1.0 PRE - APPROVAL :

1.1 Prepared By :

Dept.	Name	Designation	Signature	Date
Quality Assurance	P. Vadivel	Sr. Executive QA	P. Vadivel	28/07/2021

1.2 Verified By:

Dept.	Name	Designation	Signature	Date
Head-Production	V. Dharabal	Sr. GM		28/07/21
Head-Quality Control	M. Vijayalaxmi	AGM		29/07/21

1.3 Approved By:

Dept.	Name	Designation	Signature	Date
Head-Quality Assurance	K. Chandrasekar	AGM-QA		29/07/21

2.0 INTRODUCTION:
This report summarizes the results of validation performed as per the Process Validation Protocol No. PVP/21/028.

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.: GD210704** **Mfg. Date: JUL-2021** **Exp. Date: JUN-2024**

FIRST BATCH **B. Size: 10.0L**

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS				
			Mixing time (15 minutes)				
			Sample Location	Paracetamol (%)	Phenylephrine Hydrochloride (%)	Chlorphenamine Maleate (%)	Caffeine (%)
1	**Blend uniformity:**	Individual sample values between (85.0% to 115.0% of label claim) & RSD: NMT 5 % and Average value between (90.0% to 110.0%).	**TCL**	100.8	98.4	95.6	92.6
			TC	101.0	99.3	96.2	92.3
			TCR	101.4	99.1	96.6	92.9
			MBL	105.2	101.0	102.3	96.6
			MBC	102.1	99.2	101.4	93.6
			MBR	102.8	100.8	102.3	94.4
			BFL	101.5	98.0	90.7	92.9
			BFC	102.6	97.7	96.0	94.3
			BFR	103.8	100.2	102.6	95.5
			Avg.	102.4	99.3	98.2	93.9
			RSD	1.4	1.2	4.2	1.5
			Composite	100.9	98.0	96.1	92.3

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

QA-Sign & Date: 05/10/21

4.2 TEST DATA FOR BLENDING STAGE: FIRST BATCH

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS				
			Mixing time (20 minutes)				
			Sample Location	Paracetamol (%)	Phenylephrine Hydrochloride (%)	Chlorphenamine Maleate (%)	Caffeine (%)
1	**Blend uniformity:**	Individual sample values between (85.0% to 115.0% of label claim) & RSD: NMT 5 % and Average value between (90.0% to 110.0%).	**TCL**	99.8	99.5	98.7	106.0
			TC	99.8	98.2	97.9	106.1
			TCR	99.6	99.1	98.5	106.0
			MBL	100.0	100.4	97.4	99.6
			MBC	100.2	98.8	97.8	99.8
			MBR	100.6	100.2	97.1	100.2
			BFL	100.2	99.6	98.3	99.7
			BFC	100.2	99.5	98.1	99.6
			BFR	99.5	100.1	98.7	105.9
			DP	100.3	98.4	99.1	106.8
			Avg.	100.0	99.4	98.2	103.0
			RSD	0.4	0.7	0.6	3.3
			Composite	101.1	100.2	99.8	100.5

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

QA-Sign & Date: P.Vel 03/10/21

4.3 TEST DATA FOR LUBRICATION STAGE: FIRST BATCH

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS				
			Mixing time (5 minutes)				
			Sample Location	Paracetamol (%)	Phenylephrine Hydrochloride (%)	Chlorphenamine Maleate (%)	Caffeine (%)
1	**Blend uniformity:**	Individual sample values between (85.0% to 115.0% of label claim) & RSD: NMT 5 % and Average value between (90.0% to 110.0%).	**TCL**	95.4	93.8	93.6	96.2
			TC	98.1	94.6	94.6	98.0
			TCR	97.0	95.3	95.4	97.4
			MBL	97.4	97.9	94.9	96.2
			MBC	97.7	96.0	95.7	98.8
			MBR	98.4	94.0	93.7	99.5
			BFL	99.7	98.9	98.4	102.2
			BFC	98.4	97.1	98.0	100.4
			BFR	98.1	95.0	96.5	97.7
			DP	97.6	92.8	94.7	96.3
			Avg.	97.8	95.5	95.6	98.3
			RSD	1.1	2.0	1.7	2.0
			Composite	99.1	100.7	101.8	100.9

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

QA-Sign & Date: P.Val 02/10/21

4.4 TEST DATA FOR LUBRICATION STAGE :	B.No.: GD210704	Mfg. Date: JUL-2021	Exp. Date: JUN-2024
FIRST BATCH	B. Size: 10.0L		

S.No	ON POOLED SAMPLE		
	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS
1	**Appearance** (pooled sample)	Light yellow colour granular powder	Complies
2	**Bulk Density**	For information only	0.63g/ml
3	**Tapped Density**	For information only	0.71g/ml

QA-Sign & Date: P.Vaj 05/10/21

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 Paracetamol 500mg, Phenylephrine Hydrochloride 5mg, Chlorphenamine Maleate 2mg And Caffeine Anhydrous 30mg are found to be **Satisfactory/Not Satisfactory** After **15 Minutes** Mixing.

2. All the validation test results of Blending stage of Paracetamol 500mg, Phenylephrine Hydrochloride 5mg, Chlorphenamine Maleate 2mg And Caffeine Anhydrous 30mg are found to be **Satisfactory/Not Satisfactory** After **20 Minutes** Mixing.

