

PROCESS VALIDATION REPORT

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Doc No.: PVR/21/028

Ref. Protocol No.: PVP/21/028

Effective date: 05/10/21

GENERIC NAME

PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE, CHLORPHENAMINE MALEATE AND CAFFEINE ANHYDROUS TABLETS

1.0 PRE - APPROVAL :

1.1 Prepared By:

Dept.	Name	Designation	Signature	Date
Quality Assurance	P. Vadivel	St. Executive QA	P. 408 P	28/07/2021

1.2 Verified By:

Dept.	Name	Designation	Signature	Date
Head-Production	1. Dhenabal	Sr. Gm	0	28/07/24
Head-Quality Control	M. N. Zayd amer.	AGM	Ex.	99/61/21

1.3 Approved By:

Dept.	Name	Designation	Signature	Date
Head-Quality Assurance	h. Chandrase kar	AGM- OF	Marka	29/07/21

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2.0 INTRODUCTION:

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

3.0 REFERENCES:

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

P Circu 10 01

4.0 TEST DATA FOR VALIDATION OF DRY MIXING -FIRST BATCH

ETDCT DATCH

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					
			A A A		TEST RESULTS			
.No	MEASURED	ACCEPTANCE CRITERIA	Mixing time (15 minutes)					
,,,,,	PARAMETERS	AMETERS	Sample Location	Paracetamol (%)	Phenylephrine Hydrochloride (%)	Chlorphenamine Maleate (%)	Caffeine (%)	
1	Blend uniformity:	Individual sample values	TCL	100.8	98.4	95.6	92.6	
		between (85.0% to 115.0% of label claim) &	TC	101.0	99.3	96.2	92.3	
		RSD: NMT 5 % and	TCR	101.4	99.1	96.6	92.9	
		Average value between (90.0% to 110.0%).	MBL	105.2	101.0	.0 102.3	96.6	
	1 3000000000000000000000000000000000000	1 March - 2 C 02 C 00 C - 2 C	МВС	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.

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					TEST RESUL	TS		
.No	MEASURED	ACCEPTANCE CRITERIA	Mixing time (20 minutes)					
PARAMETERS	PARAMETERS	Accer inner charterin	Sample Location	Paracetamol (%)	Phenylephrine Hydrochloride (%)	Chlorphenamine Maleate (%)	Caffeine (%)	
1	Blend uniformity:	Individual sample values	TCL	99.8	99.5	98.7	106.0	
		between (85.0% to 115.0% of label claim) &	TC	99.8	98.2	97.9	106.1	
		RSD: NMT 5 % and	TCR	99.6	99.1	98.5	106.0	
		Average value between (90.0% to 110.0%).	MBL	100.0	100.4	97.4	99.6	
		doorse, attractively reproductive	МВС	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	
	validation test results actory/not satisfact	of blending stage are found t	o be	QA-Sign & Da	te: P.Vch = 01/10/2			



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					TEST RESULT	S		
S.No	MEASURED	ACCEPTANCE CRITERIA	Mixing time (5 minutes)					
PARAMETERS	ACCEPTANCE CRITERIA	Sample Location	Paracetamol (%)	Phenylephrine Hydrochloride (%)	Chlorphenamine Maleate (%)	Caffeine (%)		
1	Blend uniformity:	Individual sample values	TCL	95.4	93.8	93.6	96.2	
		between (85.0% to 115.0% of label claim) &	TC	98.1	94.6	94.6	98.0	
		RSD: NMT 5 % and	TCR	97.0	95.3	95.4	97.4	
		Average value between (90.0% to 110.0%).	MBL	97.4	97.9	94.9	96.2	
		West stand of Conservations	МВС	97.7	96.0	95.7	96.2 98.0 97.4	
			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. Valor Onliol21



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4.4 **TEST DATA FOR LUBRICATION STAGE:** B.No.: GD210704 Mfg. Date: JUL-2021 Exp. Date: JUN-2024 B. Size: 10.0L FIRST BATCH ON POOLED SAMPLE S.No **MEASURED PARAMETERS** ACCEPTANCE CRITERIA **TEST RESULTS** Appearance (pooled sample) Light yellow colour granular powder Complies 1

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:

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PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE, CHLORPHENAMINE MALEATE AND CAFFEINE ANHYDROUS TABLETS

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

- 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.
- 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:

(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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PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE, CHLORPHENAMINE MALEATE AND CAFFEINE ANHYDROUS TABLETS

