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 7 No.: FPS:B05
	FINISHED PRODUCT SPECIFICATION	Revision No: 01
Title:	BONCIPRO-500 mg TABLETS . (Ciprofloxacin Hydrochloride tablets BP 500 mg)	Review Period: 3 Years
	Product Code: B05	Effective Date: 07/11/2023

01	**GENERAL**	**Pharmacopoeial Reference**	**BP**
02	**Composition**	**Label Claim**	
	Each Film coated tablet contains:		
	Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin	500 mg	
03	**Shelf life**	36 months	
04	**Quantity of sample taken for analysis**	Lubricated granules: 100 gm Bulk sample : 120 's (For complete analysis) Finished product: 12 x 10's (For Physical parameter &Microbial Limit test only)	
05	**Control sample**	20 [1 x 10's]	
06	**Storage of Finished pack**	Store in a cool and dry place. protect from light and moiture.	

	Prepared by	Checked by	Approved by
Designation	Executive-QC	Sr. Executive-QC	Manager-QC
Signature			
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	FINISHED PRODUCT SPECIFICATION	Revision No: 01
Title:	BONCIPRO-500 mg TABLETS (Ciprofloxacin Hydrochloride tablets BP 500 mg)	Review Period: 3 Years
	Product Code: B05	Effective Date: 07/11/2023

BULK GRANULES SPECIFICATION

S.No.	TEST	LIMIT	METHOD
01	**DESCRIPTION**	White coloured granular powder.	Follow section I of Method of analysis
02	**ASSAY (By HPLC)** **Each 720 mg Granules Contains:** Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg	Not less than 95.0% and not more than 105.0% of labeled claim.	Follow section XI of Method of analysis

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	FINISHED PRODUCT SPECIFICATION	Revision No: 01
Title:	BONCIPRO-500 mg TABLETS (Ciprofloxacin Hydrochloride tablets BP 500 mg)	Review Period: 3 Years
	Product Code: B05	Effective Date: 07/11/2023

BULK PRODUCT SPECIFICATION

S.No.	TEST	LIMIT	METHOD
01	**DESCRIPTION**	White coloured, capsule shaped, biconvex, uncoated tablets with break line on one side and plain on other side.	Follow section I of Method of analysis
02	**AVERAGE WEIGHT**	720.00 mg ± 5.0% (Limit:684.00 mg to 756.00 mg)	Follow section III of Method of analysis
03	**UNIFORMITY OF WEIGHT**	NMT 2 tablets deviate by more than 5 % and none deviates by more than 10.0 % from the average weight.	Follow section IV of Method of analysis
04	**DIMENSIONS** Thickness Length Width	 5.20 mm to 5.60 mm 17.00 mm to 17.40 mm 7.50 mm to 7.70 mm	Follow section V of Method of analysis
05	**HARDNESS**	NLT 3 kg/cm^2	Follow section VI of Method of analysis
06	**FRIABILITY**	Not More Than 1.0 %	Follow section VI of Method of analysis
07	**DISINTEGRATION TIME**	Not more than 15 minutes	Follow section VII of Method of analysis
08	**DISSOLUTION By UV**	Not less than 85.0 % of labeled amount.	Follow section VIII of Method of analysis
09	**ASSAY (By HPLC)** **Each Uncoated tablet contains:** Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg	 Not less than 95.0% and not more than 105.0% of labeled claim.	Follow section X of Method of analysis

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Signature	J. Kanal		
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	FINISHED PRODUCT SPECIFICATION	Revision No: 01
Title:	BONCIPRO-500 mg TABLETS (Ciprofloxacin Hydrochloride tablets BP 500 mg)	Review Period: 3 Years
	Product Code: B05	Effective Date: 07/11/2023

