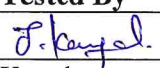
 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PRIVATE LIMITED R.S. No. 4/3, plot No. 33, Kurumbapet Industrial Estate,Villianur Commune, Pondicherry- 605009				Page 1 of 2	
QUALITY CONTROL	CERTIFICATE OF ANALYSIS				Format No: F/QCGN/022/08	
	FINISHED PRODUCT					
Product Name	:	BONCIPRO-500 TABLETS(Ciprofloxacin Hydrochloride tablets BP 500 mg)				
A.R.No.	:	BS/110422/02				
Batch No.	:	G1822068	Batch Size	:	3.0 L	
Mfg. Date	:	Apr-2022	Exp. Date	:	Mar-2025	
Sampling Date	:	11.04.2022	Sample Qty	:	120 Tablets	
Analysis Date	:	11.04.2022	Release Date	:	25.05.2022	

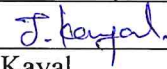
S.No.	TEST	RESULTS			LIMITS
01.	Description	Reddish pink coloured, oblong, biconvex film coated tablet with breakline on one side and plain on both sides.			Reddish pink coloured, oblong, biconvex film coated tablet with breakline on one side and plain on both sides.
02.	Identification A) By TLC B) By HPLC	Complies Complies			The Principal band in the chromatogram obtained with solution (1) corresponding to that in the chromatogram obtained with solution (2). 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 of tablets	731.60mg			736.0 mg $\pm$ 5.0% (Limit:699.20 mg to 772.80 mg)
04.	Uniformity of weight	+3.90 % to -3.64%			Not more than 2 of the individual weights deviate from the average weight by more than $\pm$ 5 % and none deviate by more than $\pm$ 10 % .
05.	Dimensions Thickness Length Width	Min 5.39 mm 17.36 mm 7.63 mm	Max 5.58mm 17.40 mm 7.68 mm	Avg. 5.45mm 17.38 mm 7.65 mm	5.30 mm to 5.70 mm 17.10 mm to 17.50 mm 7.60 mm to 7.80 mm
06.	Hardness	10.7 kg/cm ²			NLT 3.0 kg/cm ²
07.	Disintegration time	02 minutes 48 seconds			Not more than 30 minutes
08.	Dissolution By UV	Min 93.75 %	Max 99.49 %	Avg. 96.89%	Not less than 85.0 % of labeled amount.

	Tested By	Checked By	Approved By
Sign			
Name	Kayal	Ramesh	Vallarasan
Date	25/05/2022	25/05/2022	25/05/2022

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PRIVATE LIMITED R.S. No. 4/3, plot No. 33, Kurumbapet Industrial Estate,Villianur Commune, Pondicherry- 605009				Page 2 of 2	
QUALITY CONTROL	CERTIFICATE OF ANALYSIS				Format No: F/QCGN/022/08	
	FINISHED PRODUCT					
Product Name	:	BONCIPRO-500 TABLETS(Ciprofloxacin Hydrochloride tablets BP 500 mg)				
A.R.No.	:	BS/110422/02				
Batch No.	:	G1822068	Batch Size	:	3.0 L	
Mfg. Date	:	Apr-2022	Exp. Date	:	Mar-2025	
Sampling Date	:	11.04.2022	Sample Qty	:	120 Tablets	
Analysis Date	:	11.04.2022	Release Date	:	25.05.2022	

09.	Related substances:		
	Ciprofloxacin impurity C	Not Detected	Not more than 0.5%
	Ciprofloxacin impurity E	Not Detected	Not more than 0.3%
	Any individual impurity	Not Detected	Not more than 0.2%
	Total impurities	Not Detected	Not more than 1.0%
10.	Assay: Each film coated tablet contains:		
	Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg	103.56 %	Not less than 95.0% and not more than 105.0% of labeled claim.
11.	Microbiological limits:		
	Total Aerobic Microbial count	20 cfu /g	NMT 1000 cfu/g
	Total Yeasts and mould counts	<10 cfu/g	NMT 100 cfu/g
	E.Coli	Absent	Should be Absent
	Salmonella	Absent	Should be Absent
	S.aureus	Absent	Should be Absent
	P.aeruginosa	Absent	Should be Absent

Remark : The product complies/~~not complies~~ with the prescribed standard of quality with reference to BP/USP and In-house Specification.

	Tested By	Checked By	Approved By
Sign			
Name	Kayal	Ramesh	Vallarasan
Date	25/05/2022	25/05/2022	25/05/2022

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S.No. 4/3, Plot No.3, kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.	Page 1 of 1	Issued by (QA): <i>Q. J. S.</i> Date: <i>25/03/2022</i>
	TESTING AND RELEASE OF INTERMEDIATE AND FINISHED PRODUCTS	Format No.: F/QCGN/022/04	Revision No.: 01
TITLE:	CHECK LIST OF FINISHED PRODUCT	Review Period: 02 Years	Effective Date: <i>22/08/2022</i>

Name of the Product:	<i>Bondipho - 500</i>		
Analytical Report No.	<i>B3/110422/02.</i>	Batch No.	<i>641822068.</i>

Log entry Verification (Put ✓ mark on verified)	CONTENTS	S.No.	No. of Pages
Balance log entry ✓	Check list- Finished product	1-1	1
WS log entry ✓	Test request form	2-3	2
WS validity entry ✓	Observation during sampling form	NA	NA.
HPLC Column entry ✓	Certificate of analysis	4-5	2
HPLC Ins. log entry ✓	Result of analysis (Analytical work record)	NA	NA
Dissolution log entry ✓	Physical parameter sheet Tablet / Capsule / Sachet	6-13.	8.
UV-VIS log entry ✓	Graph of UV-VIS spectrophotometer	14-16.	3
pH meter log entry	Graph of IR spectrophotometer	NA	NA.
IR log entry NA.	LC chromatogram	17-49.	33
	Tapped density test report	NA	NA
	KF-Autotitra report	NA	NA.
	Microbiological test report	50-55	6
	Outside laboratory testing report	NA	NA.
	Additional test report if any	56-57.	2
	The above product consist of <u>57</u> pages		Total pages <u>57</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.3, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.	Page 1 of 1 Issued by: <i>g.s.e</i> QA/Date: <i>24/03/22</i>
	SAMPLING POLICY	No.: F/QAGN/026/01 Revision No: 01
TITLE	TEST REQUEST FORM	Review Period: 2 years Effective Date: <i>19/06/2021</i>

Date: <i>11/04/2022</i>		
From (Dept): <i>.....production.....</i>		To: Q.C. DEPARTMENT
Name of the Item/ Product/ Previous Product* :	<i>Bonicipro 250500</i>	Quantity sampled
Batch No.* :	<i>Q1822067</i>	1. <i>Coated stage</i>
Batch Size* :	<i>3.02</i>	2. <i>120 tablets</i>
Mfg. Date* :	<i>04/2022</i>	3. <i>1</i>
Exp. Date* :	<i>03/2025</i>	4. <i>1</i>
Stage* :	<i>Coated tablets</i>	Sampled on: <i>09/04/22</i>
		Sampled by: <i>Anbu</i>
		Analyzed By: <i>Kayal</i>
		Analytical Reference No.
		<i>13/1104 22/02</i>

Tests:	
1. <i>As per specification</i>	
2. <i>NA</i>	
3. <i>NA</i>	
4. <i>NA</i>	

<i>11/04/2022</i> TRF raised by Sign/Date	<i>11/04/22</i> TRF given to QC by QA Sign/Date	<i>11/04/22</i> Head of QC Sign/Date
--	--	---

*wherever not applicable write NA

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.3, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.	Page 1 of 1	Issued by <i>G. Senthil Kumar</i> QA/Date: <i>31/01/22</i>
	SAMPLING POLICY		No.: F/QAGN/026/01 Revision No: 01 Review Period: 2 years Effective Date: <i>19/06/2021</i>
TITLE		TEST REQUEST FORM	

Date: <i>11/04/2022</i>	
From (Dept): <i>Packing</i>	To: Q.C. DEPARTMENT
Name of the Item/ Product/ Previous: Product* : <i>BONCIPRO 500</i>	Quantity sampled
Batch No.* : <i>G11822068</i>	1. <i>Finished Goods</i>
Batch Size* : <i>3.01</i>	2. <i>12x10's</i>
Mfg. Date* : <i>04/2022</i>	3. <i>- NA -</i>
Exp. Date* : <i>03/2025</i>	4. <i>- NA -</i>
Stage* : <i>Finished goods</i>	Sampled on: <i>11/04/2022</i>
	Sampled by: <i>G. SENTHIL KUMAR</i>
	Analyzed By: <i>Kayal</i>
	Analytical Reference No. <i>Fp/110422/03</i>

Tests:
1. <i>AS PER SPECIFICATION</i>
2. <i>NA</i>
3. <i>NA</i>
4. <i>NA</i>

<i>Narayana</i> <i>11/04/2022</i>	<i>G. Senthil Kumar</i> <i>11/04/2022</i>	<i>Kayal</i> <i>11/04/2022</i>
TRF raised by Sign/Date	TRF given to QC by QA Sign/Date	Head of QC Sign/Date

*wherever not applicable write NA

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QUALITY
CONTROL

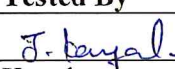
CERTIFICATE OF ANALYSIS

Format No:
F/QCGN/022/08

FINISHED PRODUCT

Product Name	:	BONCIPRO-500 TABLETS(Ciprofloxacin Hydrochloride tablets BP 500 mg)		
A.R.No.	:	BS/110422/02		
Batch No.	:	G1822068	Batch Size	: 3.0 L
Mfg. Date	:	Apr-2022	Exp. Date	: Mar-2025
Sampling Date	:	11.04.2022	Sample Qty	: 120 Tablets
Analysis Date	:	11.04.2022	Release Date	: 25.04.2022

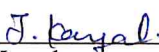
S.No.	TEST	RESULTS			LIMITS
01.	Description	Reddish pink coloured, oblong, biconvex film coated tablet with plain on both sides.			Reddish pink coloured, oblong, biconvex film coated tablet with plain on both sides.
02.	Identification A) By TLC B) By HPLC	Complies Complies			The Principal band in the chromatogram obtained with solution (1) corresponding to that in the chromatogram obtained with solution (2). 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 of tablets	731.60mg			736.0 mg $\pm$ 5.0% (Limit:699.20 mg to 772.80 mg)
04.	Uniformity of weight	+3.90 % to -3.64%			Not more than 2 of the individual weights deviate from the average weight by more than $\pm$ 5 % and none deviate by more than $\pm$ 10 % .
05.	Dimensions Thickness Length Width	Min 5.39 mm 17.36 mm 7.63 mm	Max 5.58mm 17.40 mm 7.68 mm	Avg. 5.45mm 17.38 mm 7.65 mm	5.30 mm to 5.70 mm 17.10 mm to 17.50 mm 7.60 mm to 7.80 mm
06.	Hardness	10.7 kg/cm ²			NLT 3.0 kg/cm ²
07.	Disintegration time	02 minutes 48 seconds			Not more than 30 minutes
08.	Dissolution By UV	Min 93.75 %	Max 99.49 %	Avg. 96.89%	Not less than 85.0 % of labeled amount.

	Tested By	Checked By	Approved By
Sign			
Name	Kayal	Ramesh	Vallarasan
Date	25/04/2022	25/04/2022	25/04/2022

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PRIVATE LIMITED R.S. No. 4/3, plot No. 33, Kurumbapet Industrial Estate,Villianur Commune, Pondicherry- 605009				Page 2 of 2	
QUALITY CONTROL	CERTIFICATE OF ANALYSIS				Format No: F/QCGN/022/08	
	FINISHED PRODUCT					
Product Name	:	BONCIPRO-500 TABLETS(Ciprofloxacin Hydrochloride tablets BP 500 mg)				
A.R.No.	:	BS/110422/02				
Batch No.	:	G1822068	Batch Size	:	3.0 L	
Mfg. Date	:	Apr-2022	Exp. Date	:	Mar-2025	
Sampling Date	:	11.04.2022	Sample Qty	:	120 Tablets	
Analysis Date	:	11.04.2022	Release Date	:	25.04.2022	

09.	Related substances:		
	Ciprofloxacin impurity C	Not Detected	Not more than 0.5%
	Ciprofloxacin impurity E	Not Detected	Not more than 0.3%
	Any individual impurity	Not Detected	Not more than 0.2%
	Total impurities	Not Detected	Not more than 1.0%
10.	Assay: Each film coated tablet contains:		
	Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg	103.56 %	Not less than 95.0% and not more than 105.0% of labeled claim.
11.	Microbiological limits:		
	Total Aerobic Microbial count	20 cfu /g	NMT 1000 cfu/g
	Total Yeasts and mould counts	<10 cfu/g	NMT 100 cfu/g
	E.Coli	Absent	Should be Absent
	Salmonella	Absent	Should be Absent
	S.aureus	Absent	Should be Absent
	P.aeruginosa	Absent	Should be Absent

Remark : The product complies/~~not complies~~ with the prescribed standard of quality with reference to BP/USP and In-house Specification.

	Tested By	Checked By	Approved By
Sign.			
Name	Kayal	Ramesh	Vallarasan
Date	25/04/2022	25/04/2022	25/04/2022

	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009		Issued by:  Date: 11/04/2022
	RAW DATA SHEET FOR FINISHED PRODUCT		
Name of Product: BonCipro 500			
Batch No: G11822068		A.R. Number: BS/110422/02	
Sample Qty.: 120 tablets		Stage: Coated	
Analysis Start On: 11/04/2022		Specification No: NA	
Analysis Completed On: 19/04/2022			

1) Description: Reddish pink coloured, oblong, biconvex film coated tablet with plain on both sides.

2) Identification:

3) Avg. weight of tablet:

$$\text{Avg. weight of tablet} = \frac{14.632 \text{ gm}}{20} = 0.7316 \text{ gm equivalent to } 731.6 \text{ mg}$$

4) Uniformity of Wt. of tablets:

No.	Weight in mg	No.	Weight in mg	No.	Weight in mg	No.	Weight in mg
1	0.732	6	0.721	11	0.738	16	0.733
2	0.724	7	0.759	12	0.748	17	0.732
3	0.712	8	0.749	13	0.724	18	0.729
4	0.760	9	0.714	14	0.716	19	0.705
5	0.730	10	0.728	15	0.739	20	0.735

5) Friability:

weight of Highest: 0.760, Percentage: 3.9%
 weight of Lowest: 0.705, Percentage: -3.64%

i) Weight of tablets before test: gm.

ii) Weight of tablets after test: gm.

iii) Weight difference: gm.

$$\text{Friability} = \frac{\text{Weight difference}}{\text{Weight of tablets before test}} \times 100 =$$

Analyzed By:  Date: 11/04/2022	Checked by:  Date: 19/04/2022
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6) Disintegration Time:

Time: 02 minutes 48 seconds.

7) Hardness:

Sr. No	Hardness (kg/cm ²)	Sr. No	Hardness (kg/cm ²)
1	8.0	6	11.5
2	12.0	7	10.8
3	11.0	8	9.5
4	10.8	9	10.0
5	12.3	10	11.5
Mean Hardness (kg/cm ²)		10.7 kg/cm ²	

8) Thickness:

Sr. No	Thickness (mm)	Sr. No	Thickness (mm)
1	5.47	6	5.58
2	5.45	7	5.45
3	5.40	8	5.44
4	5.42	9	5.51
5	5.39	10	5.43
Mean Thickness (mm)		5.45 mm	

9) Diameter: NA

Sr. No	Diameter (mm)	Sr. No	Diameter (mm)
1		6	
2		7	
3		8	
4		9	
5		10	
Mean Diameter (mm)			

10) Dissolution:

Dissolution Parameter:

Type	:	paddle
Medium	:	900 ml water
Volume	:	900 ml.
Speed	:	50 rpm
Time	:	30 mins.
Wavelength	:	276 nm.

Analyzed By: Date 11/04/2022Checked by: Date: 19/04/2022

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ANALYTICAL DATA SHEET

Page No. **1402**

Average length:

1. 17.38	6. 17.38
2. 17.40	7. 17.36
3. 17.37	8. 17.36
4. 17.37	9. 17.38
5. 17.40	10. 17.36

Avg: 17.38 mm

Average width:

1. 7.64	6. 7.64
2. 7.66	7. 7.66
3. 7.65	8. 7.66
4. 7.63	9. 7.68
5. 7.64	10. 7.65

Avg: 7.65 mm

Analysed by: 

Date: 11/04/2022

Checked by: 

Date: 19/04/2022

F/QCGN/003/01-01

Preparation of dissolution medium:

purified water.

