



Safetab Life Science

MASTER COPY

BATCH MANUFACTURING RECORD

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Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
Generic:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/R0
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

BATCH MANUFACTURING RECORD COVER SHEET:

PRODUCT NAME	:	GRIPEX		
LABEL CLAIM	:	Each 4.5g sachet contains: Paracetamol BP 650mg Phenylephrine Hydrochloride BP 10mg Chlorphenamine Maleate BP 20mg Ascorbic Acid BP 50mg Flavour: Lemon flavour used.		
PACK SIZE	:	10 X 4.5 Sachets		
STORAGE CONDITION	:	Store in cool and dry place. Protect from light.		
SHELF LIFE	:	36 MONTHS		
CUSTOMER NAME	:	GENERIC HEALTHCARE PVT. LTD		
EFFECTIVE BATCH NUMBER	:	G1722056	DATE:	02/04/22
MANUFACTURING LICENCE No.	:	07 22 1907		
MFG. DATE:	:	04/2022	BMR No.	STBMR:134/01
EXP. DATE:	:	03/2025	Supersedes BMR No.	STBMR:134/00
BMR ISSUED BY/DATE (QA)	:	[Signature] 22/04/22		
BMR CHECKED & RECEIVED BY/DATE (PRODUCTION)	:	[Signature] 22/04/22		
Allotted By: QA Executive Sign/Date: [Signature] 22/04/22				
DATE OF COMMENCEMENT:		22/04/22	DATE OF COMPLETION: 27/04/22	
This BMR contains 31 Pages + Additional Pages				
Checked by Competent Staff Sign/Date: [Signature] 27/04/22				

	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	[Signature] 22/04/22	[Signature] 27/04/22	[Signature] 27/04/22	CONTROLLED COPY

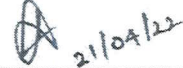
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Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
Generic:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/R0
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

1.0 LIST OF EQUIPMENTS:

S.No	Name of Equipment	Equipment ID No. to be used
1	Dispensing Booth	ST/SRDB/001
2	Balance -30 Kg Capacity	ST/SRWB/001
3	Balance -620 g Capacity	ST/SRWB/002
4	Balance -150 Kg Capacity	ST/WB/189
5	Balance -100 Kg Capacity	ST/PRWB/002
6	Balance - 220g Capacity	ST/WB/202
7	Vibro Sifter	ST/PRVS/001 or ST/PRVS/002 or ST/PRVS/003 or ST/PRVS/004
8	Octagonal blender(2200L)	ST/PROB/001

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 21/04/22	 21/04/22	 21/04/22	



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Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
Generic:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/R0
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

2.0 DISPENSING PROCESS:

2.1 LINE CLEARANCE CHECKS:

S.No	CHECKS	Observation	
		store	IPQA
1	Ensure that all empty containers, labels, used Polybags, hand gloves of previous dispensed Product/ batch are removed from the area.	✓	✓
2	Ensure that all dispensed material of previous product / batch removed from the area.	✓	✓
3	Ensure that the previous batch BMR / documents are removed from the area.	✓	✓
4	Check the housekeeping general cleanliness of the floor, walls, ceiling, tube light fixture, electrical fixtures and its panel surface, pass box, doors and door view panels. of man and material entry of dispensing area are clean.	✓	✓
5	Check the cleanliness of the working table, cupboard, washing area and waste bin.	✓	✓
6	Check the cleanliness of the drain points.	✓	✓
7	Ensure that the dispensing booth is cleaned and it's status.	✓	✓
8	Check the cleanliness of the supply and return grill.	✓	✓
9	Check the cleanliness of side wall of the dispensing booth.	✓	✓
10	Check the differential pressure of pre filter, intermediate filter and heap filter are within the limit.	✓	✓
11	Check the cleanliness of the utility line (compressed air, First RO water and purified water).	✓	✓
12	Check the cleanliness of the SS side panel and SS Stool.	✓	✓
13	Ensure that the balances are cleaned and it's calibration status.	✓	✓
14	Check the status board of the area is updated.	✓	✓
15	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.	✓	✓
16	Check the differential pressure of the area should be within the limit.	✓	✓
17	Ensure that dispensing tools or accessories like coops, spoons are cleaned and labeled with "Clean" label.	✓	✓
18	Check proper gowning procedure followed as per the SOP	✓	✓
19	Ensure the concurrent entries of log book.	✓	✓
20	Ensure that the Laminar of dispensing booth run Not less than 15 minutes after switch on.	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (Store) sign/date: *mb 22/04/22*Verified by (IPQA) sign/date: *fm 22/04/22*

Equipment	Dispensing Booth	Weighing Balance			AREA
Equipment. ID No.	ST/SRDB/001	ST/SRWB/001 (30.0 Kg)	ST/WB/189 (150.0 Kg)	ST/SRWB/002 (620.0 g)	
Previous Product & Batch No.	AB-FLO-N-S2287010D				
Cleaned By	<i>Rgh</i>	<i>Rgh</i>	<i>Rgh</i>	<i>Rgh</i>	
Checked by Stores Sign/Date	<i>mb 22/04/22</i>	<i>mb 22/04/22</i>	<i>mb 22/04/22</i>	<i>mb 22/04/22</i>	
Counter checked by IPQA/Sign/Date	<i>fm 22/04/22</i>	<i>fm 22/04/22</i>	<i>fm 22/04/22</i>	<i>fm 22/04/22</i>	

2.2 ENVIRONMENTAL CONDITIONS:

Area: Dispensing	Temperature: 23°C to 27°C	Observation	Stores Sign
		<i>24.3°C</i>	<i>mb</i>
	Relative Humidity: 45% to 55%	Observation	Stores Sign
		<i>54%</i>	<i>mb</i>

2.3 APPROVAL FOR DISPENSING BY IPQA: Sign: *fm*Date: *22/04/22*

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee	CONTROLLED COPY
Signature with Date	<i>mb 22/04/22</i>	<i>mb 21/04/22</i>	<i>mb 21/04/22</i>	

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Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
Generic:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/R0
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

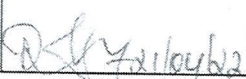
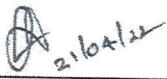
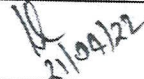
2.4 INDENT OF ACTIVE PHARMACEUTICAL INGREDIENTS:

S.No	Name of the Ingredients	Label claim per sachet in mg	Material code	Spec	Unit Qty (mg)	Std. Qty per batch (Kg)	Vendor
1	Paracetamol*	650	RMAP0030	BP	650.000	130.000	Valiant Laboratories LTD
2	Phenylephrine Hydrochloride**	10	RMAP0031	BP	10.000	2.000	Divis Laboratories
3	Chlorphenamine Maleate***	20	RMAC0064	BP	20.000	4.000	Supriya Life Science
4	Ascorbic Acid****	50	RMAA0029	BP	50.000	10.000	Bajaj Health Care