RELEASE SPECIFICATION

S.No.	TEST	LIMIT	METHOD
01	**DESCRIPTION**	Reddish pink coloured, oblong, biconvex film coated tablet with breakline on one side and plain on other side.	Follow section I of Method of analysis
02	**IDENTIFICATION**		Follow section II of Method of analysis
	A) By TLC	The Principal band in the chromatogram obtained with solution (1) corresponding to that in the chromatogram obtained with solution (2).	
	B) By HPLC	In the Assay, the retention time of the principal peak in the chromatogram obtained with solution (1) is the same as that of the principal peak in the chromatogram obtained with solution(2).	
03	**AVERAGE WEIGHT**	736.0 mg ± 5.0% (Limit:699.20 mg to 772.80 mg)	Follow section III of Method of analysis
04	**UNIFORMITY OF WEIGHT**	NMT 2 tablets deviate by more than 5 % and none deviates by more than 10.0 % from the average weight.	Follow section IV of Method of analysis
05	**DIMENSIONS** Thickness Length Width	 5.30 mm to 5.70 mm 17.10 mm to 17.50 mm 7.60 mm to 7.80 mm	Follow section V of Method of analysis
06	**HARDNESS**	NLT 3 kg/cm^2	Follow section VI of Method of analysis
07	**DISINTEGRATION TIME**	Not more than 30 minutes	Follow section VIII of Method of analysis

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Title:	BONCIPRO-500 mg TABLETS (Ciprofloxacin Hydrochloride tablets BP 500 mg)	Review Period: 3 Years
	Product Code: B05	Effective Date: 07/11/2023

S.No.	TEST	LIMIT	METHOD
08	**DISSOLUTION By UV**	Not less than 85.0 % of labeled amount.	Follow section IX of Method of analysis
09	**RELATED SUBSTANCES (By HPLC)**		Follow section X of Method of analysis
	Ciprofloxacin impurity C	NMT 0.5 %	
	Ciprofloxacin impurity E	NMT 0.3 %	
	Any other secondary peak	NMT 0.2 %	
	Total impurities	NMT 1.0 %	
10	**ASSAY (By HPLC)**		Follow section XI of Method of analysis
	Each Film coated tablet contains:		
	Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg	Not less than 95.0% and not more than 105.0% of labeled claim.	
11	**MICROBIOLOGICAL LIMITS**		Follow section XII of Method of analysis
	Total Aerobic Microbial count	NMT 1000 CFU/g	
	Total Yeasts and mould counts	NMT 100 CFU/g	
	E.Coli	Should be Absent	
	Salmonella	Should be Absent	
	S.aureus	Should be Absent	
	P.aeruginosa	Should be Absent	

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		No.: FPS:B05
	FINISHED PRODUCT SPECIFICATION	Revision No: 01
Title:	BONCIPRO-500 mg TABLETS (Ciprofloxacin Hydrochloride tablets BP 500 mg)	Review Period: 3 Years
	Product Code: B05	Effective Date: 07/11/2023

SHELF LIFE SPECIFICATION

S.No.	TEST	LIMIT	METHOD
01	DESCRIPTION	Reddish pink coloured, oblong, biconvex film coated tablet with breakline on one side and plain on other side.	Follow section I of Method of analysis
02	AVERAGE WEIGHT	736.0 mg ± 5.0% (Limit:699.20 mg to 772.80 mg)	Follow section III of Method of analysis
03	HARDNESS	NLT 3 kg/cm2	Follow section VI of Method of analysis
04	DISINTEGRATION TIME	Not more than 30 minutes	Follow section VIII of Method of analysis
05	DISSOLUTION By UV	Not less than 85.0 % of labeled amount.	Follow section IX of Method of analysis
06	RELATED SUBSTANCES By HPLC Ciprofloxacin impurity C Ciprofloxacin impurity E Any other secondary peak Total impurities	 NMT 0.5 % NMT 0.3 % NMT 0.2 % NMT 1.0	Follow section X of Method of analysis
07	ASSAY By HPLC **Each Film coated tablet contains:** Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg	 Not less than 95.0% and not more than 105.0% of labeled claim.	Follow section XI of Method of analysis
08	MICROBIOLOGICAL LIMITS Total Aerobic Microbial count Total Yeasts and mould counts E.Coli Salmonella S.aureus P.aeruginosa	 NMT 1000 CFU/g NMT 100 CFU/g Should be Absent Should be Absent Should be Absent Should be Absent	Follow section XII of Method of analysis

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	FINISHED PRODUCT SPECIFICATION	Revision No: 01
Title:	BONCIPRO-500 mg TABLETS (Ciprofloxacin Hydrochloride tablets BP 500 mg)	Review Period: 3 Years
	Product Code: B05	Effective Date: 07/11/2023

HISTORY:

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No:FPS:B05
2	Revision No.: 01	Incorporated Bulk Granules Specification, Bulk product Specification