Chromatographic Condition: NA

Column Description	:	
Column No.	:	
Flow Rate	:	
Wavelength	:	
Injection Volume	:	
Column Oven Temperature	:	

Preparation of buffer for Mobile phase:Mobile phase preparation:Standard Preparation:

27.77mg ciprofloxacin standard. in 100ml of dissomedium. sonicate and make up with volume of dissolution medium.

further diluted 2ml solution in 100ml smf in dissomedium.

Sample Preparation:

1 Tablet in 900ml water filter the solution in PDF syringe filter further diluted 2ml of this solution in 100ml smf (dissomedium)

Calculation and Results:Formula:

Analyzed By: M. V. D.	Checked by: JH
Date: 14/04/2022	Date: 19/04/2022

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11) Assay:

Chromatographic Condition:

Column Description	:	C ₁₈ (250mm x 4.6mm, 5µm)
Column No.	:	QC-1C-010
Flow Rate	:	1.5 ml/min.
Wavelength	:	278 nm.
Injection Volume	:	25 µl.
Column Oven Temperature	:	40°C.

Preparation of buffer for Mobile phase:

Dilute 4.963 g of OPA in 2000 ml of water, Adjust pH 3.0 with triethylamine.

Mobile phase preparation:

ACN : Buffer (260 : 1740).

Standard Preparation:

Dissolved 22.48 mg of ciprofloxacin HCl in 100 ml SMF with mobile phase. Further dilute 5 ml to 100 ml SMF with mobile phase.

Sample Preparation: (1)

Dissolved 295.26 mg of Sample powder in 100 ml SMF with mobile phase, Sonicate for 20 minutes, dilute with mobile phase. Filter. Further dilute 1 ml to 200 ml SMF with mobile phase.

Sample Preparation: (2)

Dissolved 293.20 mg of Sample powder in 100 ml SMF with mobile phase, Sonicate for 20 minutes, dilute with mobile phase. Filter. Further dilute 1 ml to 200 ml SMF with mobile phase.

Analyzed By: J. Kanyal

Date

13/04/2022

Checked by:

Date:

J
19/04/2022

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Calculation and Results:Formula:

Refer to Excel sheet.

12) Uniformity of dosage unit /Content Uniformity:Chromatographic Condition:

Column Description	:	
Column No.	:	
Flow Rate	:	
Wavelength	:	
Injection Volume	:	
Column Oven Temperature	:	

Preparation of buffer for Mobile phase:Mobile phase preparation:Standard Preparation:Sample Preparation:

Analyzed By: J. Kagal	Checked by: Jf
Date: 13/04/2022	Date: 19/04/2022

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(Repeat same procedure for other 9 tablets)

Calculation and Results:

Formula:

13) Related Substances/ Impurities:

Chromatographic Condition:

Refer to Assay.

Column Description	:	
Column No.	:	
Flow Rate	:	
Wavelength	:	
Injection Volume	:	
Column Oven Temperature	:	

Preparation of buffer for Mobile phase:

Refer to Assay.

Mobile phase preparation:

Refer to Assay :

Resolution/ impurity preparation:

Analyzed By: <i>J. Koyal</i>	Checked by: <i>JK</i>
Date: <i>13/04/2022</i>	Date: <i>19/04/2022</i>

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Standard/ Reference Preparation:Placebo Preparation:

Dissolved 92.78 mg of placebo in 100 ml SMF with mobile phase. Sonicate for 20 minutes. Filter. Dilute 1 ml to 20 ml SMF with mobile phase.

Sample Preparation:

Soln. 1: Dissolved 292.32 mg of sample powder in 100 ml SMF with mobile phase. Sonicate for 20 minutes. Filter. Dilute 1 ml to 20 ml SMF with mobile phase.
Soln. 2: Dilute 1 ml of Soln. (1) to 20 ml SMF with mobile phase. Further dilute 1 ml to 10 ml SMF with mobile phase.
Soln. 3: Dilute 1 ml of Soln. (2) to 5 ml SMF with mobile phase.

Calculation and Results:Formula:Known impurity:Unknown impurity:Total impurities:

Analyzed By: J. Kayal 13/04/2022	Checked by: JF Date: 19/04/2022
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EXCEL SHEET FOR DISSOLUTION CALCULATION

Name of Product	BONCIPRO-500_COATED				
Date of Analysis	14.04.2022	Batch No.	G1822068		
Mfg. Date	APR_2022	Exp. Date	MAR_2025		
WS No.	WS/CIP/059	% Purity	94.44		
WS Weight (WS)	27.77	WS Validity	02/04/2023		
Sample Weight (SW)	1	Label Claim (LC)	500		

Std. Dilution	27.77	2	1	1	1	1	CF1	0.901
	100	100	1	1	1	1		
Sample Dilution	1	2	1	1	1	1	CF2	1
	900	200	1	1	1	1		
							CF3	1
							CF4	1

Calculation Formula	Smp. Area/Abs	Std Dilution	94.44	100	CF1	CF3
	Std. Area/Abs	Sample Dilution	100	500	CF2	CF4

Sr. No.	Standard Area/Abs	Standard RT
1	0.578	
2	0.578	
3	0.578	
4	0.578	
5	0.578	
6		
Average	0.578	#DIV/0!
SD	0	#DIV/0!
%RSD	0.0	#DIV/0!

Tablet	Area/Abs.
Tab1	0.676
Tab2	0.675
Tab3	0.651
Tab4	0.637
Tab5	0.645
Tab6	0.666
Average	
Minimum	
Maximum	

Result %	Result mg
99.49	497.45
99.34	496.70
95.81	479.05
93.75	468.75
94.93	474.65
98.02	490.10
96.89	484.45
93.75	468.75
99.49	497.45

Analysed By
Date

Checked By
Date

14/04/2022

SAI PRIMUS LIFE BIOTECH PVT LTD
PHOTOMETRIC REPORT

14/04/2022 18:01:31

15

File Name: D:\UV DATA\Data\DATA 2022\APRIL-2022\14042022\BONCIPRO_500_COATED.unk

Sample Table

	Sample ID	WL276.0	Comments
1	BLANK	0.000	BONCIPRO_500mg
2	STD	0.578	
3			

[Wavelengths]

Wavelength Name: WL276.0
Wavelength: 276.00 nm

[Calibration Curve]

Cal. Curve Type: Raw Data

[Measurement Parameters(Standard)]

[Measurement Parameters(Sample)]

Data Acquired by: Instrument
Delay sample read: Disabled
Repeat: Disabled

[Equations]

[Pass Fail]

[Method Summary]

Title:
Date/Time: 14/04/2022 16:38:58
Comments:
Sample Preparations:

[Instrument Properties]

Instrument Type: UV-1900 Series
Measuring Mode: Absorbance
Slit Width: 1.0 nm
Light Source Change Wavelength: 340.8 nm
S/R Exchange: Normal

Software Information

Software Name: UVProbe
Version: 2.70
Mode: Security Mode

Data Information

Filename: D:\UV DATA\Data\DATA 2022\APRIL-2022\14042022\BONCIPRO_500_COATED.unk
Title: DISSO_STD
Analyst: KAYAL
Date/Time: 14/04/2022 16:51:59
Comments: DISSO_500

Instrument Information

Instrument Name: UV1900
Instrument Type: UV-1900 Series
Model (S/N): UV1900 (A12425780886)

.....

Analysed By: M. V. D.
Date: 14/04/2022

Checked By: J. A.
Date: 14/04/2022

SAI PRIMUS LIFE BIOTECH PVT LTD
PHOTOMETRIC REPORT

14/04/2022 17:50:52

16

File Name: D:\UV DATA\Data\DATA 2022\APRIL-2022\14042022\BONCIPRO_500_COATED_spl.unk

Sample Table

	Sample ID	Conc	WL276.0	Comments
1	JAR_1	99.541	0.676	BONCIPRO_500mg
2	JAR_2	99.383	0.675	
3	JAR_3	95.748	0.651	
4	JAR_4	93.691	0.637	
5	JAR_5	94.941	0.645	
6	JAR_6	97.998	0.666	
7				

[Wavelengths]

Wavelength Name: WL276.0
Wavelength: 276.00 nm

[Calibration Curve]

Column for Cal. Curve: WL276.0
Cal. Curve Type: K Factor
Cal. Curve Unit: mg/l
Selected Wavelength: WL276.0
Calibration Equation: $(\text{Conc}) = K1(\text{unk abs}) + K0$
K1: 147.1741
K0: 0.0000

[Measurement Parameters(Standard)]

[Measurement Parameters(Sample)]

Data Acquired by: Instrument
Delay sample read: Disabled
Repeat: Disabled

[Equations]

[Pass Fail]

[Method Summary]

Title:
Date/Time: 14/04/2022 17:40:00
Comments:
Sample Preparations:

.....

Software Information

Software Name: UVProbe
Version: 2.70
Mode: Security Mode

Data Information

Filename: D:\UV DATA\Data\DATA 2022\APRIL-2022\14042022\BONCIPRO_500_COATED_spl.unk
Title: BONCIPRO_500_COATED
Analyst: KAYAL
Date/Time: 14/04/2022 17:50:30
Comments: disso

Instrument Information

Instrument Name: UV1900
Instrument Type: UV-1900 Series
Model (S/N): UV1900 (A12425780886)

Analysed By: M. J. D.
Date: 14/04/2022

Checked By: 
Date: 14/04/2022



SAI PRIMUS

LIFE BIOTECH PVT. LTD.

EXCEL SHEET FOR ASSAY CALCULATION FP

Name of Product		BONCIPRO_500									
Date of Analysis		13.04.2022		Batch No.		G1822068					
Mfg. Date		Apr-22		Exp. Date		Mar-25					
WS No.		WS/CIP/059		% Purity		94.44					
WS Weight (WS)		22.48		WS Validity		2/4/2023					
Sample Weight (SW)		1		Label Claim (LC)		500					
CF1				CF2		1		CF3		1	
CF4										1	

Std. Dilution	22.48	5	1	1	1	1
	100	100	1	1	1	1

Sample Dilution	1	1	1	1	1	1
	100	200	1	1	1	1

Calculation Formula	Smp. Area/Abs	Std Dilution	94.44	731.6	CF1	CF3
	Std. Area/Abs	Sample Dilution	100		CF2	CF4

Sr. No.	Standard Area/Abs	Standard RT
1	1220571	8.693
2	1219009	8.687
3	1220191	8.696
4	1222646	8.701
5	1226967	8.690
Average	1221877	8.693
SD	3133.41	0.01
RSD	0.26	0.06

Assay (mg) SPL-1	515.7699
Assay (mg) SPL-2	519.8058
AVERAGE	517.7879

Sr. No.	Sample Area/Abs
1	1329650
2	1330705
3	
4	
5	
6	
Average	1330178

Assay (%) SPL-1	103.15
Assay (%) SPL-2	103.96
AVERAGE	103.56

Avg. WT	731.60
SPL-1 WT(mg)	295.26
SPL-2 WT(mg)	293.2

Analysed By	J. Kavya
Date	15/04/2022

Checked By	
Date	19/04/2022

	Vial	Inj Vol (uL)	# of Injs	SampleName	Function	Method Set / Report or Export Method	Processing	Run Time (Minutes)
1	25	25.0	1	BLANK_AS	Inject Controls	BONCIPRO_AS_FP_MSET	Normal	20.00
2	26	25.0	5	STANDARD_AS	Inject Standards	BONCIPRO_AS_FP_MSET	Normal	20.00
3	25	25.0	1	BLANK_AS	Inject Controls	BONCIPRO_AS_FP_MSET	Normal	20.00
4	27	25.0	1	BONCIPRO_250_G1822069_SP_01	Inject Samples	BONCIPRO_AS_FP_MSET	Normal	20.00
5	28	25.0	1	BONCIPRO_250_G1822069_SP_02	Inject Samples	BONCIPRO_AS_FP_MSET	Normal	20.00
6	29	25.0	1	BONCIPRO_500_G1822068_SP_01	Inject Samples	BONCIPRO_AS_FP_MSET	Normal	20.00
7	30	25.0	1	BONCIPRO_500_G1822068_SP_02	Inject Samples	BONCIPRO_AS_FP_MSET	Normal	20.00
8	31	25.0	1	BONCIPRO_750_G1822075_SP_01	Inject Samples	BONCIPRO_AS_FP_MSET	Normal	20.00
9	32	25.0	1	BONCIPRO_750_G1822075_SP_02	Inject Samples	BONCIPRO_AS_FP_MSET	Normal	20.00
0	26	25.0	1	STANDARD_AS_BKT	Inject Standards	BONCIPRO_AS_FP_MSET	Normal	20.00
1					Condition Column	WASHING SOLUTION_C_MSET		150.00
2					Condition Column	WASHING SOLUTION_D_MSET		50.00
3					Equilibrate	SHUTDOWN_MSET		0.01

J. Kuyal
13/04/2022

CH 13/04/2022



INSTRUMENT METHOD



Instrument Method: BONCIPRO_AS_FP_IM

Stored: 08/04/2022 11:07:39 IST

Method Information

Method Comments NEW INSTRUMENT CREATED
Method Modified User MONICA
Method Locked No
Method Id 4028
Old Id
Method Version 1
Method Edit User
Source S/W Info Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615

W2489 Instrument Setup

Wavelength Mode Single Wavelength
Lamp On On

Channel A

Comment
Wavelength 278(nm)
Sampling Rate 10(points/sec)
Data Mode Absorbance
Time Constant 0.1(sec)
Autozero On Wavelength Change Maintain Baseline
Autozero On Inject Start Yes

Analog 1

Sensitivity 2.0000(AUFS)
Chart Polarity Positive (+)
Voltage Offset 0(mV)
Enable Chart Mark Yes

Run Events Yes

Pulse Width 1.0(sec)
Rect Wave Period 0.2(sec)

W2690/5 Instrument Setup

Type W2690/5
Instrument Status On
Channel Name 2690/5
Description 278
Use Channel Monitor On
Monitor Parameter System Pressure

Analysed by: J. Kayal
Date: 13/04/2022

Checked by: J. Kayal
Date: 13/04/2022

Reported by User: KAYAL (KAYAL)
Report Method: INSTRUMENT METHOD
Report Method ID: 1056
Page: 1 of 3

Project Name: 2022\QC_HPL_003\APR-2022
Printed Date: 13/04/2022
Printed Time: 18:06:36 Asia/Calcutta

Stroke Volume 100uL (flow rates <= 3.030 mL/min)
 Chart Out %A
 Syringe Draw Rate Normal
 Depth Of Needle 0.0
 Degas Mode On
 Pump Mode Isocratic
 Flow 1.500
 %A 100.0
 %B 0.0
 %C 0.0
 %D 0.0
 High Limit 5000.0
 Low Limit 0.0
 Enable Sample Temp True
 Enable Column Temp True
 Bubble Detect True
 Pre Column Volume 0.0
 Sample Temp Target 25.0
 Sample Temp Range 5.0
 Sparge A 0.0
 Sparge B 0.0
 Sparge C 0.0
 Sparge D 0.0
 Column Temp Target 40.0
 Column Temp Range 5.0
 Flow Ramp 2.00
 Column choice No Change
 Column Equil Minutes 0.00
 Needle Wash Normal
 Switch 1 No Change
 Switch 2 No Change
 Switch 3 No Change
 Switch 4 No Change
 Use Events False
 Solvent A
 Solvent B
 Solvent C
 Solvent D

Revision History

Version 1 08/04/2022 11:07:39 IST User MONICA Created method 'BONCIPRO_AS_FP_IM'. NEW INSTRUMENT CREATED

Method Version Summaries

	Method Name	Method Type	Method Comments	Method Date	Method Modified User	Method Locked
1	BONCIPRO_AS_FP_IM	Instrument	NEW INSTRUMENT CREATED	08/04/2022 11:07:39 IST	MONICA	No

Analysed by:

Date

J. KAYAL
13/04/2022

Checked by:

Date

CF
13/04/2022

Reported by User: KAYAL (KAYAL)

Report Method: INSTRUMENT METHOD

Report Method ID: 1056

Page: 2 of 3

Project Name: 2022\QC_HPL_003\APR-2022

Printed Date: 13/04/2022

Printed Time: 18:06:36 Asia/Calcutta

Method Version Summaries

Method Id	Old Id	Method Version	Source S/W Info
1	4028	1	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615

Analysed by:

Date

J. Kayal
13/04/2022

Checked by:

Date

JF
13/04/2022

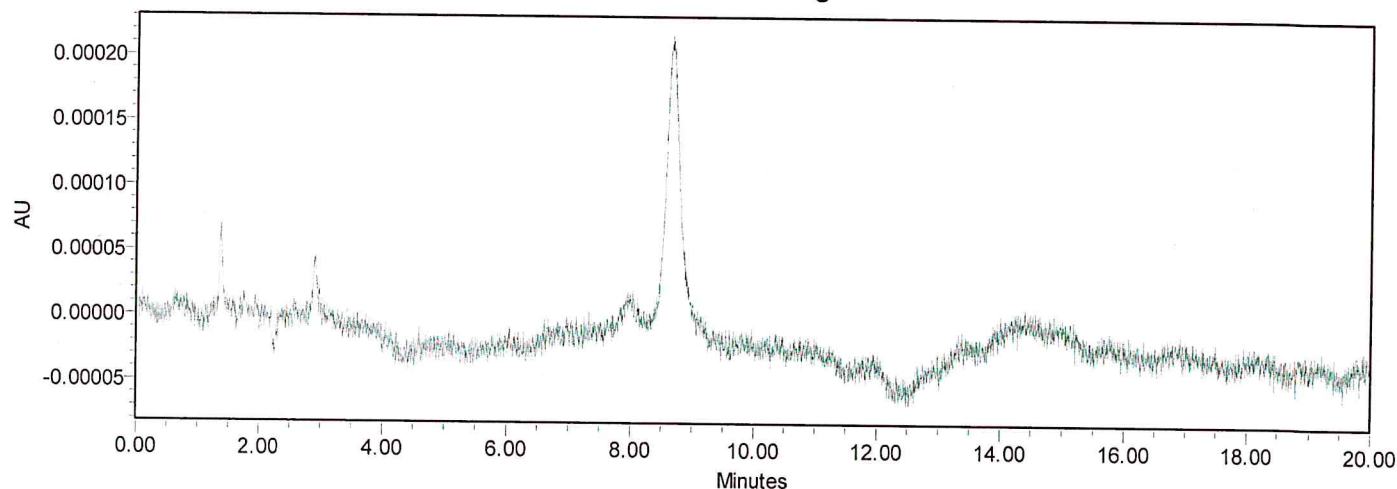
Reported by User: KAYAL (KAYAL)
Report Method: INSTRUMENT METHOD
Report Method ID: 1056
Page: 3 of 3

Project Name: 2022\QC_HPL_003\APR-2022
Printed Date: 13/04/2022
Printed Time: 18:06:36 Asia/Calcutta

SAMPLE INFORMATION

Sample Name:	BLANK_AS	Acquired By:	KAYAL
Sample Type:	Control	Sample Set Name:	13042022_BONCIPRO_AS_FP_SS
Vial:	25	Acq. Method Set:	BONCIPRO_AS_FP_MSET
Injection #:	1	Processing Method:	BONCIPRO_AS_FP_PM
Injection Volume:	25.00 ul	Channel Name:	W2489 ChA
Run Time:	20.0 Minutes	Proc. Chnl. Descr.:	W2489 ChA 278nm
Date Acquired: 13/04/2022 19:16:24 IST			
Date Processed: 15/04/2022 11:37:18 IST			

Auto-Scaled Chromatogram



Peak Results

	Name	Injection	RT	Area	% Area
1	CIPROFLOXACIN HCL	1	8.600		

Analysed by: J. Kayal
Date: 15/04/2022

Checked by: J. Kayal
Date: 15/04/2022

Reported by User: KAYAL (KAYAL)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 5808
Page: 1 of 1

Project Name: 2022\QC_HPL_003\APR-2022
Printed Date: 15/04/2022
Printed Time: 11:43:07 Asia/Calcutta

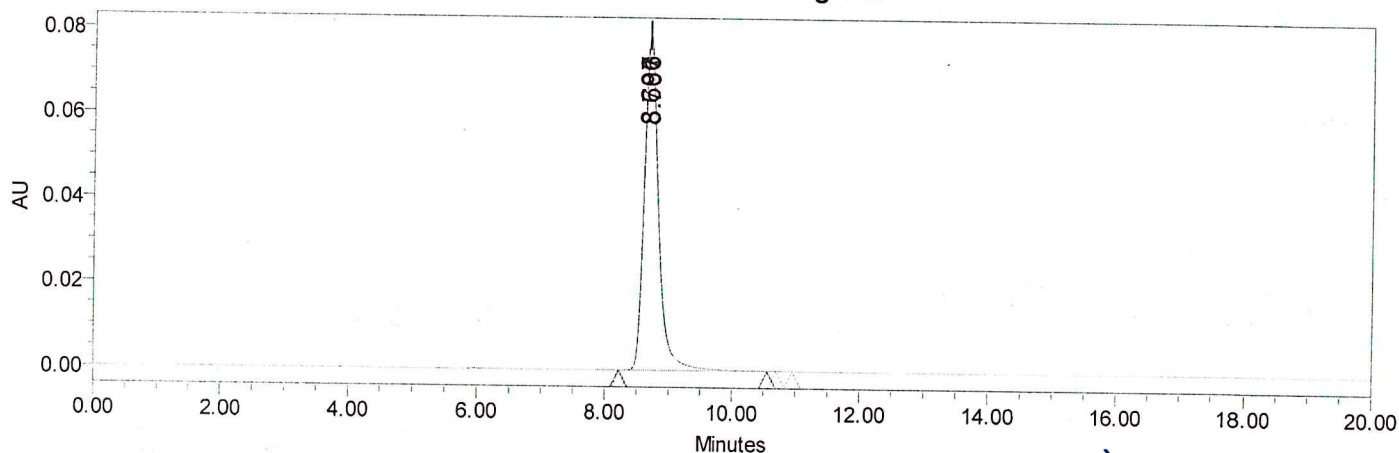
SAMPLE INFORMATION

Sample Name: STANDARD_AS
Sample Type: Standard
Vial: 26
Injection #: 1, 2, 4, 5, 3
Injection Volume: 25.00 ul
Run Time: 20.0 Minutes

Acquired By: KAYAL
Sample Set Name: 13042022_BONCIPRO_AS_FP_SS
Acq. Method Set: BONCIPRO_AS_FP_MSET
Processing Method: BONCIPRO_AS_FP_PM
Channel Name: W2489 ChA
Proc. Chnl. Descr.: W2489 ChA278nm

Date Acquired: 13/04/2022 19:37:37 IST, 13/04/2022 19:58:37 IST, 13/04/2022 20:19:35 IST, 13/04/2022 20:40:32 IST, 13/04/2022 21:01:29 IST
Date Processed: 15/04/2022 11:37:18 IST

Auto-Scaled Chromatogram



Peak Name: CIPROFLOXACIN HCL

	Peak Name	Injection	RT	Area	USP Plate Count	USP Tailing
1	CIPROFLOXACIN HCL	1	8.693	1220571	8251	1.4
2	CIPROFLOXACIN HCL	2	8.687	1219009	8245	1.4
3	CIPROFLOXACIN HCL	3	8.696	1220191	8236	1.4
4	CIPROFLOXACIN HCL	4	8.701	1222646	8204	1.4
5	CIPROFLOXACIN HCL	5	8.690	1226967	8169	1.4
Mean			8.693	1221877	8221	1.4
Std. Dev.			0.005	3133.417		
% RSD			0.1	0.3		

Analysed by: J. KAYAL
Date: 15/04/2022

Checked by: J. KAYAL
Date: 15/04/2022

Reported by User: KAYAL (KAYAL)
Report Method: RSD REPORT SYSTEM SUITABILITY
Report Method ID: 1367
Page: 1 of 1

Project Name: 2022\QC_HPL_003\APR-2022
Printed Date: 15/04/2022
Printed Time: 11:45:06 Asia/Calcutta

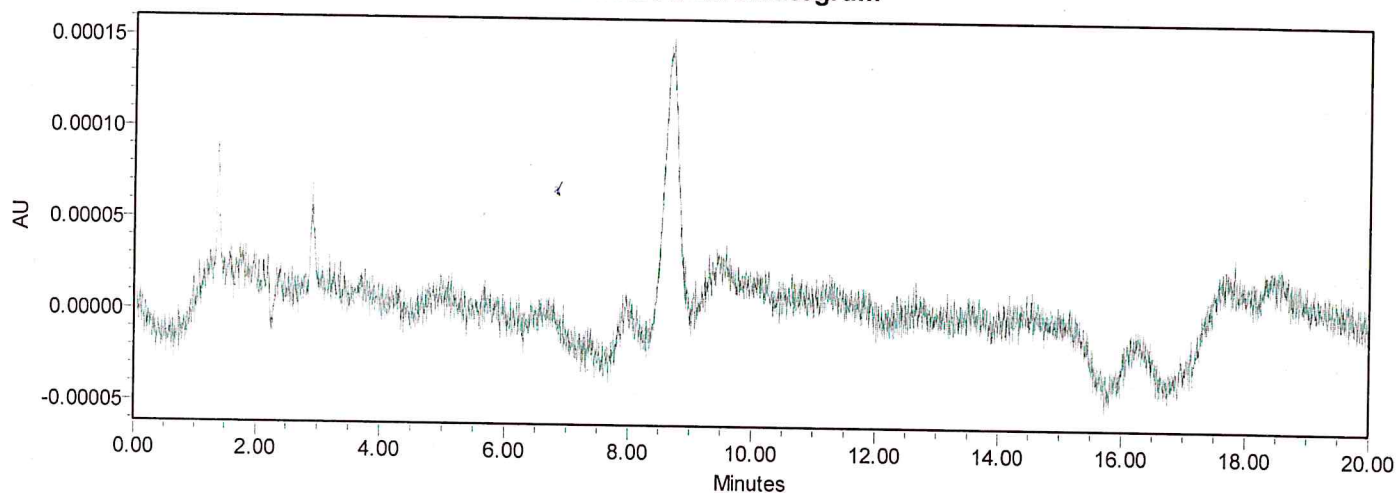
SAMPLE INFORMATION

Sample Name: BLANK_AS
Sample Type: Control
Vial: 25
Injection #: 1
Injection Volume: 25.00 ul
Run Time: 20.0 Minutes

Acquired By: KAYAL
Sample Set Name: 13042022_BONCIPRO_AS_FP_SS
Acq. Method Set: BONCIPRO_AS_FP_MSET
Processing Method: BONCIPRO_AS_FP_PM
Channel Name: W2489 ChA
Proc. Chnl. Descr.: W2489 ChA 278nm

Date Acquired: 13/04/2022 21:22:34 IST
Date Processed: 15/04/2022 11:37:18 IST

Auto-Scaled Chromatogram



Peak Results

	Name	Injection	RT	Area	% Area
1	CIPROFLOXACIN HCL	1	8.600		

Analysed by: J. Kayal
Date: 15/04/2022

Checked by: J. Kayal
Date: 15/04/2022

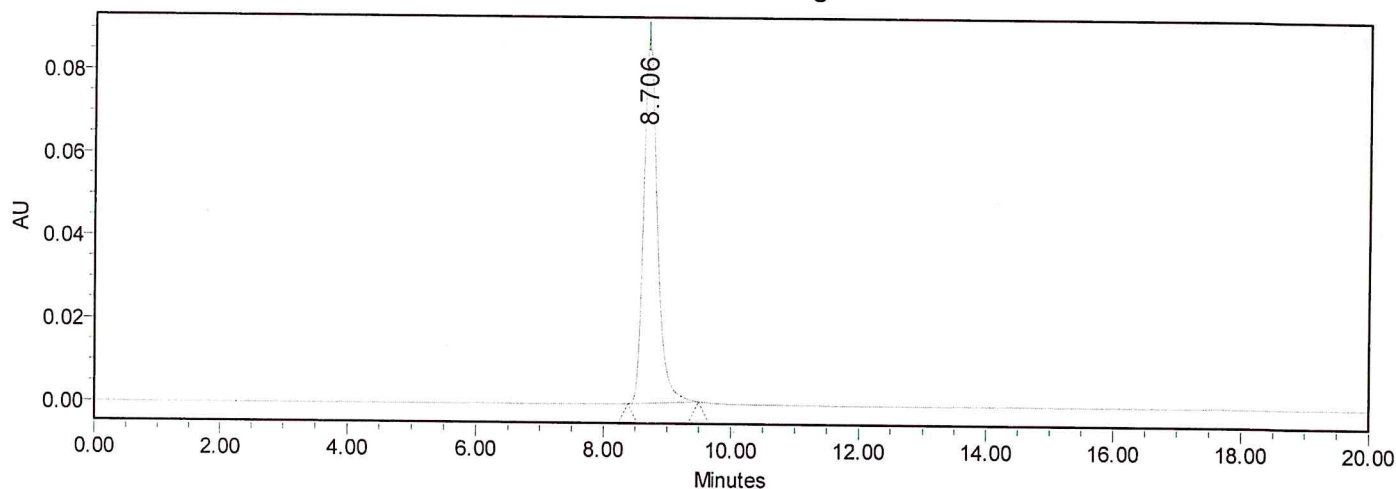
Reported by User: KAYAL (KAYAL)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 5808
Page: 1 of 1

Project Name: 2022\QC_HPL_003\APR-2022
Printed Date: 15/04/2022
Printed Time: 11:45:28 Asia/Calcutta

SAMPLE INFORMATION

Sample Name:	BONCIPRO_500_G1822068_SP_01	Acquired By:	KAYAL
Sample Type:	Unknown	Sample Set Name:	13042022_BONCIPRO_AS_FP_SS
Vial:	29	Acq. Method Set:	BONCIPRO_AS_FP_MSET
Injection #:	1	Processing Method:	BONCIPRO_AS_FP_PM
Injection Volume:	25.00 ul	Channel Name:	W2489 ChA
Run Time:	20.0 Minutes	Proc. Chnl. Descr.:	W2489 ChA 278nm
Date Acquired:	13/04/2022 22:25:35 IST		
Date Processed:	15/04/2022 11:38:17 IST		

Auto-Scaled Chromatogram



Peak Results

	Name	Injection	RT	Area	% Area
1	CIPROFLOXACIN HCL	1	8.706	1329650	100.00

Analysed by :

Date :

J. Kayal
15/04/2022

Checked by :

Date :

J. Kayal
15/04/2022

Reported by User: KAYAL (KAYAL)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 5993
Page: 1 of 1

Project Name: 2022\QC_HPL_003\APR-2022
Printed Date: 15/04/2022
Printed Time: 11:46:53 Asia/Calcutta

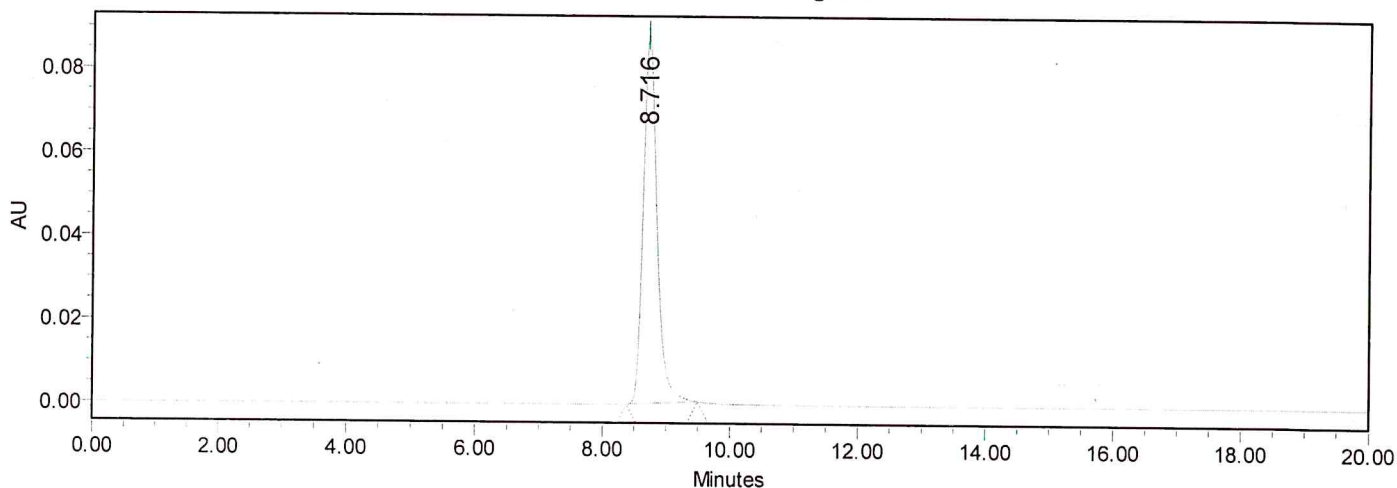
SAMPLE INFORMATION

Sample Name: BONCIPRO_500_G1822068_SP_02 Acquired By: KAYAL
 Sample Type: Unknown Sample Set Name: 13042022_BONCIPRO_AS_FP_SS
 Vial: 30 Acq. Method Set: BONCIPRO_AS_FP_MSET
 Injection #: 1 Processing Method: BONCIPRO_AS_FP_PM
 Injection Volume: 25.00 ul Channel Name: W2489 ChA
 Run Time: 20.0 Minutes Proc. Chnl. Descr.: W2489 ChA278nm