3. All the validation test results of Lubrication stage of Paracetamol 500mg, Phenylephrine Hydrochloride 5mg, Chlorphenamine Maleate 2mg And Caffeine Anhydrous 30mg 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	Rapid Mixer granulator	15 minutes
2	Blending stage	Octagonal Blender	20 minutes
3	Lubrication stage	Octagonal Blender	5 minutes

Head-Quality Assurance: 04/10/21
(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.: GD210704 | **Mfg. Date: JUL-2021** | **Exp. Date: JUN-2024**

CRITICAL PARAMETER-1:
COMPRESSION FORCE (HARDNESS -CHALLENGE)

B. Size: 10.0L

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS		
			Minimum compression force	Standard compression force	Maximum compression force
1.0	**Appearance**	Light yellow coloured flat round beveled edged tablet with break line on one side and plain on another side.	Complies	Complies	Complies
2.0	**Average Weight**	635mg±3% (615.950mg to 654.050mg)	636.73mg	634.92mg	635.09mg
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)	4.30mm ± 0.2mm (4.10mm to 4.50mm)	4.47mm	4.22mm	4.20mm
5.0	**Hardness** (Average 10 tablets)	100N-250N (To be monitored)	112.79N	198.01N	198.01N
6.0	**Disintegration time**	NMT 15 mins at 37°C±2°C	08 Minutes 12 seconds	06 Minutes 45 seconds	08 Minutes 12 seconds
7.0	**Friability**	NMT 1.0%w/w	0.40%	0.25%	0.30%
8.0	**Assay:** **Each uncoated tablet contains.** 1.Chlorphenamine Maleate BP 2.Phenylehrine Hydrochloride BP 3.Paracetamol BP 4.Caffeine (anhydrous) BP	 90.0% to 110.0% 90.0% to 110.0% 90.0% to 110.0% 90.0% to 110.0%	 1.95mg (97.4%) 4.66mg (93.1%) 486.60mg (97.3%) 29.51mg (98.4%)	 1.98mg (98.8%) 4.76mg (95.2%) 486.03mg (97.2%) 29.55mg (98.5%)	 1.95mg (97.4%) 4.71mg (94.2%) 484.74mg (96.9%) 29.94mg (99.8%)

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

QA-Sign & Date: 04/10/21

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 yellow coloured flat round beveled edged tablet with break line on one side and plain on another side.	Complies	Complies
2.0	**Average Weight**	635mg±3% (615.950mg to 654.050mg)	634.76mg	636.13mg
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)	4.30mm ± 0.2mm (4.10mm to 4.50mm)	4.22mm	4.23mm
5.0	**Hardness** (Average 10 tablets)	100N-250N (To be monitored)	186.94mm	145.57N
6.0	**Disintegration Time**	NMT 15 mins at 37°C±2°C	05Minutes 30 seconds	07Minutes 15 seconds
7.0	**Friability**	NMT 1.0%w/w	0.12%	0.18%

Comments: The above mentioned Rpm Challenge (Low and High) has been verified and found Complies with in the acceptance criteria.

QA-Sign & Date: P.Vel 05/10/21

5.3 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 yellow coloured flat round beveled edged tablet with break line on one side and plain on another side.	Complies	Complies	Complies
2.0	**Average Weight**	635mg±3% (615.950mg to 654.050mg)	634.98	635.07	635.63
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)	4.30mm ± 0.2mm (4.10mm to 4.50mm)	4.23mm	4.24mm	4.23mm
5.0	**Hardness** (Average 10 tablets)	100N-250N (To be monitored)	193.10N	188.44N	178.83mm
6.0	**Disintegration Time**	NMT 15 mins at 37°C±2°C	06Minutes 24 seconds	07Minutes 18 seconds	06Minutes 33 seconds
7.0	**Friability**	NMT 1.0%w/w	0.15%	0.14%	0.22%
9.0	**Assay:** **Each uncoated tablet contains.** 1.Chlorphenamine Maleate BP 2.Phenylehrine Hydrochloride BP 3.Paracetamol BP 4.Caffeine (anhydrous) BP	 90.0% to 110.0% 90.0% to 110.0% 90.0% to 110.0% 90.0% to 110.0%	 1.95mg (97.3%) 4.74mg (94.8%) 485.22mg (97.0%) 29.80mg (99.3%)	 1.93mg (96.7%) 4.71mg (94.3%) 482.52mg (96.5%) 29.34mg (97.8%)	 1.95mg (97.4%) 4.66mg (93.2%) 493.52mg (98.7%) 30.25mg (100.8%)

Comments: The above Mentioned Hopper level (Full, Half, Nearly empty) has been Verified and found Complies with in the allegance criteria.

QA-Sign & Date: P. Vat 5/10/21

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: 04/10/21
(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 OF DRY MIXING –2ND & 3RD BATCHES

6.1 TEST DATA FOR DRY MIXING STAGE: | **B.No.: GD210705** | **Mfg. Date: JUL-2021** | **Exp. Date: JUN-2024**

2ND BATCH | **B. Size: 10.0L**

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS – Mixing time (15 minutes)				
			Sample Location	Paracetamol (%)	Phenylephrine Hydrochloride (%)	Chlorphenamine Maleate (%)	Caffeine (%)
1	Blend uniformity:	Individual sample values between (85.0% to 115.0% of label claim) & RSD: NMT 5 % and Average value between (90.0% to 110.0%).	TCL	103.0	99.8	100.8	96.7
			TC	99.9	95.6	94.9	93.3
			TCR	101.5	96.1	95.6	94.8
			MBL	102.3	98.7	102.3	93.7
			MBC	101.8	97.0	95.1	93.9
			MBR	101.7	99.7	102.0	92.5
			BFL	101.2	98.0	101.8	92.4
			BFC	101.1	97.8	101.4	92.7
			BFR	102.8	96.0	95.2	94.9
			Avg.	101.7	97.6	98.8	93.9
			RSD	1.0	1.6	3.5	1.5
			Composite	103.2	94.8	94.4	94.5