TEST DATA OF VALIDATION OF COMPRESSION PROCESS - FIRST BATCH 5.0 5.1 **TEST DATA FOR COMPRESSION STAGE:** B.No.: GD210704 Mfg. Date: JUL-2021 Exp. Date: JUN-2024 **CRITICAL PARAMETER-1:** B. Size: 10.0L COMPRESSION FORCE (HARDNESS -CHALLENGE) TEST RESULTS Standard Maximum Minimum S.No MEASURED PARAMETERS ACCEPTANCE CRITERIA compression force compression force compression force Light yellow coloured flat round beveled edged tablet with break line Complies Complies Complies 1.0 Appearance on one side and plain on another side. 635mg±3% 635.09mg Average Weight 636.73mg 634.92mg 2.0 (615.950mg to 654.050mg) Not more than 2 of the individual masses deviate from the average Complies Complies Complies Uniformity of weight 3.0 mass by more than ±5%. $4.30mm \pm 0.2mm$ 4.20mm 4.47mm 4.22mm 4.0 Thickness (Average 10 tablets) (4.10mm to 4.50mm) Hardness (Average 10 tablets) 112.79N 198.01N 198.01N 100N-250N (To be monitored) 5.0 08 Minutes 12 seconds NMT 15 mins at 37°C±2°C 08 Minutes 12 seconds 06 Minutes 45 seconds 6.0 Disintegration time 0.30% NMT 1.0%w/w 0.40% 0.25% Friability 7.0 Assav: 8.0 Each uncoated tablet contains. 1.98mg (98.8%) 1.95mg (97.4%) 1.Chlorphenamine Maleate BP 90.0% to 110.0% 1.95mg (97.4%) 4.76mg (95.2%) 4.71mg (94.2%) 4.66mg (93.1%) 2. Phenylehrine Hydrochloride BP 90.0% to 110.0% 486.03mg (97.2%) 484.74mg (96.9%) 3.Paracetamol BP 90.0% to 110.0% 486.60mg (97.3%) 29.94mg (99.8%) 4. Caffeine (anhydrous) BP 29.51mg (98.4%) 29.55mg (98.5%) 90.0% to 110.0%

Comments: The above Meditared Minhamon, Stradonal, Maximum Compression force Newsfield and offend Complies with in the acceptance Orthonia.

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PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE, CHLORPHENAMINE MALEATE AND CAFFEINE ANHYDROUS TABLETS

CRITI	CAL PARAMETER-2: COMPRESSI	ON RATE (RPM -CHALLENGE)	TEST RESUL	TS
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%.	Complles	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 second
7.0	Friability	NMT 1.0%w/w	0.12%	0.18%

Comments: The above Menkined from Challenge (2000 and High) has been verified and reported Complied with in the acceptance extresse.

QA-Sign & Date: Partition



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CRITI	CAL PARAMETER-3: HOPPER LEV	EL CHALLENGE		TEST RESULTS	
S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	Full Hopper	Half-full Hopper	Nearly-empty Hoppe
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	Compiles
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 Hentioned Hopper lovel (Full Hold , nearly empty) has done verified and found Complian was in the acceptance extrada.

QA-Sign & Date: P. Salas 21



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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 DAT STAGE:	FA FOR DRY MIXING	B.No.: GD210	0705	Mfg. Date: JUL-20:	21 Exp. D	ate: JUN-2024	
	2 ND	BATCH	B. Size: 10.0	L		7/11		
			TEST RESULTS					
S.No	MEASURED	ACCEDTANCE COTTEDIA			Mixing time (15 minut	es)		
PARAMETERS	PARAMETERS		Sample Location	Paracetamol (%)	Phenylephrine Hydrochloride (%)	Chlorphenamin e Maleate (%)	Caffeine (%)	
1	Blend	Individual sample values	TCL	103.0	99.8	100.8	96.7	
	uniformity:	between (85.0% to 115.0% of label claim) &	TC	99.9	95.6	94.9	%) (%)	
		RSD: NMT 5 % and	TCR	101.5	96.1	95.6		
		Average value between (90.0% to 110.0%).	MBL	102.3	98.7	102.3		
			мвс	101.8	97.0	95.1		
			MBR	101.7	99.7	102.0		
	~		BFL	101.2	100 CV 10	92.4		
			BFC	101.1	97.8	101.4	(%) 96.7 93.3 94.8 93.7 93.9 92.5 92.4 92.7 94.9 93.9 1.5	
		50	BFR	102.8	96.0	95.2		
			Avg.	101.7	97.6	98.8		
			RSD	1.0	1.6	3.5		
			Composite	103.2	94.8	94.4	94.5	
	validation test resu	ults of Dry Mixing stage are fou	nd to be	QA-Sign & Date:	P. Val P.			