Date Acquired: 13/04/2022 22:46:37 IST

Date Processed: 15/04/2022 11:38:17 IST

Auto-Scaled Chromatogram



Peak Results

	Name	Injection	RT	Area	% Area
1	CIPROFLOXACIN HCL	1	8.716	1330705	100.00

Analysed by: J. Kayal
 Date: 15/04/2022

Checked by: J. Kayal
 Date: 15/04/2022

Reported by User: KAYAL (KAYAL)
 Report Method: CHROMATOGRAPHIC DATA
 Report Method ID: 5993
 Page: 1 of 1

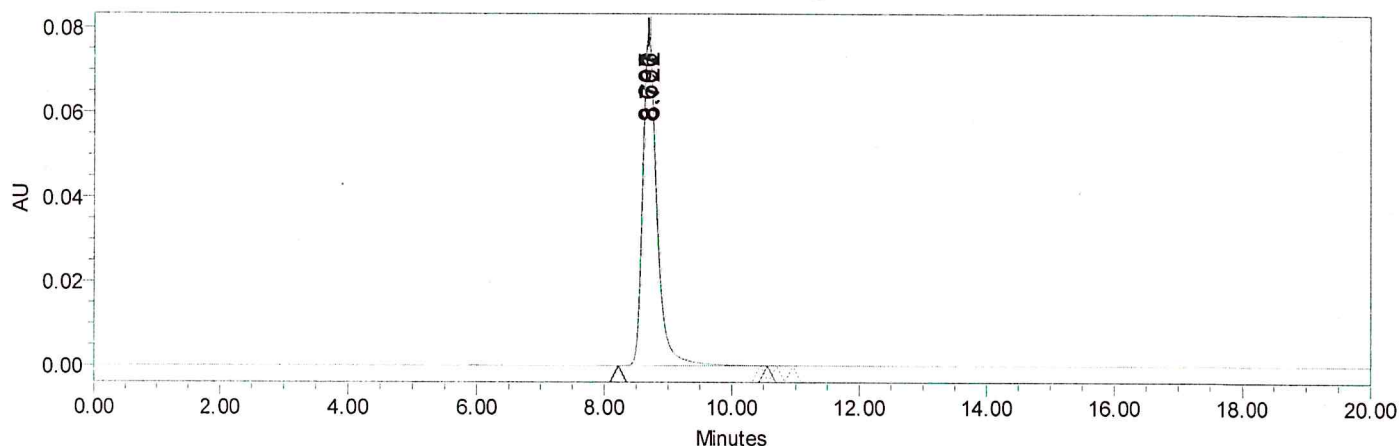
Project Name: 2022\QC_HPL_003\APR-2022
 Printed Date: 15/04/2022
 Printed Time: 11:49:03 Asia/Calcutta

SAMPLE INFORMATION

Sample Name: STANDARD_AS, STANDARD_AS_BKT Acquired By: KAYAL
Sample Type: Standard Sample Set Name: 13042022_BONCIPRO_AS_FP_SS
Vial: 26 Acq. Method Set: BONCIPRO_AS_FP_MSET
Injection #: 1, 2, 4, 5, 3 Processing Method: BONCIPRO_AS_FP_PM
Injection Volume: 25.00 ul Channel Name: W2489 ChA
Run Time: 20.0 Minutes Proc. Chnl. Descr.: W2489 ChA 278nm

Date Acquired: 13/04/2022 19:37:37 IST, 13/04/2022 19:58:37 IST, 13/04/2022 20:19:35 IST, 13/04/2022 20:40:32 IST, 13/04/2022 21:01:29 IST, 13/04/2022 23:49:43 IST
Date Processed: 15/04/2022 11:37:18 IST

Auto-Scaled Chromatogram



Peak Name: CIPROFLOXACIN HCL

	Peak Name	Injection	RT	Area	USP Plate Count	USP Tailing
1	CIPROFLOXACIN HCL	1	8.693	1220571	8251	1.4
2	CIPROFLOXACIN HCL	1	8.722	1229577	8216	1.4
3	CIPROFLOXACIN HCL	2	8.687	1219009	8245	1.4
4	CIPROFLOXACIN HCL	3	8.696	1220191	8236	1.4
5	CIPROFLOXACIN HCL	4	8.701	1222646	8204	1.4
6	CIPROFLOXACIN HCL	5	8.690	1226967	8169	1.4
Mean			8.698	1223160	8220	1.4
Std. Dev.			0.013	4211.497		
% RSD			0.1	0.3		

Analysed by: J. K. J.
Date: 15/04/2022

Checked by: J. K. J.
Date: 15/04/2022

Reported by User: KAYAL (KAYAL)
Report Method: RSD REPORT SYSTEM SUITABILITY
Report Method ID: 1367
Page: 1 of 1

Project Name: 2022\QC_HPL_003\APR-2022
Printed Date: 15/04/2022
Printed Time: 11:50:01 Asia/Calcutta

Processing Method: BONCIPRO_AS_FP_PM

Type: LC

Stored: 14/04/2022 09:55:03 IST

Method Information

Method Comments

Method Modified User

Method Locked

Method Id

Old Id

Method Version

Method Edit User

Source S/W Info

PROCESSING METHOD

CRAETED

MONICA

No

5614

5225

2

Empower 3 Software Build 3471
SPs Installed: Service Release 3
DB ID: 2530846615

Traditional

10.0

No

3

(m/z)

(m/z)

Pure

No

SET1

50.000(%)

(min)

1.0000(Da)

1.000

5

0.000(%)

Average

1.00(Da)

None

No

100.00(Da)

80.0(%)

Centroid Top(%)

80.00

Heights

0.500(Da)

None

None

5.00

Integration Algorithm

MS Ret Time Window

MS Ret Time Presearch

MS Search Depth

Start Mass Limit

End Mass Limit

PBM Search Mode

Duplicate Spectra

PBM Reference Sets

Search Threshold

Noise Baseline

Peak Separation

Baseline Multiplier

Spectra To Average

Noise Threshold

Combine Type

Expected Mass Peak Separation

Expected Mass Calculation Type

Include the uncorrected Target or Base Mass in the list of expected masses

Expected Mass Base Value

Expected Mass Base Intensity

Centroid Center Type

Centroid Top (%)

Centroid Intensity

Min. Peak Width at Half-Height

Smoothing Type

Average By

RT Window %

Analysed by:

Date:

J. K. J.

15/04/2022

Checked by:

Date:

J. K. J.

15/04/2022

Reported by User: KAYAL (KAYAL)

Report Method: PROCESSING METHOD

Report Method ID: 1057

Page: 1 of 4

Project Name: 2022\QC_HPL_003\APR-2022

Printed Date: 15/04/2022

Printed Time: 11:50:19 Asia/Calcutta

Update RT
CCalRef1
Include Internal Standard Amounts in Amount Calculation
Vial/Default Value Type
RT Reference Used to Name Unnamed Peaks by RRT

Never
Yes
Amount

System Suitability Information

Void Volume Time 0.100(min)
Calculate Suitability Yes
Flag Outside Yes
Calculate Unknowns Yes
Pharmacopoeia All
Tangent Percent (USP Plate Count) 61
Tangent Percent (USP Resolution) 50
Calculate USP, EP, and JP s/n No
Use noise centered on peak region in blank injection Yes
Half Height Multiplier for USP s/n Noise Region
Half Height Multiplier for EP s/n Noise Region
Half Height Multiplier for JP s/n Noise Region
Noise Value for s/n
% Runtime 5.0
Maximum Noise
Maximum Drift
Baseline Noise Minimum 30 Seconds
Baseline Start (min)
Baseline End (min)
Calculate Peak Statistical Moments No

Integration Parameters

Minimum Area 10000($\mu V \cdot sec$)
Minimum Height 0(μV)
Threshold 1.000($\mu V/sec$)
Peak Width 20.00(sec)

Integration Events

	Time (min)	Type	Value	Stop (min)
1	0.000	Valley to Valley		20.000
2	0.000	Inhibit Integration		8.200
3	12.000	Inhibit Integration		20.000

Component Table

	Name	Component Type	Peak Label	Retention Time (min)	RT Window (min)	Peak Match	Calculate Suit Results
1	CIPROFLOXACIN HCL			8.600	0.430	Closest	Yes

Analysed by : J. KAYAL
Date : 15/04/2022

Checked by : J. KAYAL
Date : 19/04/2022

Reported by User: KAYAL (KAYAL)
Report Method: PROCESSING METHOD
Report Method ID: 1057
Page: 2 of 4

Project Name: 2022\QC_HPL_003\APR-2022
Printed Date: 15/04/2022
Printed Time: 11:50:19 Asia/Calcutta

Component Table

	Flag Outside Limits	3D Channel Name (Description)	Channel	Y Value	X Value	Fit	Weighting	Internal Std	RT Reference
1	Yes			Area	Amount	Linear	None		

Component Table

	Rel RT Reference	RRT	Rel Resol Reference	Curve Reference	Relative Response	Impurity RRF	Must	Default Pk	Default Pk Start (min)	Default Pk End (min)	Default Units	Type
1					1.000000	1.0000	No	No				Single

Component Table

	Impurity Type	CCompRef1	CCompRef2	CCompRef3	CConst1	CConst2	CConst3	CConst4	CConst5	CConst6	CConst7
1											

Processing Method Group 'Name Groups' table contains no data.

Processing Method Group 'Time Groups' table contains no data.

Processing Method Group 'Suit Limits-'CIPROFLOXACIN HCL" table contains no data.

Processing Method Group 'Relative Limits-'CIPROFLOXACIN HCL" table contains no data.

Processing Method Group 'Def Amts-'CIPROFLOXACIN HCL" table contains no data.

Processing Method Group 'Primary Peaks (Primary MS Ions)' table contains no data.

Noise and Drift Parameters

Calculate Detector Noise and Drift No
 Detector Noise and Drift Start Time (Minutes)
 Detector Noise and Drift End Time (Minutes)
 Detector Noise and Drift Segment Width 60(sec)

Concentration Smoothing/Offset Parameters

Time Offset 0.000(Minutes)
 Smoothing Type None
 Smoothing Level None
 Empty parameters supersede the derived channel's smoothing and offset parameters No

Impurity Parameters

Calculate Total Impurities No Qualification Threshold
 Impurity Response Total Impurities Threshold
 w Value Maximum Impurity Threshold
 Main Component
 Reporting Threshold 0.05
 Identification Threshold

Excluded Component Types

Internal Standard Peaks

Revision History

Version 2 14/04/2022 09:55:03 IST User MONICA PEAK WIDTH CHANGE

Analysed by: J. Kayal
 Date: 15/04/2022

Checked by: J. Kayal
 Date: 19/04/2022

Reported by User: KAYAL (KAYAL)
 Report Method: PROCESSING METHOD
 Report Method ID: 1057
 Page: 3 of 4

Project Name: 2022\QC_HPL_003\APR-2022
 Printed Date: 15/04/2022
 Printed Time: 11:50:19 Asia/Calcutta

Method Version Summaries

	Method Name	Method Type	Method Comments	Method Date	Method Modified User
1	BONCIPRO_AS_FP_PM	Processing	PROCESSING METHOD CRAETED	15/04/2022 11:42:37 IST	KAYAL
2	BONCIPRO_AS_FP_PM	Processing	PROCESSING METHOD CRAETED	15/04/2022 11:38:02 IST	KAYAL
3	BONCIPRO_AS_FP_PM	Processing	PROCESSING METHOD CRAETED	14/04/2022 09:55:03 IST	MONICA
4	BONCIPRO_AS_FP_PM	Processing	PROCESSING METHOD CRAETED	12/04/2022 11:56:24 IST	MONICA

Method Version Summaries

	Method Locked	Method Id	Old Id	Method Version
1	No	5988	5983	4
2	No	5983	5614	3
3	No	5614	5225	2
4	No	5225		1

Method Version Summaries

	Source S/W Info
1	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
2	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
3	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
4	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615

Analysed by: J. Kayal
Date: 15/04/2022

Checked by: J. Kayal
Date: 19/04/2022

Reported by User: KAYAL (KAYAL)
Report Method: PROCESSING METHOD
Report Method ID: 1057
Page: 4 of 4

Project Name: 2022\QC_HPL_003\APR-2022
Printed Date: 15/04/2022
Printed Time: 11:50:19 Asia/Calcutta

Vial	Inj Vol (uL)	# of Injs	SampleName	Function	Method Set / Report or Export Method	Label Reference	Processing	Run Time (Minutes)
1	25.0	2	BLANK_RS	Inject Controls	BONCIPRO_AS_FP_MSET		Normal	20.00
2	25.0	1	PLACEBO_250_RS	Inject Samples	BONCIPRO_AS_FP_MSET		Normal	20.00
3	25.0	1	PLACEBO_500_RS	Inject Samples	BONCIPRO_AS_FP_MSET		Normal	20.00
4	25.0	1	PLACEBO_750_RS	Inject Samples	BONCIPRO_AS_FP_MSET		Normal	20.00
5	25.0	1	BLANK_RS	Inject Controls	BONCIPRO_AS_FP_MSET		Normal	20.00
5	25.0	1	BONCIPRO_250_G1822069_SOLN_1	Inject Samples	BONCIPRO_AS_FP_MSET		Normal	20.00
6	25.0	1	BONCIPRO_500_G1822068_SOLN_1	Inject Samples	BONCIPRO_AS_FP_MSET		Normal	20.00
7	25.0	1	BONCIPRO_750_G1822075_SOLN_1	Inject Samples	BONCIPRO_AS_FP_MSET		Normal	20.00
8	25.0	1	BLANK_RS	Inject Controls	BONCIPRO_AS_FP_MSET		Normal	20.00
8	25.0	1	BONCIPRO_250_G1822069_SOLN_2	Inject Samples	BONCIPRO_AS_FP_MSET		Normal	20.00
9	25.0	1	BONCIPRO_500_G1822068_SOLN_2	Inject Samples	BONCIPRO_AS_FP_MSET		Normal	20.00
10	25.0	1	BONCIPRO_750_G1822075_SOLN_2	Inject Samples	BONCIPRO_AS_FP_MSET		Normal	20.00
11	25.0	1	BLANK_RS	Inject Controls	BONCIPRO_AS_FP_MSET		Normal	20.00
11	25.0	1	BONCIPRO_250_G1822069_SOLN_3	Inject Samples	BONCIPRO_AS_FP_MSET		Normal	20.00
12	25.0	1	BONCIPRO_500_G1822068_SOLN_3	Inject Samples	BONCIPRO_AS_FP_MSET		Normal	20.00
13	25.0	1	BONCIPRO_750_G1822075_SOLN_3	Inject Samples	BONCIPRO_AS_FP_MSET		Normal	20.00
				Condition Column	WASHING SOLUTION_C_MSET			150.00
				Condition Column	WASHING SOLUTION_D_MSET			50.00
				Equilibrate	SHUTDOWN_MSET			0.01

J. Karyal
13/04/2022

JH 13/04/2022

Instrument Method: BONCIPRO_AS_FP_IM

Stored: 08/04/2022 11:07:39 IST

Method Information

Method Comments NEW INSTRUMENT CREATED
 Method Modified User MONICA
 Method Locked No
 Method Id 4028
 Old Id
 Method Version 1
 Method Edit User
 Source S/W Info Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615

W2489 Instrument Setup

Wavelength Mode Single Wavelength
 Lamp On On

Channel A

Comment
 Wavelength 278(nm)
 Sampling Rate 10(points/sec)
 Data Mode Absorbance
 Time Constant 0.1(sec)
 Autozero On Wavelength Change Maintain Baseline
 Autozero On Inject Start Yes

Analog 1

Sensitivity 2.0000(AUFS)
 Chart Polarity Positive (+)
 Voltage Offset 0(mV)
 Enable Chart Mark Yes

Run Events Yes

Pulse Width 1.0(sec)
 Rect Wave Period 0.2(sec)

W2690/5 Instrument Setup

Type W2690/5
 Instrument Status On
 Channel Name 2690/5
 Description 278
 Use Channel Monitor On
 Monitor Parameter System Pressure

Analysed by: J. Kaya J
 Date: 13/04/2022

Checked by: J
 Date: 13/04/2022

Stroke Volume 100uL (flow rates <= 3.030 mL/min)
Chart Out %A
Syringe Draw Rate Normal
Depth Of Needle 0.0
Degas Mode On
Pump Mode Isocratic
Flow 1.500
%A 100.0
%B 0.0
%C 0.0
%D 0.0
High Limit 5000.0
Low Limit 0.0
Enable Sample Temp True
Enable Column Temp True
Bubble Detect True
Pre Column Volume 0.0
Sample Temp Target 25.0
Sample Temp Range 5.0
Spurge A 0.0
Spurge B 0.0
Spurge C 0.0
Spurge D 0.0
Column Temp Target 40.0
Column Temp Range 5.0
Flow Ramp 2.00
Column choice No Change
Column Equil Minutes 0.00
Needle Wash Normal
Switch 1 No Change
Switch 2 No Change
Switch 3 No Change
Switch 4 No Change
Use Events False
Solvent A
Solvent B
Solvent C
Solvent D