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

QA-Sign & Date: P. Val 05/10/21

6.2 TEST DATA FOR DRY MIXING STAGE:			B.No.: GD210706		Mfg. Date: JUL-2021		Exp. Date: JUN-2024
3RD BATCH			B. Size: 10.0L				
S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS				
			Mixing time (15 minutes)				
			Sample Location	Paracetamol (%)	Phenylephrine Hydrochloride (%)	Chlorphenamine Maleate (%)	Caffeine (%)
1	Blend uniformity:	Individual sample values between (85.0% to 115.0% of label claim) & RSD: NMT 5 % and Average value between (90.0% to 110.0%).	TCL	103.9	98.7	102.1	97.1
			TC	102.5	99.2	102.6	94.4
			TCR	104.4	100.3	103.4	95.6
			MBL	100.1	96.6	95.5	91.3
			MBC	100.9	95.4	94.7	92.9
			MBR	102.1	97.3	96.3	93.9
			BFL	103.2	97.2	96.1	94.7
			BFC	106.3	100.1	102.1	96.8
			BFR	100.4	98.7	96.7	91.9
			Avg.	102.6	98.2	98.8	94.3
			RSD	2.0	1.7	3.6	2.2
			Composite	102.2	100.1	97.9	93.7

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

QA-Sign & Date: 04/10/21

6.3 TEST DATA FOR BLENDING STAGE: 2ND BATCH

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS Mixing time (20 minutes)				
			Sample Location	Paracetamol (%)	Phenylephrine Hydrochloride (%)	Chlorphenamine Maleate (%)	Caffeine (%)
1	**Blend uniformity:**	Individual sample values between (85.0% to 115.0% of label claim) & RSD: NMT 5 % and Average value between (90.0% to 110.0%).	**TCL**	100.7	98.5	98.1	107.4
			TC	100.2	99.8	99.9	106.7
			TCR	99.6	98.8	98.6	106.1
			MBL	100.5	97.9	99.1	99.8
			MBC	100.0	98.0	98.8	99.9
			MBR	100.0	99.9	99.7	99.3
			BFL	100.0	98.4	98.5	99.6
			BFC	101.7	99.0	98.4	101.2
			BFR	100.0	97.8	99.1	106.5
			DP	99.6	98.2	99.2	106.0
			Avg.	100.2	98.6	99.0	103.2
			RSD	0.6	0.8	0.6	3.4
			Composite	99.6	99.1	100.5	99.1

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

QA-Sign & Date: P_Val 04/10/21

6.4 TEST DATA FOR BLENDING STAGE: 3RD BATCH

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS				
			Mixing time (20 minutes)				
			Sample Location	Paracetamol (%)	Phenylephrine Hydrochloride (%)	Chlorphenamine Maleate (%)	Caffeine (%)
1	**Blend uniformity:**	Individual sample values between (85.0% to 115.0% of label claim) & RSD: NMT 5 % and Average value between (90.0% to 110.0%).	**TCL**	99.3	98.1	99.0	105.6
			TC	98.7	98.5	98.5	105.1
			TCR	100.4	98.6	98.7	106.9
			MBL	100.4	99.7	98.7	99.9
			MBC	99.2	96.1	96.1	98.9
			MBR	99.9	97.5	97.8	99.3
			BFL	100.9	97.0	97.1	100.6
			BFC	100.9	98.4	99.2	100.6
			BFR	99.5	99.4	98.9	106.2
			DP	99.3	96.8	97.1	105.8
			Avg.	99.8	98.0	98.1	102.9
			RSD	0.8	1.2	1.1	3.2
			Composite	100.0	97.6	98.2	99.9

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

QA-Sign & Date: P. Vaf 05/10/21

6.5 TEST DATA FOR LUBRICATION STAGE: 2ND BATCH

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS				
			Mixing time (5 minutes)				
			Sample Location	Paracetamol (%)	Phenylephrine Hydrochloride (%)	Chlorphenamine Maleate (%)	Caffeine (%)
1	**Blend uniformity:**	Individual sample values between (85.0% to 115.0% of label claim) & RSD: NMT 5 % and Average value between (90.0% to 110.0%).	**TCL**	100.1	93.3	96.8	101.4
			TC	96.1	89.7	94.5	93.4
			TCR	98.3	93.3	95.8	95.9
			MBL	98.9	94.3	98.0	101.2
			MBC	96.4	91.6	95.0	95.7
			MBR	95.9	90.4	94.6	92.2
			BFL	101.4	97.7	96.2	102.5
			BFC	98.8	95.1	96.7	100.2
			BFR	99.4	95.9	97.5	99.5
			DP	101.3	100.0	98.0	105.9
			Avg.	98.7	94.1	96.3	98.8
			RSD	2.0	3.4	1.4	4.4
			Composite	101.4	101.0	98.0	106.9

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

QA-Sign & Date: 8/10/21

6.5 TEST DATA FOR LUBRICATION STAGE: 3RD BATCH

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS				
			Mixing time (5 minutes)				
			Sample Location	Paracetamol (%)	Phenylephrine Hydrochloride (%)	Chlorphenamine Maleate (%)	Caffeine (%)
1	**Blend uniformity:**	Individual sample values between (85.0% to 115.0% of label claim) & RSD: NMT 5 % and Average value between (90.0% to 110.0%).	**TCL**	100.2	95.4	90.4	96.7
			TC	100.2	101.7	91.3	97.1
			TCR	100.5	103.1	91.9	101.2
			MBL	98.2	96.2	92.3	97.5
			MBC	98.8	105.3	94.0	97.0
			MBR	98.1	95.3	91.9	95.4
			BFL	100.1	104.7	93.5	101.3
			BFC	99.8	102.1	90.8	100.0
			BFR	98.7	97.8	93.3	98.7
			DP	100.2	97.1	92.2	99.8
			Avg.	99.5	99.9	92.2	98.5
			RSD	0.9	3.9	1.3	2.1
			Composite	99.6	95.6	91.2	104.1

