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 FINISHED PRODUCT	Format No: F/QCGN/022/08

Product Name	:	**Genset (Cetirizine hydrochloride Tablet BP 10 mg)**			
A.R.No.	:	**BS/020421/03**			
Batch No.	:	**GF210301**	**Batch Size**	:	**30.0 L**
Mfg. Date	:	**Mar-2021**	**Exp. Date**	:	**Feb-2024**
Sampling Date	:	**02.04.2021**	**Sample Qty**	:	**120 Tablets**
Analysis Date	:	**02.04.2021**	**Release Date**	:	**05.06.2021**

S.No.	TEST	RESULTS	LIMITS
01.	**Description**	White coloured, caplet shaped, film coated tablet with break line on one side and plain on other side	White coloured, caplet shaped, film coated tablet with break line on one side and plain on other side
02.	**Identification By IR**	Complies	The infrared absorption spectrum of the residue is concordant with the reference spectrum of cetirizine hydrochloride.
03.	**Average weight of tablets**	119.75 mg	120.00 mg ± 5.0 % (114.00 mg to 126.00 mg)
04.	**Uniformity of weight**	+1.87 % to -2.29 %	Not more than 2 of the individual weights deviate from the average weight by more than ± 7.5 % and none deviate by more than ± 15 % .
05.	**Dimensions:**		
	Thickness	Min 2.85 mm; Max 2.89 mm; Avg. 2.86 mm	2.50 mm to 3.10 mm
	Length	Min 10.13 mm; Max 10.18 mm; Avg. 10.15 mm	9.90 mm to 10.30 mm
	Width	Min 4.12 mm; Max 4.17 mm; Avg. 4.14 mm	3.90 mm to 4.30 mm
06.	**Hardness**	3.78 kg/cm^2	NLT 3.0 kg/cm^2
07.	**Disintegration time**	05 minutes 43 seconds	Not more than 30 minutes
08.	**Content Uniformity:**		
	Cetirizine Hydrochloride BP -10 mg	Min 99.92 %; Max 102.20 %; Avg. 101.00 %	Not less than 85.0 % and Not more than 115.0 % of labeled claim.
09.	**Dissolution:**		
	Cetirizine Hydrochloride BP -10 mg	Min 98.19 %; Max 105.39 %; Avg. 102.01 %	Not less than 85.0 % of labeled amount.
10.	**Related substances:**		
	Impurity A	Not Detected	Not more than 0.3 %
	Impurity B	Not Detected	Not more than 0.3 %
	Impurity G	Not Detected	Not more than 0.3 %
	Single maximum unknown	Not Detected	Not more than 0.2 %

	Tested By	Checked By	Approved By
Sign	D. Dhiviya		
Name	Dhiviya	Ramesh	Vallarasan
Date	05/06/2021	05/06/2021	05/06/2021

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	Format No: F/QCGN/022/08

Product Name	:	**Genset (Cetirizine hydrochloride Tablet BP 10 mg)**			
A.R.No.	:	**BS/020421/03**			
Batch No.	:	**GF210301**	**Batch Size**	:	**30.0 L**
Mfg. Date	:	**Mar-2021**	**Exp. Date**	:	**Feb-2024**
Sampling Date	:	**02.04.2021**	**Sample Qty**	:	**120 Tablets**
Analysis Date	:	**02.04.2021**	**Release Date**	:	**05.06.2021**

	impurity		
	Total impurities	Not Detected	Not more than 1.0 %
11.	**Assay: Each Film coated tablet contains:**		
	Cetirizine Hydrochloride BP -10 mg	100.18 %	Not less than 95.0 % and Not more than 105.0 %
12.	**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	Dhiviya	Ramesh	Vallarasan
Date	05/06/2021	05/06/2021	05/06/2021

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 FINISHED PRODUCT	Format No: F/QCGN/022/08

Product Name	:	**Genset (Cetirizine hydrochloride Tablet BP 10 mg)**			
A.R.No.	:	**FP/050121/03**			
Batch No.	:	**GF210101**	**Batch Size**	:	**30.0 L**
Mfg. Date	:	**Jan-2021**	**Exp. Date**	:	**Dec-2023**
Sampling Date	:	**04.01.2021**	**Sample Qty**	:	**120 Tablets**
Analysis Date	:	**04.01.2021**	**Release Date**	:	**02.02.2021**

S.No.	TEST	RESULTS	LIMITS
01.	**Description**	White coloured, caplet shaped, film coated tablet with break line on one side and plain on other side	White coloured, caplet shaped, film coated tablet with break line on one side and plain on other side
02.	**Identification By IR**	Complies	The infrared absorption spectrum of the residue is concordant with the reference spectrum of cetirizine hydrochloride.
03.	**Average weight of tablets**	119.60 mg	120.00 mg ± 5.0 % (114.00 mg to 126.00 mg)
04.	**Uniformity of weight**	+1.17 % to -1.33 %	Not more than 2 of the individual weights deviate from the average weight by more than ± 7.5 % and none deviate by more than ± 15 % .
05.	**Dimensions:**		
	Thickness	Min 2.80 mm / Max 2.84 mm / Avg. 2.82 mm	2.50 mm to 3.10 mm
	Length	Min 10.13 mm / Max 10.15 mm / Avg. 10.14 mm	9.90 mm to 10.30 mm
	Width	Min 4.11 mm / Max 4.14 mm / Avg. 4.12 mm	3.90 mm to 4.30 mm
06.	**Hardness**	3.96 kg/cm^2	NLT 3.0 kg/cm^2
07.	**Disintegration time**	04 minutes 05 seconds	Not more than 30 minutes
08.	**Content Uniformity:**		
	Cetirizine Hydrochloride BP -10 mg	Min 98.67 % / Max 103.33 % / Avg. 100.86 %	Not less than 85.0 % and Not more than 115.0 % of labeled claim.
09.	**Dissolution:**		
	Cetirizine Hydrochloride BP -10 mg	Min 93.82 % / Max 103.94 % / Avg. 98.79 %	Not less than 85.0 % of labeled amount.
10.	**Related substances:**		
	Impurity A	Not Detected	Not more than 0.3 %
	Impurity B	Not Detected	Not more than 0.3 %
	Impurity G	Not Detected	Not more than 0.3 %

	Tested By	Checked By	Approved By
Sign			
Name	Sriram	Senthilnathan	Vallarasan
Date	02/02/2021	02/02/2021	02/02/2021

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	Format No: F/QCGN/022/08

Product Name	:	**Genset (Cetirizine hydrochloride Tablet BP 10 mg)**			
A.R.No.	:	**FP/050121/03**			
Batch No.	:	**GF210101**	**Batch Size**	:	**30.0 L**
Mfg. Date	:	**Jan-2021**	**Exp. Date**	:	**Dec-2023**
Sampling Date	:	**04.01.2021**	**Sample Qty**	:	**120 Tablets**
Analysis Date	:	**04.01.2021**	**Release Date**	:	**02.02.2021**

	Single maximum unknown impurity	Not Detected	Not more than 0.2 %
	Total impurities	Not Detected	Not more than 1.0 %
11.	**Assay: Each Filmcoated tablet contains:**		
	Cetirizine Hydrochloride BP -10 mg	100.89 %	Not less than 95.0 % and Not more than 105.0 %
12.	**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	Sriram	Senthilnathan	Vallarasan
Date	02/02/2021	02/02/2021	02/02/2021

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): Date: 29/12/2020
		Format No.: F/QCGN/022/04	
	TESTING AND RELEASE OF INTERMEDIATE AND FINISHED PRODUCTS	Revision No.: 00	
TITLE:	CHECK LIST OF FINISHED PRODUCT	Review Period: 02 Years	
		Effective Date: 22/05/19	

Name of the Product: Genset	
Analytical Report No. FP/050121/08	**Batch No.** GF210101

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)	6-13	8
Dissolution log entry ✓	Physical parameter sheet Tablet / Capsule / Sachet	NA	NA
UV-VIS log entry ✓	Graph of UV-VIS spectrophotometer	14-15	2
pH meter log entry ✓	Graph of IR spectrophotometer	16-17	2
IR log entry ✓	LC chromatogram	18-48	31
	Tapped density test report	NA	NA
	KF-Autotitra report	NA	NA
	Microbiological test report	49-54	6
	Outside laboratory testing report	NA	NA
	Additional test report if any	55	1
	The above product consist of 55 pages	Total pages 55	

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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 QA/Date: 27/11/19
		No.: F/QAGN/026/01	
	SAMPLING POLICY	Revision No: 00	
TITLE	TEST REQUEST FORM	Review Period: 2 years	
		Effective Date: 27/04/19	

Date: 05/01/2024

From (Dept): PACKING		To: Q.C. DEPARTMENT
Name of the Item/: Product/ Previous: Product* :	GENSET	Quantity sampled 1. Finished goods 2. 120 Tablets 3. NA 4. NA
Batch No.* :	GF 21 0101	
Batch Size* :	30 - UL	
Mfg. Date* :	01/2024	Sampled on: 05/01/2024
Exp. Date* :	12/2023	Sampled by: Mrs Ranthini
Stage* :	Finished product	Analyzed By: 05/01/2024
		Analytical Reference No. ~~F/05012/05~~ F/05012/03

Tests:

1. As per specification
2. ~~/~~
3.
4.

05/01/2024	05/01/2024	05/01/2024
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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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/Date: 24/12/19
		No.: F/QAGN/026/01	
	SAMPLING POLICY	Revision No: 00	
TITLE	TEST REQUEST FORM	Review Period: 2 years	
		Effective Date: 27/04/19	