2.4.1 INDENT OF EXCIPIENTS:

S.No	Name of the Ingredients	Unit Qty (mg)	Spec	Material code	Std. Qty per batch (Kg)	Vendor
5	Maltodextrin #	2215.00	BP	RMAM0044	443.000	Roquette India PVT .LTD
6	Hydrophobic colloidal anhydrous silica	30.000	BP	RMEC0017	6.000	Wacker
7	Citric Acid Monohydrate	50.000	BP	RMEC0020	10.000	Sunil Chemicals
8	Orange Pekoe Extract	1200.000	IHS	RME00027	240.000	Omni Active Health Technologies
9	Sucralose	35.000	BP	RMES0034	5.000	Shangdong kanbo Bio chemical
10	Lemon lime Premaseal (75412-71)	250.000	IHS	RMEL0027	50.000	GIVAUDAN INDIA PVT.LTD

@Does not appear in final product evaporated during drying.
 *, **, ***, ****, # Refer calculation.

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
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Signature with Date	 21/04/22	 21/04/22	 21/04/22	

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Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

3.0 CALCULATION:**3.1 Potency calculation for Paracetamol BP :**

Q.C AR.No. for Paracetamol	Expiry Date	Assay of Paracetamol on dried basis	LOD %
mSp/2102/04/01/01057	12/2026	99.70	0.06
—	—	—	—

The given quantity is based on 100% Assay on dried basis and without Loss on drying.
Actual quantity to be added is calculated as:

Actual quantity, of Paracetamol = $\frac{650 \times 100 \times 100}{\text{mg/sachet}}$

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

$$\frac{6500000}{9964.018} = 652.347 \text{ mg/sachet}$$

*Qty of Paracetamol to be added per batch = 130.469 Kg's

Note: If the assay of Paracetamol is more than 100 %, calculation has to be done only for 100%

Calculation done by(store)/date:

mgo
22/04/22

Checked by(production)/date:

[Signature]
22/04/22

Verified by(QA)/date

	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<i>[Signature]</i> 21/04/22	<i>[Signature]</i> 21/04/22	<i>[Signature]</i> 21/04/22	CONTROLLED COPY

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Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

3.2 Potency calculation for Phenylephrine Hydrochloride BP :

Q.C AR.No. for Phenylephrine Hydrochloride	Expiry Date	Assay of Phenylephrine Hydrochloride on dried basis	LOD %
msp/2122056/rev/100848	10/2026	99.10	0.10
—	—	—	—

*The given quantity is based on 100% Assay on dried basis and without Loss on drying.
Actual quantity to be added is calculated as:

Actual quantity of Phenylephrine Hydrochloride = $\frac{100000}{99.10} \times 100$ mg/ sachet
% Assay on dried basis X (100 - LOD %)

$$\frac{100000}{99.10} = 1010.09 \text{ mg/sachet}$$

*Qty of Phenylephrine Hydrochloride to be added per batch = 2.020 Kg's

Note: If the assay of Phenylephrine Hydrochloride is more than 100 %, calculation has to be done only for 100%

Calculation done by(store)/date:

22/04/22

Checked by(production)/date:

22/04/22

Verified by(QA)/date

22/04/22

	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 22/04/22	 22/04/22	 22/04/22	CONTROLLED COPY

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Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
Generic:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/R0
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

3.3 Potency calculation for Chlorphenamine Maleate BP :

Q.C AR.No. for Chlorphenamine Maleate	Expiry Date	Assay of Chlorphenamine Maleate on dried basis	LOD %
msp/2122/04/04/00823	09/2026	99.40	0.32
—	—	—	—

The given quantity is based on 100% Assay on dried basis and without Loss on drying.
Actual quantity to be added is calculated as:

$$\text{Actual quantity. of Chlorphenamine Maleate} = \frac{20 \times 100 \times 100}{\% \text{ Assay on dried basis} \times (100 - \text{LOD} \%)} \text{ mg/ sachet}$$

$$\frac{200000}{99.08.192} = 20.185 \text{ mg/sachet}$$

$$\text{*Qty of Chlorphenamine Maleate to be added per batch} = 4.037 \text{ Kg's}$$

Note: If the assay of Chlorphenamine Maleate is more than 100 %, calculation has to be done only for 100%

Calculation done by(store)/date:

MAV
22/04/22

Checked by(production)/date:

22/04/22

Verified by(QA)/date

22/04/22

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	22/04/22	21/04/22	21/04/22	

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	BATCH MANUFACTURING RECORD			Page 8 of 31	
Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
Generic:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/R0
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

3.4 Potency calculation for Ascorbic Acid BP:

Q.C AR.No. for Ascorbic Acid	Expiry Date	Assay of Ascorbic Acid (%)
1250/0102/ach/ach/01098	12/0025	99.70

The given quantity is based on 100% Assay.
Actual quantity to be added is calculated as:

$$\text{Actual quantity of Ascorbic Acid} = \frac{50 \times 100}{\% \text{ Assay}} \text{ mg/ sachet}$$

$$= \frac{5000}{99.70} = 50.150 \text{ mg / sachet}$$

$$\text{*Qty of Ascorbic Acid to be added per batch} = 10.030 \text{ Kg's}$$

Quantity of Sucrose varies based on assay content of Paracetamol, Phenylephrine Hydrochloride Chlorphenamine Maleate, Ascorbic Acid for keeping the Fill weight constant

Note: If the assay of Ascorbic Acid is more than 100 %, calculation has to be done only for 100%.

3.4.1 Calculation for Quantity of Maltodextrin to be dispensed

**Actual quantity of Maltodextrin to be dispensed

= [Std. qty. of Ascorbic Acid + Std. qty. of Chlorphenamine Maleate + Std. qty. of Phenylephrine Hydrochloride + Std. qty. of Paracetamol + Std. qty. of Maltodextrin] - [Actual qty. of Ascorbic Acid + Actual qty. of Chlorphenamine Maleate + Actual qty. of Phenylephrine Hydrochloride + Actual qty. of Paracetamol]

$$= [10.000 + 4.000 + 2.000 + 130.000 + 443.000] - [10.030 + 4.057 + 130.000 + 130.268]$$

$$= 442.446 \text{ Kg}$$

$$\text{*Qty of Maltodextrin to be added per batch} = 442.446 \text{ Kg's}$$

Calculation done by(store)/date:

md
22/04/22

Checked by(production)/date:

md
22/04/22

Verified by(QA)/date:

md
22/04/22

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<i>md</i> 22/04/22	<i>md</i> 22/04/22	<i>md</i> 22/04/22	

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Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
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Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

