PROCESS VALIDATION PROTOCOL

PRODUCT : BONCIPRO 500

SHELF LIFE : 36 MONTHS

APPROVAL

S. No.	ACTIVITY	NAME	DESIGNATION	SIGNATURE/ DATE
1	PREPARED BY	Ram Kumar	QUALITY ASSURANCE	01/04/22
2	CHECKED BY	[illegible]	MANAGER PRODUCTION	01/04/2022
3	REVIEWED BY	A. Vallarasan	AGM QUALITY CONTROL	01/04/2022
4	APPROVED BY	R. Stephen	MANAGER QUALITY ASSURANCE	01/04/22

MASTER COPY

Controlled Copy No : 01
Sign / Date : 01/04/22

UNCONTROLLED COPY

INDEX

Product name	BONCIPRO 500	Effective Date	01/04/2022
Protocol No.	PVP: B05	Ref. SOP No.	QAGN/017

1.0 INTRODUCTION

The protocol describes the steps to be followed to evaluate and qualify the acceptability of the manufacturing process.

2.0 PURPOSE

To establish that the manufacturing process for **BONCIPRO 500** meets the predetermined specifications and quality attributes.

3.0 SCOPE

All critical stages in the manufacture of **BONCIPRO 500** that affect product quality with variations in process parameters are covered and a range is established to ensure that the process performs under these conditions to produce a product meeting its predetermined specifications and quality characteristics. The process parameters and results are documented in Process Validation Report. The report is reviewed, conclusion is drawn and finally certified if the recorded data's comply with the acceptance criteria.

4.0 RESPONSIBILITIES

Maintenance	:	To certify the equipment & support systems
Production	:	1. To design, Optimize & qualify manufacturing process within design limits/ specifications / requirements.
	:	2. To operate & maintain the equipment & support systems and the manufacturing process within its design limits/ specifications/ requirements.
Quality control	:	To establish and conduct testing for all samples drawn at different stages of process validation compliance with design specifications
Quality Assurance	:	To conduct the process Validation by carrying out all in process sampling and auditing the specific manufacturing process for compliance with design parameters, limits and specifications and adhere to cGMP regulations.

5.0 PROCEDURE

Execute three consecutive batches as per the Batch manufacturing record. Record the critical parameters of the manufacturing unit operations as described in the Process Validation protocol. Also compile subsequent test results in the Process Validation Report. In case of any deviation(s) observed they must be noted down in the deviation report immediately. The deviation must be noted in succession throughout the process along with the corrective action.

6.0 PRODUCT DETAILS

Product Name	**BONCIPRO 500**
Dosage Form	Tablets
Label Claim	Each film coated tablet contains: Ciprofloxacin Hydrochloride BP Equivalent to Ciprofloxacin ..... 500 mg Colour: Approved Colour used.
Batch size	3,00,000 Tablets
Shelf Life	36 Months

7.0 REFERENCE DOCUMENTS

Batch Manufacturing Record	BMR/T/305-00
Finished Product specifications	FPS-B05
SOP for Process Validation	QAGN/017

Note: All approved current version of relevant SOPs and documents must be referred

8.0 REASON FOR VALIDATION

Reasons	Tick in the appropriate row	Reasons	Tick in the appropriate row
New formulation	√	Significant changes in process	-
Change in formulation	-	Change/modification in equipment	-
Change in location	-	Any other reasons (specify)	-