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

QA-Sign & Date: P. Vaz 05/10/21

6.6 TEST DATA FOR LUBRICATION STAGE :	B.No.: GD210705	Mfg. Date: JUL-2021	Exp. Date: JUN-2024
2ND BATCH	B. Size: 10.0L		

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

QA-Sign & Date: P.Vaz 04/10/21

6.7 TEST DATA FOR LUBRICATION STAGE :	B.No.: GD210706	Mfg. Date: JUL-2021	Exp. Date: JUN-2024
3RD BATCH	B. Size: 10.0L		

S.No	ON POOLED SAMPLE		
	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS
1	**Appearance** (pooled sample)	Light yellow colour granular powder	Complies
2	**Bulk Density**	For information only	0.63g/ml
3	**Tapped Density**	For information only	0.71g/ml

QA-Sign & Date: P.Val 06/10/21

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

S.No	Observation	1st Batch No.: GD210704	2nd Batch No.: GD210705	3rd Batch No.: GD210706
1.	All the validation test results of Dry Mixing stage of Paracetamol 500mg, Phenylephrine Hydrochloride 5mg, Chlorphenamine Maleate 2mg And Caffeine Anhydrous 30mg are found to be **Satisfactory** after **15 Minutes** Mixing.	Complies/Does not comply	Complies/Does not comply	Complies/Does not comply
2.	All the validation test results of Blending stage of Paracetamol 500mg, Phenylephrine Hydrochloride 5mg, Chlorphenamine Maleate 2mg And Caffeine Anhydrous 30mg are found to be **Satisfactory** after **20 Minutes** Mixing.	Complies/Does not comply	Complies/Does not comply	Complies/Does not comply
3.	All the validation test results of Lubrication stage of Paracetamol 500mg, Phenylephrine Hydrochloride 5mg, Chlorphenamine Maleate 2mg And Caffeine Anhydrous 30mg are found to be **Satisfactory** after **5 Minutes** Mixing.	Complies/Does not comply	Complies/Does not comply	Complies/Does not comply

Head-Quality Assurance: 04/10/21
(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.: GD210705** | **Mfg. Date: JUL-2021** | **Exp. Date: JUN-2024**

CRITICAL PARAMETER-1:
COMPRESSION FORCE (HARDNESS -CHALLENGE) | **B. Size: 10.0L**

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS		
			Minimum compression force	Standard compression force	Maximum compression force
1.0	**Appearance**	Light yellow coloured flat round beveled edged tablet with break line on one side and plain on another side.	Complies	Complies	Complies
2.0	**Average Weight**	635mg±3% (615.950mg to 654.050mg)	636.33mg	633.36mg	634.72mg
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)	4.30mm ± 0.2mm (4.10mm to 4.50mm)	4.49mm	4.30mm	4.19mm
5.0	**Hardness** (Average 10 tablets)	100N-250N (To be monitored)	109.93N	173.21N	191.13N
6.0	**Disintegration time**	NMT 15 mins at 37°C±2°C	05 Minutes 06 seconds	07 Minutes 33 seconds	08 Minutes 48 seconds
7.0	**Friability**	NMT 1.0%w/w	0.32%	0.29%	0.33%

Comments: The above Mentioned Minimum / Standard / Maximum Compression force has been verified and found Complies with in-tere acceptance criteria.

QA-Sign & Date: P. Vat 05/10/21

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 yellow coloured flat round beveled edged tablet with break line on one side and plain on another side.	Complies	Complies
2.0	**Average Weight**	635mg±3% (615.950mg to 654.050mg)	628.64mg	637.34mg
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)	4.30mm ± 0.2mm (4.10mm to 4.50mm)	4.28mm	4.31mm
5.0	**Hardness** (Average 10 tablets)	100N-250N (To be monitored)	171.39mm	184.32mm
6.0	**Disintegration Time**	NMT 15 mins at 37°C±2°C	08 Minutes 57 seconds	06Minutes 59 seconds
7.0	**Friability**	NMT 1.0%w/w	0.23%	0.24%

Comments: The above Mentioned Rpm challenge (low and High) has been verified and found Complies with in the acceptance criteria.

QA-Sign & Date: P. Vel 05/10/21

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 yellow coloured flat round beveled edged tablet with break line on one side and plain on another side.	Complies	Complies	Complies
2.0	**Average Weight**	635mg±3% (615.950mg to 654.050mg)	632.38mg	632.91mg	629.25mg
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)	4.30mm ± 0.2mm (4.10mm to 4.50mm)	4.30mm	4.32mm	4.30mm
5.0	**Hardness** (Average 10 tablets)	100N-250N (To be monitored)	178.55N	171.51N	173.26N
6.0	**Disintegration Time**	NMT 15 mins at 37°C±2°C	06 Minutes 48 seconds	05 Minutes 55 seconds	06 Minutes 12 seconds
7.0	**Friability**	NMT 1.0%w/w	0.20%	0.25%	0.18%

Comments: The above mentioned Hopper level (Full, Half, Nearly empty) has been Verified and found Complies with in the acceptance criteria.