END OF DOCUMENT

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Title:	BONCIPRO-500 mg TABLETS (Ciprofloxacin Hydrochloride tablets BP 500 mg)	Review Period: 3 Years
	Product Code: B05	Effective Date:

METHOD OF ANALYSIS

SECTION – I

DESCRIPTION: (By Visual Inspection)

Check physical aspects – Colour, shape and nature of tablets, presence of foreign material, mottling etc.,

SECTION – II

IDENTIFICATION

A] Identification: (By TLC):

Chromatographic conditions:

Plate	:	Coating silica gel F254 (Merck silica gel 60 F254 HPTLC plates are suitable)
Injection volume	:	10 µL of each solution
Plate Development	:	15 cm
Air	:	Drying air for 15 minutes
Wavelength	:	254 nm and 365 nm

Preparation of Mobile Phase:

Mix 10 ml of Acetonitrile and 20 ml of 13.5 M Ammonia and 40 ml of Dichloromethane and 40 ml of Methanol.

Preparation of Solution (1):

Weight accurately about 736 mg of sample powder (equivalent to 0.5 gm of Ciprofloxacin) in to 250 ml volumetric flask, add about 150 ml of water, Sonicate for 20 minutes to dissolve and dilute up to the mark with water. Filter (PVDF 0.45µm filter).Further dilute 5 ml of above filtrate to 20 ml with water. (Concentration: 0.5 mg/ml ciprofloxacin).

Preparation of Solution (2):

Weight accurately about 55 mg of Ciprofloxacin Hydrochloride standard into 100 ml volumetric flask. Add about

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50 ml of water, sonicate to dissolve and dilute up to the mark with water.(Concentration: 0.55 mg/ml ciprofloxacin).

Preparation of Solution (3):

Mix well 10 ml of solution (1) and 10 ml of Solution (2)

System suitability:

The test is not valid unless the principal band in the chromatogram obtained with solution (3) appears as a single, compact band.

The principal band in the chromatogram obtained with solution(1) corresponding to that in the chromatogram obtained with solution(2).

B. By HPLC

In the assay, the retention time of the principal peak in the chromatogram obtained with solution(1) is the same sa that of the principal peak in the chromatogram obtained with solution(2).

SECTION – III

AVERAGE WEIGHT

Weigh 20 tablets and note down weight in g .

Determine the average weight. Report the result of average weight in mg.

$$\text{Average weight} = \frac{\text{Weight of 20 tablets in g}}{20} \times 1000 = \_\_\_\_\_ \text{ mg}$$

SECTION – IV

UNIFORMITY OF WEIGHT

Weigh individually 20 tablets taken for average weight. Calculate the percentage of highest and lowest variation of the tablets with maximum and minimum weight from the average weight of tablets by the following expression.

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Calculation:

$$\left(\frac{\text{Lowest Wt. of Tablet}}{\text{Avg. Wt of Tablet}} \times 100 \right) - 100 = - \%$$

$$\left(\frac{\text{Highest Wt. of Tablet}}{\text{Avg. Wt. of Tablet}} \times 100 \right) - 100 = + \%$$

SECTION – V

DIMENSIONS

Measure the Thickness, Length & Width of 10 tablets using Digital Vernier Calipers. Record the reading in mm.

SECTION – VI

HARDNESS

Take 10 tablets randomly from sample drawn for analysis. Place one tablet diagonally in between the space provided in the hardness tester. Operate the instrument for tablet hardness tester. Note down the reading when tablet breaks. Repeat the test for remaining 9 tablets and record the values in Kg/cm^2. Express the results as the minimum and maximum values in Kg/cm^2.

SECTION – VII

FRIABILITY

Weigh accurately about 10 tablets note down the mass in grams (a).Place weighed tablets in friability test apparatus and operate the instrument as per SOP for tablet friability test apparatus, for 100 rotations. After completion of test collect the tablets from the sample collector carefully. Remove broken particles, chipped pieces (if any) by means of gentle brushing. Weigh the tablet and record the mass in grams (b).

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Calculate the weight loss (c= a-b).