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GENERIC NAME

	6.2 TEST DAT STAGE:	FA FOR DRY MIXING	B.No.: GD21	0706	Mfg. Date: JUL-20:	21 Exp.	Date: JUN-2024
	3 RD	BATCH	B. Size: 10.0	L			
					TEST RESULTS		
S.No	MEASURED	ACCEPTANCE CRITERIA			Mixing time (15 minut	es)	
-	PARAMETERS		Sample Location	Paracetamol (%)	Phenylephrine Hydrochloride (%)	Chlorphenam e Maleate (%	
1	Blend Individual sample values between (85.0% to 115.0% of label claim) &		TCL	103.9	98.7	102.1	97.1
		115.0% of label claim) &	тс	102.5	99.2	102.6	94.4
		RSD: NMT 5 % and Average value between	TCR	104.4	100.3	103.4	95.6
		(90.0% to 110.0%).	MBL	100.1	96.6	95.5	91.3
			МВС	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	102.1 96.8 96.7 91.9
			RSD	2.0	1.7	3.6	2.2
			Composite	102.2	100.1	97.9	93.7
	validation test resu	alts of Dry Mixing stage are fou	nd to be	QA-Sign & Date:	8-451-P		

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6.3 TEST DATA FOR BLENDING STAGE: 2ND BATCH TEST RESULTS Mixing time (20 minutes) MEASURED S.No **ACCEPTANCE CRITERIA** PARAMETERS Sample Paracetamol Phenylephrine Chlorphenamine Caffeine Location (%) Hydrochloride (%) Maleate (%) (%) 1 Blend Individual sample values TCL 100.7 98.5 98.1 107.4 uniformity: between (85.0% to TC 100.2 99.8 99.9 105.7 115.0% of label claim) & RSD: NMT 5 % and TCR 99.6 98.8 98.6 106.1 Average value between MBL 100.5 97.9 99.1 99.8 (90.0% to 110.0%). MBC 100.0 98.0 98.8 99.9 100.0 99.9 99.7 99.3 MBR BFL 100.0 98.4 98.5 99.6 98.4 101.2 BFC 101.7 99.0 97.8 106.5 BFR 100.0 99.1 DP 99.6 98.2 99.2 106.0 100.2 98.6 99.0 103.2 Avg. 0.8 0.6 3.4 RSD 0.6 Composite 99.6 99.1 100.5 99.1 All the validation test results of blending stage are found to be QA-Sign & Date: satisfactory/not satisfactory.

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					TEST RESUL	rs		
S.No	MEASURED	ACCEPTANCE CRITERIA	Mixing time (20 minutes)					
PARAMETERS	ACCEPTANCE CRETERIA	Sample Location	Paracetamol (%)	Phenylephrine Hydrochloride (%)	Chlorphenamine Maleate (%)	Caffeine (%)		
1	Blend uniformity:		TCL	99.3	98.1	99.0	105.6	
	uniformity.		тс	98.7	98.5	98.5	105.1	
			TCR	100.4	98.6	98.7	106.9	
		(90.0% to 110.0%).	MBL	100.4	99.7	98.7	99.9	
			МВС	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	8.0	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. Vol Oxilid 21

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6.5 TEST DATA FOR LUBRICATION STAGE: 2ND BATCH TEST RESULTS Mixing time (5 minutes) MEASURED S.No ACCEPTANCE CRITERIA **PARAMETERS** Phenylephrine Chlorphenamine Caffeine Sample Paracetamol Hydrochloride (%) Location (%) Maleate (%) (%) Individual sample values TCL 100.1 93.3 96.8 101.4 1 Blend uniformity: between (85.0% to TC 89.7 94.5 93.4 96.1 115.0% of label claim) & RSD: NMT 5 % and TCR 98.3 93.3 95.8 95.9 Average value between 98.9 94.3 98.0 101.2 MBL (90.0% to 110.0%). 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 98.8 95.1 96.7 100.2 BFC 99.5 95.9 97.5 BFR 99.4 DP 101.3 100.0 98.0 105.9 Avg. 98.7 94.1 96.3 98.8 3.4 1.4 4.4 RSD 2.0 101.0 98.0 106.9 Composite 101.4 All the validation test results of Lubrication stage are found to be QA-Sign & Date: satisfactory/not satisfactory.