QA-Sign & Date: 05/10/21

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

8.1 TEST DATA FOR COMPRESSION STAGE: | **B.No.: GD210706** | **Mfg. Date: JUL-2021** | **Exp. Date: JUN-2024**

CRITICAL PARAMETER-1:
COMPRESSION FORCE (HARDNESS -CHALLENGE)

B. Size: 10.0L

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS		
			Minimum compression force	Standard compression force	Maximum compression force
1.0	**Appearance**	Light yellow coloured flat round beveled edged tablet with break line on one side and plain on another side.	Complies	Complies	Complies
2.0	**Average Weight**	635mg±3% (615.950mg to 654.050mg)	636.3mg	637.3mg	635.4mg
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)	4.30mm ± 0.2mm (4.10mm to 4.50mm)	4.24mm	4.25mm	4.29mg
5.0	**Hardness** (Average 10 tablets)	100N-250N (To be monitored)	128.7N	128.5N	125.4N
6.0	**Disintegration time**	NMT 15 mins at 37°C±2°C	06 Minutes 05 seconds	06 Minutes 14 seconds	05 Minutes 50 seconds
7.0	**Friability**	NMT 1.0%w/w	0.11%	0.12%	0.17%

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 04/10/21

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 yellow coloured flat round beveled edged tablet with break line on one side and plain on another side.	Complies	Complies
2.0	**Average Weight**	635mg±3% (615.950mg to 654.050mg)	636.92mg	636.00mg
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)	4.30mm ± 0.2mm (4.10mm to 4.50mm)	4.32mm	4.35mm
5.0	**Hardness** (Average 10 tablets)	100N-250N (To be monitored)	177.11N	181.06N
6.0	**Disintegration Time**	NMT 15 mins at 37°C±2°C	05 Minutes 00 seconds	04 Minutes 48 seconds
7.0	**Friability**	NMT 1.0%w/w	0.16%	0.07%

Comments: The above Mentioned Rpm challenge (Low and High) has been verified and found complies with in the acceptance criteria.

QA-Sign & Date: P. Vat 05/10/21

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 yellow coloured flat round beveled edged tablet with break line on one side and plain on another side.	Complies	Complies	Complies
2.0	**Average Weight**	635mg±3% (615.950mg to 654.050mg)	638.65mg	636.15mg	639.36mg
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)	4.30mm ± 0.2mm (4.10mm to 4.50mm)	4.36mm	4.30mm	4.36mm
5.0	**Hardness** (Average 10 tablets)	100N-250N (To be monitored)	191.62N	188.03N	185.67N
6.0	**Disintegration Time**	NMT 15 mins at 37°C±2°C	05 Minutes 22 seconds	04 Minutes 57 seconds	06 Minutes 02 seconds
7.0	**Friability**	NMT 1.0%w/w	0.09%	0.24%	0.08%

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

QA-Sign & Date: 05/10/21

8.4 CONCLUSION ON VALIDATION OF COMPRESSION PROCESS OF COMMERCIAL BATCHES

S.No	Observation	1st Batch No.: GD210704	2nd Batch No.: GD210705	3rd Batch No.: GD210706
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.Vaid 05/10/21
(Sign & Date)

Head-Quality Assurance: 04/10/21
(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.: GD210704** | **Mfg. Date: JUL-2021** | **Exp. Date: JUN-2024**

CRITICAL PARAMETER | **B. Size: 10.0L**

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS
1.0	**Appearance**	Light yellow coloured flat round beveled edged tablet with break line on one side and plain on another side.	Complies
2.0	**Average Weight**	635mg±3% (615.950mg to 654.050mg)	634.6mg
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)	4.30mm ± 0.2mm (4.10mm to 4.50mm)	4.22mm
5.0	**Disintegration time**	NMT 15 mins at 37°C±2°C	06 Minutes 19 seconds
6.0	**Friability**	NMT 1.0%w/w	0.24%
7.0	**Hardness**	100N-250N (To be monitored)	195.50N
8.0	**Dissolution:** 1.Chlorphenamine Maleate BP	Not less than 80% of stated amount released in 45 minutes	Min:97.0%, Max:100.0%, Avg:98.2%
	2.Phenylehrine Hydrochloride BP	Not less than 80% of stated amount released in 45 minutes	Min:80.6%, Max:95.5%, Avg:91.7%
	3.Paracetamol BP	Not less than 80% of stated amount released in 45 minutes	Min:95.2%, Max:100.4%, Avg:98.1%
	4.Caffeine (anhydrous) BP	Not less than 80% of stated amount released in 45 minutes	Min:96.1%, Max:102.7%, Avg:99.1%

9.0	**Assay:** **Each uncoated tablet contains.**		
	1.Chlorphenamine Maleate BP	90.0% to 110.0% of the labeled claim	1.96mg (98.1%)
	2.Phenylehrine Hydrochloride BP	90.0% to 110.0% of the labeled claim	4.89mg (97.8%)
	3.Paracetamol BP	90.0% to 110.0% of the labeled claim	497.00mg (99.4%)
	4.Caffeine (anhydrous) BP	90.0% to 110.0% of the labeled claim	30.66mg (102.2%)
10.0	**Related Substances:** Single Maximum unknown impurity	Not more than 0.20%	0.04%
	Total Impurities	Not more than 0.50%	0.07%

Comments: The above Mentioned parameters, Assay, Dissolution, Related Substances has been verified and found Complies with in the acceptance Criteria.

