

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 1 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: <u>GF 210301</u> Generic Health Care Pvt. Ltd.

BATCH MANUFACTURING RECORD COVER SHEET

PRODUCT NAME : GENSET
 GENERIC NAME : Cetirizine Tablets BP 10 mg
 LABEL CLAIM : Each film coated tablet contains:
 Cetirizine Hydrochloride BP10 mg
 Excipients q.s.
 Colour: Approved colour used
 MFR No. / Reference Document No. : MFR/T/106-00
 BMR No. : BMR/T/195-00
 REVISION No. : 00
 SUPERSEDES No. : NIL
 BMR EFFECTIVE BATCH NUMBER/DATE : GF 210101 / 01/01/2021
 MFG.LIC No. : PON/DRUGS/19 13 4323
 STORAGE : Store in cool and dry place. Protect from light and moisture.
 BMR ISSUED BY/DATE (QA) : [Signature] 25/03/2021
 BMR CHECKED & RECEIVED BY/DATE (PRODUCTION) : L. Ke 25/03/2021
 SHELF LIFE : 36 Months
 BATCH SIZE : 30,00,000 Tablets (362.400 Kg)
 MFG. DATE: 03/2021 EXP. DATE: 02/2024

RECOVERY ADDITION RECORD

BATCH NO	MFG	EXP	QUANTITY	REVISED BATCH SIZE
1		NB		1

ALLOTTED BY: [Signature] 25/03/2021
 QA SIGN/DATE:
 DATE OF COMMENCEMENT: 31/03/2021
 DATE OF COMPLETION: 03/05/2021
 RELEASED QUANTITY OF TABLETS FOR PACKING : 2907455 Nos
 RELEASE FOR PACKING STAGE : [Signature] 03/05/2021
 HEAD OF QA SIGN/DATE:

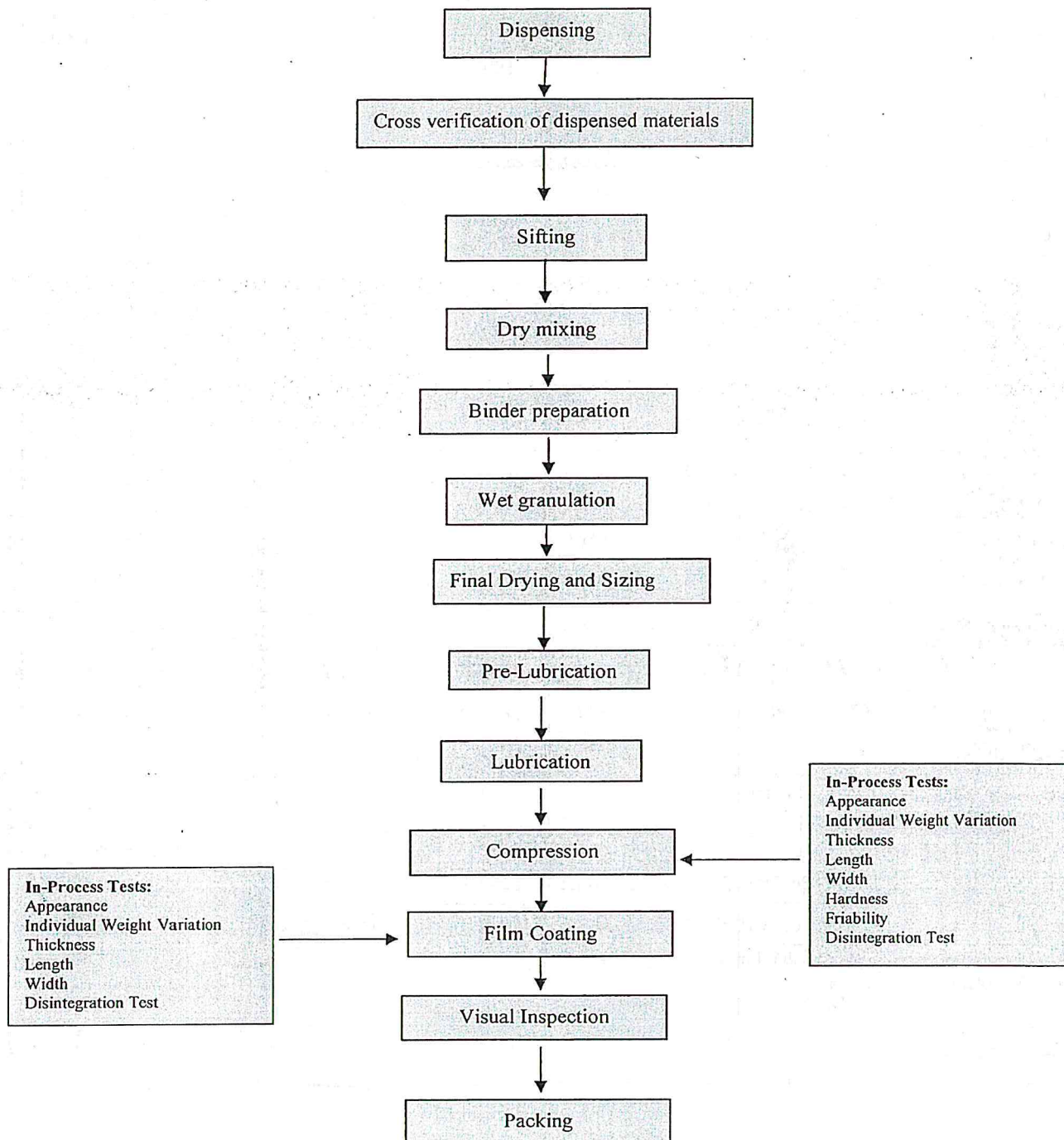
This BMR contains 58 Pages + 10 Additional Pages