9.0 EQUIPMENT DESCRIPTION

9.1 Process Equipment Details

S. No.	Equipment name	Equipment ID No	Calibration/qualification status
1.	Dispensing Booth	ST/DSB/001	Qualified
2.	Vibratory sifter	PD/VBS/001	Qualified
3.	RMG	RD/RMG/001	Qualified
4.	FBD	RD/FBD/001	Qualified
5.	Multi mill	RD/MLM/001	Qualified
6.	Octagonal blender	PD/OCB/001	Qualified
7.	Compression machine	PD/COM/002	Qualified
8.	Packing machine (Blister Packing)	PD/BLP/001	Qualified
9.	Weighing balance (IPQA)	QA/BAL/002	Calibrated
10.	Vernier caliper	QA/VEC/001	Calibrated
11.	Friability apparatus	QA/FRT/001	Calibrated
12.	Hardness tester	QA/HRT/001	Calibrated
13.	Moisture balance	QA/MTA/001	Calibrated
14.	Tap density tester	QC/TDA/001	Calibrated
15.	Dissolution test apparatus	QC/DIS/001	Qualified
16.	Sieve Shaker	QC/SSH/001	Qualified
17.	HPLC	QC/HPL/001	Qualified
18.	UV	QC/UVS/001	Qualified

Note – The equipment to be used should be validated and calibrated one.

10.0 FLOW CHART FOR THE MANUFACTURING PROCESS

SIFTING

Ciprofloxacin Hydrochloride	40#
Microcrystalline cellulose PH102	40#
Sodium Stach Glycollate	60#
Colloidal Silicon Dioxide	60#
Magnesium Stearate	60#

↓

DRY MIXING

Load the sifted Material of Ciprofloxacin Hydrochloride, Microcrystalline cellulose PH 102 in to RMG and Mix for 10 minutes with impeller at slow speed and chopper off.

↓

GRANULATION, DRYING & SIZING

Add Purified water into the contents of RMG take 2 - 5 min for water addition with impeller slow speed and Chopper OFF. After Water addition allow mixing to form a coherent mass. If required allow mixing for 1 min or till required consistency of granules obtained with impeller at slow speed and chopper at slow speed. Discharge the wet mass to FBD bowl or Tray drier operating slow speed of Impeller and slow speed of Chopper.

Load the wet mass in to FBD at inlet temperature 60-65°C until the LOD reach to desirable limit.

Pass the dried granules through SS sieve 20#. Retained granules pass through multi mill using with 2.0 mm and sieve through SS sieve 20#.

→ • LOD of dried granules

↓

Load the dried and sifted material in to the blender. Add Sodium Starch Glycollate, Colloidal Silicon Dioxide. Then mix for 10 minutes at 10 RPM. Add Magnesium Stearate in to the blender and run the machine for about 3 minutes at 10 RPM.

→
- Description of the blend
- Assay
- Bulk Density *
- Tapped Density *
- LOD *

↓

COMPRESSION

→
- Appearance
- Group weight
- Individual weight Variation
- Thickness
- Hardness
- Friability
- Assay
- Thickness

↓

COATING

←
- Appearance
- Group weight
- Individual weight Variation
- Thickness

↓

PACKING

* For Information only

11.0 MANUFACTURING FORMULA (REFER INDENT)

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$			736.000	220.800		220.800

12.0 PROCESS CONTROL STEPS

S. No	STAGES	TESTS TO BE CARRIED OUT
1	Drying	LOD of dried granules
2	Blending & Lubrication	Assay of Ciprofloxacin Hydrochloride #, Description of blend #, Bulk density#*, Tapped density#*
3	Compression (Initial, middle and end)	Appearance, Group weight, Individual weight Variation, Thickness, Hardness Friability, Thickness, Assay
4	Compression (Low hardness and high hardness)(RPM Challenge)	Appearance, Group weight, Individual weight Variation, Thickness, Hardness Friability, Thickness, Assay
5	Coating	Appearance, Group weight, Individual weight Variation, Thickness, Assay
6	Packing (Initial, middle and end)	Sealing / Forming Temperature, Sealing quality, Batch coding details Leak test

* For information only
# Composite Sample

13.0 MANUFACTURING PROCESS

13.1 SIFTING

Sift Ciprofloxacin Hydrochloride (40#), Microcrystalline Cellulose PH 102 (40#), Sodium Starch Glycollate (60#), Colloidal Silicon Dioxide (60#) and Magnesium Stearate (60#).