Date: 04/01/2021

From (Dept): Production		**To: Q.C. DEPARTMENT**
Name of the Item/: Product/ Previous: Product* :	Cronsob	Quantity sampled 1. Composite Stage 1 2. Chemical 100 Tab 3. Micro 20 Tab 4. NA
Batch No.* :	GF210101	
Batch Size* :	30.0L	
Mfg. Date* :	01/2021	Sampled on: 04/01/2021
Exp. Date* :	12/2023	Sampled by: Prabhakaran
Stage* :	Coated tablets	Analyzed By: 04/01/2021
		Analytical Reference No. ~~BS/04/01/21/07~~ * BS/04/01/21/05

Tests:

1. As per Specification
2.
3.
4.

04/01/2021	04/01/2021	04/01/2021
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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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 FINISHED PRODUCT	Format No: F/QCGN/022/08

Product Name	:	**Genset (Cetirizine hydrochloride Tablet BP 10 mg)**			
A.R.No.	:	**FP/050121/03**			
Batch No.	:	**GF210101**	**Batch Size**	:	**30.0 L**
Mfg. Date	:	**Jan-2021**	**Exp. Date**	:	**Dec-2023**
Sampling Date	:	**04.01.2021**	**Sample Qty**	:	**120 Tablets**
Analysis Date	:	**04.01.2021**	**Release Date**	:	**02.02.2021**

S.No.	TEST	RESULTS	LIMITS
01.	**Description**	White coloured, caplet shaped, film coated tablet with break line on one side and plain on other side	White coloured, caplet shaped, film coated tablet with break line on one side and plain on other side
02.	**Identification By IR**	Complies	The infrared absorption spectrum of the residue is concordant with the reference spectrum of cetirizine hydrochloride.
03.	**Average weight of tablets**	119.60 mg	120.00 mg ± 5.0 % (114.00 mg to 126.00 mg)
04.	**Uniformity of weight**	+1.17 % to -1.33 %	Not more than 2 of the individual weights deviate from the average weight by more than ± 7.5 % and none deviate by more than ± 15 % .
05.	**Dimensions:**		
	Thickness	Min 2.80 mm / Max 2.84 mm / Avg. 2.82 mm	2.50 mm to 3.10 mm
	Length	Min 10.13 mm / Max 10.15 mm / Avg. 10.14 mm	9.90 mm to 10.30 mm
	Width	Min 4.11 mm / Max 4.14 mm / Avg. 4.12 mm	3.90 mm to 4.30 mm
06.	**Hardness**	3.96 kg/cm^2	NLT 3.0 kg/cm^2
07.	**Disintegration time**	04 minutes 05 seconds	Not more than 30 minutes
08.	**Content Uniformity:**		
	Cetirizine Hydrochloride BP -10 mg	Min 98.67 % / Max 103.33 % / Avg. 100.86 %	Not less than 85.0 % and Not more than 115.0 % of labeled claim.
09.	**Dissolution:**		
	Cetirizine Hydrochloride BP -10 mg	Min 93.82 % / Max 103.94 % / Avg. 98.79 %	Not less than 85.0 % of labeled amount.
10.	**Related substances:**		
	Impurity A	Not Detected	Not more than 0.3 %
	Impurity B	Not Detected	Not more than 0.3 %
	Impurity G	Not Detected	Not more than 0.3 %

	Tested By	Checked By	Approved By
Sign			
Name	Sriram	Senthilnathan	Vallarasan
Date	02/02/2021	02/02/2021	02/02/2021

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	Format No: F/QCGN/022/08

Product Name	:	**Genset (Cetirizine hydrochloride Tablet BP 10 mg)**			
A.R.No.	:	**FP/050121/03**			
Batch No.	:	**GF210101**	**Batch Size**	:	**30.0 L**
Mfg. Date	:	**Jan-2021**	**Exp. Date**	:	**Dec-2023**
Sampling Date	:	**04.01.2021**	**Sample Qty**	:	**120 Tablets**
Analysis Date	:	**04.01.2021**	**Release Date**	:	**02.02.2021**

	Single maximum unknown impurity	Not Detected	Not more than 0.2 %
	Total impurities	Not Detected	Not more than 1.0 %
11.	**Assay: Each Filmcoated tablet contains:**		
	Cetirizine Hydrochloride BP -10 mg	100.89 %	Not less than 95.0 % and Not more than 105.0 %
12.	**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	Sriram	Senthilnathan	Vallarasan
Date	02/02/2021	02/02/2021	02/02/2021

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	Issued by : Date: 05/01/2021

RAW DATA SHEET FOR FINISHED PRODUCT

Name of Product: Grenset	
Batch No: GF 21010I	**A.R. Number:** FP/050121/03
Sample Qty.: 120 Tablets	**Stage:** FP
Analysis Start On: 05/01/2021	**Specification No:** G113
Analysis Completed On: 27/01/2021	

1) Description: white coloured, caplet Shaped, film coated tablet with break line on one side and plain on other side.

2) Identification: Complies

3) Avg. weight of tablet:

Avg. weight of tablet = $\frac{2.392 \text{ gm}}{20}$ = 0.1196 **gm equivalent to** 119.6 **mg**

4) Uniformity of Wt. of tablets:

No.	Weight in mg	No.	Weight in mg	No.	Weight in mg	No.	Weight in mg
1	0.120	6	0.120	11	0.120	16	0.121
2	0.119	7	0.120	12	0.121	17	0.120
3	0.120	8	0.120	13	0.118	18	0.120
4	0.119	9	0.119	14	0.119	19	0.119
5	0.118	10	0.119	15	0.120	20	0.120

5) Friability: weight of highest : 0.121 (1.17%) weight of lowest : 0.118 (-1.33%)

i) Weight of tablets before test: NA **gm.**

ii) Weight of tablets after test: NA **gm.**

iii) Weight difference: NA **gm.**

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

Analyzed By:	Checked by:
Date 05/01/2021	Date: 27/01/2021

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6) Disintegration Time: 04 minutes 05 Seconds

7) Hardness:

Sr. No	Hardness (kg/cm2)	Sr. No	Hardness (kg/cm2)
1	3.5	6	4.5
2	4.0	7	4.0
3	3.9	8	3.9
4	3.5	9	4.5
5	3.9	10	3.9
	Mean Hardness (kg/cm2)		3.96 kg

8) Thickness:

Sr. No	Thickness (mm)	Sr. No	Thickness (mm)
1	2.80	6	2.83
2	2.83	7	2.83
3	2.82	8	2.82
4	2.83	9	2.83
5	2.84	10	2.83
	Mean Thickness (mm)		2.82 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)		NA

10) Dissolution:

Dissolution Parameter:

Type	:	paddle
Medium	:	water (purified water)
Volume	:	900ml
Speed	:	50 RPM
Time	:	30mm
Wavelength	:	230 nm

Analyzed By:	Checked by: PP
Date 05/01/2021	Date: 27/01/2021

Preparation of dissolution medium: 6000ml of water.

Chromatographic Condition: NA

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

Preparation of buffer for Mobile phase: NA

Mobile phase preparation: NA

Standard Preparation: 24.50mg of cetirizine HCl std into 100mL volumetric flask. 70ml of water sonicate and make up to mark. Further 2ml to 100ml dilute volumetric flask. make up to mark with water.

Sample Preparation:

1 Tablet into 900ml of disso medium withdraw 10ml of aliquot fro. each specimen. Filter through filter paper and further 5ml to 10ml dilute.

Calculation and Results: Refer to Excel.

Formula:

Analyzed By: 27/01/2021 Date	Checked by: Date: 27/01/2021

11) Assay:

Chromatographic Condition:

Column Description	:	C_{18} 250mm x 4.6mm, 5µ
Column No.	:	QC-LC-009 (Zodiac)
Flow Rate	:	1.0mL
Wavelength	:	230nm
Injection Volume	:	20 µL
Column Oven Temperature	:	30°C

Preparation of buffer for Mobile phase: 0.341g of KH_2PO_4 taken in to 1000ml water Sonicate to dissolve and adjust the pH 1.5 (OPA)

Mobile phase preparation: mixed 700ml of buffer Solution and 300ml of acetonitril) Filter through 0.45 micron membranee filter.

Standard Preparation: weight accurately 40.6mg of cetirizine HCl Stendard into 200m volumetric flask. added about 50ml of mobile phase. Sonicated with intermediate shaking to dissolved and dilute up to the volume with mobile phase. further dilute 10ml of this Solution to 100ml with mobile phas

Sample Preparation: (1) weight accurately 480.8mg of Sample powder into 200ml Volumetric flask. Added about 50ml of mobile phase. Sonicate for 10minutes with intermediate shaking to dissolved and dilutes upto the volume with mobile phase. Filter Sufficient quantity of the Solution. Further dilute 10ml of this solution to 100ml with mobile phase.

Sample Preparation: (2)

weight accurately 480.9mg of Sample powders (50ml)

Analyzed By: 24/11/2021 Date	Checked by: PJ Date: 27/11/2021

Calculation and Results: Refer to Excel

Formula:

12) Uniformity of dosage unit /Content Uniformity:

Chromatographic Condition:

Column Description	:	C18, 250mm × 4.6mm, 5µm
Column No.	:	QC-LC-009 (Zodiac life Sciences)
Flow Rate	:	1.0mL
Wavelength	:	230 nm
Injection Volume	:	20µL
Column Oven Temperature	:	30°C

Preparation of buffer for Mobile phase: 0.3411g of KH_2PO_4 in to 1000ml of water. Sonicate to dissolve and adjust the pH. 1.5 (OPA)

Mobile phase preparation: Mixed 700ml of buffer solution and 300ml acetonitrile

Standard Preparation: weight accurately 10.10mg of cetirizine HCl standard into 200ml volumetric flask. added about 50ml of mobile phase. Sonicate with intermediate shaking to dissolve and dilute up to the volume with mobile phase.