Calculate the percentage as follows:

Calculation

$$\frac{c \times 100}{a} = \quad \% \text{ w/w}$$

SECTION – VIII

DISINTEGRATION TIME

Determine on 6 tablets using water at 37°C ± 2°C.Place one tablet each in six tubes of the disintegration test apparatus, add a disc and suspend the assembly in water maintained at 37 ± 2°C.Operate the apparatus till all residue passes through the mesh and note down the time taken.The time taken should not be more than the limit indicated in the product specification.If the tablets adhere to the disc repeat the test omitting the disc.

SECTION – IX

DISSOLUTION By UV

Dissolution Parameters:

Apparatus	:	Type II (Paddle)
Dissolution Medium	:	Water
Volume	:	900 ml
RPM	:	50
Temperature	:	37°C ± 0.5°C
Time	:	30 minutes

Preparation of Standard solution:

Weigh accurately and transfer 27.7 mg of Ciprofloxacin hydrochloride working standard in to a 100 ml volumetric flask. Dissolve and dilute to volume with dissolution medium. Further dilute 2 ml of this solution to 100 ml with

dissolution medium

Procedure:

After 30 minutes withdraw a 10 ml sample of the medium and measure the absorbance of the filtered sample (PVDF 0.45µm filter). Further dilute 2 ml of this filtered sample into 200 ml of water. Measure the absorbance of a suitable solution of Ciprofloxacin Hydrochloride BPCRS in water at the maximum at 276 nm using dissolution medium in the reference cell.

Determination of content:

Calculate the total content of Ciprofloxacin, C17H18FN3O3, in the medium from the absorbance obtained and from the declared content of C17H18FN3O3, HCL in ciprofloxacin hydrochloride. Each mg of C17H18FN3O3, HCl is equivalent to 0.9010 mg of C17H18FN3O3.

Calculations:

Calculate the % content released of ciprofloxacin hydrochloride equivalent to Ciprofloxacin by using following formula,

$$= \frac{A}{B} \times \frac{W}{100} \times \frac{2}{100} \times \frac{900}{1} \times \frac{200}{2} \times \frac{P}{100} \times \frac{100}{LC} \times 0.901$$

Where,

A = Absorbance of Sample solution

B = Absorbance of Standard solution

W = Weight of standard in mg

LC = Label claim

P = Purity of Ciprofloxacin Hydrochloride working standard in %

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	FINISHED PRODUCT STANDARD TEST PROCEDURE	Revision No: 01
Title:	BONCIPRO-500 mg TABLETS (Ciprofloxacin Hydrochloride tablets BP 500 mg)	Review Period: 3 Years
	Product Code: B05	Effective Date: 07/11/2023

SECTION –X

Related Substance (By HPLC):

Chromatographic Condition:

Column	:	Stainless steel column (25cm x 4.6 mm) packed with base- deactivated octadecylsilyl silica gel for chromatography (5µm) (Hypersil BDS is suitable).
Flow rate	:	1.5 ml/ minute
Detector wavelength	:	278 nm
Column oven temperature	:	40 °C
Injection volume	:	25 µL
Retention time	:	2 times of Ciprofloxacin hydrochloride peak

Preparation of 0.245 % w/v solution of Orthophosphoric Acid:

Weigh accurately about 2.45 g of Orthophosphoric Acid in 1000 ml volumetric flask, add about 800 ml of water and adjust the pH with Triethylamine having to 3.0, make volume up to the mark with water.

Preparation of Mobile phase:

Mix 13 volumes of Acetonitrile and 87 volumes of a 0.245% w/v solution of Orthophosphoric Acid . Filter through 0.45 micron membrane filter and degas.

Preparation of Placebo:

Weight accurately about 95 mg of placebo powder (equivalent to 0.2 gm of Ciprofloxacin) in to 100 ml volumetric flask, add about 75 ml of mobile phase sonicate for 20 minutes to dissolve and dilute up to the mark with mobile phase. Filter (PVDF 0.45µm filter). Dilute 1 ml of the filtrate to 20 ml with the mobile phase.

Preparation of Solution (1):

Weight accurately about 295 mg of sample powder (equivalent to 0.2 gm of Ciprofloxacin) in to 100 ml volumetric flask, add about 75 ml of mobile phase sonicate for 20 minutes to dissolve and dilute up to the mark with mobile phase. Filter (PVDF 0.45µm filter). Dilute 1 ml of the filtrate to 20 ml with the mobile phase.

(Concentration of ciprofloxacin: 0.1 mg/ml).