13.2 DRY MIXING

Load the sifted Material of Ciprofloxacin Hydrochloride and Microcrystalline Cellulose PH 102 in to RMG and Mix for 10 minutes with impeller at slow speed and chopper off.

13.3 GRANULATION, DRYING & SIZING

Add Purified water into the contents of RMG take 2 - 5 min for water addition with impeller slow speed and Chopper OFF. After Water addition allow mixing to form a coherent mass. If required allow mixing for 1 min or till required consistency of granules obtained with impeller at slow speed and chopper at slow speed. Discharge the wet mass to FBD bowl by operating slow speed of Impeller and slow speed of Chopper.
Load the wet mass in to FBD at inlet temperature 60-65°C until the LOD reach to desirable limit.
Pass the dried granules through SS sieve 20#. Retained granules pass through multi mill using with 2.0 mm and sieve through SS sieve 20#.

13.4 BLENDING & LUBRICATION

Load the dried and sifted material in to the blender. Add Sodium Starch Glycollate, Colloidal Silicon Dioxide. Then mix for 10 minutes at 10 RPM. Add Magnesium Stearate in to the blender and run the machine for about 3 minutes at 10 RPM.

13.5 COMPRESSION PARAMETER:

Sr. No.	Parameter	Limits
1.	Appearance	White coloured caplet shaped uncoated tablet with breakline on one side and plain on other side.
2.	Average weight (mg)	720.000 mg ± 3.0 % (698.400 mg – 741.600 mg)
3.	Group Weight	14.400 g ± 3.0 % (13.968 g to 14.832 g)
4.	Uniformity of weight Tablets	720.000 mg ± 5.0 % (684.000 mg – 756.000 mg)
5.	Hardness	NLT 3.0 Kg (To be Established)
6.	Thickness (mm)	5.20 mm ± 0.2 (5.00 mm – 5.40 mm) (To be Established)
7.	Friability	NMT 1% w/w
8.	Disintegration Time	NMT 15 Minutes

Controlled Copy No : 01
Sign / Date : 8.4.22
01/04/22

UNCONTROLLED COPY

13.6 COLOUR COATING SOLUTION PREPARATION & COATING PROCEDURE

Take Purified water in a SS Vessel. Slowly disperse HPMC 6 cps, Titanium dioxide, Ponceau 4R Lake, Purified Talc and Polyethylene Glycol 6000 and stir well to disperse completely. If required mill the solution through colloidal mill

Pre-warm the tablet with inlet temp. 50°C ±5°C and exhaust temp. 45°C ±5°C. Arrange the spray gun in such a way that the spray droplets just touch the tablet bed on upper rim. The spray should not fall on the wall of the pan. When the spraying is complete, dry the tablets perfectly, in the pan by hot air at NMT 45°C with intermittently flipping the tablets, until no more solvent odour is observed.

14.0 Acceptance Criteria

Table 1 (GRANULATION STAGE)

Description of the test	Source of Data	Acceptance Criteria
Description	Quality Control Testing	White coloured powder
Assay		95.0 % to 105.0 %
Bulk Density		Record Results*
Tapped Density		Record Results*
Loss on Drying		Record Results*

* For information only

Table 02 (TABLET COMPRESSION)

Carryout tests for physical parameters as mentioned in the following table.

TEST	SOURCE OF DATA	ACCEPTANCE CRITERIA
Appearance	In-process Testing	White coloured caplet shaped uncoated tablet with breakline on one side and plain on other side.
Average weight	In-process Testing	720.000 mg ± 3.0 % (698.400 mg – 741.600 mg)
Weight of 20 tablets	In-process Testing	14.400 g ± 3.0 % (13.968 g to 14.832 g)
Uniformity of weight	In-process Testing	720.000 mg ± 5.0 % (684.000 mg – 756.000 mg)
Hardness	In-process Testing	NLT 3.0 Kg (To be Established)
Thickness	In-process Testing	5.20 mm ± 0.2 (5.00 mm – 5.40 mm) (To be Established)
Friability	In-process Testing	NMT 1% w/w
Disintegration Time	In-process Testing	NMT 15 Minutes

Table 03 (Coated Stage)

Carryout tests for physical parameters as mentioned in the following table.