Further dilute 10ml of this solution to 100ml with mobile phase.

Sample Preparation: Taken 1 tablet into 50ml volumetric flask contain 10ml of water keeped as it is until the complete dispersion of tablet. added 20ml of mobile phase, Sonicate for 10ml minutes with intermediate shaking and dilute up to volume with mobile phase.

Further dilute 5ml of this solution to 50ml with mobile phase and inject.

Analyzed By: 24/11/2021 Date	Checked by: Date: 27/11/2021

(Repeat same procedure for other 9 tablets)

Calculation and Results: Refer to Excel

Formula:

13) Related Substances/ Impurities:

Chromatographic Condition:

Column Description	:	C18 250 mm x 4.6mm, 5M
Column No.	:	RL-LC (Zodiac life Sciences)
Flow Rate	:	1.0ml
Wavelength	:	230 nm
Injection Volume	:	20M
Column Oven Temperature	:	30°c

Preparation of buffer for Mobile phase: NA

Mobile phase preparation: (A) Mixed 100ml of Acetonitrile and 830 ml of water adjusted pH to 1.5 (OPA)
mobile phase (B) Mixed 350ml of Acetonitrile and 650 ml of water adjust pH to 1.5 (OPA)

Resolution/ impurity preparation:

Analyzed By: [illegible] 24/01/2024 Date	Checked by: RL Date: 27/01/2024

Standard/ Reference Preparation: taken 50.7 mg cetirizine HCl standard into 50ml volumetric flask. Added about 20ml of mobile phase, sonicate with intermediate shaking to dissolve and dilute up to the volume with mobile phase. 1ml of this solution to 100ml of mobile phase. Further dilute 10ml of this solution to 50ml of with mobile phase.

Placebo Preparation: Taken 230.2 mg of placebo into 20ml volumetric flask added about 10ml of mobile phase. Sonicate with intermediate shaking to dissolve and dilute up to the volume with mobile phase.

Sample Preparation: taken 252.6mg of sample powder into 20ml of volumetric flask, added about 10ml of mobile phase, sonicate for 10min. with intermediate shaking to dissolve and dilute up to the volume with mobile phase.

Calculation and Results:

Formula:

Known impurity: ND

Unknown impurity: ND

Total impurities: ND

Analyzed By: Date 24/11/2021	Checked by: Date: 27/11/2021

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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 QA Sign/Date: 8/10/21
		No.: F/QCGN/003/01	
	GOOD LABORATORY PRACTICES	Revision No.: 00	
TITLE:	ANALYTICAL DATA SHEET	Review Period: 02 years	
		Effective Date: 18/05/19	

Average Length (mm) [9.90 – 10.30)

1) 10.13
2) 10.15
3) 10.14
4) 10.15
5) 10.13
6) 10.14
7) 10.15
8) 10.14
9) 10.14
10) 10.15

Average: 10.14 mm

Average width (mm) [3.90 – 4.30)

1) 4.11
2) 4.11
3) 4.13
4) 4.12
5) 4.11
6) 4.13
7) 4.12
8) 4.12
9) 4.11
10) 4.14

Average: 4.12 mm

Analysed by: Date: 25/10/2021

Checked by: Date: 27/10/2021

SAI PRIMUS
LIFE BIOTECH PVT LTD

EXCEL SHEET FOR DISSOLUTION CALCULATION

Name of Product	GENSET TABLETS(CETIRIZINE HYDROCHLORIDE)		
Date of Analysis	01-02-2021	**Batch No.**	GF210101
Mfg. Date	Jan-21	**Exp. Date**	Dec-23
WS No.	NA	**% Purity**	99.72
WS Weight (WS)	24.5	**WS Validity**	NA
Sample Weight (SW)	1	**Label Claim (LC)**	10

Std.	24.5	2	1	1	1	1
Dilution	100	100	1	1	1	1

Sample	1	5	1	1	1	1
Dilution	900	10	1	1	1	1

Calculatio	Smp. Area/Abs	Std Dilution	99.72	100	CF1	CF3
n	Std. Area/Abs	Sample Dilution	100	10	CF2	CF4

CF1	1
CF2	1
CF3	1
CF4	1

Sr. No.	Standard Area/Abs	Standard RT
1	0.165	0
2	0.165	0
3	0.165	0
4	0.165	0
5	0.165	0
6		
Average	0.165	0.000
SD	0	0
%RSD	0.0	#DIV/0!

Tablet	Area/Abs.
Tab1	0.176
Tab2	0.184
Tab3	0.195
Tab4	0.185
Tab5	0.193
Tab6	0.179
Average	
Minimum	
Maximum	

Result %	Result mg
93.82	9.38
98.08	9.81
103.94	10.39
98.61	9.86
102.88	10.29
95.42	9.54
98.79	**9.88**
93.82	**9.38**
103.94	**10.39**

Analysed I J. Rajput
Date 01/02/2021

Checked By PS
Date 01/02/2021

SAI PRIMUS LIFE BIOTECH PVT LTD

Photometric Method Report

01/02/2021 15:33:47

File Name: C:\UVProbe-Data\Data\DATA-2021\FEB-2021\01022021\Cetirizine STD disso.unk

Sample Table

	Sample ID	WL230.0	WL260.0	Comments
1	STD	0.170	0.005	0.170-0.005=0.165
2	Jar_1	0.186	0.010	0.186-0.010=0.176
3	Jar_2	0.197	0.013	0.197-0.013=0.184
4	Jar_3	0.204	0.009	0.204-0.009=0.195
5	Jar_4	0.192	0.007	0.192-0.007=0.185
6	Jar_5	0.201	0.008	0.201-0.008=0.193
7	Jar_6	0.185	0.006	0.185-0.006=0.179
8				

[Wavelengths]
Wavelength Name: WL230.0
Wavelength: 230.00 nm
Wavelength Name: WL260.0
Wavelength: 260.00 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: 01/02/2021 15:05:32
Comments:
Sample Preparations:

[Instrument Properties]
Instrument Type: UV-1900 Series
.....

Software Information
Software Name: UVProbe
Version: 2.70
Mode: Normal Mode

Data Information
Filename: C:\UVProbe-Data\Data\DATA-2021\FEB-2021\01022021\Cetirizine STD disso.unk
Title: Dissolution Standard
Analyst: Rajesh
Date/Time: 01/02/2021 15:33:39
Comments:

Instrument Information
Instrument Name: Instrument 1
Instrument Type: UV-1900 Series
Model (S/N): UV1900 (A12425780886)

Analysed By : Rajesh
Date : 01/02/2021

Checked By : PL
Date : 01/02/2021

SAI PRIMUS
LIFE BIOTECH PVT LTD

EXCEL SHEET FOR ASSAY CALCULATION FP

Name of Product	GENSET TABLETS(CETIRIZINE HYDROCHLORIDE)						
Date of Analysis	05.01.2021			**Batch No.**	GF210101		
Mfg. Date	JAN-2021			**Exp. Date**	DEC-2023		
WS No.	NA			**% Purity**	99.72		
WS Weight (WS)	40.60			**WS Validity**	NA		
Sample Weight (SW)	480.8			**Label Claim (LC)**	10		
CF1	1	**CF2**	1	**CF3**	1	**CF4**	1

Std. Dilution	40.60	10	1	1	1
	200	100	1	1	1

Sample Dilution	480.8	10	1	1	1
	200	100	1	1	1

Avg.WT	119.60

Calculation Formula	Smp. Area/Abs	Std Dilution	99.72	119.60	1	CF3
	Std. Area/Abs	Sample Dilution	100		CF2	CF4

Sr. No.	Standard Area/Abs	Standard RT
1	763382	15.927
2	779038	15.927
3	772658	15.923
4	765916	15.923
5	769262	15.919
6		
Average	770051	15.924
SD	6118.801451	0.00334664
RSD	0.8	0.0

Sr. No.	Sample Area/Abs
1	775253
2	767555
3	
4	
5	
6	
Average	771404

Assay (mg)	**10.0888**

Assay (%)	**100.89**

Analysed By [signature]
Date 05/01/2021

Checked By [signature]
Date 20/01/2021

SAI PRIMUS
LIFE BIOTECH PVT LTD

EXCEL SHEET FOR UNIFORMITY OF CONTENT

Name of Product	GENSET TABLETS(CETIRIZINE HYDROCHLORIDE)				
Date of Analysis	05.01.2021	**Batch No.**	GF210101	**Conversion Factor1**	1
Mfg. Date	JAN-2021	**Exp. Date**	DEC-2023	**Conversion Factor2**	1
WS No.	NA	**% Purity**	99.72	**Conversion Factor3**	1
WS Weight (WS)	40.60	**WS Validity**	NA	**Conversion Factor4**	1
Sample Weight (SW)	1	**Label Claim (LC)**	10		

Std. Dilution	40.6	10	1	1	1
	200	100	1	1	1
Sample Dilution	1	5	1	1	1
	50	50	1	1	1

Calculation Formula	Smp. Area	Std Dilution	99.72	100	**Conversion Factor1**	**Conversion Factor3**	**% Assay**
	Std. Area	Sample Dilution	100	10	**Conversion Factor2**	**Conversion Factor4**	

Sr. No.	**Standard Area**	**Standard RT**
1	763382	15.927
2	779038	15.927
3	772658	15.923
4	765916	15.923
5	769262	15.919
Average	770051	15.924
SD	6118.801451	0.00334664
RSD	0.8	0.0