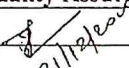
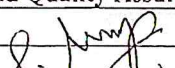
Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ke</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>

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	BATCH MANUFACTURING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMRT/195-00	Batch No.: G13210301
		Customer:	Generic Health Care Pvt. Ltd.

2.0 PROCESS FLOW CHART



Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.			
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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	BATCH MANUFACTURING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
	Product	GENSET	BMR. No.: BMR/T/195-00 Batch No.: 5210201 Customer: Generic Health Care Pvt. Ltd.

3.0 INDENT OF ACTIVE PHARMACEUTICAL INGREDIENTS & EXCIPIENTS:

Sr. No.	Name of the Ingredient	Spec.	Item Code	Quantity/ Tablets (mg)	Std. quantity per 30,00,000 tablets (kg)	OA/ PL (%)	Req. quantity per 30,00,000 tablets (kg)
Dry mixing material:							
1	Cetirizine Hydrochloride*	BP	RAI/SP/C018	10.000	30.000	-	30.000
2	Dried Maize Starch**	BP	IRM/SP/M001	59.900	179.700	-	179.700
3	Lactose Monohydrate	BP	REX/SP/L003	32.800	98.400	-	98.400
Binder Material:							
4	Dried Maize Starch	BP	IRM/SP/M001	4.270	12.810	-	12.810
5	Purified Water	BP	NA	q.s.	40.000	-	40.000
Theoretical Weight of Dried Granules				106.970	320.910	-	320.910
Lubrication Material:							
6	Colloidal Silicon Dioxide	BP	REX/GH/C001	0.470	1.410	-	1.410
7	Sodium Starch Glycollate	BP	REX/GH/S001	5.880	17.640	-	17.640
8	Purified Talc	BP	REX/SP/P011	2.340	7.020	-	7.020
9	Magnesium Stearate	BP	REX/GH/M001	2.340	7.020	-	7.020
Theoretical Weight of the Lubricated granules				118.000	354.000	-	354.000
Theoretical weight of Compressed tablet				118.000	354.000	-	354.000
Coating Material:							
10	Instacoat White (IC-U-3849)	IHS	REX/SP/I006	3.500	10.500	-	10.500
11	Purified Water	BP	NA	q.s.	25.000	-	25.000
Theoretical weight of Coated tablet				121.500	364.500	-	364.500
Actual weight of Coated tablet				120.800@	362.400@	-	362.400@

NOTE: *API quantity shall be calculated based on potency.

OA: Overages, PL: Process loss

@Average weight has calculated and rounded off to 80% of coating material

Potency calculation:

Theoretical Quantity of Cetirizine Hydrochloride required in Kg for a batch size of 30,00,000 Tablets are calculated.

** Excess Quantity shall be compensating from Dried Maize Starch

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	POA	31/12/2020	8. [Signature]
Date	31/12/2020	21/12/2020		31/12/2020

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