TEST	SOURCE OF DATA	ACCEPTANCE CRITERIA
Appearance	In-process Testing	Pink coloured caplet shaped film coated tablet with breakline on one side and plain on other side
Theoretical weight per tablet	In-process Testing	736.000 mg ± 3 % (713.920 mg – 758.080 mg)
Weight of 20 tablets	In-process Testing	14.720 g ± 3 % (14.278 g – 15.162 g)
Uniformity of weight	In-process Testing	736.000 mg ± 5 % (699.200 mg – 772.800 mg)
Thickness	In-process Testing	5.50 mm ± 0.2 mm (5.30 mm to 5.70 mm)
Disintegration Time	In-process Testing	NMT 30 Minutes

15.0 CHEMICAL ANALYSIS ACCEPTANCE CRITERIA

TEST	API	SOURCE OF DATA	ACCEPTANCE CRITERIA
Assay	Ciprofloxacin Hydrochloride	Quality Control Testing	95.0 % to 105.0 %
Dissolution*	Ciprofloxacin Hydrochloride	Quality Control Testing	NLT 85.0% of Labeled amount

* Composite sample

16.0 VALIDATION CRITERIA:

The data will be collected, summarized and compared for three consecutive batches and a conclusion will be drawn. The results should meet the limits of acceptance criteria .Any out of specification (OOS) /Deviation should be investigated.

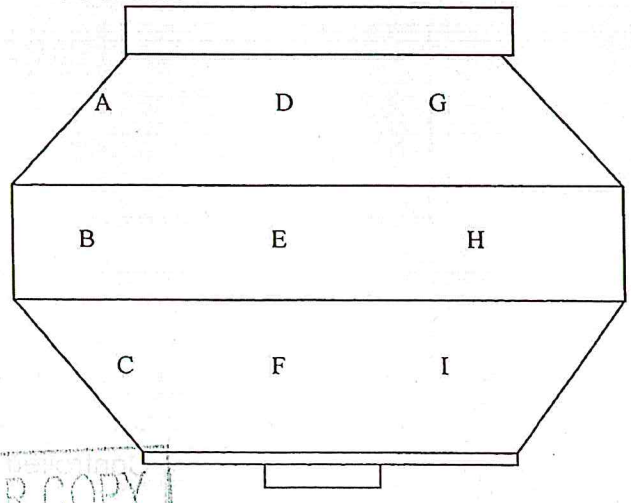
17.0 SAMPLING AND TESTING PLAN

Stage	Sample Location	Sampled by	Sample size	Test
Drying	After final drying	Validation Team	Approximately 5g	Loss on drying
Lubrication	From 9 sampling positions of Octagonal Blender	Validation Team	Approximately 100mg to 300mg	Assay of Ciprofloxacin Hydrochloride
Lubrication	Composite sample from all the containers	Validation Team	Approx. 50 g	1. Description*
				2. Loss on Drying*
				3.Tapped density *
				4. Bulk density*
				5. Assay*
Compression	Initial, Middle & End Sample	Validation Team	20 Tablets	Weight of 20 Tablets, Individual weight variation,
			10 Tablets	Thickness Hardness
			22 Tablets	Friability
			20 Tablets	Assay
			10 Tablets	Dissolution*
Coating	Composite sample	Validation Team	20 Tablets	Weight of 20 Tablets, Individual weight variation,
			10 Tablets	Thickness
			20 Tablets	Assay
			10 Tablets	Dissolution*

