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	MASTER FORMULA RECORD		PAGE NO.:2 OF 9	
GENERIC NAME:	PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE, CHLORPHENAMINE MALEATE AND CAFFEINE ANHYDROUS TABLETS.			
MFC NO.: ST/MFC/119	SHELF LIFE: 36 MONTHS	PRODUCT ID NO.: 978	REVISION NO.: R5	
DOSAGE FORM : TABLET	SUPERSEDES NO: ST/MFC/119(R4)	MARKET : EXPORT	EFFECTIVE DATE: 02/04/2024	

2.0 MANUFACTURING FORMULA								
Sr. No	NAME OF INGREDIENTS	FUNCTION	MATERIAL CODE	SPEC	LABEL CLAIM IN mg	OVERAGE %	UNIT QTY IN mg	QTY IN KG/1 LAC
Dry mixing:								
1.	Paracetamol *	Pain Reliever	RMAP0030	BP	500.000	NIL	500.000	50.000
2.	Phenylephrine Hydrochloride *	Sinusitis	RMAP0031	BP	5.000	NIL	5.000	0.500
3.	Chlorphenamine Maleate *	Antihistamine	RMAC0064	BP	2.000	NIL	2.000	0.200
4.	Caffeine Anhydrous *	Central nervous system stimulant	RMAC0065	BP	30.000	NIL	30.000	3.000
5.	Pregelatinized Starch 1500	Diluent	RMEP0046	BP	NA	NIL	15.000	1.500
6.	Microcrystalline Cellulose PH 101#	Diluent	RMEM0031	BP	NA	NIL	24.735	2.474
Binder Preparation:								
7.	Povidone K 90	Binder	RMEP0045	BP	NA	NIL	12.500	1.250
8.	Purified Water @	Vehicle	RMEP0033	BP	NA	NIL	100.000	10.000
9.	Tartrazine Supra	Colourant	RMET0011	INH	NA	NIL	0.135	0.014
10.	Methyl Paraben Sodium	Preservative	RMEM0032	BP	NA	NIL	0.500	0.050
Blending and Lubrication:								
11.	Pregelatinized Starch 1500	Diluent	RMEP0046	BP	NA	NIL	10.000	1.000
12.	Sodium Starch Glycolate	Disintegrant	RMES0029	BP	NA	NIL	17.000	1.700
13.	Purified Talc	Glidant	RMET0012	BP	NA	NIL	7.000	0.700
14.	Colloidal anhydrous silica	Adsorbent	RMEC0017	BP	NA	NIL	5.000	0.500
15.	Tartrazine Lake	Colourant	RMET0013	INH	NA	NIL	0.130	0.013
16.	Magnesium Stearate	Lubricant	RMEM0033	BP	NA	NIL	6.000	0.600
Total weight							635.000	63.500


Note: @ Does not appear in final product evaporator during processing.