4.0 A AFFIX DISPENSING CARD

		DISPENSING CARD	
Name of the Product : <u>GripeX</u>			
Material Name : <u>Lemon Lime PREMASEAL (75412-71)</u>			
A.R. No. : <u>msj02012021/01064</u>		G. wt. : <u>24.754</u>	
Batch No. : / Lot No. <u>G1722056</u>		T. wt. : <u>0.200</u>	
Batch Size : <u>200000</u>		N. wt. : <u>24.55414</u>	
Sign :	Stores : <u>msj</u>	Date : <u>22/04/22</u>	
	QA : <u>fr</u>	Date : <u>22/04/22</u>	
LBST : 001			

		DISPENSING CARD	
Name of the Product : <u>GripeX</u>			
Material Name : <u>Lemon Lime PREMASEAL (75412-71)</u>			
A.R. No. : <u>msj02012021/01255</u>		G. wt. : <u>28.000</u>	
Batch No. : / Lot No. <u>G1722056</u>		T. wt. : <u>3.000</u>	
Batch Size : <u>200000</u>		N. wt. : <u>25.000</u>	
Sign :	Stores : <u>msj</u>	Date : <u>22/04/22</u>	
	QA : <u>fr</u>	Date : <u>22/04/22</u>	
LBST : 001			

Dispensed by: msj / 22/04/22 Verified by (IPQA) sign/date: [Signature] / 22/04/22

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee
Signature with Date	<u>[Signature]</u> / <u>22/04/22</u>	<u>[Signature]</u> / <u>22/04/22</u>	<u>[Signature]</u> / <u>22/04/22</u>

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Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
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Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

4.0 B AFFIX DISPENSING CARD:

		DISPENSING CARD (16)	
Name of the Product : <u>GRIPEX</u>			
Material Name : <u>Paracetamol BP</u>			
A.R. No. <u>195/221215/150101052</u>		G. wt. : <u>25-250h</u>	
Batch No. : / Lot No. <u>G1722056</u>		T. wt. : <u>0-250h</u>	
Batch Size : <u>200000</u>		N. wt. : <u>25.000h</u>	
Sign :	Stores : <u>msb</u>	Date : <u>24/4/22</u>	
	QA : <u>FR</u>	Date : <u>22/04/22</u>	
LBST : 001			

		DISPENSING CARD (16)	
Name of the Product : <u>GRIPEX</u>			
Material Name : <u>Paracetamol BP</u>			
A.R. No. <u>195/221215/150101052</u>		G. wt. : <u>25-250h</u>	
Batch No. : / Lot No. <u>G1722056</u>		T. wt. : <u>0-250h</u>	
Batch Size : <u>200000</u>		N. wt. : <u>25.000h</u>	
Sign :	Stores : <u>msb</u>	Date : <u>22/04/22</u>	
	QA : <u>FR</u>	Date : <u>22/04/22</u>	
LBST : 001			

Dispensed materials label pasted by (production sign/date):

verified by (IPQA) sign/date:

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee	CONTROLLED COPY
Signature with Date	<u>21/04/22</u>	<u>21/04/22</u>	<u>21/04/22</u>	

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Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
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Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

4.0 C AFFIX DISPENSING CARD

		DISPENSING CARD 9/10	
Name of the Product : <u>GRIPEX</u>			
Material Name : <u>Orange PEKOE Extract</u>			
A.R. No. : <u>MSP/2021/00591</u>		G. wt. : <u>27.300 g</u>	
Batch No. : / Lot No. <u>G1722056</u>		T. wt. : <u>2.300 g</u>	
Batch Size : <u>200000</u>		N. wt. : <u>25.000 g</u>	
Sign :	Stores : <u>myh</u>	Date : <u>22/04/22</u>	
	QA : <u>FE</u>	Date : <u>22/04/22</u>	
LBST : 001			

		DISPENSING CARD 6/10	
Name of the Product : <u>GRIPEX</u>			
Material Name : <u>Orange PEKOE Extract</u>			
A.R. No. : <u>MSP/2021/00591</u>		G. wt. : <u>27.300 g</u>	
Batch No. : / Lot No. <u>G1722056</u>		T. wt. : <u>2.300 g</u>	
Batch Size : <u>200000</u>		N. wt. : <u>25.000 g</u>	
Sign :	Stores : <u>myh</u>	Date : <u>22/04/22</u>	
	QA : <u>FE</u>	Date : <u>22/04/22</u>	
LBST : 001			

Dispensed materials label pasted by (production sign/date: 22/04/22) verified by (IPQA) sign/date: 22/04/22

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee	CONTROLLED COPY
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BATCH MANUFACTURING RECORD					
Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
Generic:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/R0
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

4.0 D AFFIX DISPENSING CARD:

		DISPENSING CARD	
Name of the Product : <u>GRIPEX</u>			
Material Name : <u>Orange PEROE Extract</u>			
A.R. No. : <u>MSD/2021/001/002/00591</u>		G. wt. : <u>27.300</u>	
Batch No. : / Lot No. <u>G1722056</u>		T. wt. : <u>2.300</u>	
Batch Size : <u>200000</u>		N. wt. : <u>25.000</u>	
Sign :	Stores : <u>msb</u>	Date : <u>22/04/22</u>	
	QA : <u>[Signature]</u>	Date : <u>22/04/22</u>	
LBST : 001			

		DISPENSING CARD	
Name of the Product : <u>GRIPEX</u>			
Material Name : <u>Orange PEROE Extract</u>			
A.R. No. : <u>MSD/2021/001/002/00591</u>		G. wt. : <u>27.300</u>	
Batch No. : / Lot No. <u>G1722056</u>		T. wt. : <u>2.300</u>	
Batch Size : <u>200000</u>		N. wt. : <u>25.000</u>	
Sign :	Stores : <u>msb</u>	Date : <u>22/04/22</u>	
	QA : <u>[Signature]</u>	Date : <u>22/04/22</u>	
LBST : 001			

Dispensed materials label pasted by (production sign/date): <u>[Signature] 22/04/22</u>	verified by (IPQA) sign/date: <u>[Signature] 22/04/22</u>
---	---

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>[Signature] 21/04/22</u>	<u>[Signature] 21/04/22</u>	<u>[Signature] 21/04/22</u>	

		Safetab Life Science		MASTER COPY	
BATCH MANUFACTURING RECORD					
Page 14 of 31					
Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
Generic:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/R0
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

4.0 E AFFIX DISPENSING CARD:

		DISPENSING CARD	
Name of the Product : <u>GRIPEX</u>			
Material Name : <u>Orange PEKOE Extract</u>			
A.R. No. : <u>msp/2021/0001/2000056</u>		G. wt. : <u>27.300 kg</u>	
Batch No. : / Lot No. <u>G1722056</u>		T. wt. : <u>2.300 kg</u>	
Batch Size : <u>200000</u>		N. wt. : <u>25.000 kg</u>	
Sign :	Stores : <u>msb</u>	Date : <u>22/04/22</u>	
	QA : <u>Free</u>	Date : <u>22/04/22</u>	
LBST : 001			