Sample

UC	AREA	Smp. Weight	%	mcg	Minimum %
UC1	762822	1	100.27	10.03	98.67
UC2	752661	1	98.93	9.89	
UC3	775282	1	101.90	10.19	
UC4	766165	1	100.71	10.07	
UC5	750706	1	98.67	9.87	**Maximum %**
UC6	770549	1	101.28	10.13	103.33
UC7	776144	1	102.02	10.20	
UC8	772257	1	101.51	10.15	
UC9	786146	1	103.33	10.33	
UC10	760437	1	99.95	10.00	
		AVG	**100.86**		

Analysed By		**Checked By**	
Date	6/1/2021	**Date**	27/01/2021

Vial	Inj Vol (uL)	# of Injs	SampleName	Function	Method Set / Report Method	Run Time (Minutes)
1	20.0	1	ASSAY_BLANK	Inject Samples	GENSET TAB_ASSAY_DISSO_FP_MSET	22.00
2	20.0	5	ASSAY_STANDARD	Inject Samples	GENSET TAB_ASSAY_DISSO_FP_MSET	22.00
1	20.0	1	ASSAY_BLANK	Inject Samples	GENSET TAB_ASSAY_DISSO_FP_MSET	22.00
3	20.0	1	GENSET_GF210101_ASSAY_SPL_01	Inject Samples	GENSET TAB_ASSAY_DISSO_FP_MSET	22.00
4	20.0	1	GENSET_GF210101_ASSAY_SPL_02	Inject Samples	GENSET TAB_ASSAY_DISSO_FP_MSET	22.00
2	20.0	1	ASSAY_BKT_STD	Inject Samples	GENSET TAB_ASSAY_DISSO_FP_MSET	22.00
5	20.0	1	GENSET_GF210101_UOC_SPL_01	Inject Samples	GENSET TAB_ASSAY_DISSO_FP_MSET	22.00
6	20.0	1	GENSET_GF210101_UOC_SPL_02	Inject Samples	GENSET TAB_ASSAY_DISSO_FP_MSET	22.00
7	20.0	1	GENSET_GF210101_UOC_SPL_03	Inject Samples	GENSET TAB_ASSAY_DISSO_FP_MSET	22.00
8	20.0	1	GENSET_GF210101_UOC_SPL_04	Inject Samples	GENSET TAB_ASSAY_DISSO_FP_MSET	22.00
9	20.0	1	GENSET_GF210101_UOC_SPL_05	Inject Samples	GENSET TAB_ASSAY_DISSO_FP_MSET	22.00
2	20.0	1	ASSAY_BKT_STD	Inject Samples	GENSET TAB_ASSAY_DISSO_FP_MSET	22.00
10	20.0	1	GENSET_GF210101_UOC_SPL_06	Inject Samples	GENSET TAB_ASSAY_DISSO_FP_MSET	22.00
11	20.0	1	GENSET_GF210101_UOC_SPL_07	Inject Samples	GENSET TAB_ASSAY_DISSO_FP_MSET	22.00
12	20.0	1	GENSET_GF210101_UOC_SPL_08	Inject Samples	GENSET TAB_ASSAY_DISSO_FP_MSET	22.00
13	20.0	1	GENSET_GF210101_UOC_SPL_09	Inject Samples	GENSET TAB_ASSAY_DISSO_FP_MSET	22.00
14	20.0	1	GENSET_GF210101_UOC_SPL_10	Inject Samples	GENSET TAB_ASSAY_DISSO_FP_MSET	22.00
2	20.0	1	ASSAY_BKT_STD	Inject Samples	GENSET TAB_ASSAY_DISSO_FP_MSET	22.00
				Equilibrate	WASHING SOLUTION_B_MSET	122.00
				Equilibrate	SHUTDOWN_MSET	0.01

05/01/2021

05/01/2021

Empower 3 FEATURE RELEASE

INSTRUMENT METHOD

SAI PRIMUS

Instrument Method: GENSET TAB_ASSAY_DISSO_FP_IN

Stored: 1/5/2021 11:25:49 AM IST

Method Information

Method Comments	INSTRUMENT METHOD
Method Modified User	SRIRAM
Method Locked	No
Method Id	1887
Old Id	
Method Version	1
Method Edit User	
Source S/W Info	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2404097152

W2690/5 Instrument Setup

Type	W2690/5
Instrument Status	On
Channel Name	2690/5
Description	PRESSURE ENABLE
Use Channel Monitor	On
Monitor Parameter	System Pressure
Stroke Volume	100uL (flow rates <= 3.030 mL/min)
Chart Out	%A
Syringe Draw Rate	Normal
Depth Of Needle	0.0
Degas Mode	Off
Pump Mode	Isocratic
Flow	1.000
%A	100.0
%B	0.0
%C	0.0
%D	0.0
High Limit	5000.0
Low Limit	0.0
Enable Sample Temp	False
Enable Column Temp	True
Bubble Detect	True
Pre Column Volume	0.0
Sample Temp Target	-1.0
Sample Temp Range	5.0
Sparge A	0.0

Analysed by:
Date : 05/01/2021

Checked by:
Date : 05/01/2021

Sparge B	0.0
Sparge C	0.0
Sparge D	0.0
Column Temp Target	30.0
Column Temp Range	5.0
Flow Ramp	2.00
Column choice	No Change
Column Equil Minutes	0.00
Needle Wash	Extended
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	

W2487 Instrument Setup

Type	W2487
Instrument Status	On
Dual Wavelength	False
Pulse Period Seconds	1.0
Pulse Repeat Period Seconds	1.0

W2487 Channel Information

Channel Name	2487Channel 1
Description	
Use Channels	On
Wavelength	230
Output Mode	Absorbance A (Ch1)
Data Mode	Absorbance A (Ch1)
Sampling Rate	1
Filter Type	Hamming
Aufs	2.0000
Time Constant	1.0
AU Offset	0.000
Voltage Offset	0
Polarity	+
AutoZero Wavelength	True
AutoZero Keypad	True
AutoZeroEvent Input	True
AutoZero Inject	True
Chart Mark Enable	True
Ratio AuMinimum	0.1000
Minimum Ratio	0.00
Maximum Ratio	2.00

Revision History

Version 1 1/5/2021 11:25:49 AM IST User SRIRAM Created method 'GENSET TAB_ASSAY_DISSO_FP_IM'. INSTRUMENT METHOD

Method Version Summaries

	Method Name	Method Type	Method Comments	Method Date	Method Modified User
1	GENSET TAB_ASSAY_DISSO_FP_IM	Instrument	INSTRUMENT METHOD	1/5/2021 11:25:49 AM IST	SRIRAM

Analysed by: Date : 05/01/2021

Checked by: Date : 05/01/2021

Method Version Summaries

	Method Locked	Method Id	Old Id	Method Version
1	No	1887		1

Method Version Summaries

	Source S/W Info
1	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2404097152

Analysed by:
Date : 05/01/2021

Checked by:
Date : 05/01/2021

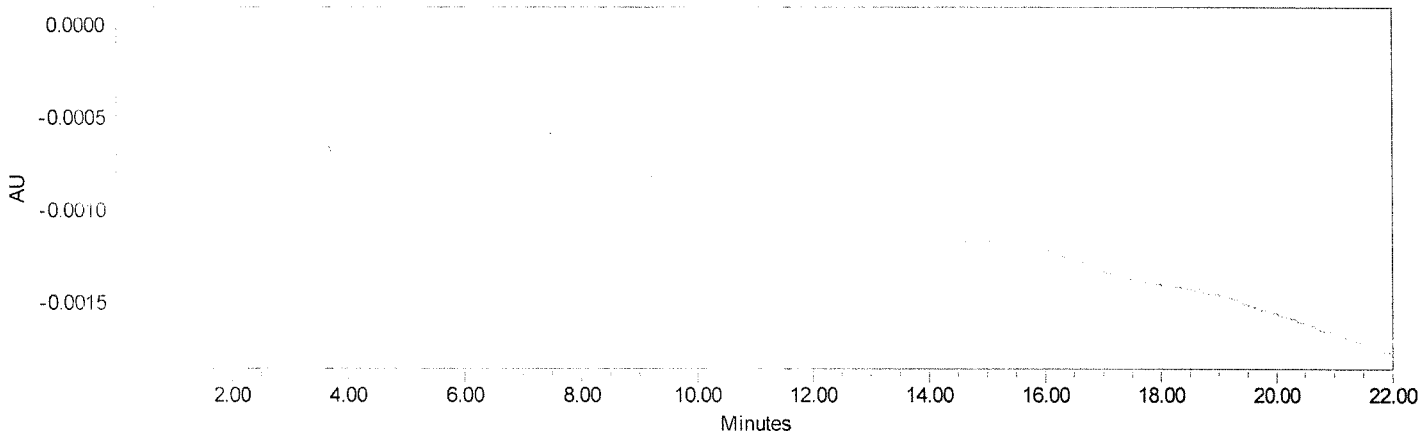
CHROMATOGRAPHIC DATA

SAI PRIMUS
LIFE BIOTECH PVT LTD

SAMPLE INFORMATION

Sample Name:	ASSAY_BLANK		Acquired By: SRIRAM
Sample Type:	Unknown	Sample Set Name	05012021_GENSET_ASSAY_DISSO_FP
Vial:	1	Acq. Method Set:	GENSET TAB_ASSAY_DISSO_FP_MSE
Injection #:	1	Processing Method	GENSET_ASSAY_FP_PM
Injection Volume:	20.00 ul	Channel Name:	2487Channel 1
Run Time:	22.0 Minutes	Proc. Chnl. Descr.:	2487Channel 1
Date Acquired:	1/5/2021 1:07:23 PM IST		
Date Processed:	1/6/2021 9:17:04 AM IST		

Auto-Scaled Chromatogram



Peak Results

	Name	RT	Area
1	CETIRIZINE HCl	15.927	

Analysed by: 06/1/2021
Date :