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Preparation of Solution (2):

Dilute 1 ml of solution (1) to 20 ml with the mobile phase and further dilute 1 ml to 10 ml with the mobile phase.

Preparation of Solution (3):

Weight accurately and transfer about 5 mg of Ciprofloxacin impurity standard BPCRS into 50 ml of volumetric flask. Add about 20 ml of mobile phase, sonicate with intermediate shaking to dissolve and dilute up to the volume with mobile phase.(Concentration: 0.1 mg/ml)

Preparation of Solution (4):

Dilute 1 ml of solution (2) to 5 ml with the mobile phase.

Relative Retention time of Impurity W.R.T. to Ciprofloxacin:

Sr. No	Name of impurity	RRT	Response factor (Rf)
1	Impurity B	0.6	0.7
2	Impurity C	0.7	0.6
3	Impurity D	1.2	1.4
4	Impurity E	0.4	6.7
5	Impurity F	0.5	-

Sequence of injection:

1) Blank
2) Placebo
3) Blank
4) Solution -3
5) Blank
6) Solution-1
7) Blank
8) Solution-2
9) Blank

10) Solution-4

11) Blank

When the chromatograms are recorded under the prescribed conditions, the relative retentions with reference to ciprofloxacin (retention time about 9 minutes) are: Impurity E, about 0.4; Impurity F, about 0.5; impurity B, about 0.6; Impurity C, about 0.7; and impurity D, about 1.2.

System Suitability Requirement:

The test is not valid unless:

In the chromatogram obtained with solution (3), the resolution between the peaks due to impurity B and impurity C is at least 1.3;

The signal-to-noise ratio of the principal peak in the chromatogram obtained with solution(4) is at least 70.

Limits:

Identify any peaks in the chromatogram obtained with solution (1) corresponding to impurities B, C, D and E using solution (3) and multiply the area of these peaks by the following correction factors: 0.7, 0.6, 1.4, and 6.7 respectively.

In the chromatogram obtained with solution (1):

1) The area of any peak corresponding to impurity C is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (0.5%);
2) The area of any peak corresponding to impurity E is not greater than 0.6 times the area of the principal peak in the chromatogram obtained with solution (2) (0.3%);
3) The area of any other secondary peak is not greater than twice the area of the principal peak in the chromatogram obtained with solution (4) (0.2%)
4) The sum of the areas of all the secondary peaks is not greater than twice the area of the principal peak in the chromatogram obtained with solution (2) (1.0%).
5) Disregard any peak with an area less than the area of the principal peak in the chromatogram obtained with solution (4) (0.1%)

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Calculation:

1)Calculate the % Known impurity by using following formula,

$$= \frac{A}{B} \times \frac{W1}{100} \times \frac{1}{20} \times \frac{1}{20} \times \frac{1}{10} \times \frac{100}{W2} \times \frac{20}{1} \times \frac{P}{100} \times \frac{100}{LC} \times Av \times 0.901$$

Where,

A = Peak area response of known impurity obtained from the sample solution.
B = Peak area response of Ciprofloxacin peak obtained with solution (2).
W1 = Equivalent weight of Ciprofloxacin in mg
W2 = Weight of sample in mg
Av = Average weight of sample in mg
P = % Purity of Ciprofloxacin working standard on as is basis.
LC = label claim

2) Calculate the % Any other secondary peak by using following formula,

$$= \frac{A}{B} \times \frac{W1}{100} \times \frac{1}{20} \times \frac{1}{20} \times \frac{1}{10} \times \frac{100}{W2} \times \frac{20}{1} \times \frac{P}{100} \times \frac{100}{LC} \times Av \times 0.901$$

Where,

A = Peak area response of unknown impurity obtained from the sample solution.
B = Peak area response of Ciprofloxacin peak obtained with solution (2).
W1 = Equivalent weight of Ciprofloxacin in mg
W2 = Weight of sample in mg
Av = Average weight of sample in mg
P = % Purity of Ciprofloxacin working standard on as is basis.
LC = label claim

Total impurities = Known Impurity + Any other secondary peak

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	Product Code: B05	Effective Date: 07/11/2023

SECTION – XI

Assay (By HPLC):

Chromatographic Condition:

Column	:	Stainless steel column (25cm x 4.6 mm) packed with base- deactivated octadecylsilyl silica gel for chromatography (5µm) (Hypersil BDS is suitable).
Flow rate	:	1.5 ml/ minute.
Detector wavelength	:	278 nm
Column oven temperature	:	40°C.
Injection volume	:	25 µL
Retention time	:	2 times of Ciprofloxacin hydrochloride peak

Preparation of 0.245 % w/v solution of Orthophosphoric Acid:

Weigh accurately about 2.45 g of Orthophosphoric Acid in 1000 ml volumetric flask, add about 800 ml of water and adjust the pH with Triethylamine having to 3.0, make volume up to the mark with water.