*Composite Sample

18.0 SAMPLING POSITIONS

A. OCTAGONAL BLENDER



SYMBOL	Location	SAMPLING LOCATION DETAILS
A	Left- Top	From the left side corner near wall side of the blender approx. 2 inch below the top surface of the powder bed.
B	Left- Middle	From the left middle corner near wall side of the blender approx. 5 inch below the top surface of the powder bed.
C	Left- Bottom	From the left side bottom wall side of the blender approx. 2 inch away from the left side of the wall.
D	Center- Top	From the center of the blender approx. 2 inch below the top surface of the powder bed.
E	Center- Middle	From the center of the blender middle surface of the powder bed.
F	Center- Bottom	From the center bottom of the blender bottom layer of the powder bed.
G	Right-Top	Approx. center of the discharge port of the blender.
H	Right- Middle	From the right middle corner near side of the blender approx. 2 inch below the top surface of the powder bed.
I	Right- Bottom	From the right-side bottom wall of the blender approx. 2 inch away from the right side of wall.
Composite Sample		Composite sample from all location.

19.0 REVISION HISTORY

S. No.	Revision No	Reason for changes
01	00	New document

PROCESS VALIDATION REPORT

PRODUCT : BONCIPRO 500

SHELF LIFE : 36 MONTHS

APPROVAL

S. No.	ACTIVITY	NAME	DESIGNATION	SIGNATURE	DATE
1	PREPARED BY	Ram Kumar	QUALITY ASSURANCE		01/04/22
2	CHECKED BY	Balasubramanian.B	MANAGER PRODUCTION		01/04/2022
3	REVIEWED BY	A. Valavan.	AGM QUALITY CONTROL		01/04/22
4	APPROVED BY	R. Stephen	MANAGER QUALITY ASSURANCE		01/04/22

MASTER COPY

Controlled Copy No : 01
Sign / Date : 01/04/22

UNCONTROLLED COPY

INDEX

1.0 INTRODUCTION

Process validation of **BONCIPRO 500** having batch size of 3, 00,000 Tablets was carried out. Process & Sampling was carried out as per sampling protocol & Process validation protocol

2.0 PURPOSE

To prepare the process validation report based on the data obtained from the validation batches of **BONCIPRO 500** manufactured at Sai Primus Life Biotech India Private Limited, Puducherry.

3.0 SCOPE

This Report is applicable for the Process validation of **"BONCIPRO 500"**, based on the validation data.

4.0 RESPONSIBILITIES

Maintenance : Rectification of Breakdown during Manufacturing. (If any)

Production : Execution of Process Validation Batch and process validation Report.

Quality control :
1. Analysis of Validation batch Samples.
2. Preparation of Analytical report and submit to Quality Assurance Department.
3. Review of Process validation Report.

Quality Assurance :
1. Co-ordination with Production and QC to carryout Process validation batch.
2. Monitoring and sampling at the different stages.
3. Preparation and approval of Process Validation Report.

5.0 PRODUCT DETAILS

Product Name	**BONCIPRO 500**
Dosage Form	Tablets
Label Claim	Each film coated tablet contains: Ciprofloxacin Hydrochloride BP Equivalent to Ciprofloxacin ..... 500 mg Colour: Approved Colour used.
Batch size	3,00,000 Tablets
Shelf Life	36 Months

6.0 BATCH DETAILS

Parameter	1st Batch	2nd Batch	3rd Batch
Batch No.	G1822068	G1822116	G1822117
Batch Size	3.0L	3.0L	3.0L
Mfg. Date	04/2022	09/2022	09/2022
Exp. Date	03/2025	08/2025	08/2025
Date of commencement	02/04/2022	05/09/2022	05/09/2022
Date of completion	13/04/2022	15/09/2022	16/09/2022

Product name	BONCIPRO 500	Effective Date	01/04/2022
Protocol No.	PVR: B05	Ref. SOP No.	QAGN/017