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6.5 TEST DATA FOR LUBRICATION STAGE: 3RD BATCH TEST RESULTS Mixing time (5 minutes) MEASURED S.No **ACCEPTANCE CRITERIA PARAMETERS** Sample Paracetamol Phenylephrine Chlorphenamine Caffeine Maleate (%) Hydrochloride (%) (%) Location (%) 96.7 90.4 Individual sample values TCL 100.2 95.4 1 Blend uniformity: between (85.0% to 91.3 TC 100.2 101.7 97.1 115.0% of label claim) & RSD: NMT 5 % and 91.9 101.2 TCR 100.5 103.1 Average value between 92.3 97.5 MBL 98.2 96.2 (90.0% to 110.0%). 105.3 94.0 97.0 MBC 98.8 95.3 91.9 95.4 MBR 98.1 104.7 93.5 101.3 BFL 100.1 102.1 99.8 90.8 100.0 BFC 97.8 93.3 98.7 98.7 BFR 97.1 92.2 99.8 DP 100.2 99.9 92.2 98.5 Avg. 99.5 3.9 1.3 2.1 0.9 RSD 91.2 99.6 95.6 104.1 Composite

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

QA-Sign & Date:





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	6.6 TEST DATA FOR LUBR	ICATION STAGE :	B.No.: GD210705	Mfg. Date: JUL-2021	Exp. Date: JUN-2024
	2 ND BATCH		B. Size: 10.0L		
S.No			ON POOLED SAMPLE		
	MEASURED PARAMETERS		ACCEPTANCE CRITER	IA .	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:



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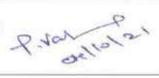
Effective date: of 10/21

GENERIC NAME

PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE, CHLORPHENAMINE MALEATE AND CAFFEINE ANHYDROUS TABLETS

6.7 Mfg. Date: JUL-2021 **TEST DATA FOR LUBRICATION STAGE:** B.No.: GD210706 Exp. Date: JUN-2024 B. Size: 10.0L 3RD BATCH ON POOLED SAMPLE S.No **MEASURED PARAMETERS ACCEPTANCE CRITERIA** TEST RESULTS Appearance (pooled sample) Light yellow colour granular powder 1 Complies 2 **Bulk Density** For information only 0.63g/ml 3 **Tapped Density** For information only 0.71g/ml

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GENERIC NAME

PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE, CHLORPHENAMINE MALEATE AND CAFFEINE ANHYDROUS TABLETS

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

S.No	Observation	1st Batch No.: GD210704	2 nd 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:

(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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Effective date: OS(10)21

GENERIC NAME

PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE, CHLORPHENAMINE MALEATE AND CAFFEINE ANHYDROUS TABLETS

TEST DATA OF VALIDATION OF COMPRESSION PROCESS - 2ND BATCH 7.0 7.1 TEST DATA FOR COMPRESSION STAGE: Mfg. Date: JUL-2021 Exp. Date: JUN-2024 B.No.: GD210705 B. Size: 10.0L **CRITICAL PARAMETER-1:** COMPRESSION FORCE (HARDNESS -CHALLENGE) TEST RESULTS MEASURED Maximum ACCEPTANCE CRITERIA Minimum Standard S.No PARAMETERS compression force compression force compression force Light yellow coloured flat round beveled Complies edged tablet with break line on one side Complies 1.0 Complies Appearance and plain on another side. 635mg±3% 633,36mg 634.72mg 636.33mg **Average Weight** 2.0 (615.950mg to 654.050mg) Not more than 2 of the individual masses Complies Complies Complies Uniformity of weight deviate from the average mass by more 3.0 than ±5%. Thickness 4.49mm 4.30mm 4.19mm 4.0 4.30mm ± 0.2mm (4.10mm to 4.50mm) (Average 10 tablets) Hardness 191.13N 109.93N 173,21N 100N-250N (To be monitored) 5.0 (Average 10 tablets) 08 Minutes 48 seconds 07 Minutes 33 seconds 05 Minutes 06 seconds 6.0 Disintegration time NMT 15 mins at 37°C±2°C 0.29% 0.33% Friability NMT 1.0%w/w 0.32% 7.0

Comments: The above Hentined Himmun, Standard, Maximum Compression force by been verified and Lound Comples with in tere acceptance ortable.

