

STABILITY BATCH

VALIDATION BATCH

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 37
SAI PRIMUS LIFE BIOTECH PVT LTD	BATCH MANUFACTURING RECORD	Product Code: B05
Product	BONCIPRO 500	Batch Size: 3,00,000 Tablets
		BMR. No.: BMR/T/305-00
		Batch No.: <u>G1822068</u>
		Customer: Generic Health Care Pvt. Ltd.

BATCH MANUFACTURING RECORD COVER SHEET

PRODUCT NAME : BONCIPRO 500

GENERIC NAME : Ciprofloxacin Tablets BP 500 mg

LABEL CLAIM : Each film coated tablet contains:
Ciprofloxacin Hydrochloride BP
Equivalent to Ciprofloxacin 500 mg
Colour: Approved Colour used.

MFR No. / Reference Document No. : MFR/T/177-00

BMR No. : BMR/T/305-00

REVISION No. : 00

SUPERSEDES No. : NIL

BMR EFFECTIVE BATCH NUMBER/DATE : G1822068 / 01/04/2022

MFG. LIC No. : PON/DRUGS/21 14 4376

STORAGE : Store in cool and dry place. Protect from light and moisture.

BMR ISSUED BY/DATE (QA) : [Signature] 01/04/22

BMR CHECKED & RECEIVED BY/DATE (PRODUCTION) : L. Ka 01/04/2022

SHELF LIFE : 36 Months

BATCH SIZE : 3,00,000 Tablets (220.800 Kg)

MFG. DATE: 04/02/22 : EXP. DATE: 03/2025

RECOVERY ADDITION RECORD

BATCH NO	MFG	EXP	QUANTITY	REVISED BATCH SIZE
		<u>NA</u>		

ALLOTTED BY: [Signature] 01/04/22 : COUNTER CHECKED BY: [Signature] 01/04/22

QA SIGN/DATE: : QA SIGN/DATE:

DATE OF COMMENCEMENT: 04/04/22 : DATE OF COMPLETION: 12/04/2022

RELEASED QUANTITY OF TABLETS FOR PACKING : 292707 Nos

RELEASE FOR PACKING STAGE : [Signature] 12/04/22

HEAD OF QA SIGN/DATE:

This BMR contains 37 Pages + 05 Additional Pages

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>P. Anand</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>