		DISPENSING CARD	
Name of the Product : <u>GRIPEX</u>			
Material Name : <u>MALTO DEXTRIN</u>			
A.R. No. : <u>msp/2021/0001/2000056</u>		G. wt. : <u>25.250 kg</u>	
Batch No. : / Lot No. <u>G1722056</u>		T. wt. : <u>0.250 kg</u>	
Batch Size : <u>200000</u>		N. wt. : <u>25.000 kg</u>	
Sign :	Stores : <u>msb</u>	Date : <u>22/04/22</u>	
	QA : <u>Free</u>	Date : <u>22/04/22</u>	
LBST : 001			

Dispensed materials label pasted by (production sign/date: 22/04/22) verified by (IPQA) sign/date: 22/04/22

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee
Signature with Date	<u>[Signature]</u> 21/04/22	<u>[Signature]</u> 21/04/22	<u>[Signature]</u> 21/04/22

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BATCH MANUFACTURING RECORD

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Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
Generic:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/R0
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

4.0 F AFFIX DISPENSING CARD:

		DISPENSING CARD (3/18)	
Name of the Product : <u>GRIPEX</u>			
Material Name : <u>MALTODEXTRIN</u>			
A.R. No. : <u>msg/10223/04/04/00066</u>		G. wt. : <u>25.250 h.</u>	
Batch No. / Lot No. <u>G1722056</u>		T. wt. : <u>0.250 h.</u>	
Batch Size : <u>200000</u>		N. wt. : <u>25.000</u>	
Sign :	Stores : <u>ms</u>	Date : <u>22/04/22</u>	
	QA : <u>FD</u>	Date : <u>22/04/22</u>	
LBST : 001			

		DISPENSING CARD (1/18)	
Name of the Product : <u>GRIPEX</u>			
Material Name : <u>MALTODEXTRIN</u>			
A.R. No. : <u>msg/10223/04/04/00066</u>		G. wt. : <u>25.250 h.</u>	
Batch No. / Lot No. <u>G1722056</u>		T. wt. : <u>0.250 h.</u>	
Batch Size : <u>200000</u>		N. wt. : <u>25.000</u>	
Sign :	Stores : <u>ms</u>	Date : <u>22/04/22</u>	
	QA : <u>FD</u>	Date : <u>22/04/22</u>	
LBST : 001			

Dispensed materials label pasted by(production sign/date: 22/04/22 verified by(IPQA) sign/date: 22/04/22

	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	CONTROLLED COPY
Signature with Date	<u>22/04/22</u>	<u>22/04/22</u>	<u>22/04/22</u>	

	Safetab Life Science			MASTER COPY Page 16 of 31	
	BATCH MANUFACTURING RECORD				
Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
Generic:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/R0
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

4.0 G AFFIX DISPENSING CARD :

		DISPENSING CARD ^{10/18}	
Name of the Product : <u>GRIPEX</u>			
Material Name : <u>MALTODEXTRIN</u>			
A.R. No. : <u>msp/2223/105/102/100066</u>		G. wt. : <u>25-250 g</u>	
Batch No. : / Lot No. <u>G1722056</u>		T. wt. : <u>0-250 g</u>	
Batch Size : <u>200000</u>		N. wt. : <u>25.000 g</u>	
Sign :	Stores : <u>ms</u>	Date : <u>22/04/22</u>	
	QA : <u>Free</u>	Date : <u>22/04/22</u>	
LBST : 001			

		DISPENSING CARD ^{11/18}	
Name of the Product : <u>GRIPEX</u>			
Material Name : <u>MALTODEXTRIN</u>			
A.R. No. : <u>msp/2223/105/102/100066</u>		G. wt. : <u>25-250 g</u>	
Batch No. : / Lot No. <u>G1722056</u>		T. wt. : <u>0-250 g</u>	
Batch Size : <u>200000</u>		N. wt. : <u>25.000 g</u>	
Sign :	Stores : <u>ms</u>	Date : <u>22/04/22</u>	
	QA : <u>Free</u>	Date : <u>22/04/22</u>	
LBST : 001			

Dispensed materials label pasted by (production sign/date: 22/04/22 verified by (IPQA) sign/date: 22/04/22

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee
Signature with Date	<u>22/04/22</u>	<u>21/04/22</u>	<u>21/04/22</u>

CONTROLLED COPY

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page 17 of 31	
Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
Generic:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/R0
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

5.0 DISPENSING OF RAW MATERIALS AGAINST RAW MATERIAL INDENT:

Dispensing Started at Date 22/04/22 Time 16:50

S.No	Name of the Ingredients	Actual Qty. per batch (Kg)	A.R No:	Gross Weight (Kg)	Tare Weight (Kg)	Net Weight (Kg)	Weighed By Stores	Checked by stores	Verified by IPQA
1	Paracetamol BP	*	MSP/2122/ACH/ACR/01057	25.250	0.250	25.000	Ragu	mh	Pro
			MSP/2122/ACH/ACR/01057	25.250	0.250	25.000	Ragu	mh	Pro
			MSP/2122/ACH/ACR/01057	25.250	0.250	25.000	Ragu	mh	Pro
			MSP/2122/ACH/ACR/01057	25.250	0.250	25.000	Ragu	mh	Pro
2	Phenylephrine Hydrochloride BP	**	MSP/2122/ACH/ACR/00848	2.080	0.080	2.000	Ragu	mh	Pro
3	Chlorphenamine Maleate BP ***	***	MSP/2122/ACH/ACR/00823	4.237	0.237	4.000	Ragu	mh	Pro
4	Ascorbic Acid BP ****	****	MSP/2122/ACH/ACR/01098	10.250	0.250	10.000	Ragu	mh	Pro
5	Maltodextrin	443.000	MSP/2223/ACH/ACR/00066	25.250	0.250	25.000	Ragu	mh	Pro
			MSP/2223/ACH/ACR/00066	25.250	0.250	25.000	Ragu	mh	Pro
			MSP/2223/ACH/ACR/00066	25.250	0.250	25.000	Ragu	mh	Pro
			MSP/2223/ACH/ACR/00066	25.250	0.250	25.000	Ragu	mh	Pro
			MSP/2223/ACH/ACR/00066	25.250	0.250	25.000	Ragu	mh	Pro
			MSP/2223/ACH/ACR/00066	25.250	0.250	25.000	Ragu	mh	Pro
			MSP/2223/ACH/ACR/00066	25.250	0.250	25.000	Ragu	mh	Pro
			MSP/2223/ACH/ACR/00066	25.250	0.250	25.000	Ragu	mh	Pro
			MSP/2223/ACH/ACR/00066	25.250	0.250	25.000	Ragu	mh	Pro
			MSP/2223/ACH/ACR/00066	25.250	0.250	25.000	Ragu	mh	Pro