Revision History

Version 1 08/04/2022 11:07:39 IST User MONICA Created method 'BONCIPRO_AS_FP_IM'. NEW INSTRUMENT CREATED

Method Version Summaries

	Method Name	Method Type	Method Comments	Method Date	Method Modified User	Method Locked
1	BONCIPRO_AS_FP_IM	Instrument	NEW INSTRUMENT CREATED	08/04/2022 11:07:39 IST	MONICA	No

Analysed by: J. KAYAL
Date: 13/04/2022

Checked by: J.
Date: 13/04/2022

Reported by User: KAYAL (KAYAL)
Report Method: INSTRUMENT METHOD
Report Method ID: 1056
Page: 2 of 3

Project Name: 2022\QC_HPL_003\APR-2022
Printed Date: 13/04/2022
Printed Time: 11:34:14 Asia/Calcutta

Method Version Summaries

	Method Id	Old Id	Method Version	Source S/W Info
1	4028		1	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615

Analysed by: J. Kaya
Date: 13/04/2022

Checked by: J. Kaya
Date: 13/04/2022

Reported by User: KAYAL (KAYAL)
Report Method: INSTRUMENT METHOD
Report Method ID: 1056
Page: 3 of 3

Project Name: 2022\QC_HPL_003\APR-2022
Printed Date: 13/04/2022
Printed Time: 11:34:14 Asia/Calcutta

SAMPLE INFORMATION

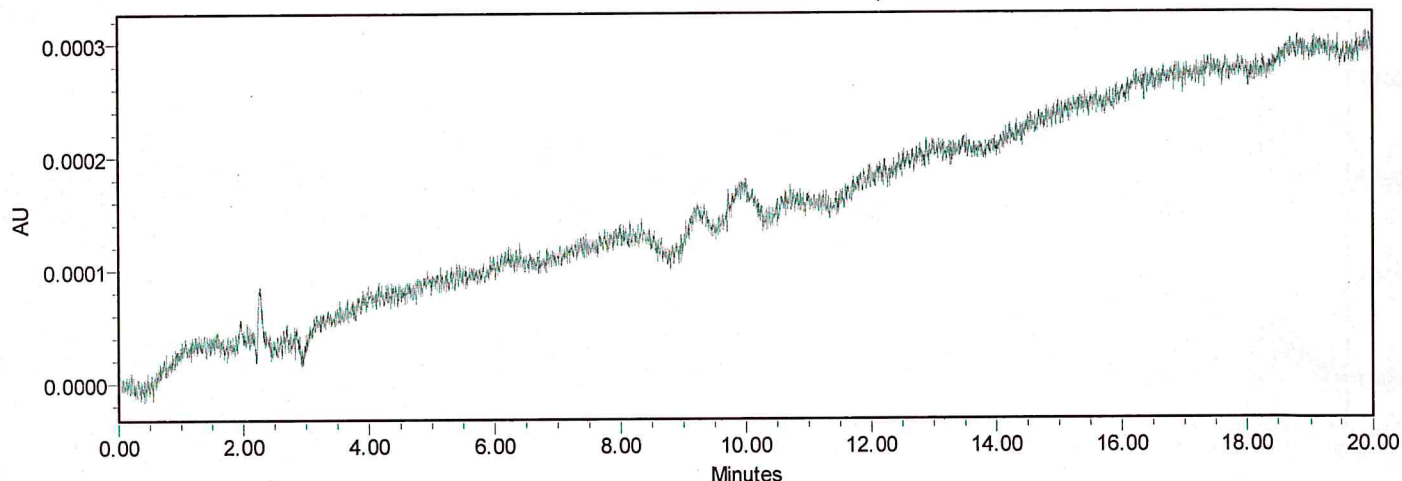
Sample Name: BLANK_RS
Sample Type: Control
Vial: 1
Injection #: 1
Injection Volume: 25.00 ul
Run Time: 20.0 Minutes

Acquired By: KAYAL
Sample Set Name: 13042022_BONCIPRO_RS_FP_SS
Acq. Method Set: BONCIPRO_AS_FP_MSET
Processing Method: BONCIPRO_RS_FP_PM
Channel Name: W2489 ChA
Proc. Chnl. Descr.: W2489 ChA278nm

Date Acquired: 13/04/2022 11:40:45 IST

Date Processed: 19/04/2022 08:38:52 IST

Auto-Scaled Chromatogram



Peak Results

	Name	Injection	RT	Area	% Area
1	IMPURITY-F	1			
2	IMPURITY-B	1			
3	IMPURITY-E	1			
4	IMPURITY-C	1			
5	IMPURITY-D	1			
6	CIPROFLOXACIN HCL	1	9.713		

Analysed by:

Date:

J. Kayal
19/04/2022

Checked by:

Date:

J.
19/04/2022

Reported by User: KAYAL (KAYAL)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 6626
Page: 1 of 1

Project Name: 2022\QC_HPL_003\APR-2022
Printed Date: 19/04/2022
Printed Time: 08:42:57 Asia/Calcutta

SAMPLE INFORMATION

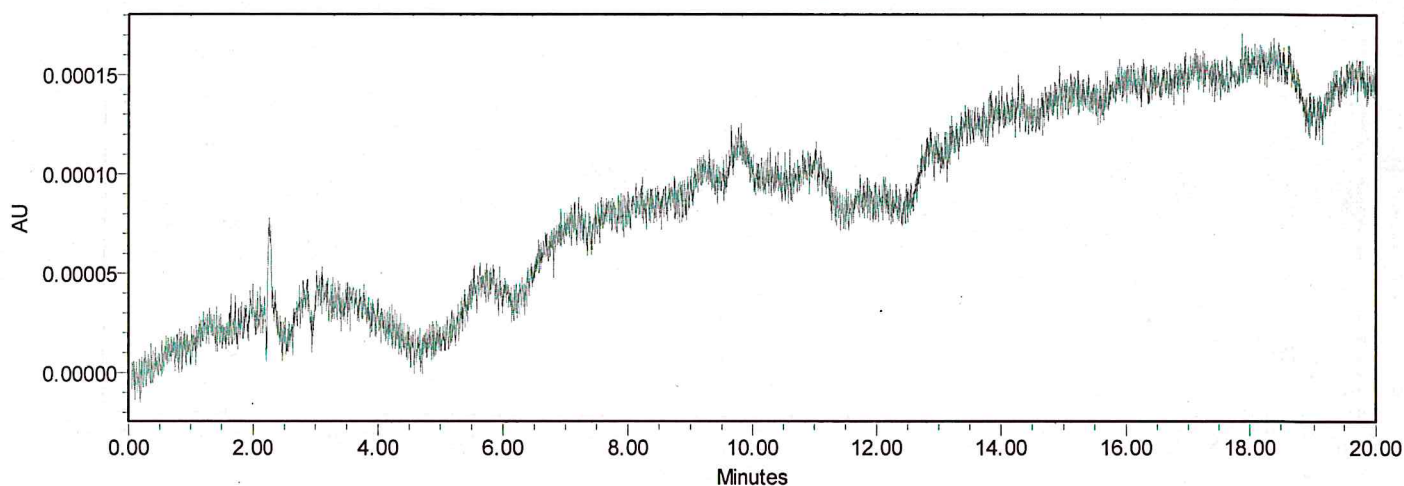
Sample Name: BLANK_RS
Sample Type: Control
Vial: 1
Injection #: 2
Injection Volume: 25.00 ul
Run Time: 20.0 Minutes

Acquired By: KAYAL
Sample Set Name: 13042022_BONCIPRO_RS_FP_SS
Acq. Method Set: BONCIPRO_AS_FP_MSET
Processing Method: BONCIPRO_RS_FP_PM
Channel Name: W2489 ChA
Proc. Chnl. Descr.: W2489 ChA 278nm

Date Acquired: 13/04/2022 12:02:15 IST

Date Processed: 19/04/2022 08:38:52 IST

Auto-Scaled Chromatogram



Peak Results

	Name	Injection	RT	Area	% Area
1	IMPURITY-C	2			
2	IMPURITY-B	2			
3	IMPURITY-F	2			
4	IMPURITY-D	2			
5	IMPURITY-E	2			
6	CIPROFLOXACIN HCL	2	9.713		

Analysed by: J. Kayal
Date: 19/04/2022

Checked by: [Signature]
Date: 19/04/2022

Reported by User: KAYAL (KAYAL)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 6626
Page: 1 of 1

Project Name: 2022\QC_HPL_003\APR-2022
Printed Date: 19/04/2022
Printed Time: 08:43:34 Asia/Calcutta

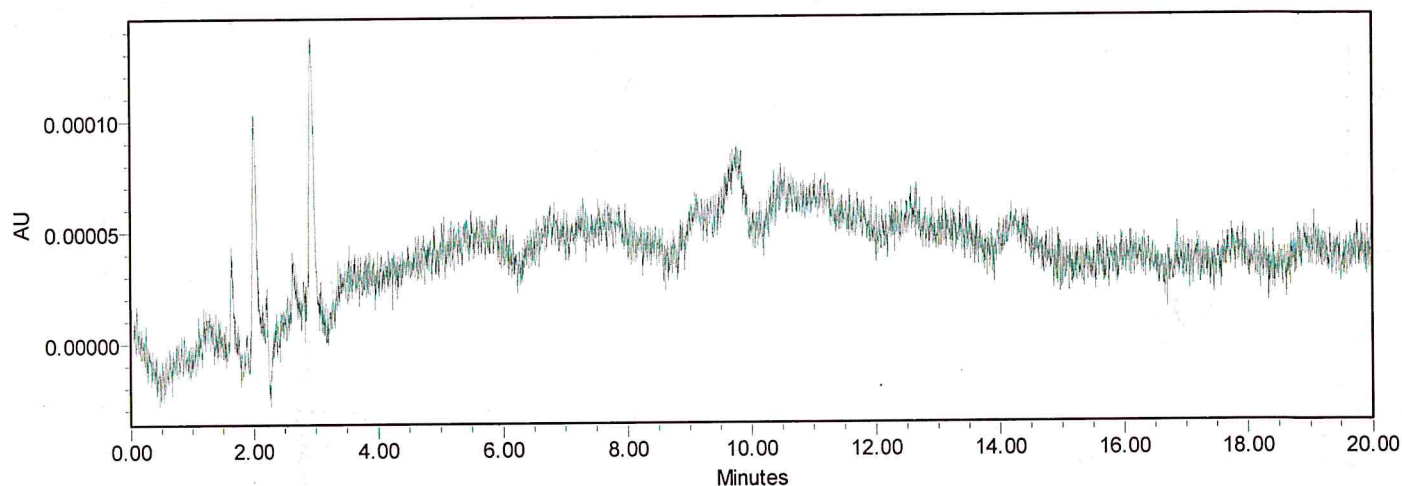
SAMPLE INFORMATION

Sample Name: PLACEBO_750_RS
Sample Type: Unknown
Vial: 4
Injection #: 1
Injection Volume: 25.00 ul
Run Time: 20.0 Minutes

Acquired By: KAYAL
Sample Set Name: 13042022_BONCIPRO_RS_FP_SS
Acq. Method Set: BONCIPRO_AS_FP_MSET
Processing Method: BONCIPRO_RS_FP_PM
Channel Name: W2489 ChA
Proc. Chnl. Descr.: W2489 ChA278nm

Date Acquired: 13/04/2022 13:05:30 IST
Date Processed: 19/04/2022 08:42:31 IST

Auto-Scaled Chromatogram



Peak Results

	Name	Injection	RT	Area	% Area
1	IMPURITY-C	1			
2	IMPURITY-B	1			
3	IMPURITY-F	1			
4	IMPURITY-D	1			
5	IMPURITY-E	1			
6	CIPROFLOXACIN HCL	1	9.713		

Analysed by: J. Kayal
Date: 19/04/2022

Checked by: J
Date: 19/04/2022

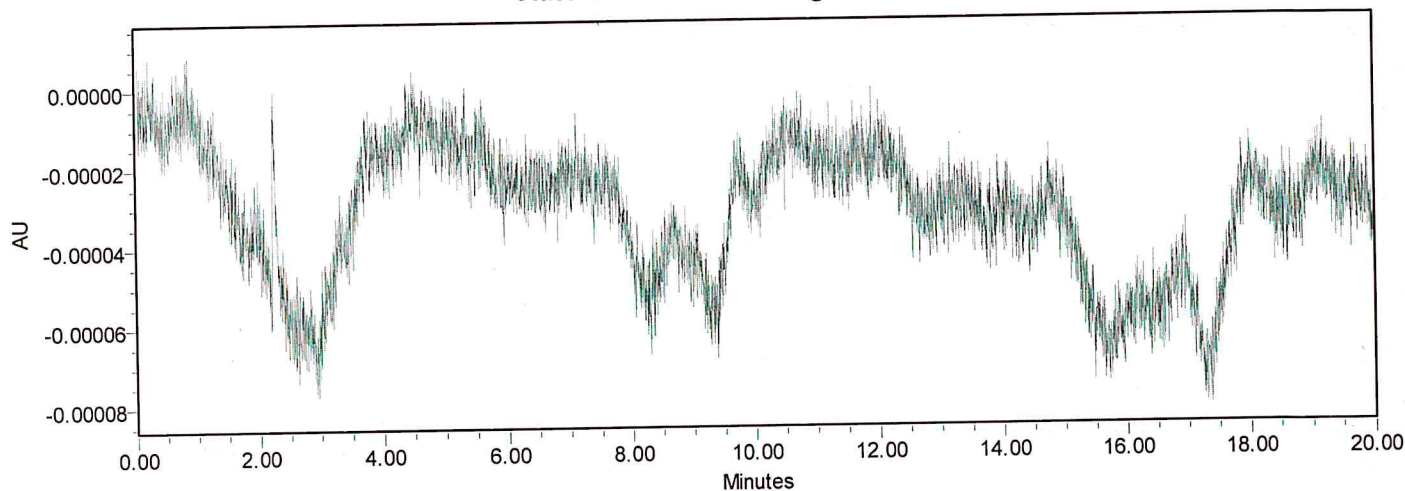
Reported by User: KAYAL (KAYAL)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 6745
Page: 1 of 1

Project Name: 2022\QC_HPL_003\APR-2022
Printed Date: 19/04/2022
Printed Time: 08:45:25 Asia/Calcutta

SAMPLE INFORMATION

Sample Name:	BLANK_RS	Acquired By:	KAYAL
Sample Type:	Control	Sample Set Name:	13042022_BONCIPRO_RS_FP_SS
Vial:	1	Acq. Method Set:	BONCIPRO_AS_FP_MSET
Injection #:	1	Processing Method:	BONCIPRO_RS_FP_PM
Injection Volume:	25.00 ul	Channel Name:	W2489 ChA
Run Time:	20.0 Minutes	Proc. Chnl. Descr.:	W2489 ChA278nm
Date Acquired: 13/04/2022 13:26:36 IST			
Date Processed: 19/04/2022 08:38:52 IST			

Auto-Scaled Chromatogram



Peak Results

	Name	Injection	RT	Area	% Area
1	IMPURITY-C	1			
2	IMPURITY-B	1			
3	IMPURITY-F	1			
4	IMPURITY-D	1			
5	IMPURITY-E	1			
6	CIPROFLOXACIN HCL	1	9.713		

Analysed by: J. Kayal
Date: 19/04/2022

Checked by: [Signature]
Date: 19/04/2022

Reported by User: KAYAL (KAYAL)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 6745
Page: 1 of 1

Project Name: 2022QC_HPL_003APR-2022
Printed Date: 19/04/2022
Printed Time: 08:45:36 Asia/Calcutta