*, # - Refer potency calculation

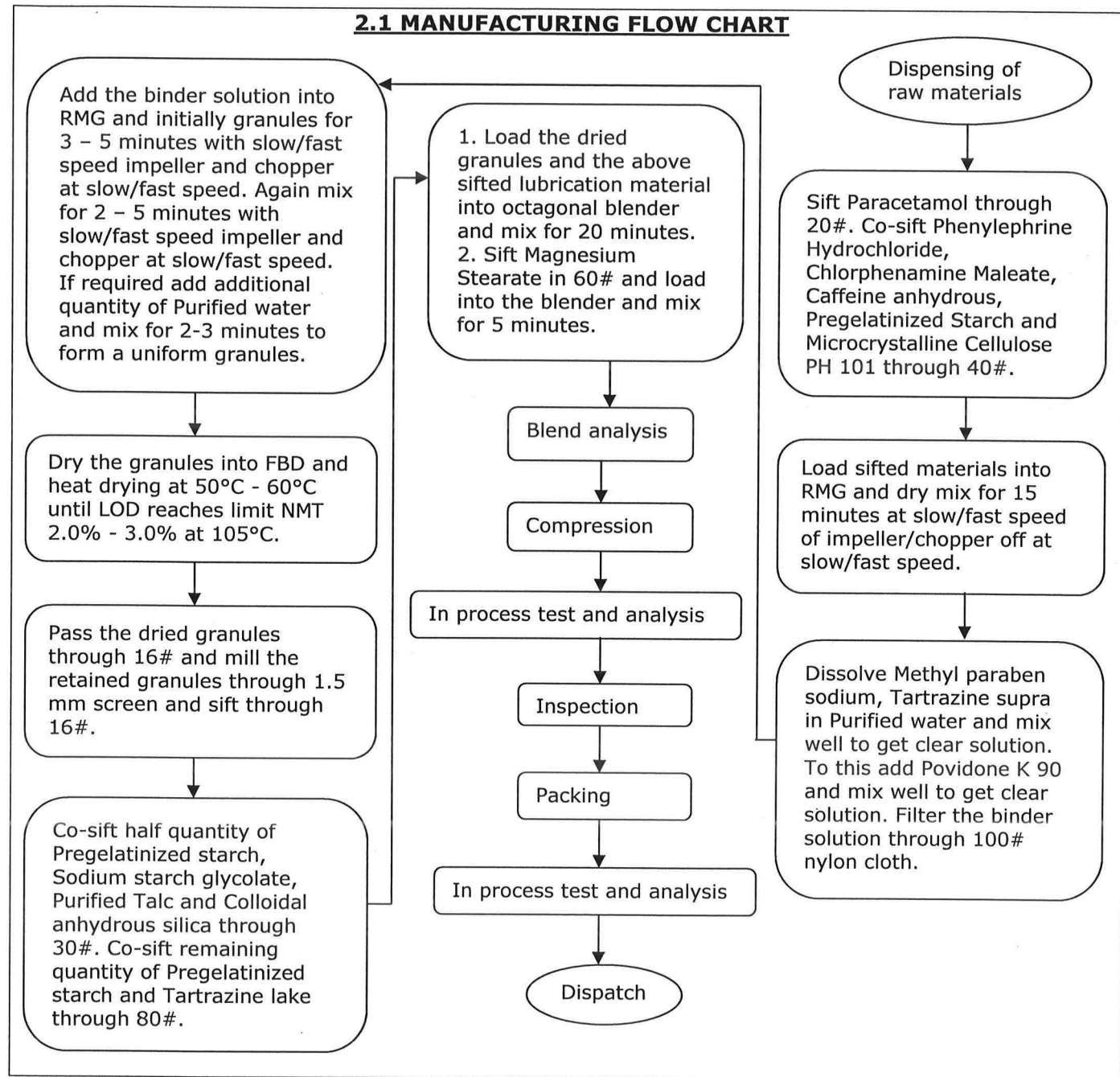
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2.1 MANUFACTURING FLOW CHART



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3.0 POTENCY CALCULATION**3.1 Potency Calculation for Paracetamol:**

*The mentioned quantity of Paracetamol is based on 100% assay on dried basis and without LOD.
Actual quantity of Paracetamol to be calculated as below.

$$500 \times 100 \times 100$$

Actual quantity of = -----mg/tablet

Paracetamol % Assay on dried basis X (100 - % LOD)

3.2 Potency Calculation for Phenylephrine Hydrochloride:

*The mentioned quantity of Phenylephrine Hydrochloride is based on 100% assay on dried basis and without LOD. Actual quantity of Phenylephrine Hydrochloride to be calculated as below.

$$5.000 \times 100 \times 100$$

Actual quantity of = -----mg/tablet

Phenylephrine Hydrochloride % Assay on dried basis X (100 - % LOD)

3.3 Potency Calculation for Chlorphenamine Maleate:

*The mentioned quantity of Chlorphenamine Maleate is based on 100% assay on dried basis and without LOD. Actual quantity of Chlorphenamine Maleate to be calculated as below.

$$2.000 \times 100 \times 100$$

Actual quantity of = -----mg/tablet

Chlorphenamine Maleate % Assay on dried basis X (100 - % LOD)

3.4 Potency Calculation for Caffeine Anhydrous:

*The mentioned quantity of Caffeine anhydrous is based on 100% assay on dried basis and without LOD. Actual quantity of Caffeine anhydrous to be calculated as below.

$$30.000 \times 100 \times 100$$

Actual quantity of = -----mg/tablet

Caffeine Anhydrous % Assay on dried basis X (100 - % LOD)

##Quantity of Microcrystalline Cellulose PH 101 varies based on Assay and water content of Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous for keeping the core tablet weight constant.