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GENERIC NAME

PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE, CHLORPHENAMINE MALEATE AND CAFFEINE ANHYDROUS TABLETS

CRITI	CAL PARAMETER-2: COMPRES	SION 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 $\pm 5\%$.	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%	
Comm	ents: The above N	contained from challenge the	ed (28th base)	hean venter	

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GENERIC NAME	
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PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE, CHLORPHENAMINE MALEATE AND CAFFEINE ANHYDROUS TABLETS

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GENERIC NAME

PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE, CHLORPHENAMINE MALEATE AND CAFFEINE ANHYDROUS TABLETS

TEST DATA OF VALIDATION OF COMPRESSION PROCESS - 3RD BATCH 8.0 8.1 **TEST DATA FOR COMPRESSION STAGE:** B.No.: GD210706 Mfg. Date: JUL-2021 Exp. Date: JUN-2024 CRITICAL PARAMETER-1: B. Size: 10.0L COMPRESSION FORCE (HARDNESS -CHALLENGE) TEST RESULTS MEASURED Standard compression Maximum S.No ACCEPTANCE CRITERIA Minimum PARAMETERS compression force compression force force Light yellow coloured flat round beveled edged tablet with break line Complies Complies Complies 1.0 Appearance on one side and plain on another side. 635ma±3% 2.0 **Average Weight** 636.3mg 637.3mg 635.4mg (615.950mg to 654.050mg) Not more than 2 of the individual Complies Complies 3.0 Uniformity of weight masses deviate from the average Complies mass by more than $\pm 5\%$. Thickness 4.30mm ± 0.2 mm (4.10mm to 4.0 4.24mm 4.25mm 4.29mg (Average 10 tablets) 4.50mm) Hardness 5.0 100N-250N (To be monitored) 128.7N 128.5N 125.4N (Average 10 tablets) 06 Minutes 05 Disintegration time NMT 15 mins at 37°C±2°C 06 Minutes 14 seconds 05 Minutes 50 seconds 6.0 seconds 0.12% 0.17% Friability NMT 1.0%w/w 0.11% 7.0 Comments: 150 munisport, brokers, maximum dorce Mentioned Compression above and Apund Complies with in the had been washed accordance

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GENERIC NAME

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 $\pm 5\%$.	Complies	Complles	
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%	
Comm	found complie	workened Rem challenge Esons	and Higher has	been verified	



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GENERIC NAME	PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE, CHLORPHENAMINE MALEATE AND CAFFEINE ANHYDROUS TABLETS
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CRITI	CAL PARAMETER-3: HOPPER	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.	Complles	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%

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GENERIC NAME

PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE, CHLORPHENAMINE MALEATE AND CAFFEINE ANHYDROUS TABLETS

8.4 CONCLUSION ON VALIDATION OF COMPRESSION PROCESS OF COMMERCIAL BATCHES

S.No	Observation	1st Batch No.: GD210704	2 nd Batch No.: GD210705	3 rd 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:

(Sign & Date)

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. Repeat the complete process validation on next 3 consecutive batches.