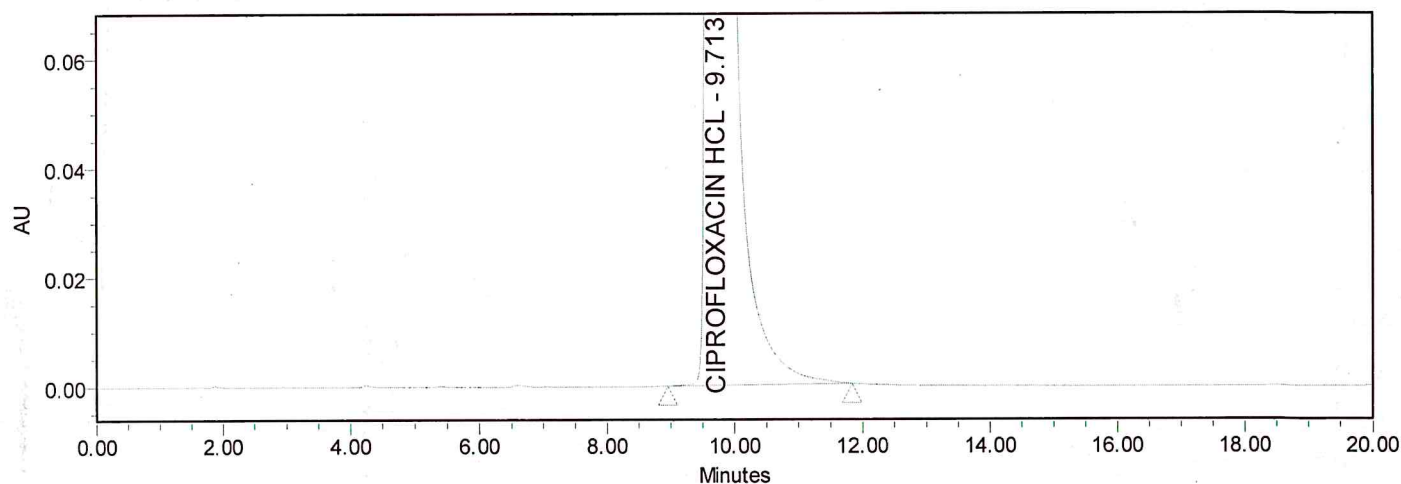
SAMPLE INFORMATION

Sample Name: BONCIPRO_250_G1822069_SOLN_1 Acquired By: KAYAL
Sample Type: Unknown Sample Set Name: 13042022_BONCIPRO_RS_FP_SS
Vial: 5 Acq. Method Set: BONCIPRO_AS_FP_MSET
Injection #: 1 Processing Method: BONCIPRO_RS_FP_PM
Injection Volume: 25.00 ul Channel Name: W2489 ChA
Run Time: 20.0 Minutes Proc. Chnl. Descr.: W2489 ChA278nm

Date Acquired: 13/04/2022 13:53:17 IST

Date Processed: 19/04/2022 08:40:18 IST

Auto-Scaled Chromatogram



Peak Results

	Name	Injection	RT	Area	% Area
1	IMPURITY-E	1	3.885		
2	IMPURITY-F	1	4.856		
3	IMPURITY-B	1	5.828		
4	IMPURITY-C	1	6.799		
5	CIPROFLOXACIN HCL	1	9.713	11750301	100.00
6	IMPURITY-D	1	11.655		

Analysed by: J. Kayal
Date: 19/04/2022

Checked by: J.
Date: 19/04/2022

Reported by User: KAYAL (KAYAL)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 6746
Page: 1 of 1

Project Name: 2022\QC_HPL_003\APR-2022
Printed Date: 19/04/2022
Printed Time: 08:46:55 Asia/Calcutta

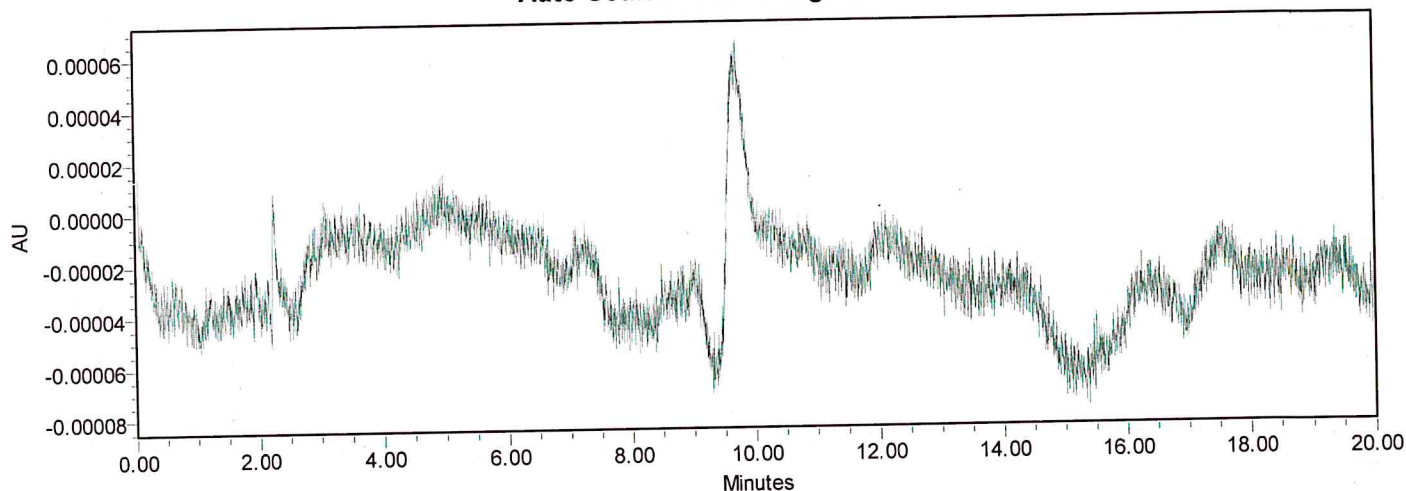
SAMPLE INFORMATION

Sample Name: BLANK_RS
Sample Type: Control
Vial: 1
Injection #: 1
Injection Volume: 25.00 ul
Run Time: 20.0 Minutes

Acquired By: KAYAL
Sample Set Name: 13042022_BONCIPRO_RS_FP_SS
Acq. Method Set: BONCIPRO_AS_FP_MSET
Processing Method: BONCIPRO_RS_FP_PM
Channel Name: W2489 ChA
Proc. Chnl. Descr.: W2489 ChA 278nm

Date Acquired: 13/04/2022 14:58:03 IST
Date Processed: 19/04/2022 08:38:52 IST

Auto-Scaled Chromatogram



Peak Results

	Name	Injection	RT	Area	% Area
1	IMPURITY-C	1			
2	IMPURITY-B	1			
3	IMPURITY-F	1			
4	IMPURITY-D	1			
5	IMPURITY-E	1			
6	CIPROFLOXACIN HCL	1	9.713		

Analysed by: J. Kayal
Date: 19/04/2022

Checked by: [Signature]
Date: 19/04/2022

Reported by User: KAYAL (KAYAL)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 6746
Page: 1 of 1

Project Name: 2022\QC_HPL_003\APR-2022
Printed Date: 19/04/2022
Printed Time: 08:47:23 Asia/Calcutta

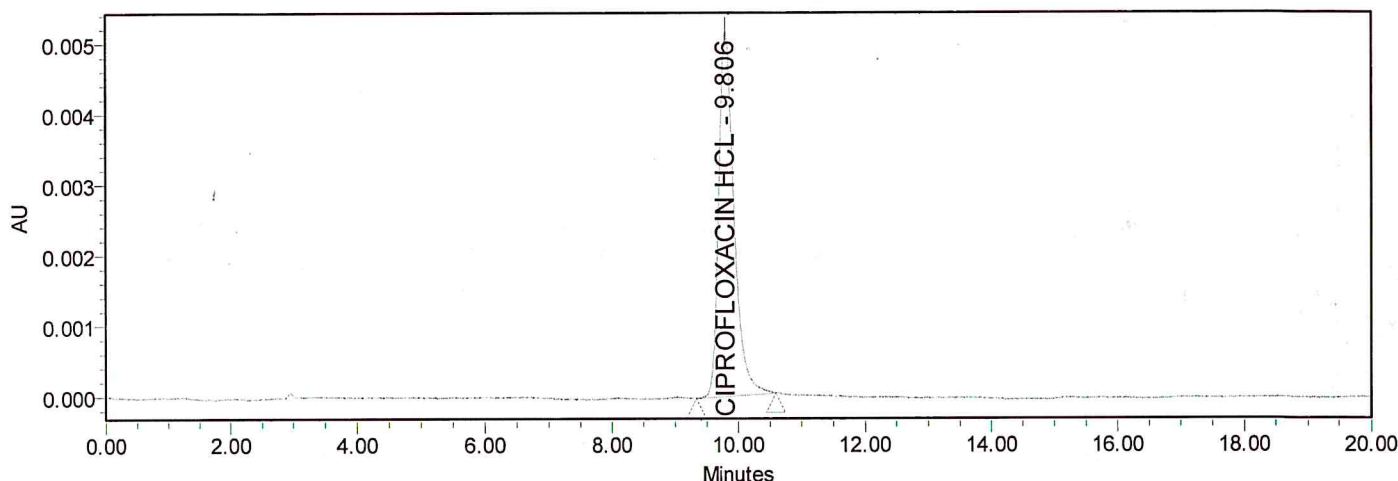
SAMPLE INFORMATION

Sample Name: BONCIPRO_250_G1822069_SOLN_2 Acquired By: KAYAL
Sample Type: Unknown Sample Set Name: 13042022_BONCIPRO_RS_FP_SS
Vial: 8 Acq. Method Set: BONCIPRO_AS_FP_MSET
Injection #: 1 Processing Method: BONCIPRO_RS_SOLUTION_2_4_FP_PM
Injection Volume: 25.00 ul Channel Name: W2489 ChA
Run Time: 20.0 Minutes Proc. Chnl. Descr.: W2489 ChA278nm

Date Acquired: 13/04/2022 15:19:18 IST

Date Processed: 19/04/2022 08:37:33 IST

Auto-Scaled Chromatogram



Peak Results

	Name	Injection	RT	Area	% Area
1	CIPROFLOXACIN HCL	1	9.806	87444	100.00

Analysed by: J. Kayal
Date: 19/04/2022

Checked by: J. Kayal
Date: 19/04/2022

Reported by User: KAYAL (KAYAL)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 6747
Page: 1 of 1

Project Name: 2022\QC_HPL_003\APR-2022
Printed Date: 19/04/2022
Printed Time: 08:48:10 Asia/Calcutta

SAMPLE INFORMATION

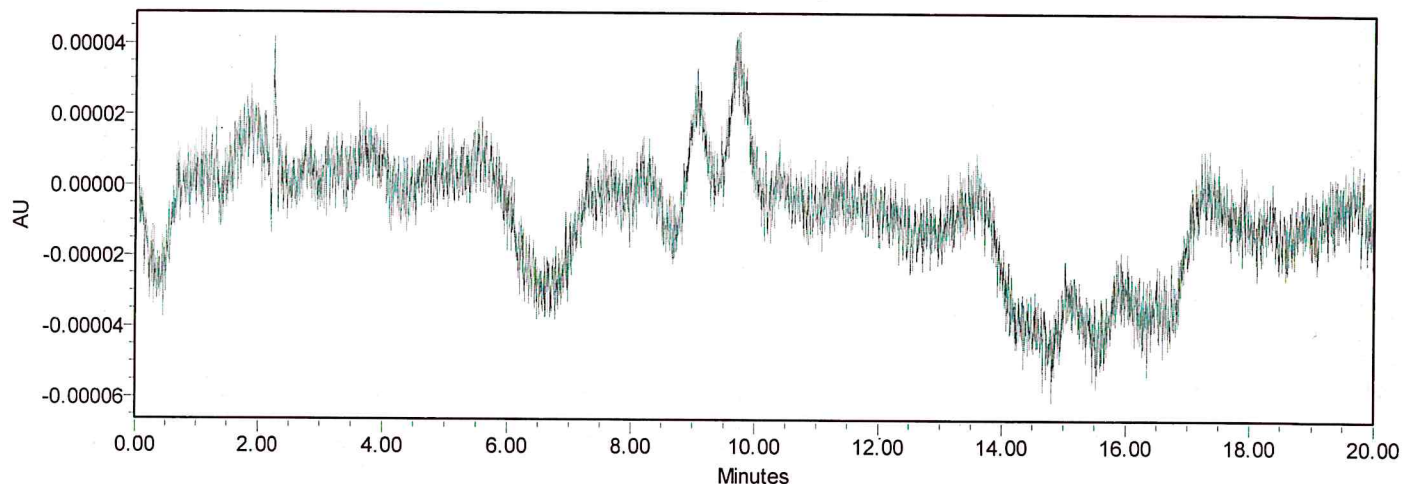
Sample Name: BLANK_RS
Sample Type: Control
Vial: 1
Injection #: 1
Injection Volume: 25.00 ul
Run Time: 20.0 Minutes

Acquired By: KAYAL
Sample Set Name: 13042022_BONCIPRO_RS_FP_SS
Acq. Method Set: BONCIPRO_AS_FP_MSET
Processing Method: BONCIPRO_RS_FP_PM
Channel Name: W2489 ChA
Proc. Chnl. Descr.: W2489 ChA278nm

Date Acquired: 13/04/2022 16:22:22 IST

Date Processed: 19/04/2022 08:38:52 IST

Auto-Scaled Chromatogram



Peak Results

	Name	Injection	RT	Area	% Area
1	IMPURITY-C	1			
2	IMPURITY-B	1			
3	IMPURITY-F	1			
4	IMPURITY-D	1			
5	IMPURITY-E	1			
6	CIPROFLOXACIN HCL	1	9.713		

Analysed by:

Date

J. Kayal
19/04/2022

Checked by:

Date

J. Kayal
19/04/2022

Reported by User: KAYAL (KAYAL)

Report Method: CHROMATOGRAPHIC DATA

Report Method ID: 6747

Page: 1 of 1

Project Name: 2022\QC_HPL_003\APR-2022

Printed Date: 19/04/2022

Printed Time: 08:48:38 Asia/Calcutta

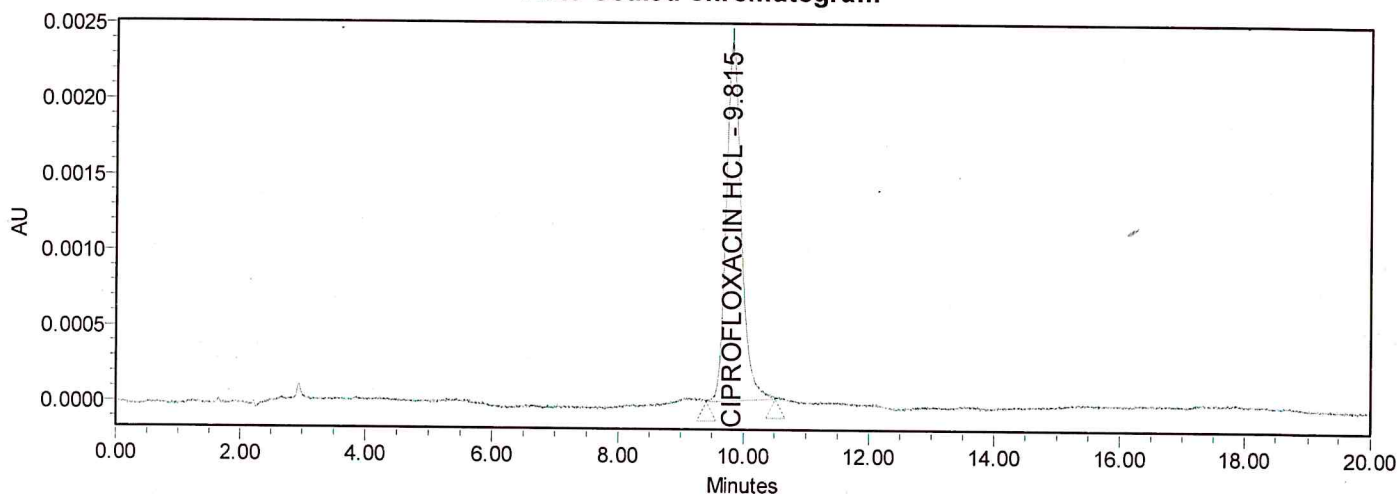
SAMPLE INFORMATION

Sample Name: BONCIPRO_250_G1822069_SOLN_4 Acquired By: KAYAL
 Sample Type: Unknown Sample Set Name: 13042022_BONCIPRO_RS_FP_SS
 Vial: 11 Acq. Method Set: BONCIPRO_AS_FP_MSET
 Injection #: 1 Processing Method: BONCIPRO_RS_SOLUTION_2_4_FP_PM
 Injection Volume: 25.00 ul Channel Name: W2489 ChA
 Run Time: 20.0 Minutes Proc. Chnl. Descr.: W2489 ChA278nm

Date Acquired: 13/04/2022 16:43:23 IST

Date Processed: 19/04/2022 08:37:34 IST

Auto-Scaled Chromatogram



Peak Results

	Name	Injection	RT	Area	% Area	s/n
1	CIPROFLOXACIN HCL	1	9.815	39602	100.00	74.6

Analysed by: J. Kaya
 Date: 19/04/2022

Checked by: J. Kaya
 Date: 19/04/2022

Reported by User: KAYAL (KAYAL)
 Report Method: CHROMATOGRAPHIC DATA
 Report Method ID: 6748
 Page: 1 of 1