Checked by: PZ
Date : 27/01/2021

Reported by User: SRIRAM (SRIRAM)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 1721
Page: 1 of 1

Project Name: 2021\QC_HPL_002\JAN-2021
Printed Date 1/6/2021
Printed Time 9:26:16 AM A:

RSD REPORT

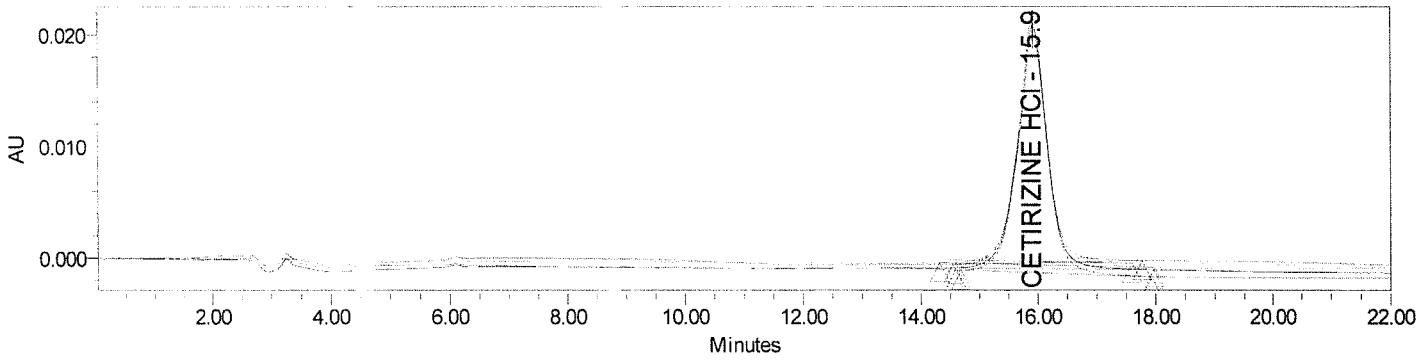
SAMPLE INFORMATION

Sample Name:	ASSAY_STANDARD	Acquired By:	SRIRAM
Sample Type:	Unknown	Sample Set Name:	05012021_GENSET_ASSAY_DISSO_FP
Vial:	2	Acq. Method Set:	GENSET
Injection #:	1, 2, 4, 5, 3	Processing Method	GENSET_ASSAY_FP_PM
Injection Volume:	20.00 ul	Channel Name:	2487Channel 1
Run Time:	22.0 Minutes	Proc. Chnl. Descr.:	2487Channel 1

Date Acquired: 1/5/2021 1:30:56 PM IST, 1/5/2021 1:54:25 PM IST, 1/5/2021 2:17:55 PM IST, 1/5/2021 2:41:24 PM IST, 1/5/2021 3:05:07 PM IST

Date Processed: 1/6/2021 9:17:04 AM IST

Auto-Scaled Chromatogram



Peak Name: CETIRIZINE HCl

	Injection	Peak Name	RT	Area	USP Plate Count	USP Tailing
1	1	CETIRIZINE HCl	15.927	763382	4734	1.0
2	2	CETIRIZINE HCl	15.927	779038	4686	1.0
3	3	CETIRIZINE HCl	15.923	772658	4793	1.0
4	4	CETIRIZINE HCl	15.923	765916	4732	1.0
5	5	CETIRIZINE HCl	15.919	769262	4899	0.9
Mean			15.924	770051	4769	1.0
Std. Dev.			0.003	6118.895		
% RSD			0.0	0.8		

Analysed by: Date : 05/01/2021

Checked by: Date : 27/01/2021

Reported by User: SRIRAM (SRIRAM)
Report Method: RSD REPORT SYSTEM
Report Method ID 1522
Page: 1 of 1

Project Name: 2021\QC_HPL_002\JAN-2021
Printed Date 1/6/2021
Printed Time 9:27:47 AM A

Empower 3 SOFTWARE

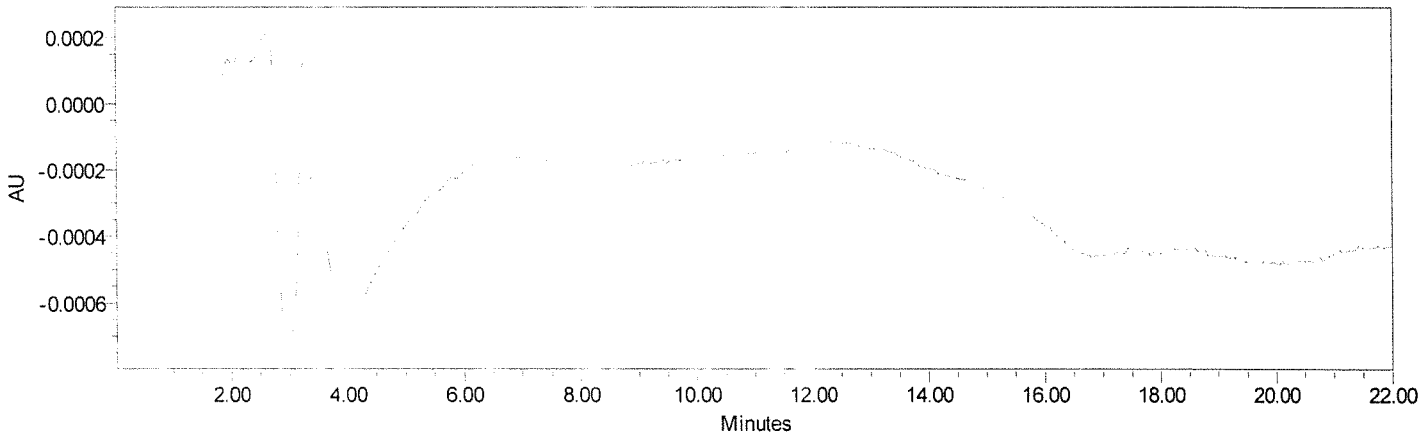
CHROMATOGRAPHIC DATA

SAI PRIMUS LIFE BIOTECH PVT LTD

SAMPLE INFORMATION

Sample Name:	ASSAY_BLANK		Acquired By: SRIRAM
Sample Type:	Unknown	Sample Set Name:	05012021_GENSET_ASSAY_DISSO_FP
Vial:	1	Acq. Method Set:	GENSET TAB_ASSAY_DISSO_FP_MSE
Injection #:	1	Processing Method	GENSET_ASSAY_FP_PM
Injection Volume:	20.00 ul	Channel Name:	2487Channel 1
Run Time:	22.0 Minutes	Proc. Chnl. Descr.:	2487Channel 1
Date Acquired:	1/5/2021 3:29:08 PM IST		
Date Processed:	1/6/2021 9:17:04 AM IST		

Auto-Scaled Chromatogram



Peak Results

	Name	RT	Area
1	CETIRIZINE HCl	15.927	

Analysed by: 06/01/2021
Date :

Checked by:
Date : 27/01/2021

Reported by User: SRIRAM (SRIRAM)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 1721

Project Name: 2021\QC_HPL_002\JAN-2021
Printed Date 1/6/2021
Printed Time 9:28:13 AM A

Empower 3 SOFTWARE

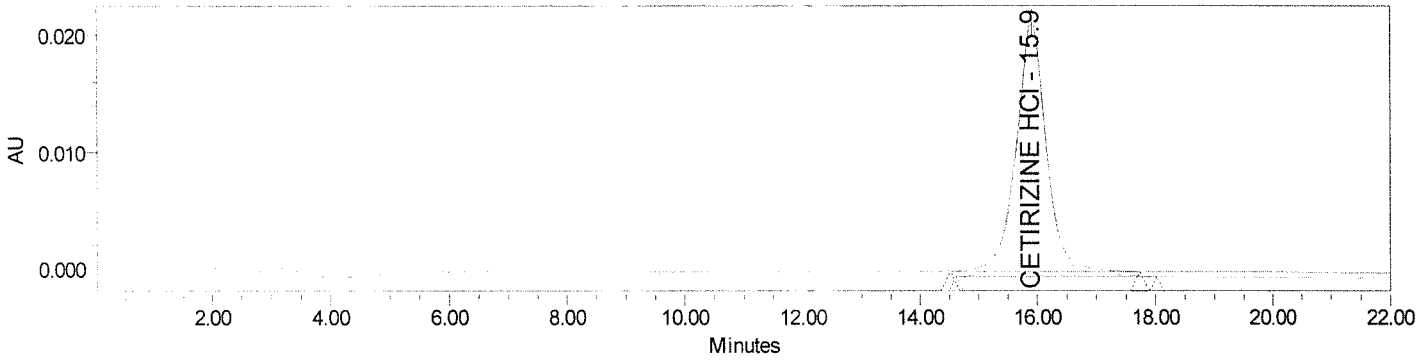
RSD REPORT

SAI PRIMUS LIFE BIOTECH PVT LTD

SAMPLE INFORMATION

Sample Name:	GENSET_GF210101_ASSAY_SPL_01,	Acquired By:	SRIRAM
Sample Type:	Unknown	Sample Set Name:	05012021_GENSET_ASSAY_DISSO_FP
Vial:	3, 4	Acq. Method Set:	GENSET
Injection #:	1	Processing Method	GENSET_ASSAY_FP_PM
Injection Volume:	20.00 ul	Channel Name:	2487Channel 1
Run Time:	22.0 Minutes	Proc. Chnl. Descr.:	2487Channel 1
Date Acquired:	1/5/2021 3:57:30 PM IST, 1/5/2021 4:20:54 PM IST		
Date Processed:	1/6/2021 9:17:04 AM IST		