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>Ragu</u> 21/04/22	<u>[Signature]</u> 21/04/22	<u>[Signature]</u> 21/04/22	



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BATCH MANUFACTURING RECORD

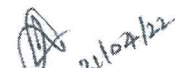
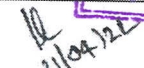
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Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
Generic:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/R0
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

S.No	Name of the Ingredients	Actual Qty. per batch (Kg)	A.R No:	Gross Weight (Kg)	Tare Weight (Kg)	Net Weight (Kg)	Weighed By Stores	Checked by stores	Verified by IPQA
6	Hydrophobic colloidal anhydrous silica	6.000	MSP/2022/GRH/GR/00560	2.100	0.100	2.000	Ragu	mb	FD
			MSP/2022/GRH/GR/00560	2.100	0.100	2.000	Ragu	mb	FD
			MSP/2022/GRH/GR/00560	2.100	0.100	2.000	Ragu	mb	FD
7	Citric Acid Monohydrate	10.000	MSP/2022/GRH/GR/00564	10.200	0.200	10.000	Ragu	mb	FD
8	Orange Pekoe Extract	240.000	MSP/2022/GRH/GR/00591	27.300	2.300	25.000	Ragu	mb	FD
			MSP/2022/GRH/GR/00591	27.300	2.300	25.000	Ragu	mb	FD
			MSP/2022/GRH/GR/00591	27.300	2.300	25.000	Ragu	mb	FD
			MSP/2022/GRH/GR/00591	27.300	2.300	25.000	Ragu	mb	FD
			MSP/2022/GRH/GR/00591	27.300	2.300	25.000	Ragu	mb	FD
			MSP/2022/GRH/GR/00591	27.300	2.300	25.000	Ragu	mb	FD
			MSP/2022/GRH/GR/00591	27.300	2.300	25.000	Ragu	mb	FD
9	Sucralose	5.000	MSP/2022/GRH/GR/00565	5.100	0.100	5.000	Ragu	mb	FD
10	Lemon lime Premaseal (75412-71)	50.000	MSP/2022/GRH/GR/0064	24.700	0.700	24.000	Ragu	mb	FD
			MSP/2022/GRH/GR/0064	24.700	0.700	24.000	Ragu	mb	FD
			MSP/2022/GRH/GR/0064	24.700	0.700	24.000	Ragu	mb	FD

Dispensing Completed at Date 22/04/22 Time 18:00

[*,**,***,****,# refer calculation]

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee	CONTROLLED COPY
Signature with Date	 21/04/22	 21/04/22	 21/04/22	

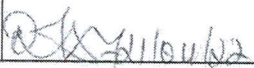
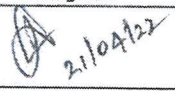
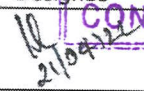
	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page 19 of 31	
Prod. ID:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
Generic:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/R0
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

6.0 VERIFICATION OF DISPENSED MATERIALS:

Date: 23/04/22

S.No.	Name of the Ingredients	Gross weight in Kg	A.R.No	Checked by Production Sign/date	Checked by IPQA Sign/date
1	Paracetamol BP	25.25	m&P/2122/QW/QR/01057	23/04/22	23/04/22
		25.25	m&P/2122/QW/QR/01057	23/04/22	23/04/22
		25.25	m&P/2122/QW/QR/01057	23/04/22	23/04/22
		25.25	m&P/2122/QW/QR/01057	23/04/22	23/04/22
		5.67	m&P/2122/QW/QR/01057	23/04/22	23/04/22
2	Phenylephrine Hydrochloride BP	2.08	m&P/2122/QW/QR/00848	23/04/22	23/04/22
		N.P			
3	Chlorphenamine Maleate BP	4.24	m&P/2122/QW/QR/00823	23/04/22	23/04/22
		N.P			
4	Ascorbic Acid BP	10.23	m&P/2122/QW/QR/01098	23/04/22	23/04/22
		N.P			
5	Maltodextrin BP	25.25	m&P/2223/QW/QR/00066	23/04/22	23/04/22
		25.25	m&P/2223/QW/QR/00066	23/04/22	23/04/22
		25.25	m&P/2223/QW/QR/00066	23/04/22	23/04/22
		25.25	m&P/2223/QW/QR/00066	23/04/22	23/04/22
		25.25	m&P/2223/QW/QR/00066	23/04/22	23/04/22
		25.25	m&P/2223/QW/QR/00066	23/04/22	23/04/22
6	Hydrophobic colloidal anhydrous silica	2.10	m&P/2122/QW/QR/00860	23/04/22	23/04/22
		2.10	m&P/2122/QW/QR/00860	23/04/22	23/04/22
7	Citric Acid Monohydrate BP	10.20	m&P/2021/QW/QR/00544	23/04/22	23/04/22
		N.P			
8	Orange Pekoe Extract IHS	27.30	m&P/2021/QW/QR/00591	23/04/22	23/04/22
		27.30	m&P/2021/QW/QR/00591	23/04/22	23/04/22
		27.30	m&P/2021/QW/QR/00591	23/04/22	23/04/22
9	Sucralose BP	5.10	m&P/2021/QW/QR/00543	23/04/22	23/04/22
		N.P			
10	Lemon lime Premaseal (75412-71)	24.76	m&P/2021/QW/QR/01064	23/04/22	23/04/22
		28.00	m&P/2122/QW/QR/01255	23/04/22	23/04/22
		0.47	m&P/2122/QW/QR/01255	23/04/22	23/04/22

Note: If any difference in weights same shall be routed through deviation and accordingly investigated and corrective action to be taken.

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 21/04/22	 21/04/22	 21/04/22	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page 19 of 31 (a)	
Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
Generic:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/RO
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

6.0 VERIFICATION OF DISPENSED MATERIALS:

Date: 23/04/23

S.No.	Name of the Ingredients	Gross weight in Kg	A.R.No	Checked by Production Sign/date	Checked by IPQA Sign/date
1	Paracetamol BP				
2	Phenylephrine Hydrochloride BP				
3	Chlorphenamine Maleate BP				
4	Ascorbic Acid BP				
5	Maltodextrin BP	25.25 25.25 25.25 25.25 25.25 17.64	mcp/2223/den/202/00066 mcp/2223/den/202/00066 mcp/2223/den/202/00066 mcp/2223/den/202/00066 mcp/2223/den/202/00066 mcp/2223/den/202/00066	323/04/23 323/04/23 323/04/23 323/04/23 323/04/23 323/04/23	323/04/23 323/04/23 323/04/23 323/04/23 323/04/23 323/04/23
6	Hydrophobic colloidal anhydrous silica				
7	Citric Acid Monohydrate BP				
8	Orange Pekoe Extract IHS	27.30 27.30 27.30 27.30	mcp/2021/den/202/00091 mcp/2021/den/202/00091	323/04/23 323/04/23	323/04/23 323/04/23
9	Sucralose BP				
10	Lemon lime Premaseal (75412-71)				

Note: If any difference in weights same shall be routed through deviation and accordingly investigated and corrective action to be taken.