Project Name: 2022\QC_HPL_003\APR-2022
 Printed Date: 19/04/2022
 Printed Time: 08:49:40 Asia/Calcutta

Processing Method: BONCIPRO_RS_FP_PM

Type: LC

Stored: 19/04/2022 08:40:01 IST

Method Information

Method Comments

Method Modified User

Method Locked

Method Id

Old Id

Method Version

Method Edit User

Source S/W Info

PROCESSING METHOD

CRAETED

KAYAL

No

6716

6693

2

Empower 3 Software Build 3471

SPs Installed: Service Release 3

DB ID: 2530846615

Traditional

10.0

No

3

(m/z)

(m/z)

Pure

No

SET1

50.000(%)

(min)

1.0000(Da)

1.000

5

0.000(%)

Average

1.00(Da)

None

No

100.00(Da)

80.0(%)

Centroid Top(%)

80.00

Heights

0.500(Da)

None

None

5.00

Analysed by: J. Kayal

Date: 19/04/2022

Checked by: J. Kayal

Date: 19/04/2022

Reported by User: KAYAL (KAYAL)

Report Method: PROCESSING METHOD

Report Method ID: 1057

Page: 1 of 5

Project Name: 2022\QC_HPL_003\APR-2022

Printed Date: 19/04/2022

Printed Time: 08:50:27 Asia/Calcutta

Update RT Never
 CCalRef1
 Include Internal Standard Amounts in Amount Calculation Yes
 Vial/Default Value Type Amount
 RT Reference Used to Name Unnamed Peaks by RRT CIPROFLOXACIN HCL

System Suitability Information

Void Volume Time 0.100(min)
 Calculate Suitability Yes
 Flag Outside Yes
 Calculate Unknowns Yes
 Pharmacopoeia All
 Tangent Percent (USP Plate Count) 61
 Tangent Percent (USP Resolution) 50
 Calculate USP, EP, and JP s/n No
 Use noise centered on peak region in blank injection Yes
 Half Height Multiplier for USP s/n Noise Region
 Half Height Multiplier for EP s/n Noise Region
 Half Height Multiplier for JP s/n Noise Region
 Noise Value for s/n Baseline
 Noise
 % Runtime 5.0
 Maximum Noise
 Maximum Drift
 Baseline Noise Minimum 30 Seconds
 Baseline Start (min)
 Baseline End (min)
 Calculate Peak Statistical Moments No

Integration Parameters

Minimum Area 39602($\mu V \cdot sec$)
 Minimum Height 0(μV)
 Threshold 1.000($\mu V/sec$)
 Peak Width 10.00(sec)

Integration Events

	Time (min)	Type	Value	Stop (min)
1	0.000	Valley to Valley		20.000

Component Table

	Name	Component Type	Peak Label	Retention Time (min)	RT Window (min)	Peak Match	Calculate Suit Results
1	IMPURITY-E				0.194	Closest	Yes
2	IMPURITY-F				0.243	Closest	Yes
3	IMPURITY-B				0.291	Closest	Yes
4	IMPURITY-C				0.340	Closest	Yes
5	CIPROFLOXACIN HCL			9.713	0.430	Closest	Yes

Analysed by: J. KAYAL
 Date: 19/04/2022

Checked by: J. KAYAL
 Date: 19/04/2022

Reported by User: KAYAL (KAYAL)
 Report Method: PROCESSING METHOD
 Report Method ID: 1057
 Page: 2 of 5

Project Name: 2022\QC_HPL_003\APR-2022
 Printed Date: 19/04/2022
 Printed Time: 08:50:27 Asia/Calcutta

Component Table

	Name	Component Type	Peak Label	Retention Time (min)	RT Window (min)	Peak Match	Calculate Suit Results
6	IMPURITY-D				0.583	Closest	Yes

Component Table

	Flag Outside Limits	3D Channel Name (Description)	Channel	Y Value	X Value	Fit	Weighting	Internal Std
1	Yes			Area	Amount	Linear	None	
2	Yes			Area	Amount	Linear	None	
3	Yes			Area	Amount	Linear	None	
4	Yes			Area	Amount	Linear	None	
5	Yes			Area	Amount	Linear	None	
6	Yes			Area	Amount	Linear	None	

Component Table

	RT Reference	Rel RT Reference	RRT	Rel Resol Reference	Curve Reference	Relative Response	Impurity RRF	Must	Default Pk	Default Pk Start (min)	Default Pk End (min)
1	CIPROFLOXACIN HCL		0.400			1.000000	1.0000	No	No		
2	CIPROFLOXACIN HCL		0.500			1.000000	1.0000	No	No		
3	CIPROFLOXACIN HCL		0.600			1.000000	1.0000	No	No		
4	CIPROFLOXACIN HCL		0.700			1.000000	1.0000	No	No		
5						1.000000	1.0000	No	No		
6	CIPROFLOXACIN HCL		1.200			1.000000	1.0000	No	No		

Component Table

	Default Units	Type	Impurity Type	CCompRef1	CCompRef2	CCompRef3	CConst1	CConst2	CConst3	CConst4	CConst5
1		Single									
2		Single									
3		Single									
4		Single									
5		Single									
6		Single									

Component Table

	CConst6	CConst7		CConst6	CConst7
1			5		
2			6		
3					
4					

Analysed by: J. KAYAL
Date: 19/04/2022

Checked by: J. KAYAL
Date: 19/04/2022

Reported by User: KAYAL (KAYAL)
Report Method: PROCESSING METHOD
Report Method ID: 1057
Page: 3 of 5

Project Name: 2022\QC_HPL_003\APR-2022
Printed Date: 19/04/2022
Printed Time: 08:50:27 Asia/Calcutta

Processing Method Group 'Name Groups' table contains no data.

Processing Method Group 'Time Groups' table contains no data.

Processing Method Group 'Suit Limits-'IMPURITY-E'" table contains no data.

Processing Method Group 'Relative Limits-'IMPURITY-E'" table contains no data.

Processing Method Group 'Def Amts-'IMPURITY-E'" table contains no data.

Processing Method Group 'Suit Limits-'IMPURITY-F'" table contains no data.

Processing Method Group 'Relative Limits-'IMPURITY-F'" table contains no data.

Processing Method Group 'Def Amts-'IMPURITY-F'" table contains no data.

Processing Method Group 'Suit Limits-'IMPURITY-B'" table contains no data.

Processing Method Group 'Relative Limits-'IMPURITY-B'" table contains no data.

Processing Method Group 'Def Amts-'IMPURITY-B'" table contains no data.

Processing Method Group 'Suit Limits-'IMPURITY-C'" table contains no data.

Processing Method Group 'Relative Limits-'IMPURITY-C'" table contains no data.

Processing Method Group 'Def Amts-'IMPURITY-C'" table contains no data.

Processing Method Group 'Suit Limits-'CIPROFLOXACIN HCL" table contains no data.

Processing Method Group 'Relative Limits-'CIPROFLOXACIN HCL" table contains no data.

Processing Method Group 'Def Amts-'CIPROFLOXACIN HCL" table contains no data.

Processing Method Group 'Suit Limits-'IMPURITY-D'" table contains no data.

Processing Method Group 'Relative Limits-'IMPURITY-D'" table contains no data.

Processing Method Group 'Def Amts-'IMPURITY-D'" table contains no data.

Processing Method Group 'Primary Peaks (Primary MS Ions)' table contains no data.

Noise and Drift Parameters

Calculate Detector Noise and Drift	No
Detector Noise and Drift Start Time	3.000(Minutes)
Detector Noise and Drift End Time	20.000(Minutes)
Detector Noise and Drift Segment Width	60(sec)

Concentration Smoothing/Offset Parameters

Time Offset	0.000(Minutes)
Smoothing Type	None
Smoothing Level	None
Empty parameters supersede the derived channel's smoothing and offset parameters	No

Impurity Parameters

Calculate Total Impurities	No	Qualification Threshold
Impurity Response		Total Impurities Threshold
w Value		Maximum Impurity Threshold
Main Component		
Reporting Threshold	0.05	
Identification Threshold		

Analysed by: J. Kaya
Date: 19/04/2022

Checked by: J. Kaya
Date: 19/04/2022

Reported by User: KAYAL (KAYAL)
Report Method: PROCESSING METHOD
Report Method ID: 1057
Page: 4 of 5

Project Name: 2022\QC_HPL_003\APR-2022
Printed Date: 19/04/2022
Printed Time: 08:50:27 Asia/Calcutta

Excluded Component Types

Internal Standard Peaks

Revision History

Version 2 19/04/2022 08:40:01 IST User KAYAL MINIMUM AREA CHANGE(SOLUTION-4)
 Version 1 19/04/2022 08:33:43 IST User KAYAL Created method 'BONCIPRO_RS_FP_PM'. PROCESSING
 METHOD CRAETED

Method Version Summaries

	Method Name	Method Type	Method Comments	Method Date	Method Modified User
1	BONCIPRO_RS_FP_PM	Processing	PROCESSING METHOD CRAETED	19/04/2022 08:42:18 IST	KAYAL
2	BONCIPRO_RS_FP_PM	Processing	PROCESSING METHOD CRAETED	19/04/2022 08:41:09 IST	KAYAL
3	BONCIPRO_RS_FP_PM	Processing	PROCESSING METHOD CRAETED	19/04/2022 08:40:01 IST	KAYAL
4	BONCIPRO_RS_FP_PM	Processing	PROCESSING METHOD CRAETED	19/04/2022 08:33:43 IST	KAYAL

Method Version Summaries

	Method Locked	Method Id	Old Id	Method Version
1	No	6735	6725	4
2	No	6725	6716	3
3	No	6716	6693	2
4	No	6693		1

Method Version Summaries

	Source S/W Info
1	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
2	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
3	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
4	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615

Analysed by: J. Kayal
 Date: 19/04/2022

Checked by: J. Kayal
 Date: 19/04/2022

Reported by User: KAYAL (KAYAL)
 Report Method: PROCESSING METHOD
 Report Method ID: 1057
 Page: 5 of 5

Project Name: 2022\QC_HPL_003\APR-2022
 Printed Date: 19/04/2022
 Printed Time: 08:50:27 Asia/Calcutta

 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 6	Issued by QA/Date: <u>26/03/22</u>
	MICROBIAL LIMIT TEST		No.: F/QCMB/006/02
TITLE:	MICROBIAL LIMIT TEST REPORT	Revision No.: 01	
		Review Period: 02 years	
		Effective Date: <u>01/01/2021</u>	

MICROBIOLOGICAL TEST REPORT

Name of Product:		<u>Bonapso - 500 mg</u>			
Type of Product:		<u>Finished Goods</u>			
Batch No./ Lot No.		<u>G1822068</u>		Quality Control A.R. No.	<u>FP/110422/03</u>
Microbiology A.R. No.		<u>MD/0422/0041</u>	Mfg. Date	<u>Apr-2022</u>	Exp.Date <u>Mar-2025</u>
Date of Receipt	<u>11/04/2022</u>	Date of test	<u>11/04/2022</u>	Date of Completion	<u>16/04/2022</u>

S.No:	Test Required	Result	Specification
1.	Total aerobic microbial count	<u>20 cfu</u>	Not more than <u>1000</u> cfu g or ml
2.	Total yeast and mould count	<u>< 10 cfu</u>	Not more than <u>100</u> cfu g or ml
3.	Pathogens		
	a.E.coli	<u>Absent</u>	Should be absent in g or ml
	b.Salmonella sp.	<u>Absent</u>	Should be absent in 10g or 10ml
	c.Pseudomonas aeruginosa	<u>Absent</u>	Should be absent in g or ml
	d.Staphylococcus aureus	<u>Absent</u>	Should be absent in g or ml
	e.Shigella sp.	<u>NA</u>	Should be absent in 10g or 10ml
	f.Enterobacteria	<u>NA</u>	Not more than <u>NA</u> cfu g or ml / Should be absent in g or ml

Analysed by: <u>D. Shetty</u> Date: <u>11/04/2022</u>	Reported by: <u>D. Shetty</u> Date: <u>11/04/2022</u>	Checked by: <u>J</u> Date: <u>19/04/2022</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 2 of 6
	MICROBIAL LIMIT TEST	No.: F/QCMB/006/02
TITLE:	MICROBIAL LIMIT TEST REPORT	Revision No.: 00
		Review Period: 02 years
		Effective Date: 01/01/2021

Media and Accessories used:

Autoclave Id. No: MB/BCE/001

Micropipette Id. No:

MB/mop/003
MB/mop/005
MB/mop/006

S. No.	Name of the Media	Media Preparation Details		Media Batch No.
		Date	Sterilization cycle No.	
1	SCDM	06/04/2022	MS-22-0010	MP/22/0025
2	BSC-Peptone	NA	NA	NA
3	SCDA	11/04/2022	MS-22-0018	MP/22/0049
4	SDA	11/04/2022	MS-22-0018	MP/22/0050
5	MCB	09/04/2022	MS-22-0016	MP/22/0042
6	MCA	09/04/2022	MS-22-0016	MP/22/0046
7	RVSE	NA	NA	NA
8	XLDA	09/04/2022	NA	MP/22/0045
9	MSA	07/04/2022	MS-22-0012	MP/22/0033
10	CA	07/04/2022	MS-22-0012	MP/22/0032
11	GN Broth	NA		
12	XLDA			
13	EE Broth			
14	VRBGA			

Note: Rappaport Vassiliadis Salmonella Enrichment Broth (Readymade form):

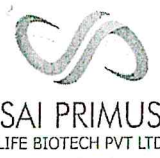
Media Mfg.: Microbials Media Lot No: RUSEB-2155 Expiry at: 15/10/2022

Note: GN broth (Readymade form):

Media Mfg.: NA Media Lot No: NA Expiry at: NA

D. D. D.
11/04/2022

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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 3 of 6
	MICROBIAL LIMIT TEST	No.: F/QCMB/006/02
TITLE:	MICROBIAL LIMIT TEST REPORT	Revision No.: 00
		Review Period: 02 years
		Effective Date: 01/01/2021

S. No.	Temperature	Incubator Id. No.
1	30-35°C	MB/BOD/002
2	20-25°C	MB/BOD/001
3	42-44°C	MB/BOD/003

LAF Id. No: MB/LAF/001

BSC Id. No: MB/BSC/001

a) Sample Preparation.

Take 10.01844 10g/10ml of sample and dissolve in 90 /100 ml Buffered sodium chloride- peptone solution pH 7.0. or suitable mixer.

b) Procedure:

Pipette 1ml of the diluted sample in to each of four sterile Petri dishes.

Promptly add two plates with 15-20ml of Soyabean casein digest agar and two plates Sabouraud Dextrose agar that previously has been sterilized and cooled to approximately 45°C. Cover the Petri dishes, mix the sample with agar by tilting or rotating the dishes and allow the contents to solidify at Room temperature. Invert the Petri dishes and incubate the Soyabean casein digest agar at 30 - 35°C for 3- 5 days and 20 - 25°C for 5-7 days for Sabouraud Dextrose agar.

c) Pathogen Testing for *E. coli*, *S. aureus* & *P.aeruginosa*:

Take 10 ml of diluted sample (Solution A) transfer in to 90 ml of Soyabean casein digest medium and incubate at 30 -35°C for not less than 18-24 hours.

d) Pathogen testing for *salmonella abony* / *Shigella Species*...

Take 10.12266 10g/10ml of sample and dissolve in 90 /100 ml of Soyabean casein digest medium incubate at 30 -35°C for not less than 18-24 hours.

e) Pathogen Testing for Enterobacteria gram negative:

Take ND 1.0 g, 0.1 g, 0.01 g and 0.001 g or 1.0 ml, 0.1 ml, 0.01 ml, and 0.001 ml Suitable quantity of sample transfer in to Enterobacteria Enrichment Broth (EE Broth) Incubate at 30° to 35° for 24 to 48 hours.