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GENERIC NAME

9.1 TEST DATA FOR UN C	OATED STAGE: 1ST BATCH	B.No.: GD210704	Mfg. Date: J	UL-2021	Exp. Date: JUN-2024
CAL PARAMETER	B. Size: 10.0L				
MEASURED PARAMETERS	ACCEPTANCE CRITERIA			TEST RESULTS	
Appearance	Light yellow coloured flat round beveled edged tablet with break line on one side and plain on another side.		Complies		
Average Weight	635mg±3% (615.950mg to 654.050mg)		634.6mg		
Uniformity of weight	Not more than 2 of the individual masses deviate from the average mass by more than $\pm 5\%$.		Complies		
Thickness (Average 10 tablets)	4.30mm ± 0.2mm (4.10mm to 4.50mm)		4.22mm		
Disintegration time	NMT 15 mins at 37°C±2°C		06 Minute	s 19 seconds	
Friability	NMT 1.0%w/w		0.24%		
Hardness	100N-250N (To be monitored)		195.50N		
Dissolution: 1.Chlorphenamine Maleate BP 2.Phenylehrine Hydrochloride BP 3.Paracetamol BP	Not less than 80% of stated a	nmount released in 45 n	ninutes ninutes	Min:80.69 Min:95.29	6, Max:100.0%, Avg:98.2% 6, Max:95.5%, Avg:91.7% 6, Max:100.4%, Avg:98.1% 6, Max:102.7%, Avg:99.1%
	CAL PARAMETER MEASURED PARAMETERS Appearance Average Weight Uniformity of weight Thickness (Average 10 tablets) Disintegration time Friability Hardness Dissolution: 1.Chlorphenamine Maleate BP 2.Phenylehrine Hydrochloride BP	MEASURED PARAMETERS Appearance Light yellow coloured flat roun on one side and plain on anot on one side and plain on anot (615.950mg to 654.050mg) Uniformity of weight Not more than 2 of the individuants by more than ±5%. Thickness (Average 10 tablets) A.30mm ± 0.2mm (4.10mm to 1.20mm) MMT 15 mins at 37°C±2°C Friability NMT 1.0%w/w Hardness 100N-250N (To be monitored to 1.20mm) 1.Chlorphenamine Maleate BP Not less than 80% of stated at 3.Paracetamol BP Not less than 80% of stated at 3.Paracetamol BP Not less than 80% of stated at 3.Paracetamol BP Not less than 80% of stated at 3.Paracetamol BP Not less than 80% of stated at 3.Paracetamol BP Not less than 80% of stated at 3.Paracetamol BP	MEASURED PARAMETERS Appearance Light yellow coloured flat round beveled edged tablet to none side and plain on another side. Average Weight G35mg±3% (615.950mg to 654.050mg) Uniformity of weight Not more than 2 of the individual masses deviate from mass by more than ±5%. Thickness (Average 10 tablets) A.30mm ± 0.2mm (4.10mm to 4.50mm) Disintegration time NMT 15 mins at 37°C±2°C Friability NMT 1.0%w/w Hardness 100N-250N (To be monitored) Dissolution: 1.Chlorphenamine Maleate BP Not less than 80% of stated amount released in 45 m 3.Paracetamol BP Not less than 80% of stated amount released in 45 m Not less than 80% of stated amount released in 45 m	MEASURED PARAMETERS Appearance Light yellow coloured flat round beveled edged tablet with break line on one side and plain on another side. Average Weight 635mg±3% (615.950mg to 654.050mg) Uniformity of weight Not more than 2 of the individual masses deviate from the average mass by more than ±5%. Thickness (Average 10 tablets) 4.30mm ± 0.2mm (4.10mm to 4.50mm) Disintegration time NMT 15 mins at 37°C±2°C Friability NMT 1.0%w/w Hardness 100N-250N (To be monitored) Dissolution: 1.Chlorphenamine Maleate BP Not less than 80% of stated amount released in 45 minutes 3.Paracetamol BP Not less than 80% of stated amount released in 45 minutes	MEASURED PARAMETERS Appearance Light yellow coloured flat round beveled edged tablet with break line on one side and plain on another side. Average Weight G35mg±3% (615.950mg to 654.050mg) Uniformity of weight Not more than 2 of the individual masses deviate from the average mass by more than ±5%. Thickness (Average 10 tablets) 4.30mm ± 0.2mm (4.10mm to 4.50mm) 4.22mm Disintegration time NMT 15 mins at 37°C±2°C 06 Minute Friability NMT 1.0%w/w Hardness 100N-250N (To be monitored) Dissolution: 1.Chlorphenamine Maleate BP Not less than 80% of stated amount released in 45 minutes Min:97.09 3.Paracetamol BP Not less than 80% of stated amount released in 45 minutes Min:95.29



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GENERIC NAME

PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE, CHLORPHENAMINE MALEATE AND CAFFEINE ANHYDROUS TABLETS

0.0	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%

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CENEDIC NAME	PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE, CHLORPHENAMINE MALEATE AND
GENERIC NAME	CAFFEINE ANHYDROUS TABLETS