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Actual quantity of Microcrystalline Cellulose PH 101 to be dispensed:

= Standard quantity of (Microcrystalline Cellulose PH 101 + Paracetamol + Phenylephrine Hydrochloride + Chlorphenamine maleate + Caffeine anhydrous) - Actual quantity of (Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine maleate and Caffeine anhydrous)

Note: If the assay of Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine anhydrous is more than 100%, calculation has to be done only for 100%.

4.0 MANUFACTURER DETAILS


Material Name	Vendor
Paracetamol	Bharat chemicals/Farmson
Phenylephrine Hydrochloride	Aarti Industries Ltd/Divis
Chlorphenamine Maleate	Supriya Life Science Ltd
Caffeine Anhydrous	Aarti Industries Ltd
Pregelatinized Starch	Colorcon
Microcrystalline Cellulose 101	Sigachi Industries
Povidone K 90	Haungshan Bonsun Pharmaceuticals
Tartrazine Supra	Standardcon
Methyl Paraben Sodium	Alta Laboratories Ltd
Sodium Starch Glycolate	Roquette
Purified Talc	Imerys/Neelkanth
Colloidal anhydrous silica	Wacker
Tartrazine Lake	Standardcon
Magnesium Stearate	Nitika

Note: If any change in vendor, same shall be approved by Quality Assurance.

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5.0 LIST OF MAJOR EQUIPMENTS USED

1. Vibro Sifter
2. Rapid Mixer Granulator
3. Fluid Bed Drier
4. IR moisture Balance Analyzer
5. Multi Mill
6. Octagonal Blender
7. Compression Machine
8. Digital Vernier Caliper
9. Tablet Hardness Tester
10. Friabilator
11. Disintegration Tester

Note: The equipment's shall be selected based upon batch size and customer sales orders.


6.0 GENERAL INSTRUCTIONS AND SAFETY PRECAUTIONS

1. All of the manufacturing activities shall be handled in controlled environment. (Temp $25 \pm 2^\circ\text{C}$ / RH $50 \pm 5\%$)
2. In case of any abnormalities & discrepancies observed during process, should be reported.
3. During manufacturing respective Personal Protective Equipment (PPE) should be used.
4. Must wear the gloves/ mask while product handling.
5. Appropriate status label shall use for every stage.
6. Check the sieve/ screen integrity before and after usage.
7. During granulation process, if required add additional Qty of solvent and document in BMR.

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7.0 MANUFACTURING PROCEDURE (4 LOT)

Critical Control Points:

1. Selection of sieves
2. LOD Check
3. Dry mixing, Wet mixing Timings
4. Blending, Lubrication timings & Sampling
5. Labelling & Storage.

7.1 Sifting:

7.1.1 Sift Paracetamol through 20#. Co-sift Phenylephrine Hydrochloride, Chlorphenamine Maleate, Caffeine Anhydrous, Pregelatinized Starch and Microcrystalline Cellulose PH 101 through 40#.

7.2 Dry mixing:

7.2.1 Load the sifted material of step 7.1.1 into RMG and mix for 15 minutes at slow/fast speed of impeller.

7.3 Binder Preparation:

7.3.1 Dissolve Methyl Paraben Sodium, Tartrazine supra in Purified water and mix well to get clear solution. To this add Povidone K 90 and mix well to get clear solution.

7.4 Wet granulation:

7.4.1 Add the binder solution of step 7.3.1 into the step of 7.2.1 and mix for 3 - 5 minutes with slow/Fast speed impeller and chopper at slow/fast speed followed by racking.