Auto-Scaled Chromatogram



Peak Name: CETIRIZINE HCl

	Injection	Peak Name	RT	Area	USP Plate Count	USP Tailing
1	1	CETIRIZINE HCl	15.914	775253	4857	1.0
2	1	CETIRIZINE HCl	15.914	767555	4795	1.0
Mean			15.914	771404	4826	1.0
Std. Dev.			0.000	5443.162		
% RSD			0.0	0.7		

Analysed by: [signature] 04/01/2021
Date : 04/01/2021

Checked by: [signature]
Date : 20/01/2021

Reported by User: SRIRAM (SRIRAM)
Report Method: RSD REPORT SYSTEM
Report Method ID 1522
Page: 1 of 1

Project Name: 2021\QC_HPL_002\JAN-2021
Printed Date 1/6/2021
Printed Time 9:28:47 AM A

Empower 3 SOFTWARE

RSD REPORT

SAI PRIMUS LIFE BIOTECH PVT LTD

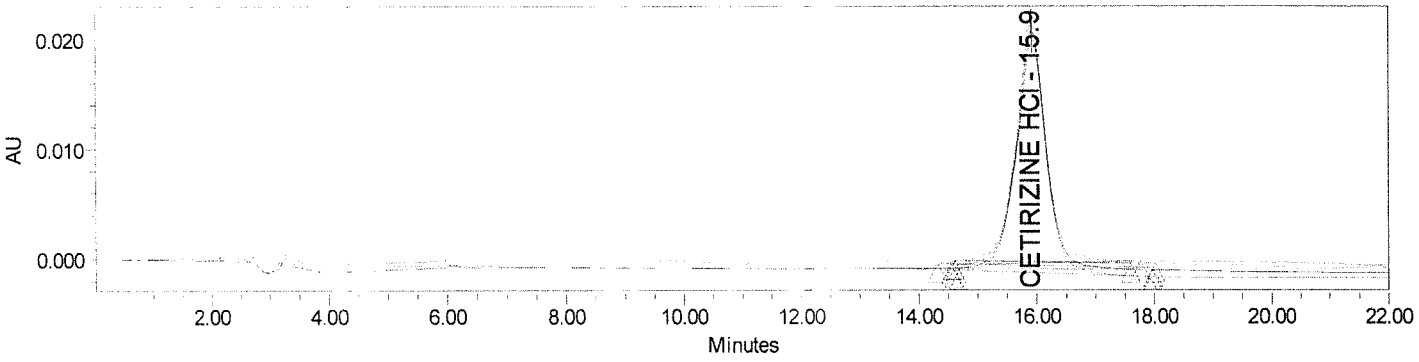
SAMPLE INFORMATION

Sample Name:	ASSAY_STANDARD, ASSAY_BKT_STD	Acquired By:	SRIRAM
Sample Type:	Unknown	Sample Set Name:	05012021_GENSET_ASSAY_DISSO_FP
Vial:	2	Acq. Method Set:	GENSET
Injection #:	1, 2, 4, 5, 3	Processing Method	GENSET_ASSAY_FP_PM
Injection Volume:	20.00 ul	Channel Name:	2487Channel 1
Run Time:	22.0 Minutes	Proc. Chnl. Descr.:	2487Channel 1

Date Acquired: 1/5/2021 1:30:56 PM IST, 1/5/2021 1:54:25 PM IST, 1/5/2021 2:17:55 PM IST, 1/5/2021 2:41:24 PM IST, 1/5/2021 3:05:07 PM IST, 1/5/2021 4:44:31 PM IST

Date Processed: 1/6/2021 9:17:04 AM IST

Auto-Scaled Chromatogram



Peak Name: CETIRIZINE HCl

	Injection	Peak Name	RT	Area	USP Plate Count	USP Tailing
1	1	CETIRIZINE HCl	15.927	763382	4734	1.0
2	1	CETIRIZINE HCl	15.911	792210	4830	1.0
3	2	CETIRIZINE HCl	15.927	779038	4686	1.0
4	3	CETIRIZINE HCl	15.923	772658	4793	1.0
5	4	CETIRIZINE HCl	15.923	765916	4732	1.0
6	5	CETIRIZINE HCl	15.919	769262	4899	0.9
Mean			15.922	773744	4779	1.0
Std. Dev.			0.006	10572.846		
% RSD			0.0	1.4		

Analysed by: Date : 06/1/2021

Checked by: Date : 7/1/2021

Reported by User: SRIRAM (SRIRAM)
Report Method: RSD REPORT SYSTEM
Report Method ID 1522
Page: 1 of 1

Project Name: 2021\QC_HPL_002\JAN-2021
Printed Date 1/6/2021
Printed Time 9:29:01 AM A

Empower 3 SOFTWARE

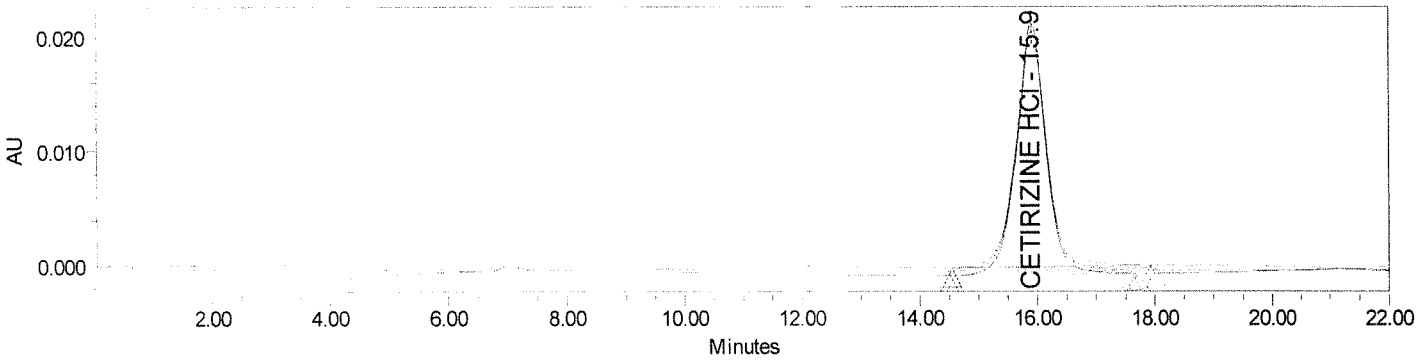
RSD REPORT

SAI PRIMUS LIFE BIOTECH PVT LTD

SAMPLE INFORMATION

Sample Name:	GENSET_GF210101_UOC_SPL_04,	Acquired By:	SRIRAM
Sample Type:	Unknown	Sample Set Name	05012021_GENSET_ASSAY_DISSO_FP
Vial:	6, 8, 5, 7, 9	Acq. Method Set:	GENSET
Injection #:	1	Processing Method	GENSET_ASSAY_FP_PM
Injection Volume:	20.00 ul	Channel Name:	2487Channel 1
Run Time:	22.0 Minutes	Proc. Chnl. Descr.:	2487Channel 1
Date Acquired:	1/5/2021 5:08:17 PM IST, 1/5/2021 5:31:52 PM IST, 1/5/2021 5:55:27 PM IST, 1/5/2021 6:19:03 PM IST, 1/5/2021 6:42:35 PM IST		
Date Processed:	1/6/2021 9:18:48 AM IST		

Auto-Scaled Chromatogram



Peak Name: CETIRIZINE HCl

	Injection	Peak Name	RT	Area	USP Plate Count	USP Tailing
1	1	CETIRIZINE HCl	15.913	762822	4940	1.0
2	1	CETIRIZINE HCl	15.917	752661	4834	1.0
3	1	CETIRIZINE HCl	15.916	775282	4678	1.0
4	1	CETIRIZINE HCl	15.915	766165	4782	1.0
5	1	CETIRIZINE HCl	15.914	750706	4819	1.0
Mean			15.915	761527	4811	1.0
Std. Dev.			0.002	10100.827		
% RSD			0.0	1.3		

Analysed by: Date : 06/01/2021

Checked by: Date : 7/01/2021

Reported by User: SRIRAM (SRIRAM)
Report Method: RSD REPORT SYSTEM
Report Method ID: 1522

Project Name: 2021\QC_HPL_002\JAN-2021
Printed Date 1/6/2021
Printed Time 9:29:16 AM A

Empower 3 SOFTWARE

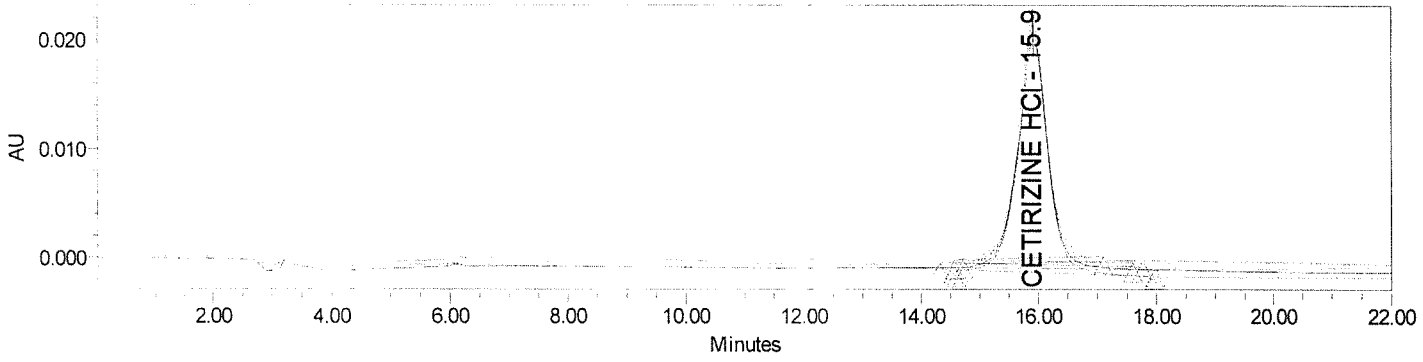
RSD REPORT

SAI PRIMUS LIFE BIOTECH PVT LTD

SAMPLE INFORMATION

Sample Name:	ASSAY_STANDARD, ASSAY_BKT_STD	Acquired By:	SRIRAM
Sample Type:	Unknown	Sample Set Name:	05012021_GENSET_ASSAY_DISSO_FP
Vial:	2	Acq. Method Set:	GENSET
Injection #:	1, 2, 4, 5, 3	Processing Method	GENSET_ASSAY_FP_PM
Injection Volume:	20.00 ul	Channel Name:	2487Channel 1
Run Time:	22.0 Minutes	Proc. Chnl. Descr.:	2487Channel 1
Date Acquired:	1/5/2021 1:30:56 PM IST, 1/5/2021 1:54:25 PM IST, 1/5/2021 2:17:55 PM IST, 1/5/2021 2:41:24 PM IST, 1/5/2021 3:05:07 PM IST, 1/5/2021 7:06:12 PM IST		
Date Processed:	1/6/2021 9:17:04 AM IST, 1/6/2021 9:25:36 AM IST		