	9.2 TEST DATA FOR UN C	OATED STAGE: 2ND BATCH	B.No.: GD210705	Mfg. Date: J	UL-2021	Exp. Date: JUN-2024
RITI	CAL PARAMETER		B. Size: 10.0L			
s.No	MEASURED PARAMETERS ACCEPTANCE CRITERIA				TEST RESULTS	
1.0	Appearance	Light yellow coloured flat rour on one side and plain on anot		with break line	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 Minute	s 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 2.Phenylehrine Hydrochloride BP 3.Paracetamol BP	Not less than 80% of stated a Not less than 80% of stated a Not less than 80% of stated a	amount released in 45 n	ninutes	Min:89.2%	6, Max:101.0%, Avg:99.1% 6, Max:95.9%, Avg:93.7% 6, Max:100.9%, Avg:98.5%
	4.Caffeine (anhydrous) BP	Not less than 80% of stated a	amount released in 45 n	ninutes		6, Max:104.2%, Avg:101.1%



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PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE, CHLORPHENAMINE MALEATE AND CAFFEINE ANHYDROUS TABLETS

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
Comm	nents: The above +	removed Romanchers, Assey, or	issolution, Rolated directiones

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GENERIC NAME

	9.3 TEST DATA FOR UN C	COATED STAGE: 3RD BATCH	B.No.: GD210706	Mfg. Date	e: JUL-2021 Exp. Date: JUN-20:	
CRITI	CAL PARAMETER		B. Size: 10.0L			
S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA			TE	ST RESULTS
1.0	Appearance	Light yellow coloured flat roun line on one side and plain on a		with break	Complles	
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 $\pm 5\%$.		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 2	0 seconds	
6.0	Friability	NMT 1.0%w/w		0.10%		
7.0	Hardness	100N-250N (To be monitored)	100N-250N (To be monitored)		180.10N	
8.0	Dissolution: 1.Chlorphenamine Maleate BP 2.Phenylehrine Hydrochloride BP 3.Paracetamol BP	Not less than 80% of stated at Not less than 80% of stated at Not less than 80% of stated at	mount released in 45 m	inutes	Min:95.2%,	Max:100.1%, Avg:99.1% Max:98.4%, Avg:96.8% 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%	



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GENERIC NAME

PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE, CHLORPHENAMINE MALEATE AND CAFFEINE ANHYDROUS TABLETS

9.0	Assay: Each uncoated tablet contains.	00 000 to 110 000 of the labeled daim	1 D4ma (07 286)
	1.Chlorphenamine Maleate BP	90.0% to 110.0% of the labeled claim	1.94mg (97.2%)
	2.Phenylehrine Hydrochloride	90.0% to 110.0% of the labeled claim	4.90mg (97.9%)
	BP	90.0% to 110.0% of the labeled claim	493.12mg (98.6%)
	Paracetamol BP Caffeine (anhydrous) BP	90.0% to 110.0% of the labeled claim	29.76mg (99.2%)
10.0	Related Substances: Single Maximum unknown impurity Total impurities	Not more than 0.20% Not more than 0.50%	Below Disregard Limit
omm		I sammation action of the parameter of t	Marx VII. Will
Subs	stences has been	e Mentioned Parameters. Assa	Comples wire in
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GENERIC NAME

	10.1 TEST DATA FOR PA	ACKING VALIDATION:	B.No.: GD210704	Mfg. Date: JUL-2021	Exp. Date: JUN-2024
CRITI	CAL PARAMETER		B. Size: 10.0L	111	10
S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA			TEST RESULTS
1.0	Appearance	Strip appearance is acceptable	e & 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



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GENERIC NAME	CAFFEINE ANHYDROUS TABLETS
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6.0	Low temperature _100°C High speed_40RPM	No Strip should fall 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%
Re Un	lated Substant tre acceptance gn & Date:		Acut Pest a via



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GENERIC NAME

	10.2 TEST DATA FOR PA	ACKING VALIDATION:	B.No.: GD210705	Mfg. Date: JUL-2021	Exp. Date: JUN-2024
CRITI	CAL PARAMETER		B. Size: 10.0L	160	
S.No MEASURED PARAMETERS ACCEPTANCE CRITERIA				TEST RESULTS	
1.0	Appearance	Strip appearance is acceptab	le & 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.		Complles	
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 fall in leak test.			Complies

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GENERIC NAME

PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE, CHLORPHENAMINE MALEATE AND CAFFEINE ANHYDROUS TABLETS

Low temperature _100°C 6.0 Complies No Strip should fail in leak test. High speed 40RPM High temperature 120°C 7.0 Complies No Strip should fail in leak test. Low speed 15RPM Cutting should be uniform on all sided without any angular cuts over printing Strip quality 8.0 should be visible and Readable and knurling should be proper. Complies 9.0 De striped tablets: Related Substances: Single Maximum unknown 0.01% Not more than 0.20% impurity Total impurities 0.01% Not more than 0.50%

Comments: The above Mattered Parameters , bealing tremperature , Leat test, Related Substances has been wert field and found complies with a tre acceptance contents.