Preparation of Mobile phase:

Mix 13 volumes of Acetonitrile and 87 volumes of a 0.245% w/v solution of Orthophosphoric Acid . Filter through 0.45 micron membrane filter and degas.

Preparation of sample powder:

Weigh accurately 20 tablets and make the powder by using mortar and pestle. Use the same for preparation of sample solution. Calculate the average weight by taking weight of 20 tablets taken above and use the same for calculation.

Preparation of solution (1):

Weight accurately about 295.00 mg of sample powder (equivalent to 200 mg of Ciprofloxacin) in to 100 ml volumetric flask, add about 50 ml of mobile phase sonicate 20 minutes to dissolve and dilute up to the mark with mobile phase. Filter (PVDF 0.45µm filter). Dilute 1 ml of the filtrate to 200 ml with the mobile phase.

(Concentration of ciprofloxacin: 0.01 mg/ml).

	Prepared by	Checked by	Approved by
Designation	Executive-QC	Sr. Executive-QC	Manager-QC
Signature			
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Department: Quality Control		**Date of Issue:** 07/11/2023	

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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 11 of 12
		No.: FPSTP:B05
	FINISHED PRODUCT STANDARD TEST PROCEDURE	Revision No: 01
Title:	BONCIPRO-500 mg TABLETS (Ciprofloxacin Hydrochloride tablets BP 500 mg)	Review Period: 3 Years
	Product Code: B05	Effective Date: 07/11/2023

Note: Prepare sample solution in duplicate.

Preparation of Solution (2):

Weight accurately about 22.20 mg of Ciprofloxacin Hydrochloride standard into 100 ml volumetric flask. Add about 50 ml of mobile phase, sonicate to dissolve and dilute up to the mark with mobile phase. Further dilute 5 ml of this solution to 100 ml with mobile phase. (Concentration of ciprofloxacin: 0.01 mg/ml)

Procedure:

Equilibrate the chromatographic system with mobile phase till stable baseline is obtained. Separately inject equal volume (25 µL) of solutions as per sequence of injections into the chromatograph and record the peak area responses for the major peaks and check for the system suitability requirements. Calculate the impurities as per the formula mentioned under calculation parameter.

Sequence of injection:

1) Blank
2) Standard Solution 1 ---- 5
3) Blank
4) Sample solution 1
5) Sample solution 2
6) Standard solution (Bkt)

Determination of content:

Calculate the content of C17H18FN3O3 in the tablets using the declared content of C17H18FN3O3, Hcl in ciprofloxacin hydrochloride BPCRS.Each mg of C17H18FN3O3, Hcl is equivalent to 0.9010 mg of C17H18FN3O3.

Calculation:

Calculate the % content released of ciprofloxacin hydrochloride equivalent to Ciprofloxacin by using following formula,

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$$= \frac{A}{B} \times \frac{W1}{100} \times \frac{5}{100} \times \frac{100}{W2} \times \frac{200}{1} \times \frac{P}{100} \times \frac{100}{LC} \times \text{Average weight} \times 0.901$$

Where,

A = Peak area response of ciprofloxacin peak obtained with sample solution.

B = Average peak area response of ciprofloxacin peak obtained with standard solution.

W1= Weight of ciprofloxacin working standard taken in mg.

W2 = Weight of Sample taken in mg.

P = Purity of Ciprofloxacin working standard in %on as is basis.

LC = label claim

SECTION-XII

MICROBIOLOGICAL LIMITS

Refer to SOP No. QCMB 006.

HISTORY:

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No:FPSTP:B05
2	Revision No.: 01	Incorporated Bulk Granules Specification, Bulk product Specification

END OF DOCUMENT

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Designation	Executive-QC	Sr. Executive-QC	Manager-QC
Signature			
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