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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 6
	MICROBIAL LIMIT TEST	No.: F/QCMB/006/02
	TITLE:	MICROBIAL LIMIT TEST REPORT Revision No.: 00 Review Period: 02 years Effective Date: 01/01/2021

TAMC & TYMC :								
Tested for	Incubation details		Incubated on		Observed on		Done by	Observed by
	Temp. (°C)	Duration (days)	Date	Time	Date	Time		
TAMC	30-35	3-5	11/04/2022	18:19	16/04/2022	14:01	D. Suresh 11/04/2022	D. Suresh 16/04/2022
TYMC	20-25	5-7	11/04/2022	18:24	16/04/2022	14:10	D. Suresh 11/04/2022	D. Suresh 16/04/2022

Enrichment :								
Tested for	Incubation details		Incubated on		Observed on		Done by	Observed by
	Temp. (°C)	Duration (hours)	Date	Time	Date	Time		
Pre enrichment for <i>E. coli</i> , <i>P. aeruginosa</i> , <i>S. aureus</i>	30-35	18-24	11/04/2022	18:19	12/04/2022	14:01	D. Suresh	D. Suresh 12/04/2022
Pre enrichment for <i>Salmonella abony</i> & <i>Shigella</i> Species	30-35	18-24	11/04/2022	18:19	12/04/2022	14:01	D. Suresh	D. Suresh 12/04/2022
<i>Enterobacteria</i> gram negative	30-35	24-48	NO					

Test for Specified Microorganisms:

- E. coli*:** Transfer 1 ml of enrichment sample to 100 ml of Mac Conkey broth and incubate at 42-44°C for 24-48 hrs. After incubation, subculture on Mac Conkey agar and incubate at 30-35°C for 18-72 hrs.
- Salmonella* sp.:** Transfer 0.1 ml of enrichment sample to 10 ml of Rappaport vassiliadis salmonella enrichment broth and incubate at 30-35°C for 24-48 hrs. After incubation subculture on Xylose lysine deoxycholate agar and incubate at 30-35°C for 24-48 hrs.
- Pseudomonas aeruginosa*:** Subculture on plate of cetrimide agar and incubation at 30-35°C for 18-72 hrs.

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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 5 of 6
	MICROBIAL LIMIT TEST	No.: F/QCMB/006/02
	MICROBIAL LIMIT TEST REPORT	Revision No.: 00 Review Period: 02 years Effective Date: 01/01/2021
TITLE:		

4. ***Staphylococcus aureus***: Subculture on plate of mannitol salt agar and incubation at 30-35°C for 18-72 hrs.
5. **Enterobacteria gram negative**: Subculture on a plate of Violet red bile glucose agar with dextrose. Incubate at 30° to 35° for 18 to 24 hours. Growth of well-developed reddish colonies of Gram negative bacteria is considered positive.
6. ***Shigella* Species**: Transfer 1 ml of enrichment sample in 100 ml or 0.1ml to 10 ml of GN broth and incubate at 30-35°C for 24 to 48 hours. After incubation, Subculture on Xylose lysine deoxycholate agar and incubate at 30-35°C for 24 to 48 hours.

Test for Specified Microorganisms:									
Tested for	selective Media	Incubation Details		Incubated on		Observed on		Done by	Observed by
		Temp. (°C)	Duration (Hours)	Date	Time	Date	Time		
<i>E. coli</i>	MCB	42 -44	24 - 48	12/04/2022	16:36	14/04/2022	14:15	Asokan	Asokan
	MCA	30 -35	18 - 72	14/04/2022	16:24	16/04/2022	14:30	Asokan	Asokan
<i>Salmonella</i> Species.	RVSE	30 -35	24 -48	12/04/2022	16:31	14/04/2022	14:10	Asokan	Asokan
	XLDA	30 -35	24 - 48	14/04/2022	16:24	16/04/2022	14:01	Asokan	Asokan
<i>S. aureus</i>	MSA	30 -35	18 -72	12/04/2022	16:31	15/04/2022	14:03	Asokan	Asokan
<i>P. aeruginosa</i>	CA	30 -35	18 -72	12/04/2022	16:31	15/04/2022	14:03	Asokan	Asokan
<i>Shigella</i> Species.	GN	30-35	24-48						
	XLDA	30-35	24-48						
<i>Enterobacteria</i> gram negative	VRBGA	30-35	18-24						

Asokan
12/04/2022

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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 6 of 6
	MICROBIAL LIMIT TEST	No.: F/QCMB/006/02
TITLE:	MICROBIAL LIMIT TEST REPORT	Revision No.: 00
		Review Period: 02 years
		Effective Date: 01/01/2021

Observation:

Parameter	TAMC		TYMC	
	Plate 1	Plate 2	Plate 1	Plate 2
Count per plate	01	02	<1	<1
Average	02		<1	

Calculation:

TAMC: Average Count X Dilution factor = 02 Countx10 = 20 cfu/gm/ml

TYMC: Average Count X Dilution factor = <1 Countx10 = <10 cfu/gm/ml

Test for Specified Microorganisms									
Enrichment and Conformation Test:									
MCB	MCA	RVSE	XLDA	MSA	CA	GN Broth	XLDA	EE Broth	VRBGA
X	X	X	X	X	X	ND	ND	ND	ND

- 1) **Positive Control:** Shown growth / ~~not shown growth~~.
- 2) **Negative Control:** ~~Shown growth~~ / not shown growth.

Note: ✓ - Shown Growth, X - Not Shown Growth

Result: The above sample complies/~~does not comply~~ with the Specification No.

Refer GIITPL as per IP/BP/USP/IHS.

Analysed by: <u>D. D. D. D.</u>	Reported by: <u>D. D. D. D.</u>	Checked by: <u>J. J. J. J.</u>
Date: <u>11/04/2022</u>	Date: <u>11/04/2022</u>	Date: <u>19/04/2022</u>

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SAI PRIMUS
LIFE BIOTECH PVT LTD

ANALYTICAL DATA SHEET

Page No. **1764**

Spl-1

SPL BIOTECH
Model: RUM220
S/N: D450041599
ID: QC/ABL/002
Date: 2022/04/13
Start: 18:12:07
Sample: 000

STAT	
001	295.82 m9
002	0.56 m9

RESULT	
n	2
total	296.38 m9
max	295.82 m9
min	0.56 m9
diff	295.26 m9
x	148.190 m9
s	88.780348 m9
srel	40.886934 %

Date: 2022/04/13
End: 18:12:24

Signature

J. Kargal
13/04/2022

Spl-2

SPL BIOTECH
Model: RUM220
S/N: D450041599
ID: QC/ABL/002
Date: 2022/04/13
Start: 18:13:59
Sample: 000

STAT	
001	293.48 m9
002	0.28 m9

RESULT	
n	2
total	293.76 m9
max	293.48 m9
min	0.28 m9
diff	293.20 m9
x	146.880 m9
s	87.323708 m9
srel	41.151762 %

Date: 2022/04/13
End: 18:14:23

Signature

J. Kargal
13/04/2022

Spl-PS

SPL BIOTECH
Model: RUM220
S/N: D450041599
ID: QC/ABL/002
Date: 2022/04/13
Start: 14:00:12
Sample: 000

STAT	
001	292.37 m9
002	0.05 m9

RESULT	
n	2
total	292.42 m9
max	292.37 m9
min	0.05 m9
diff	292.32 m9
x	146.210 m9
s	86.701454 m9
srel	41.372994 %

Date: 2022/04/13
End: 14:00:39

Signature

J. Kargal
13/04/2022

Placebo

SPL BIOTECH
Model: RUM220
S/N: D450041599
ID: QC/ABL/002
Date: 2022/04/13
Start: 11:08:22
Sample: 000

STAT	
001	92.78 m9
002	0.00 m9

RESULT	
n	2
total	92.78 m9
max	92.78 m9
min	0.00 m9
diff	92.78 m9
x	46.390 m9
s	65.605367 m9
srel	41.421356 %

Date: 2022/04/13
End: 11:08:57

Signature

J. Kargal
13/04/2022

Analysed by: J. Kargal
Date: 13/04/2022

Checked by: J. Kargal
Date: 19/04/2022



SAI PRIMUS
LIFE BIOTECH PVT LTD

ANALYTICAL DATA SHEET

Page No. **1767**

TLC.

SPL BIOTECH
Model: RUM220
S/N: 0450041593
ID: QC/QBL/002
Date: 2022/04/18
Start: 17:37:33
Sample: 000

	<STAT>
001	732.10 m9
002	0.04 m9

	<RESULT>
n	2
total	732.14 m9
max	732.10 m9
min	0.04 m9
diff	732.06 m9
X	366.070 m9
S	617.644590 m9
sp1	141.405503 %

Date: 2022/04/18
End: 17:38:05

Signature: J-Kayal
18/04/2022

⇒ Dissolution standard weight print refer to

Bonipso - 250 - C1822069.

⇒ Assay standard weight print refer to Bonipso - 250 - C1822069

⇒ TLC standard weight print refer to Bonipso-250

C1822069

Analysed by: J-Kayal

Date: 18/04/2022

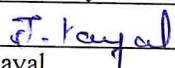
Checked by: J

Date: 19/04/2022

F/CCGN/003/01-01

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PRIVATE LIMITED R.S. No. 4/3, plot No. 33, Kurumbapet Industrial Estate, Villianur Commune, Pondicherry- 605009		Page 1 of 2
	CERTIFICATE OF ANALYSIS FINISHED PRODUCT		Format No: F/QCGN/022/08
Product Name	: BONCIPRO-500 TABLETS(Ciprofloxacin Hydrochloride tablets BP 500 mg)		
A.R.No.	: BS/080922/01		
Batch No.	: G1822116	Batch Size	: 3.0 L
Mfg. Date	: Sep-2022	Exp. Date	: Aug-2025
Sampling Date	: 08.09.2022	Sample Qty	: 120 Tablets
Analysis Date	: 08.09.2022	Release Date	: 21.09.2022

S.No.	TEST	RESULTS	LIMITS
01.	Description	Reddish pink coloured, oblong, biconvex film coated tablet with breakline on one side and plain on both sides.	Reddish pink coloured, oblong, biconvex film coated tablet with breakline on one side and plain on both sides.
02.	Identification A) By TLC B) By HPLC	Complies Complies	The Principal band in the chromatogram obtained with solution (1) corresponding to that in the chromatogram obtained with solution (2). 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 of tablets	740.00 mg	736.0 mg $\pm$ 5.0% (Limit:699.20 mg to 772.80 mg)
04.	Uniformity of weight	+3.38 % to -2.16%	Not more than 2 of the individual weights deviate from the average weight by more than $\pm$ 5 % and none deviate by more than $\pm$ 10 % .
05.	Dimensions Thickness Length Width	Min Max Avg. 5.32 mm 5.43mm 5.37mm 17.36 mm 17.38 mm 17.37 mm 7.65 mm 7.67 mm 7.66 mm	5.30 mm to 5.70 mm 17.10 mm to 17.50 mm 7.60 mm to 7.80 mm
06.	Hardness	12.64 kg/cm ²	NLT 3.0 kg/cm ²
07.	Disintegration time	02 minutes 26 seconds	Not more than 30 minutes
08.	Dissolution By UV	Min Max Avg. 92.42 % 99.64 % 95.81%	Not less than 85.0 % of labeled amount.

	Tested By	Checked By	Approved By
Sign			
Name	Kayal	Ramesh	Vallarasan
Date	21/09/2022	21/09/2022	21/09/2022

QUALITY
CONTROL

CERTIFICATE OF ANALYSIS

Format No:
F/QCGN/022/08

FINISHED PRODUCT

Product Name	:	BONCIPRO-500 TABLETS(Ciprofloxacin Hydrochloride tablets BP 500 mg)		
A.R.No.	:	BS/080922/01		
Batch No.	:	G1822116	Batch Size	: 3.0 L
Mfg. Date	:	Sep-2022	Exp. Date	: Aug-2025
Sampling Date	:	08.09.2022	Sample Qty	: 120 Tablets
Analysis Date	:	08.09.2022	Release Date	: 21.09.2022

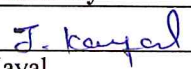
09.	Related substances:		
	Ciprofloxacin impurity C	Not Detected	Not more than 0.5%
	Ciprofloxacin impurity E	Not Detected	Not more than 0.3%
	Any individual impurity	Not Detected	Not more than 0.2%
	Total impurities	Not Detected	Not more than 1.0%
10.	Assay: Each film coated tablet contains:		
	Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg	104.77 %	Not less than 95.0% and not more than 105.0% of labeled claim.
11.	Microbiological limits:		
	Total Aerobic Microbial count	<10 cfu/g	NMT 1000 cfu/g
	Total Yeasts and mould counts	<10 cfu/g	NMT 100 cfu/g
	E.Coli	Absent	Should be Absent
	Salmonella	Absent	Should be Absent
	S.aureus	Absent	Should be Absent
	P.aeruginosa	Absent	Should be Absent

Remark : The product complies/~~not complies~~ with the prescribed standard of quality with reference to BP/USP and In-house Specification.

Sign	Tested By	Checked By	Approved By
Name	Kayal	Ramesh	Vallarasan
Date	21/09/2022	21/09/2022	21/09/2022

	SAI PRIMUS LIFE BIOTECH PRIVATE LIMITED R.S. No. 4/3, plot No. 33, Kurumbapet Industrial Estate, Villianur Commune, Pondicherry- 605009		Page 1 of 2
	CERTIFICATE OF ANALYSIS FINISHED PRODUCT		Format No: F/QCGN/022/08
Product Name	: BONCIPRO-500 TABLETS(Ciprofloxacin Hydrochloride tablets BP 500 mg)		
A.R.No.	: BS/090922/06		
Batch No.	: G1822117	Batch Size	: 3.0 L
Mfg. Date	: Sep-2022	Exp. Date	: Aug-2025
Sampling Date	: 09.09.2022	Sample Qty	: 120 Tablets
Analysis Date	: 10.09.2022	Release Date	: 21.09.2022

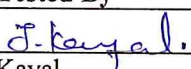
S.No.	TEST	RESULTS	LIMITS
01.	Description	Reddish pink coloured, oblong, biconvex film coated tablet with breakline on one side and plain on both sides.	Reddish pink coloured, oblong, biconvex film coated tablet with breakline on one side and plain on both sides.
02.	Identification A) By TLC B) By HPLC	Complies Complies	The Principal band in the chromatogram obtained with solution (1) corresponding to that in the chromatogram obtained with solution (2). 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 of tablets	730.15 mg	736.0 mg $\pm$ 5.0% (Limit:699.20 mg to 772.80 mg)
04.	Uniformity of weight	+2.99 % to -1.93%	Not more than 2 of the individual weights deviate from the average weight by more than $\pm$ 5 % and none deviate by more than $\pm$ 10 % .
05.	Dimensions Thickness Length Width	Min 5.32 mm Max 5.41mm Avg. 5.35mm 17.36 mm 17.40 mm 17.38 mm 7.65 mm 7.69 mm 7.67 mm	5.30 mm to 5.70 mm 17.10 mm to 17.50 mm 7.60 mm to 7.80 mm
06.	Hardness	11.30 kg/cm ²	NLT 3.0 kg/cm ²
07.	Disintegration time	02 minutes 42 seconds	Not more than 30 minutes
08.	Dissolution By UV	Min 90.17 % Max 100.41 % Avg. 94.08%	Not less than 85.0 % of labeled amount.

	Tested By	Checked By	Approved By
Sign			
Name	Kayal	Ramesh	Vallarasan
Date	21/09/2022	21/09/2022	21/09/2022

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PRIVATE LIMITED R.S. No. 4/3, plot No. 33, Kurumbapet Industrial Estate, Villianur Commune, Pondicherry- 605009		Page 2 of 2
	QUALITY CONTROL		CERTIFICATE OF ANALYSIS FINISHED PRODUCT
Product Name : BONCIPRO-500 TABLETS(Ciprofloxacin Hydrochloride tablets BP 500 mg)		Format No: F/QCGN/022/08	
A.R.No. : BS/090922/06			
Batch No. : G1822117	Batch Size : 3.0 L		
Mfg. Date : Sep-2022	Exp. Date : Aug-2025		
Sampling Date : 09.09.2022	Sample Qty : 120 Tablets		
Analysis Date : 10.09.2022	Release Date : 21.09.2022		

09.	Related substances:		
	Ciprofloxacin impurity C	Not Detected	Not more than 0.5%
	Ciprofloxacin impurity E	Not Detected	Not more than 0.3%
	Any individual impurity	Not Detected	Not more than 0.2%
	Total impurities	Not Detected	Not more than 1.0%
10.	Assay: Each film coated tablet contains:		
	Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin-500 mg	104.29 %	Not less than 95.0% and not more than 105.0% of labeled claim.
11.	Microbiological limits:		
	Total Aerobic Microbial count	10 cfu/g	NMT 1000 cfu/g
	Total Yeasts and mould counts	<10 cfu/g	NMT 100 cfu/g
	E.Coli	Absent	Should be Absent
	Salmonella	Absent	Should be Absent
	S.aureus	Absent	Should be Absent
	P.aeruginosa	Absent	Should be Absent

Remark : The product complies/not complies with the prescribed standard of quality with reference to BP/USP and In-house Specification.

	Tested By	Checked By	Approved By
Sign			
Name	Kayal	Ramesh	Vallarasan
Date	21/09/2022	21/09/2022	21/09/2022