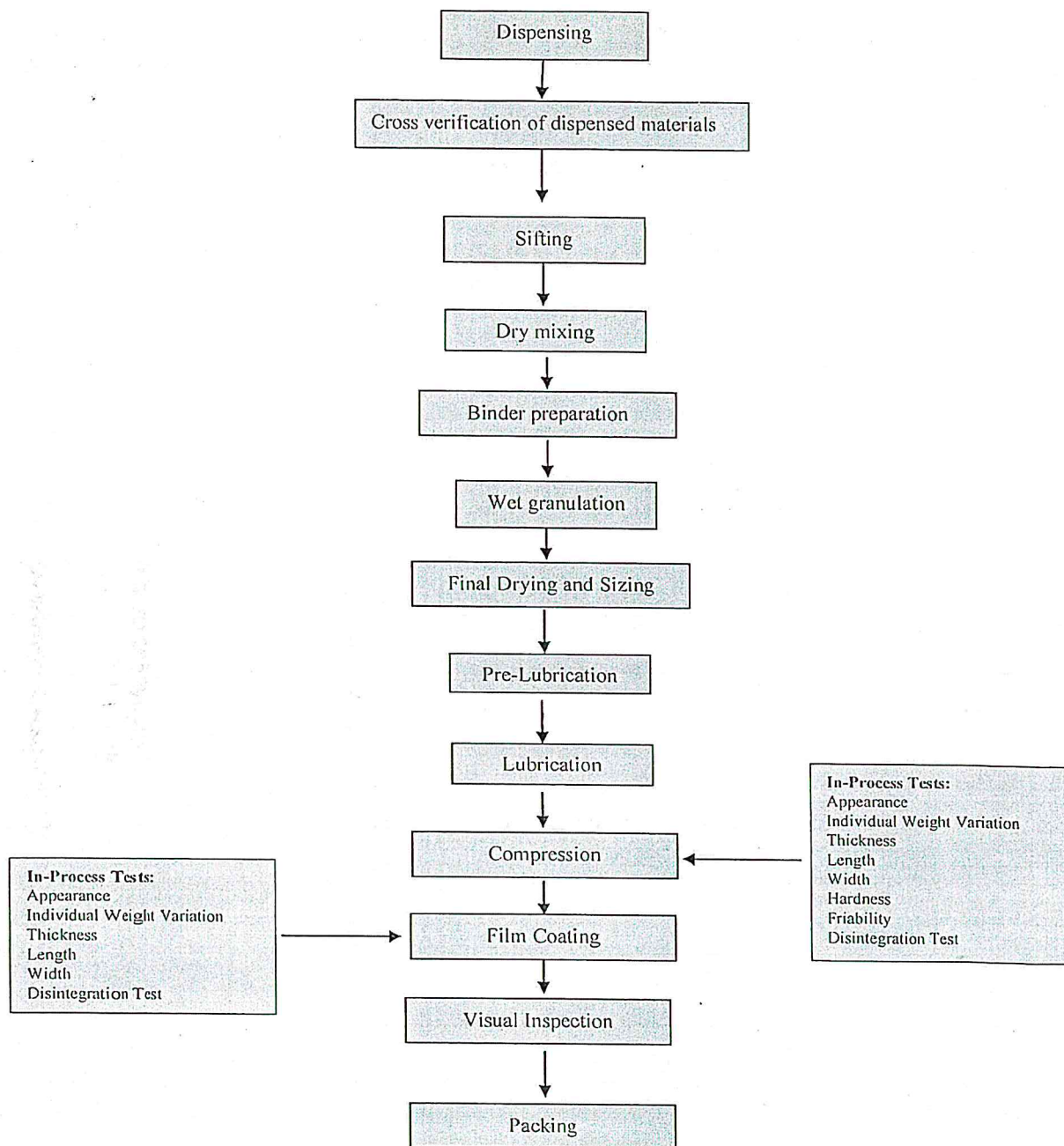
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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 3 of 37
	BATCH MANUFACTURING RECORD	Product Code: B05	Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00	Batch No.: 61822068
		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. Ka	P. Anub	V. S.	V. S.
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 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 4 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
	Product BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: 618 22068 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 3,00,000 tablets (kg)	OA/ PL (%)	Req. quantity per 3,00,000 tablets (kg)
Dry mixing material:							
1	Ciprofloxacin Hydrochloride*	BP	RAI/SP/C015	582.200	174.660	-	174.660
2	Microcrystalline cellulose PH102 **	BP	REX/SP/M010	108.050	32.415	-	32.415
Binder Material:							
3	Purified Water	BP	NA	q.s.	83.000	-	83.000
Theoretical Weight of Dried Granules				690.250	207.075	-	207.075
Lubrication Material:							
4	Sodium Stach Glycollate	BP	REX/SP/S004	21.000	6.300	-	6.300
5	Colloidal Silicon Dioxide	BP	REX/SP/C022	1.750	0.525	-	0.525
6	Magnesium Stearate	BP	REX/SP/M011	7.000	2.100	-	2.100
Theoretical Weight of the Lubricated granules				720.000	216.000	-	216.000
Theoretical weight of Compressed tablet				720.000	216.000	-	216.000
Coating Material:							
7	Hydroxy Propyl Methyl Cellulose (6 cps)	BP	REX/SP/H016	10.800	3.240	25	4.050
8	Titanium Dioxide	BP	REX/SP/T002	1.200	0.360	25	0.450
9	Ponceau 4R Lake	IHS	REX/SP/P006	0.600	0.180	25	0.225
10	Purified Talc	BP	REX/SP/P017	1.000	0.300	25	0.375
11	Polyethylene Glycol 6000	BP	REX/SP/P003	2.400	0.720	25	0.900
12	Purified Water	BP	NA	q.s.	42.500	-	42.500
Theoretical weight of Coated tablet^s				736.000	220.800	-	220.800

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

** Excess Quantity shall be compensating from Microcrystalline cellulose PH 102

\$ Average weight rounded off.

OA: Overages, PL: Process loss

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. Anil	V. Anil	V. Anil
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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