7.4.2 Mixing 2 - 5 minutes with slow/fast speed impeller and chopper at slow/fast speed followed by racking.

7.4.3 If required add additional quantity of Purified water and mix for 2 - 3 minutes to form a uniform granules.

7.4.4 Unload the wet granules into FBD bowl for drying.

7.5 Drying and Sizing:


7.5.1 Load the wet granules into the FBD bowl and Steam drying at 50°C -60°C with intermittent racking at every 10 - 15 minutes until LOD reaches the limit NMT 2.0 - 3.0%.

7.5.2 Sift the dried granules through 16# and mill the retained granules through 1.5 mm screen and again pass through 16#.

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7.6 Blending and Lubrication:

- 7.6.1 Co-sift half quantity of Pregelatinized Starch, Sodium Starch Glycolate, Purified Talc, and Colloidal anhydrous silica through 30#.Co-sift remaining quantity of Pregelatinized Starch and Tartrazine Lake through 80#.
- 7.6.2 Load the sifted material of step 7.6.1 and dried granules of step 7.5.2 into the octagonal blender and mix for 20 minutes.
- 7.6.3 Sift the Magnesium Stearate through 60# and distribute/sprinkle over the blended material and mix for 5 minutes.
- 7.6.4 Unload the final blend into suitable containers lined with double poly bag with proper status label.
- 7.6.5 Send the lubricated blend samples to QC and conform the analytical results.

7.7 COMPRESSION

Critical Control Points:

1. Selection of Punches & Cleaning
2. Initial checks Verification
3. In process check
4. Storage & Labeling.

Set the 27/20 station double rotary compression machine with 12.70 MM circular shape, flat beveled edge punch with break line one side and plain on other side.

7.7.1 Compress the Lubricated blend with following Parameters:

Parameter	Limit
Description	Light yellow coloured, flat, round beveled edged uncoated tablets with break line on one side and plain on other side.
Average weight	635 mg \pm 3% (615.95 mg – 654.05 mg)
Weight of 20 tablets	12.700 g \pm 3% (12.319 g – 13.081 g)
Uniformity of weight	Average weight \pm 5% (603.25 mg – 666.75 mg)
Thickness	4.30 \pm 0.2 mm (4.10mm – 4.50mm)
Hardness	100 – 250N
Friability	NMT 1.0% w/w
Disintegration Test	NMT 15 minutes at 37°C \pm 2°C

- Send the Compressed tablets sample to QC and conform the Analytical results.

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8.0 YEILD

Reconciliation to be done after each processing stage.

Actual weight of the granules

Blending : ----- X 100

Theoretical weight of the granules

Yield Limit : NLT 99.00 %

Actual weight of the tablets

Compression : ----- X 100

Theoretical weight of the tablets

Yield Limit : NLT 98.00%

9.0 REVISION HISTORY

Date of Revision	Revision Number	Reason for Change	Effective Date
07.01.2020	R0	New MFR prepared. Refer change control No: ST/CC/20/005	13.01.2020
23.06.2020	R1	Hardness and thickness parameter fixed based on Previous batch trend data .Refer change control No: ST/CC/20/032	26.06.2020
26.09.2020	R2	1. Artwork revised (Foil size changed to 302 mm from 180 mm). Refer change control No: ST/CC/20/066 2. Yield limit fixed based on previous batch trend data. Refer change control No: ST/CC/20/066	05.10.2020
28.11.2020	R3	Hardness and thickness parameter fixed based on Previous batch trend data .Refer change control No: ST/CC/20/094	31.11.2020
26.07.2021	R4	New granulation area and equipment used. Refer change control No.: ST/CC/21/103	27.07.2021
02/04/2024	R5	1. Manufacturing from Safetab Life science to GHPL Loan License. 2. Hydrophobic Colloidal anhydrous silica BP name has been corrected as per BP monograph. Refer change control No.: ST/CC/24/039	02/04/2024

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