7.0 VALIDATION REPORT OF BLEND

ASSAY											
Location →	1	2	3	4	5	6	7	8	9	Composite sample	Avg %
Batch No : G1822068											
Description*	C	C	C	C	C	C	C	C	C	C	C
Limit	**95.0% to 105.0 %**										
Ciprofloxacin Hydrochloride (%)	98.1.	99.4	98.3	100.1.	98.4	99.1.	98.1.	99.7	100.1.	102.1.	104.1.
Batch No : G1822116											
Description*	C	C	C	C	C	C	C	C	C	C	C
Limit	**95.0% to 105.0 %**										
Ciprofloxacin Hydrochloride (%)	98.1.	99.7	100.1.	98.7	99.1.	100.1.	102.1.	100.1.	98.4	97.1.	98.1.
Batch No : G1822117											
Description*	C	C	C	C	C	C	C	C	C	C	C
Limit	**95.0% to 105.0 %**										
Ciprofloxacin Hydrochloride (%)	99.1.	98.3	100.1.	104.1	100.1.	97.1.	98.1.	100.1.	98.4	99.1.	100.1.

* Description of Blend: White coloured Granules (write 'C' for complies and 'NC' for non complies)

7.1 VALIDATION REPORT OF BLEND (Composite sample)

Batch No -→	G1822068	G1822116	G1822117
Description*	C	C	C
Assay Ciprofloxacin Hydrochloride	98.1.	99.1.	102.12.1.
Moisture Content	—	—	—
Bulk density	0.67	0.68	0.67
Tap density	0.69	0.70	0.71

* Description of Blend: White coloured Granules (write 'C' for complies and 'NC' for non complies)

7.2 VALIDATION REPORT OF COMPRESSION TABLETS

COMPRESSION TABLETS AT DIFFERENT INTERVAL

INITIAL, MIDDLE AND END

Observation	Batch No →		G1822068			G1822116			G1822117		
	Acceptance criteria		Initial	Middle	End	Initial	Middle	End	Initial	Middle	End
Description	*		C	C	C	C	C	C	C	C	C
Avg. weight	720.000 mg ± 3.0 %		719	718	717	716	715	718	719	718	717
Uniformity of Weight	720.000 mg ± 5.0 %	Min.	719	718	717	716	715	717	718	719	716
		Max.	720	719	718	719	718	719	726	721	720
Hardness	NLT 3.0 kg/cm²	Min.	3.0	3.0	3.5	3.0	3.5	3.0	3.0	3.0	3.5
		Max.	4.0	4.0	4.5	4.0	4.0	3.5	3.5	3.5	4.0
Thickness	5.0-5.40 mm	Min.	5.35	5.32	5.33	5.31	5.30	5.28	5.37	5.35	536
		Max.	5.36	5.35	5.36	5.35	5.36	5.38	5.38	5.39	5.38
Assay Ciprofloxacin Hydrochloride	95.0 to 105.0 %		98.1%	100.1%	104.1%	102.1%	100.1%	99.7.1%	98.3%	99.1%	100.2%
Ciprofloxacin Hydrochloride	NLT 85.00%		80.1%	83.1%	82.1%	81.1%	83.1%	84.1%	85.1%	83%	83.1%

* White coloured caplet shaped uncoated tablet with breakline on one side and plain on other side.
(Write 'C' for complies and 'NC' for non complies)

COMPRESSION TABLETS AT DIFFERENT INTERVAL

(LOW, HIGH) RPM AND (LOW, HIGH) HARDNESS

Observation	Batch No →		G1822068				G1822116				G1822117			
	Acceptance criteria		L.R	H.R	L.H	H.H	L.R	H.R	L.H	H.H	L.R	H.R	L.H	H.H
Description	*		C	C	C	C	C	C	C	C	C	C	C	C
Avg. weight	720.000 mg ± 3.0 %		719	718	717	716	716	718	719	716	715	718	719	720
Uniformity of Weight	720.000 mg ± 5.0 %	Min.	721	722	718	718	719	720	721	720	715	719	719	718
		Max.	722	723	720	719	720	721	722	721	718	720	721	720
Hardness	NLT 3.0 kg/cm²	Min.	3.0	3.0	3.5	3.0	3.5	3.0	3.0	3.0	3.5	3.0	3.5	3.0
		Max.	3.5	3.5	3.0	3.5	4.0	3.5	4.0	3.5	4.0	3.5	4.0	3.5
Thickness	5.0-5.40 mm	Min.	5.38	5.35	5.36	5.37	5.36	5.35	5.36	5.36	5.38	5.37	5.35	5.37
		Max.	5.39	5.36	5.38	5.38	5.37	5.36	5.38	5.39	5.40	5.39	5.37	5.38
Assay Ciprofloxacin Hydrochloride	95.0 to 105.0 %		99.1%	100.1%	97.1%	98.1%	108.1%	103.1%	98.2%	99.1%	101.1%	102.1%	97.1%	99.1%
Ciprofloxacin Hydrochloride	NLT 85.00%		80%	84%	83%	82%	80%	83%	82%	82%	81.1%	80%	83%	82%