Auto-Scaled Chromatogram



Peak Name: CETIRIZINE HCl

	Injection	Peak Name	RT	Area	USP Plate Count	USP Tailing
1	1	CETIRIZINE HCl	15.927	763382	4734	1.0
2	1	CETIRIZINE HCl	15.913	777772	4631	1.0
3	2	CETIRIZINE HCl	15.927	779038	4686	1.0
4	3	CETIRIZINE HCl	15.923	772658	4793	1.0
5	4	CETIRIZINE HCl	15.923	765916	4732	1.0
6	5	CETIRIZINE HCl	15.919	769262	4899	0.9
Mean			15.922	771338	4746	1.0
Std. Dev.			0.005	6315.747		
% RSD			0.0	0.8		

Analysed by: Date : 06/01/2021

Checked by: Date : 27/01/2021

Empower 3 SOFTWARE

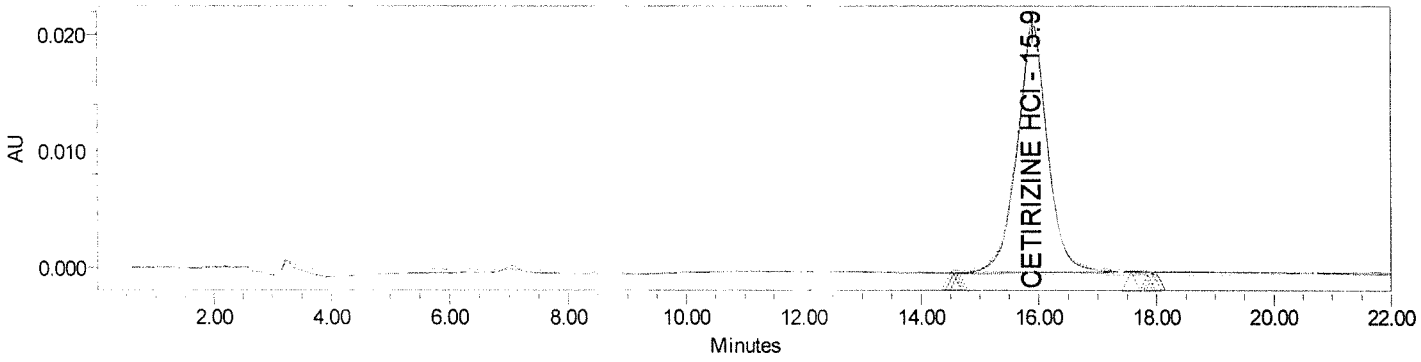
RSD REPORT

SAI PRIMUS LIFE BIOTECH PVT LTD

SAMPLE INFORMATION

Sample Name:	GENSET_GF210101_UOC_SPL_08,	Acquired By:	SRIRAM
Sample Type:	Unknown	Sample Set Name:	05012021_GENSET_ASSAY_DISSO_FP
Vial:	13, 11, 12, 10, 14	Acq. Method Set:	GENSET
Injection #:	1	Processing Method	GENSET_ASSAY_FP_PM
Injection Volume:	20.00 ul	Channel Name:	2487Channel 1
Run Time:	22.0 Minutes	Proc. Chnl. Descr.:	2487Channel 1
Date Acquired:	1/5/2021 7:29:48 PM IST, 1/5/2021 7:53:23 PM IST, 1/5/2021 8:16:58 PM IST, 1/5/2021 8:40:33 PM IST, 1/5/2021 9:04:06 PM IST		
Date Processed:	1/6/2021 9:18:48 AM IST, 1/6/2021 9:18:49 AM IST		

Auto-Scaled Chromatogram



Peak Name: CETIRIZINE HCl

	Injection	Peak Name	RT	Area	USP Plate Count	USP Tailing
1	1	CETIRIZINE HCl	15.915	770549	4703	1.0
2	1	CETIRIZINE HCl	15.913	776144	4330	1.0
3	1	CETIRIZINE HCl	15.906	772257	4046	0.9
4	1	CETIRIZINE HCl	15.917	786146	4520	1.0
5	1	CETIRIZINE HCl	15.918	760437	4545	1.0
Mean			15.914	773107	4429	1.0
Std. Dev.			0.005	9314.384		
% RSD			0.0	1.2		

Analysed by: 6/1/2021
Date :

Checked by:
Date : 27/01/2021

Reported by User: SRIRAM (SRIRAM)
Report Method: RSD REPORT SYSTEM
Report Method ID 1522
Page: 1 of 1

Project Name: 2021\QC_HPL_002\JAN-2021
Printed Date 1/6/2021
Printed Time 9:29:49 AM A

Empower 3 SOFTWARE

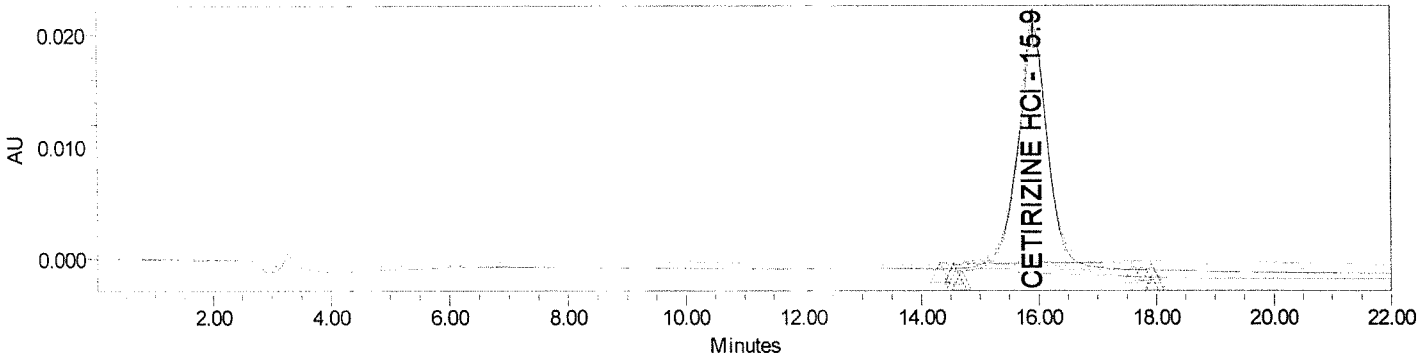
RSD REPORT

SAI PRIMUS LIFE BIOTECH PVT LTD

SAMPLE INFORMATION

Sample Name:	ASSAY_STANDARD, ASSAY_BKT_STD	Acquired By:	SRIRAM
Sample Type:	Unknown	Sample Set Name:	05012021_GENSET_ASSAY_DISSO_FP
Vial:	2	Acq. Method Set:	GENSET
Injection #:	1, 2, 4, 5, 3	Processing Method	GENSET_ASSAY_FP_PM
Injection Volume:	20.00 ul	Channel Name:	2487Channel 1
Run Time:	22.0 Minutes	Proc. Chnl. Descr.:	2487Channel 1
Date Acquired:	1/5/2021 1:30:56 PM IST, 1/5/2021 1:54:25 PM IST, 1/5/2021 2:17:55 PM IST, 1/5/2021 2:41:24 PM IST, 1/5/2021 3:05:07 PM IST, 1/5/2021 9:27:41 PM IST		
Date Processed:	1/6/2021 9:17:04 AM IST, 1/6/2021 9:18:49 AM IST		

Auto-Scaled Chromatogram



Peak Name: CETIRIZINE HCl

	Injection	Peak Name	RT	Area	USP Plate Count	USP Tailing
1	1	CETIRIZINE HCl	15.927	763382	4734	1.0
2	1	CETIRIZINE HCl	15.905	789284	4158	1.0
3	2	CETIRIZINE HCl	15.927	779038	4686	1.0
4	3	CETIRIZINE HCl	15.923	772658	4793	1.0
5	4	CETIRIZINE HCl	15.923	765916	4732	1.0
6	5	CETIRIZINE HCl	15.919	769262	4899	0.9
Mean			15.921	773257	4667	1.0
Std. Dev.			0.008	9571.028		
% RSD			0.1	1.2		

Analysed by: Date : 06/01/2021

Checked by: Date : 27/01/2021

Reported by User: SRIRAM (SRIRAM)
Report Method: RSD REPORT SYSTEM
Report Method ID 1522
Page: 1 of 1

Project Name: 2021\QC_HPL_002\JAN-2021
Printed Date 1/6/2021
Printed Time 9:30:03 AM A