MA 04/10/21

QA-Sign & Date : Pvat 04/10/21

9.2 TEST DATA FOR UN COATED STAGE: 2ND BATCH		B.No.: GD210705	Mfg. Date: JUL-2021	Exp. Date: JUN-2024
CRITICAL PARAMETER		**B. Size: 10.0L**		
S.No	**MEASURED PARAMETERS**	**ACCEPTANCE CRITERIA**		**TEST RESULTS**
1.0	**Appearance**	Light yellow coloured flat round beveled edged tablet with break line on one side and plain on another side.		Complies
2.0	**Average Weight**	635mg±3% (615.950mg to 654.050mg)		634.8mg
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)	4.30mm ± 0.2mm (4.10mm to 4.50mm)		4.30mm
5.0	**Disintegration time**	NMT 15 mins at 37°C±2°C		06 Minutes 27 seconds
6.0	**Friability**	NMT 1.0%w/w		0.22%
7.0	**Hardness**	100N-250N (To be monitored)		154.53N
8.0	**Dissolution:** 1.Chlorphenamine Maleate BP	Not less than 80% of stated amount released in 45 minutes		Min:97.0%, Max:101.0%, Avg:99.1%
	2.Phenylehrine Hydrochloride BP	Not less than 80% of stated amount released in 45 minutes		Min:89.2%, Max:95.9%, Avg:93.7%
	3.Paracetamol BP	Not less than 80% of stated amount released in 45 minutes		Min:97.0%, Max:100.9%, Avg:98.5%
	4.Caffeine (anhydrous) BP	Not less than 80% of stated amount released in 45 minutes		Min:98.5%, Max:104.2%, Avg:101.1%

9.0	**Assay:** **Each uncoated tablet contains.**		
	1.Chlorphenamine Maleate BP	90.0% to 110.0% of the labeled claim	1.96mg (98.1%)
	2.Phenylehrine Hydrochloride BP	90.0% to 110.0% of the labeled claim	4.93mg (98.6%)
	3.Paracetamol BP	90.0% to 110.0% of the labeled claim	505.94mg (101.2%)
	4.Caffeine (anhydrous) BP	90.0% to 110.0% of the labeled claim	30.90mg (103.0%)
10.0	**Related Substances:** Single Maximum unknown impurity	Not more than 0.20%	Below Disregard Limit
	Total impurities	Not more than 0.50%	Below Disregard Limit

Comments: The above Mentioned Parameters, Assay, Dissolution, Related substances has been verified and found Complies w.r.t. the acceptance criteria.

MA 05/10/21

QA-Sign & Date : P. Vat 05/10/21

9.3 TEST DATA FOR UN COATED STAGE: 3RD BATCH		B.No.: GD210706	Mfg. Date: JUL-2021	Exp. Date: JUN-2024
CRITICAL PARAMETER		B. Size: 10.0L		
S.No	**MEASURED PARAMETERS**	**ACCEPTANCE CRITERIA**	**TEST RESULTS**	
1.0	**Appearance**	Light yellow coloured flat round beveled edged tablet with break line on one side and plain on another side.	Complies	
2.0	**Average Weight**	635mg±3% (615.950mg to 654.050mg)	635.9mg	
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)	4.30mm ± 0.2mm (4.10mm to 4.50mm)	4.31mm	
5.0	**Disintegration time**	NMT 15 mins at 37°C±2°C	04 Minutes 20 seconds	
6.0	**Friability**	NMT 1.0%w/w	0.10%	
7.0	**Hardness**	100N-250N (To be monitored)	180.10N	
8.0	**Dissolution:** 1.Chlorphenamine Maleate BP	Not less than 80% of stated amount released in 45 minutes	Min:97.6%, Max:100.1%, Avg:99.1%	
	2.Phenylehrine Hydrochloride BP	Not less than 80% of stated amount released in 45 minutes	Min:95.2%, Max:98.4%, Avg:96.8%	
	3.Paracetamol BP	Not less than 80% of stated amount released in 45 minutes	Min:97.7%, Max:100.1%, Avg:99.3%	
	4.Caffeine (anhydrous) BP	Not less than 80% of stated amount released in 45 minutes	Min:96.2%, Max:102.9%, Avg:98.3%	

9.0	**Assay:** **Each uncoated tablet contains.**		
	1.Chlorphenamine Maleate BP	90.0% to 110.0% of the labeled claim	1.94mg (97.2%)
	2.Phenylehrine Hydrochloride BP	90.0% to 110.0% of the labeled claim	4.90mg (97.9%)
	3.Paracetamol BP	90.0% to 110.0% of the labeled claim	493.12mg (98.6%)
	4.Caffeine (anhydrous) BP	90.0% to 110.0% of the labeled claim	29.76mg (99.2%)
10.0	**Related Substances:** Single Maximum unknown impurity	Not more than 0.20%	Below Disregard Limit
	Total impurities	Not more than 0.50%	0.01%

Comments: The above Mentioned Parameters, Assay, Dissolution, Related Substances has been Verified and found Complies with in the alleptance Criteria.