Orange Pekoe Extract IHS

27.30
15.20

mcp/2021/den/202/00091
mcp/2021/den/202/00091

323/04/23
323/04/23

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee	CONTROLLED COPY
Signature with Date	 21/04/22	 21/04/22	 21/04/22	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page 20 of 31	
Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
Generic:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/R0
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

7.0 MANUFACTURING PROCESS:

7.1 LINE CLEARANCE CHECKS:

S.No	Check	Observation	
		Production	IPQA
1	Ensure that all empty containers, labels, used polybags, hand gloves of previous Product/ batch are removed from the area.	✓	✓
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.	✓	✓
3	Ensure that the previous batch BMR/ documents are removed from the area.	✓	✓
4	Check the housekeeping general cleanliness of the floor, walls ceiling, tube light fixture, supply grills, riser grills, filters, electrical fixtures and its panel surface are clean.	✓	✓
5	Check the cleanliness of the doors, door view panel, SOP stand and compressed air filter outer surface.	✓	✓
6	Check for absence of previous batch/product from area below machine and inside the vessel.	✓	✓
7	Check whether the equipment body of Sifter, RMG, FBD and Multimill, Utensils are clean.	✓	✓
8	Ensure that the balances are cleaned and it's calibration status.	✓	✓
9	Check whether the Equipments/ Instruments to be used are within calibration/preventive maintenance due date.	✓	✓
10	Check the cleanliness of the utility line (compressed air, First RO water and purified water).	✓	✓
11	Check the cleanliness of the drain points.	✓	✓
12	Check the status board of the area is updated.	✓	✓
12	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.	✓	✓
13	Check the differential pressure of the area should be within the limit	✓	✓
14	Ensure the concurrent entries of log book.	✓	✓
15	Ensure that all empty containers, labels, used polybags, hand gloves of previous Product/ batch are removed from the area.	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (Production) sign/date: 23/04/22

Verified by (IPQA) sign/date: 23/04/22

Equipment	Vibro sifter	Balance	Balance
		100.00Kg	6000.0g
Equipment ID No:	ST/PRVS/001		
Previous Product:	ABFLO N(N)		
Batch No.	S2287010P		
Cleaned by:	Manikandan		
Checked by:	Production: <u>23/04/22</u>	IPQA: <u>23/04/22</u>	

7.2 ENVIRONMENTAL CONDITIONS

Refer current version of SOP	Temperature: 23°C to 27°C	Date: 23/04/22	Time: 15:00	Date:	Time:
		Observation	Production Sign	Observation	Production Sign
	Relative Humidity: 45% to 55%	23.2°C	✓	NA	✓
		52%	✓		

7.3 APPROVAL FOR GRANULATION:

Production Sign/Date: 23/04/22

IPQA Sign/Date: 23/04/22

Designation	Prepared by:	Checked by:	Approved by:
	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	<u>23/04/22</u>	<u>23/04/22</u>	<u>23/04/22</u>

CONTROLLED COPY

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page 21 of 31	
Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
General:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/RO
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

7.4 MANUFACTURING PROCESS INSTRUCTIONS:

Date: 23/04/22

S. NO	PROCESS INSTRUCTIONS
1	Check the cleanliness of the mechanical sifter and RMG and FBD.
2	Use hand gloves while handling the materials.
3	Carryout the operation as per current version of SOP.
4	Check the integrity of sieve before and after sifting and record in the BMR.
5	Collect sifted and dried materials in cleaned containers in polythene bag.
6	Attach the dispensed material label in BMR.

7.5 SIFTING AND SIEVE INTEGRITY CHECK:

S. No	Name of Ingredient	Mesh size of sieve	Integrity checked before use	Checked By Production/ Date	Verified by IPQA/ date	Integrity checked after use	Checked By Production/ Date	Verified by IPQA/ date
1	Phenylephrine Hydrochloride BP	30#	OK/ Not OK	23/04/22	23/04/22	OK/ Not OK	23/04/22	23/04/22
2	Chlorphenamine Maleate BP	30#	OK/ Not OK	23/04/22	23/04/22	OK/ Not OK	23/04/22	23/04/22
3	Ascorbic acid BP	30#	OK/ Not OK	23/04/22	23/04/22	OK/ Not OK	23/04/22	23/04/22
4	Paracetamol BP	20#	OK/ Not OK	23/04/22	23/04/22	OK/ Not OK	23/04/22	23/04/22
5	Maltodextrin BP	30#	OK/ Not OK	23/04/22	23/04/22	OK/ Not OK	23/04/22	23/04/22
6	Hydrophobic colloidal anhydrous silica	20#	OK/ Not OK	23/04/22	23/04/22	OK/ Not OK	23/04/22	23/04/22
7	Orange Pekoe Extract IHS	60#	OK/ Not OK	23/04/22	23/04/22	OK/ Not OK	23/04/22	23/04/22
8	Sucralose	60#	OK/ Not OK	23/04/22	23/04/22	OK/ Not OK	23/04/22	23/04/22
9	Citric acid Monohydrate	20#	OK/ Not OK	23/04/22	23/04/22	OK/ Not OK	23/04/22	23/04/22
10	Lemon lime Premaseal (75412-71)	60#	OK/ Not OK	23/04/22	23/04/22	OK/ Not OK	23/04/22	23/04/22

Note: If any sieve damage observed same shall be reported for further course of action.