* White coloured caplet shaped uncoated tablet with breakline on one side and plain on other side.
(Write 'C' for complies and 'NC' for non complies)

7.3 VALIDATION REPORT OF COATED TABLETS

COATED TABLETS AT DIFFERENT INTERVAL

Observation	Batch No →		G1822062			G1822116			G1822117		
Description	*		C			C			C		
Avg. weight	736.000 mg ± 3.0 %		735			736			734		
Uniformity of Weight	736.000 mg ± 5.0 %	Min.	735			736			735		
		Max.	737			738			736		
Thickness	5.30-5.70 mm	Min.	5.62			5.65			5.66		
		Max.	5.69			5.66			5.68		
Assay Ciprofloxacin Hydrochloride	95.0 to 105.0 %		98.1%	100%	99%	101.1%	98.1%	102%	98.9%	100%	98.9%
Ciprofloxacin Hydrochloride	NLT 85.00%		80.1%	82.1%	83%	82.1%	81.1%	83.1%	84.1%	83%	82.1%

Pink coloured caplet shaped film coated tablet with breakline on one side and plain on other side.
(write 'C' for complies and 'NC' for non complies)

7.4 VALIDATION REPORT FOR PACKING STAGE

PACKING STAGE AT DIFFERENT INTERVAL INITIAL, MIDDLE AND END										
Observation	Batch No →	G1822068			G1822116			G1822117		
	Acceptance criteria	Initial	Middle	End	Initial	Middle	End	Initial	Middle	End
Sealing / forming temperature		C	C	C	C	C	C	C	C	C
Sealing quality	Should be proper*	C	C	C	C	C	C	C	C	C
Batch coding details	Should be legible*	C	C	C	-	C	C	C	C	C
Leak test	Should pass*	-	C	C	C	C	C	C	C	C

*Write 'C' for complies and 'NC' for Non complies.

8 REVIEW OF OOS AND DEVIATIONS IF ANY:

Batch No.: G1822068
- Nil -

Batch No.: G1822116
- Nil -

Batch No.: G1822117
- Nil -

9 SUMMARY: The process of Boncipro 500 Tablet has been validated and found satisfactory
No deviation recorded.

10 CONCLUSION: The process validation of boncipro 500 tablet has been carried out and results obtained from blending, compression and coating found satisfactory
Hence the process stand validated and recommended to follow the same process for upcoming batches.

11 REPORT APPROVAL:

The process validation report of batch **"BONCIPRO 500"** having batch size of 3,00,000 Tablets has been reviewed and complies with requirements.

Prepared By:
Name : RAMKUMAR Sign / Date : 23/09/22 Quality Assurance

Checked and Reviewed By:	
Sign / Date : 23/09/2022 Name : BHARATHIRAMANAN R. Production	Sign / Date : 23/09/2022 Name : A. VALLIARASAN, Quality Control

Comments: We certify that the process validation report for **"BONCIPRO 500"** having batch size of 3,00,000 Tablets has been accepted.

Summary Report Approval:
Sign / Date : 29/09/22 Name : R. Stephen Manager - QA

MASTER COPY

Controlled Copy No : 01
Sign / Date : 01/04/22

UNCONTROLLED COPY