QA-Sign & Date : P.Vat 06/10/21

10.0 TEST DATA OF PACKING VALIDATION – 1ST,2ND & 3RD BATCHES

10.1 TEST DATA FOR PACKING VALIDATION : 1ST BATCH	**B.No.: GD210704**	**Mfg. Date: JUL-2021**	**Exp. Date: JUN-2024**
CRITICAL PARAMETER	**B. Size: 10.0L**		

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS
1.0	**Appearance**	Strip appearance is acceptable & edge cutting is proper.	Complies
2.0	**Sealing temperature**	Set sealing temperature limit (100°C to 120°C)	117°C
3.0	**Leak Test:** Set machine to maximum Speed **40 RPM** and set the regular temperature	No Foil Damage, No broken Tablets, No Tablets Sticking to Foil, No ink lifting shall be observed, Strip should have proper cutting and knurling, Free flowing of tablets from hopper to guide track, Over printed details Are legible. No Strip should fail in leak test.	Complies
4.0	Set machine to standard Speed **25 RPM** and set the regular temperature	No Foil Damage, No broken Tablets, No Tablets Sticking to Foil, No ink lifting shall be observed, Strip should have proper cutting and knurling, Free flowing of tablets from hopper to guide track, Over printed details Are legible. No Strip should fail in leak test.	Complies
5.0	Set machine to minimum Speed **15 RPM** and set the regular temperature	No Foil Damage, No broken Tablets, No Tablets Sticking to Foil, No ink lifting shall be observed, Strip should have proper cutting and knurling, Free flowing of tablets from hopper to guide track, Over printed details Are legible. No Strip should fail in leak test.	Complies

Low speed Achieved:_15 RPM **High speed achieved:_40 RPM**

6.0	Low temperature _100°C High speed_40RPM	No Strip should fail in leak test.	Complies
7.0	High temperature _120°C Low speed_15RPM	No Strip should fail in leak test.	Complies
8.0	**Strip quality**	Cutting should be uniform on all sided without any angular cuts over printing should be visible and Readable and knurling should be proper.	Complies
9.0	**De striped tablets:** **Related Substances:** Single Maximum unknown impurity Total impurities	Not more than 0.20% Not more than 0.50%	0.01% 0.01%

Comments: The above Mentioned Parameters, Sealing temperature, Seal test, Related Substances has been verified and found complies with the acceptance criteria.

QA-Sign & Date : P. Val 05/10/21

10.2 TEST DATA FOR PACKING VALIDATION : 2ND BATCH	B.No.: GD210705	Mfg. Date: JUL-2021	Exp. Date: JUN-2024
CRITICAL PARAMETER	**B. Size: 10.0L**		

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS
1.0	**Appearance**	Strip appearance is acceptable & edge cutting is proper.	Complies
2.0	**Sealing temperature**	Set sealing temperature limit (100°C to 120°C)	116°C
3.0	**Leak Test:** Set machine to maximum Speed **40 RPM** and set the regular temperature	No Foil Damage, No broken Tablets, No Tablets Sticking to Foil, No ink lifting shall be observed, Strip should have proper cutting and knurling, Free flowing of tablets from hopper to guide track, Over printed details Are legible. No Strip should fail in leak test.	Complies
4.0	Set machine to standard Speed **25 RPM** and set the regular temperature	No Foil Damage, No broken Tablets, No Tablets Sticking to Foil, No ink lifting shall be observed, Strip should have proper cutting and knurling, Free flowing of tablets from hopper to guide track, Over printed details Are legible. No Strip should fail in leak test.	Complies
5.0	Set machine to minimum Speed **15 RPM** and set the regular temperature	No Foil Damage, No broken Tablets, No Tablets Sticking to Foil, No ink lifting shall be observed, Strip should have proper cutting and knurling, Free flowing of tablets from hopper to guide track, Over printed details Are legible. No Strip should fail in leak test.	Complies

Low speed Achieved:_15 RPM **High speed achieved:_40 RPM**

6.0	Low temperature _100°C High speed_40RPM	No Strip should fail in leak test.	Complies
7.0	High temperature _120°C Low speed_15RPM	No Strip should fail in leak test.	Complies
8.0	**Strip quality**	Cutting should be uniform on all sided without any angular cuts over printing should be visible and Readable and knurling should be proper.	Complies
9.0	**De striped tablets:** **Related Substances:** Single Maximum unknown impurity Total impurities	 Not more than 0.20% Not more than 0.50%	 0.01% 0.01%

Comments: The above Mentioned Parameters, Sealing temperature, Leak test, Related Substances has been verified and found complies with the acceptance Criteria.

QA-Sign & Date : P. Vat 04/11/21

10.3 TEST DATA FOR PACKING VALIDATION : 3RD BATCH		B.No.: GD210706	Mfg. Date: JUL-2021	Exp. Date: JUN-2024
CRITICAL PARAMETER		**B. Size: 10.0L**		
S.No	**MEASURED PARAMETERS**	**ACCEPTANCE CRITERIA**		**TEST RESULTS**
1.0	**Appearance**	Strip appearance is acceptable & edge cutting is proper.		Complies
2.0	**Sealing temperature**	Set sealing temperature limit (100°C to 120°C)		119°C
3.0	**Leak Test:** Set machine to maximum Speed **40 RPM** and set the regular temperature	No Foil Damage, No broken Tablets, No Tablets Sticking to Foil, No ink lifting shall be observed, Strip should have proper cutting and knurling, Free flowing of tablets from hopper to guide track, Over printed details Are legible. No Strip should fail in leak test.		Complies
4.0	Set machine to standard Speed **25 RPM** and set the regular temperature	No Foil Damage, No broken Tablets, No Tablets Sticking to Foil, No ink lifting shall be observed, Strip should have proper cutting and knurling, Free flowing of tablets from hopper to guide track, Over printed details Are legible. No Strip should fail in leak test.		Complies
5.0	Set machine to minimum Speed **15 RPM** and set the regular temperature	No Foil Damage, No broken Tablets, No Tablets Sticking to Foil, No ink lifting shall be observed, Strip should have proper cutting and knurling, Free flowing of tablets from hopper to guide track, Over printed details Are legible. No Strip should fail in leak test.		Complies
Low speed Achieved:_15 RPM			**High speed achieved:_40 RPM**	

6.0	Low temperature _100°C High speed_40RPM	No Strip should fail in leak test.	Complies
7.0	High temperature _120°C Low speed_15RPM	No Strip should fail in leak test.	Complies
8.0	**Strip quality**	Cutting should be uniform on all sided without any angular cuts over printing should be visible and Readable and knurling should be proper.	Complies
9.0	**De striped tablets:** **Related Substances:** Single Maximum unknown impurity Total impurities	Not more than 0.20% Not more than 0.50%	0.01% 0.01%

Comments: The above Mentioned Parameters, Sealing temperature, Leak test, Related Substances has been Verified and Found Complies with in the acceptance Criteria.