QA-Sign & Date :



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GENERIC NAME

PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE, CHLORPHENAMINE MALEATE AND CAFFEINE ANHYDROUS TABLETS

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



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GENERIC NAME

PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE, CHLORPHENAMINE MALEATE AND CAFFEINE ANHYDROUS TABLETS

Low temperature _100°C 6.0 No Strip should fail in leak test. Complies High speed 40RPM High temperature _120°C 7.0 No Strip should fail in leak test. Complies Low speed_15RPM Cutting should be uniform on all sided without any angular cuts over printing 8.0 Strip quality should be visible and Readable and knurling should be proper. Complies 9.0 De striped tablets: Related Substances: Single Maximum unknown 0.01% Not more than 0.20% impurity Total impurities 0.01% Not more than 0.50% Comments: The above Herrand Powermoters, Sealing temperature,

Loak fest, Related Substances has been verified and Arand

Complies with in the acceptance wideric.

QA-Sign & Date:

P. Voltania



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GENERIC NAME

	11.1 TEST DATA FOR FIN	IISHED PRODUCT : 15T BATCH	B.No.: GD210704	Mfg. Date:	JUL-2021	Exp. Date: JUN-2024	
RITI	CAL PARAMETER	14	B. Size: 10.0L				
S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA		TES	T RESULTS		
1.0	Appearance	Light yellow coloured flat round on one side and plain on another	[1] [1] [1] [1] [1] [1] [1] [1] [1] [1]	ith break line	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. a) Total aerobic microbial count. b) Total yeast and mould count. ii) Pseudomonas aeruginosa. iii) Salmonella species. iv) Esherichia coll. v) Staphylococcus aureus.	Not more than 1000 cfu/g Not more than 100 cfu/g Should be absent/g			20cfu/g Found abser Found abser Found abser Found abser Found abser	nt nt nt nt	
Comm	ents: The above	1 Armal Comple	camptell as	of rue	T Por accepta	ranetees how	



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GENERIC NAME

PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE, CHLORPHENAMINE MALEATE AND CAFFEINE ANHYDROUS TABLETS

	11.2 TEST DATA FOR FIN	ISHED PRODUCT: 2ND BATCH	B.No.: GD210705	Mfg. Date: J	UL-2021	Exp. Date: JUN-2024
CRIT	CAL PARAMETER		B. Size: 10.0L			
S.No	MEASURED PARAMETERS	ACCEPTANCE CRITERIA	TES		T 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) 63		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. d) Total yeast and mould count. ii) Pseudomonas aeruginosa. iii) Salmonella species. iv) Esherichia coli. v) Staphylococcus aureus.	Not more than 100 cfu/g < Should be absent/g Should be absent/g Fo		20cfu/g <10cfu/g Found abs Found abs Found abs Found abs	ent ent	

Comments: The above Mentioned Parameters, Microbiological Parameters but been von fied and found Complies with in the acceptance witesta

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GENERIC	NAME
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PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE, CHLORPHENAMINE MALEATE AND CAFFEINE ANHYDROUS TABLETS

RITI	CAL PARAMETER		B. Size: 10.0L			
S.No	MEASURED PARAMETERS	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. e) Total aerobic microbial count. f) Total yeast and mould count. ii) Pseudomonas aeruginosa. iii) Salmonella species. iv) Esherichia coli. v) Staphylococcus aureus.	Not more than 1000 cfu/g Not more than 100 cfu/g Should be absent/g			20cfu/g <10cfu/g Found absortion of the count	ent ent

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GENERIC NAME

PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE, CHLORPHENAMINE MALEATE AND CAFFEINE ANHYDROUS TABLETS

13.0 POST APPROVAL:

13.1 Compiled By:

Dept.	Name	Designation		Signature	Date
Quality Assurance	P. Vadivel	Sr. Executive	AB	P-Val-P	04/10/01

13.2 Verified By:

Dept.	Name	Designation	Signature	Date
Head-Production	V. Dharabal	Sr. Cm	0	04/10/21
Head-Quality Control	7. Vigayabumar.	ARM.	- Elean	orliops

13.3 Approved By:

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