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	23/04/22	21/04/22	21/04/22	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page 22 of 31	
Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
Generic:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/R0
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

8.0 BLENDING AND LUBRICATION PROCESS:

8.1 LINE CLEARANCE CHECKS:

S.No	Checks	Observation	
		production	IPQA
1	Ensure that all empty containers, used polybags, labels, hand gloves of previous Product/ batch are removed from the area.	✓	✓
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.	✓	✓
3	Ensure that the previous batch BMR / documents are removed from the area.	✓	✓
4	Check the housekeeping general cleanliness of the floor, walls ceiling, tube light fixture, supply grills, riser grills, filters electrical fixtures and its panel surface are clean.	✓	✓
5	Check the cleanliness of the doors, door view panel and SOP stand.	✓	✓
6	Check the cleanliness of the utility line (compressed air, First RO water and purified water).	✓	✓
7	Check the cleanliness of the drain points.	✓	✓
8	Check for absence of previous batch/product from area below machine and inside machine by opening the guards of Octagonal blender.	✓	✓
9	Check whether the machine body and control panel of octagonal blender is clean.	✓	✓
10	Ensure that the balances are cleaned and it's calibration status.	✓	✓
11	Check whether the Equipments/ Instruments to be used are within calibration/preventive maintenance due date.	✓	✓
12	Check the status board of the area is updated with cleaned label.	✓	✓
13	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.	✓	✓
14	Check the differential pressure of the area should be within the limit.	✓	✓
15	Ensure the concurrent entries of log book.	✓	✓
16	Check the functioning and cleaning of return riser.	✓	✓
17	In case of materials / Intermediate products transferred between Block A and Block B, ensure that the containers received are clean and free from contamination.	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (production) sign/date: 23/04/22

Verified by (IPQA) sign/date: 23/04/22

Equipment	Octagonal blender		
Code No	ST/PROB/001		
Previous product	ABFLO N		
Batch No	S 2287010D		
Cleaned by:	Suresh		
Checked by:	Production: <u>23/04/22</u>	IPQA: <u>23/04/22</u>	

8.2 ENVIRONMENTAL CONDITIONS:

		Date: 23/04/22	Time: 15:05	Date:	Time
		Observation	Production Sign	Observation	Production Sign
Refer to current version of SOP	Temperature: 23°C to 27°C	23.2°C	✓	N/A	✓
	Relative Humidity: 45% to 55%	50%	✓		

8.3 APPROVAL FOR BLENDING AND LUBRICATION:

Production Sign/Date: 23/04/22 IPQA Sign/Date: 23/04/22

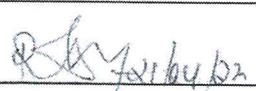
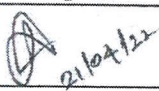
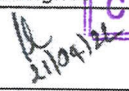
	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>23/04/22</u>	<u>21/04/22</u>	<u>21/04/22</u>	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page 23 of 31	
Product ID:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
Generic:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/R0
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

8.4 BLENDING PROCESS INSTRUCTION:

Step No	Process Instructions	Date : 23/04/22		Done By	Checked by
		Time			
		Started	Completed		
1	Operate the octagonal blender as per current version of SOP.				
2	Step (I): Co-sift Phenylephrine Hydrochloride, Chlorphenamine Maleate and ascorbic acid through 30#.	15:15	15:35	balaji	
3	Step (II): Mix step (I) material with maltodextrin in geometrical dilution method by sifting through 30#.	15:37	15:55	balaji	
4	Co-sift step (III) with paracetamol through 20#.	15:57	16:45	balaji	
5	Step (iv) Load the above sifted material into the octagonal blender and mix for 20 minutes and then sift through 20#.	17:10	17:30	balaji	
6	Step (v) Hydrophobic colloidal anhydrous silica and Citric acid Monohydrate through 20#.	17:58	18:15	balaji	
7	Step (vi) Sift sucralose, lemon lime premaseal 75412-71 and Orange Pekoe Extract through 60#.	18:20	18:35	balaji	
8	Transfer the sifted material step (iv), step (v) and step (vi) into the octagonal blender and mix for 20 minutes *	18:50	19:10	balaji	
9	Unload the final blend into double polybag lined container with Proper status label.	19:20	19:45	balaji	

8-1 * Blending 5 mins - 19:12 19:17 Balaji 

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 21/04/22	 21/04/22	 21/04/22	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page 24 of 31	
Product ID:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
General:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/R0
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

8.5 WEIGHING OF LUBRICATED BLEND:

Date: 23/04/22

Container No	Gross weight in kg	Tare weight in kg	Net weight in kg	Container No	Gross weight in kg	Tare weight in kg	Net weight in kg
1	34.93	2.60	32.33	30			
2	30.30	2.70	27.60	31			
3	28.86	2.74	26.12	32			
4	40.82	2.90	37.92	33			
5	39.48	2.94	36.54	34			
6	39.96	3.04	36.92	35			
7	40.04	2.80	37.24	36			
8	40.39	2.89	37.50	37			
9	39.79	2.95	36.84	38			
10	42.47	2.97	39.50	39			
11	32.45	2.70	29.75	40			
12	39.69	3.18	36.51	41			
13	40.91	2.80	38.11	42			
14	34.88	3.10	31.78	43			
15	39.43	3.02	36.41	44			
16	45.47	3.17	42.30	45			
17	40.57	2.93	37.64	46			
18	32.65	2.64	30.01	47			
19	30.95	2.55	28.40	48			
20	38.19	3.00	35.19	49			
21	31.84	2.64	29.20	50			
22	40.82	2.90	37.92	51			
23	40.77	2.86	37.91	52			
24	30.96	2.65	28.31	53			
25	38.88	3.17	35.71	54			
26	37.84	3.00	34.84	55			
27				56			
28				57			
29				58			

Weighed by: Mami Kandy

Checked by:

Total weight of lubricated blend

898.50 kg

Intimate to IPQA for collect the Lubricated blend sample.

Sample withdrawn by IPQA.

Production Sign: Date: 23/04/22

IPQA Sign: Date: 23/04/22

Send Test request form and Lubricated blend sample to QC for analysis purpose.

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	23/04/22	23/04/22	23/04/22	

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	BATCH MANUFACTURING RECORD			Page 25 of 31	
Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
Generic:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/R0
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

9.0 RECONCILIATION:

1.0	Theoretical weight of Lubricated blend	:	900.00 Kg
2.0	Actual weight of Lubricated blend	:	898.50 Kg
3.0	Manufacturing Loss (1.0 - 6.0)	:	0.48 Kg
4.0	In-process samples		
	A IPQA Samples	:	- Kg
	B QC Samples	:	0.05 Kg
	C Validation Samples + Pooled sample	:	0.20 + 0.250 Kg
	D Others Hold time Study		0.50
5.0	Total samples: (A + B + C)	:	1.02 Kg
6.0	Total: (5.0+2.0)	:	899.52 Kg
7.0	% Yield = $\frac{6.0}{1.0} \times 100$ (Limit- NLT 99.00%)	:	99.95 %
Yield reconciliation Done by Production sign/Date: <u>23/04/22</u> Checked by IPQA sign/Date: <u>23/04/22</u>			
Total rejects destroyed: <u>0.48</u> Kg. (Rejected materials should be destroyed in the presence of QA.)			
Rejection destroyed by Production sign/Date: <u>23/04/22</u> Checked by IPQA sign/Date: <u>23/04/22</u>			

9.1 BLEND APPROVAL CHECK FOR SACHET FILLING AND PACKING:

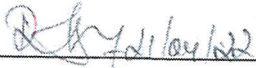
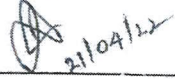
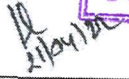
Reconciliation checked and blend released for sachet filling and packing.