QA-Sign & Date :

P. Vat
01/10/21

11.0 TEST DATA OF VALIDATION OF FINISHED PRODUCT – 1ST,2ND & 3RD BATCHES

11.1 TEST DATA FOR FINISHED PRODUCT : 1ST BATCH | **B.No.: GD210704** | **Mfg. Date: JUL-2021** | **Exp. Date: JUN-2024**

CRITICAL PARAMETER | **B. Size: 10.0L**

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS
1.0	**Appearance**	Light yellow coloured flat round beveled edged tablet with break line on one side and plain on another side.	Complies
2.0	**Average Weight**	635mg±3% (615.950mg to 654.050mg)	634.6mg
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	**Microbiological parameter**		
	i) Total viable aerobic count.		20cfu/g
	a) Total aerobic microbial count.	Not more than 1000 cfu/g	Found absent
	b) Total yeast and mould count.	Not more than 100 cfu/g	Found absent
	ii) Pseudomonas aeruginosa.	Should be absent/g	Found absent
	iii) Salmonella species.	Should be absent/g	Found absent
	iv) Escherichia coli.	Should be absent/g	Found absent
	v) Staphylococcus aureus.	Should be absent/g	Found absent

Comments: The above Mentioned Parameters and MLT Parameters has been Verified and Found Complies with in the acceptance criteria.

QA-Sign & Date : R. Vani 05/10/21

11.2 TEST DATA FOR FINISHED PRODUCT : 2ND BATCH | **B.No.: GD210705** | **Mfg. Date: JUL-2021** | **Exp. Date: JUN-2024**

CRITICAL PARAMETER | **B. Size: 10.0L**

S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TEST RESULTS
1.0	**Appearance**	Light yellow coloured flat round beveled edged tablet with break line on one side and plain on another side.	Complies
2.0	**Average Weight**	635mg±3% (615.950mg to 654.050mg)	634.8mg
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	**Microbiological parameter**		
	i) Total viable aerobic count.		
	c) Total aerobic microbial count.	Not more than 1000 cfu/g	20cfu/g
	d) Total yeast and mould count.	Not more than 100 cfu/g	<10cfu/g
	ii) Pseudomonas aeruginosa.	Should be absent/g	Found absent
	iii) Salmonella species.	Should be absent/g	Found absent
	iv) Esherichia coli.	Should be absent/g	Found absent
	v) Staphylococcus aureus.	Should be absent/g	Found absent

Comments: The above Mentioned Parameters, Microbiological Parameters has been verified and found Complies with in the acceptance criteria.

QA-Sign & Date : P. Vat 05/10/21

11.3 TEST DATA FOR FINISHED PRODUCT : 3RD BATCH			B.No.: GD210706	Mfg. Date: JUL-2021	Exp. Date: JUN-2024
CRITICAL PARAMETER			**B. Size: 10.0L**		
S.No	**MEASURED PARAMETERS**	**ACCEPTANCE CRITERIA**	**TEST RESULTS**		
1.0	**Appearance**	Light yellow coloured flat round beveled edged tablet with break line on one side and plain on another side.	Complies		
2.0	**Average Weight**	635mg±3% (615.950mg to 654.050mg)	635.9mg		
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	**Microbiological parameter** i) Total viable aerobic count.		20cfu/g		
	e) Total aerobic microbial count.	Not more than 1000 cfu/g	<10cfu/g		
	f) Total yeast and mould count.	Not more than 100 cfu/g	Found absent		
	ii) Pseudomonas aeruginosa.	Should be absent/g	Found absent		
	iii) Salmonella species.	Should be absent/g	Found absent		
	iv) Esherichia coli.	Should be absent/g	Found absent		
	v) Staphylococcus aureus.	Should be absent/g	Found absent		

Comments: The above Mentioned Parameters, Microbiological parameters has been verified and found Complies with in the acceptance criteria.

QA-Sign & Date : P. Vaz 05/10/21

12.0 EVALUATION OF RESULTS, CONCLUSION AND RECOMMENDATIONS:

Based on the above 3 batches Process Validation Study.
The following Stage Samples have been analysed and test results are found Complies with Specification Limits.

1. Dry mixing
2. Blending
3. Lubricated blend
4. Compressed tablets
5. Packing
6. Finished Product

Based on the Satisfactory outcome of Validation Study.
The Validation Parameters are recommended for the routine Process

NM 04/10/21

Head-Quality Assurance: 04/10/21
(Sign & Date)

13.0 POST APPROVAL :

13.1 Compiled By :

Dept.	Name	Designation	Signature	Date
Quality Assurance	P. Vadivel	Sr. Executive QA	P. Val	04/10/21

13.2 Verified By:

Dept.	Name	Designation	Signature	Date
Head-Production	V. Dharabai	Sr. Gm		04/10/21
Head-Quality Control	M. Vijayakumar.	AGM.		04/10/21

13.3 Approved By:

Dept.	Name	Designation	Signature	Date
Head-Quality Assurance	K. Chandrasekar	AGM-QA		05/10/21