0%)		
10.0	**Related Substances:** Single Maximum unknown impurity Total impurities	Not more than 0.20% Not more than 0.50%	0.04% 0.07%		

Comments: The above Mentioned Parameters / Assay / Dissolution / Related Substances has been verified and found Complies with in the acceptance criteria.

QA-Sign & Date : P. Vat 23/07/21

10.0 EVALUATION OF RESULTS, CONCLUSION AND RECOMMENDATIONS:

Based on the above 3 batches Process Validation study, The following Stage Samples has been analysed and test results are found Complies with Specification limit.

1. Dry mixing
2. Blending
3. Lubricated blend
4. compressed tablets.

During validation of Compression parameters, the achieved Hardness value found higher than the set limit (which a to be monitored). The Hardness limit shall be fixed based on the further 10 more batches Hardness trend data.

The Validation parameters recommended for the routine process

NA 23/07/21

Head-Quality Assurance: 24/07/2021
(Sign & Date)

11.0 POST APPROVAL :

10.1 Compiled By :

Dept.	Name	Designation	Signature	Date
Quality Assurance	P. Vadivel	Sr. Executive QA	P. Vadivel	24/07/21

10.2 Verified By:

Dept.	Name	Designation	Signature	Date
Head-Production	V. Dharabai	Sr. GM		24/07/21
Head-Quality Control	V. Jayakumar	AGM		24/07/21

10.3 Approved By:

Dept.	Name	Designation	Signature	Date
Head-Quality Assurance	K. Chandrasekar	AGM		26/07/21