Production sign/Date: 29/04/22 IPQA sign/Date: 29/04/22

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>29/04/22</u>	<u>29/04/22</u>	<u>29/04/22</u>	

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	BATCH MANUFACTURING RECORD			Page 26 of 31	
Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
Generic:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/R0
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

10.0 PROCESS HISTORY
/ NA 29/04/22

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 21/04/22	 21/04/22	 21/04/22	

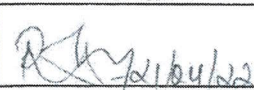
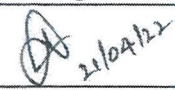
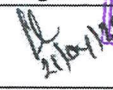
	Safetab Life Science			MASTER COPY Page 27 of 31	
	BATCH MANUFACTURING RECORD				
Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
Generic:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/R0
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

11.0 Following the BMR records in additional attached.		Checked by Production Head	Reviewed by QA Head
1	Raw Materials dispensed labels	✓	✓
2	Lubricated blend analytical report	✓	✓
Note: Tick mark (✓) if Complies and (X) if Does not comply.			
This Batch Manufacturing Record reviewed on date..... <u>27/04/22</u> Production Head or designee sign/date.....<u>[Signature]</u>.....<u>27/04/22</u>			
This Batch Manufacturing Record received, reviewed and batch is released for Filling and packing on date..... <u>27/04/22</u> Reviewed by QA Head.....<u>[Signature]</u>.....<u>27/04/22</u>			

	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee	CONTROLLED COPY
Designation				
Signature with Date	<u>[Signature]</u> <u>21/04/22</u>	<u>[Signature]</u> <u>21/04/22</u>	<u>[Signature]</u> <u>21/04/22</u>	

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	BATCH MANUFACTURING RECORD			Page 28 of 31	
Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
Generic:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/R0
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

12.0 ABBREVIATIONS					
S.no	Short form	Abbreviation	S.no	Short form	Abbreviation
1	BP	British Pharmacopeia	19	Spec	Specification
2	BMR	Batch Manufacturing Record	20	SOP	Standard Operating Procedure
3	MFG	Manufacturing	21	°C	Degree Celsius
4	QA	Quality Assurance	22	%	Percentage
5	Kg	Kilogram	23	WB	Weighing Balance
6	g	Gram	24	LOD	Loss On Drying
7	Min	Minutes	25	AR.No.	Analytical Report Number
8	RMG	Rapid Mixing Granulator	26	IPQA	In Process Quality Assurance
9	FBD	Fluid Bed Drier	27	TRF	Test Request Form
10	B.No	Batch number	28	ID no.	Identification Number
11	mg	Milligram	29	Std	Standard
12	Qty	Quantity	30	No's	Numbers
13	QC	Quality Control	31	Sign	Signature
14	IHS	In House Specification	32	MFC	Master Formula Card
15	NMT	Not More than	33	L	Liter
16	±	Plus or Minus	34	IR	Infra-Red
17	ST	Safetab	35	RO	Reverse osmosis
18	Exp	Expired	36	SS	Stainless steel

	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 21/04/22	 21/04/22	 21/04/22	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page 29 of 31	
Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
Generic:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/RO
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

BMR COPY/QUALITY CONTROL COPY

13.0 TEST REQUEST FORM FOR LUBRICATED BLEND:

From: Manufacturing Department To be filled by production Date of Mfg.: 04/2022 Date of exp.: 03/2025 Test Request for: Complete analysis TRF raised by: [Signature] on date: 23/04/22		To: Q.A. Department To be filled by IPQA Quantity Sampled: 50gms Sampled by: [Signature] on date: 23/04/22 No. of containers: 26	
To be filled by QC TRF & sample received on Sign and Date: [Signature] 24/04/22 Sample tested on: 24/04/22			
Test Results		Limits	
Each 4500mg granular contains: Assay: phenylephrine HCl: 9.84mg (98.4%) paracetamol: 637.83mg (98.1%) chlorphenamine maleate: 20.26mg (101.3%) Ascorbic Acid: 51.53mg (103.1%)			
Analytical Reference no.: 6D/00444/2022 Analysed By: [Signature] on: 27/04/2022		Space for QC Approval (Stamping and Signing)  Sign: [Signature] Date: 27/04/22	

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	[Signature] 21/04/22	[Signature] 21/04/22	[Signature] 21/04/22	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page 30 of 31	
Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
Generic:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/RO
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

14.0 BATCH MANUFACTURING RECORD REVIEW CHECK LIST		
S.No. No.	CHECK POINTS	Status
1	The entire Page no: <u>01</u> to <u>31</u> are available, verified and found correct.	Yes / No
2	Batch numbers available in all pages verified and are correct.	Yes / No
3	Manufacturing and expiry is correctly allotted verified.	Yes / No
4	Dispensing carried out on calibrated balance verified.	Yes / No
5	Dispensing Cards attached.	Yes / No
6	Line clearance is taken prior to all dispensing and manufacturing activities.	Yes / No
7	Dispensing is carried out as per indent of raw materials are correct.	Yes / No
8	Environmental conditions comply during all the manufacturing steps.	Yes / No
9	All wrong entries if any have been strike out and signed and verified.	Yes / No
10	Actual equipment used is as specified and verified.	Yes / No
11	Blending reconciliation is filled and variance is within acceptance limit.	Yes / No
Note:	If any abnormalities noticed during batch manufacturing record review it should be brought to the notice of QA Head.	

Batch Manufacturing Record reviewed by IPQA Sign/Date: 21/04/22

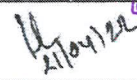
QA Head Sign/Date: 21/04/22

	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>21/04/22</u>	<u>21/04/22</u>	<u>21/04/22</u>	

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	BATCH MANUFACTURING RECORD				
Product:	GRIPEX	Product ID No.:	1048	Batch Size	200000 sachets
Generic:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Ascorbic Acid Powder	MFC NO:	ST/MFC/136/R1	Supersedes MFC No:	ST/MFC/136/RO
Batch No.:	G1722056	Mfg. Date:	04/2022	Exp. Date	03/2025

15.0 REVISION HISTORY:

Revision No.	Date of Revision	Changes Made	Effective Batch No.	Effective Date.
00	13.11.2020	1. New product refer change control no: ST/CC/20/074.	NA	NA
01	21/04/22	1. Bill of material changed. Refer change control no: ST/CC/22/024	G1722056	22/04/22

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 21/04/22	 21/04/22	 21/04/22	