Empower 3

PROCESSING METHOD

SAI PRIMUS LIFE BIOTECH PVT LTD

Processing Method: GENSET_ASSAY_FP_PM

Type: LC *Stored: 1/6/2021 9:25:15 AM IST*

Method Information

Method Comments	PROCESSING METHOD
Method Modified User	SRIRAM
Method Locked	No
Method Id	2165
Old Id	2105
Method Version	2
Method Edit User	
Source S/W Info	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2404097152
Integration Algorithm	Traditional
Search Depth	3
Retention Time Presearch	No
RT Presearch Window	10.0
Start Mass Limit	(m/z)
End Mass Limit	(m/z)
PBM Search Mode	Pure
Duplicate Spectra	No
PBM Reference Sets	SET1
Search Threshold	50.000(%)
Noise Baseline	(min)
Peak Separation	1.0000(Da)
Baseline Multiplier	1.000
Spectra To Average	5
Noise Threshold	0.000(%)
Combine Type	Average
Expected Mass Peak Separation	1.00(Da)
Expected Mass Calculation Type	None
Include the uncorrected Target or Base Mass in the list of expected masses	No
Expected Mass Base Value	100.00(Da)
Expected Mass Base Intensity	80.0(%)
Centroid Center Type	Centroid Top(%)

Analysed by: RSM
Date : 02/01/2021

Checked by: PK
Date : 2/01/2021

Centroid Top (%)	80.00
Centroid Intensity	Heights
Min. Peak Width at Half-Height	0.500(Da)
Smoothing Type	None
Average By	None
RT Window %	5.00
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	

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)

Integration Parameters

Minimum Area	0(µV*sec)
Minimum Height	0(µV)
Threshold	20.000(µV/sec)
Peak Width	80.00(sec)

Integration Events

	Time (min)	Type	Value	Stop (min)
1	0.000	Valley to Valley		
2	0.000	Inhibit Integration		14.272
3	18.018	Inhibit Integration		

Integration Information 'Relative Limits-'CETIRIZINE HCl'' table contains no data.

Integration Information 'Primary Peaks (Primary MS Ions)' table contains no data.

Analysed by: [illegible]
Date : 06/01/2021

Checked by: PS
Date : 27/01/2021

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 1/6/2021 9:25:15 AM IST User SRIRAM PROCESSING METHOD
Version 1 1/6/2021 9:16:45 AM IST User SRIRAM Created method 'GENSET_ASSAY_FP_PM'.
PROCESSING METHOD

Method Version Summaries

	Method Name	Method Type	Method Comments	Method Date	Method Modified User
1	GENSET_ASSAY_FP_PM	Processing	PROCESSING METHOD	1/6/2021 9:25:15 AM IST	SRIRAM
2	GENSET_ASSAY_FP_PM	Processing	PROCESSING METHOD	1/6/2021 9:16:45 AM IST	SRIRAM

Method Version Summaries

	Method Locked	Method Id	Old Id	Method Version
1	No	2165	2105	2
2	No	2105		1

Method Version Summaries

	Source S/W Info
1	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2404097152
2	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2404097152

Analysed by:
Date : 02/01/2021

Checked by:
Date : 2/1/2021

Empower 3 SOFTWARE

PROCESSING METHOD

SAI PRIMUS LIFE BIOTECH PVT LTD

Processing Method: GENSET_DISSO_FP_PM

Type: LC *Stored: 1/6/2021 9:22:07 AM IST*

Method Information

Method Comments	PROCESSING METHOD
Method Modified User	SRIRAM
Method Locked	No
Method Id	2134
Old Id	
Method Version	1
Method Edit User	
Source S/W Info	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2404097152
Integration Algorithm	Traditional
Search Depth	3
Retention Time Presearch	No
RT Presearch Window	10.0
Start Mass Limit	(m/z)
End Mass Limit	(m/z)
PBM Search Mode	Pure
Duplicate Spectra	No
PBM Reference Sets	SET1
Search Threshold	50.000(%)
Noise Baseline	(min)
Peak Separation	1.0000(Da)
Baseline Multiplier	1.000
Spectra To Average	5
Noise Threshold	0.000(%)
Combine Type	Average
Expected Mass Peak Separation	1.00(Da)
Expected Mass Calculation Type	None
Include the uncorrected Target or Base Mass in the list of expected masses	No
Expected Mass Base Value	100.00(Da)
Expected Mass Base Intensity	80.0(%)
Centroid Center Type	Centroid Top(%)

Analysed by: PM
Date : 06/01/2021

Checked by: PK
Date : 27/01/2021

Centroid Top (%)	80.00
Centroid Intensity	Heights
Min. Peak Width at Half-Height	0.500(Da)
Smoothing Type	None
Average By	None
RT Window %	5.00
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	

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)

Integration Parameters

Minimum Area	50000(µV*sec)
Minimum Height	0(µV)
Threshold	2.000(µV/sec)
Peak Width	80.00(sec)

Integration Events

	Time (min)	Type	Value	Stop (min)
1	0.000	Valley to Valley		
2	0.000	Inhibit Integration		14.504
3	19.048	Inhibit Integration		

Integration Information 'Relative Limits-'CETIRIZINE HCl'' table contains no data.

Integration Information 'Primary Peaks (Primary MS Ions)' table contains no data.

Analysed by: MM
Date : 06/1/2021

Checked by: PZ
Date : 27/01/2021

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 1 1/6/2021 9:22:07 AM IST User SRIRAM Created method 'GENSET_DISSO_FP_PM'.
PROCESSING METHOD

Method Version Summaries

	Method Name	Method Type	Method Comments	Method Date	Method Modified User
1	GENSET_DISSO_FP_PM	Processing	PROCESSING METHOD	1/6/2021 9:22:07 AM IST	SRIRAM

Method Version Summaries

	Method Locked	Method Id	Old Id	Method Version
1	No	2134		1

Method Version Summaries

	Source S/W Info
1	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2404097152

Analysed by:
Date : 06/1/2021

Checked by:
Date : 27/01/2021

	Vial	Inj Vol (uL)	# of Injs	SampleName	Function	Method Set / Report Method	Run Time (Minutes)
1	1	20.0	1	RS_BLANK	Inject Samples	GENSET_RS_FP_MSET	60.00
2	2	20.0	1	RS_PLACEBO	Inject Samples	GENSET_RS_FP_MSET	60.00
3	3	20.0	1	RS_BLANK	Inject Samples	GENSET_RS_FP_MSET	60.00
4	4	20.0	6	RS_STANDARD	Inject Samples	GENSET_RS_FP_MSET	60.00
5	5	20.0	1	GENSET_GF210101_TS	Inject Samples	GENSET_RS_FP_MSET	60.00
6	4	20.0	1	RS_BKT_STD	Inject Samples	GENSET_RS_FP_MSET	60.00
7					Equilibrate	WASHING SOLUTION_C_MSET	120.00
8					Equilibrate	SHUTDOWN_MSET	0.01

23/01/2024

23/01/2024

Empower 3

INSTRUMENT METHOD

SAI PRIMUS LIFE BIOTECH PVT LTD

Instrument Method: GENSET_RS_FP_IM

Stored: 1/23/2021 2:23:15 PM IST

Method Information

Method Comments	IM
Method Modified User	SRIRAM
Method Locked	No
Method Id	3935
Old Id	
Method Version	1
Method Edit User	
Source S/W Info	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2404097152

W2690/5 Instrument Setup

Type	W2690/5
Instrument Status	On
Channel Name	2690/5
Description	PRESSURE ENABLE
Use Channel Monitor	On
Monitor Parameter	System Pressure
Stroke Volume	100uL (flow rates <= 3.030 mL/min)
Chart Out	%A
Syringe Draw Rate	Normal
Depth Of Needle	0.0
Degas Mode	Off
Pump Mode	Gradient
Flow	1.000
%A	100.0
%B	0.0
%C	0.0
%D	0.0
High Limit	5000.0
Low Limit	0.0
Enable Sample Temp	False
Enable Column Temp	True
Bubble Detect	True
Pre Column Volume	0.0
Sample Temp Target	-1.0
Sample Temp Range	5.0
Sparge A	0.0

Analysed by:
Date : 23/01/2021

Checked by:
Date : 23/01/2021

Sparge B	0.0
Sparge C	0.0
Sparge D	0.0
Column Temp Target	30.0
Column Temp Range	5.0
Flow Ramp	2.00
Column choice	No Change
Column Equil Minutes	0.00
Needle Wash	Extended
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	

W2690/5 Gradient Table

	Time	Flow	%A	%B	%C	%D	Curve
1		1.00	100.0	0.0	0.0	0.0	
2	50.00	1.00	0.0	100.0	0.0	0.0	6
3	53.00	1.00	0.0	100.0	0.0	0.0	6
4	54.00	1.00	100.0	0.0	0.0	0.0	6
5	60.00	1.00	100.0	0.0	0.0	0.0	6

W2487 Instrument Setup

Type	W2487
Instrument Status	On
Dual Wavelength	False
Pulse Period Seconds	1.0
Pulse Repeat Period Seconds	1.0

W2487 Channel Information

Channel Name	2487Channel 1	Voltage Offset	0
Description		Polarity	+
Use Channels	On	AutoZero Wavelength	True
Wavelength	230	AutoZero Keypad	True
Output Mode	Absorbance A (Ch1)	AutoZeroEvent Input	True
Data Mode	Absorbance A (Ch1)	AutoZero Inject	True
Sampling Rate	1	Chart Mark Enable	True
Filter Type	Hamming	Ratio AuMinimum	0.1000
Aufs	2.0000	Minimum Ratio	0.00
Time Constant	1.0	Maximum Ratio	2.00
AU Offset	0.000		

Analysed by: 23/01/2021
Date : 23/01/2021

Checked by: RR
Date : 23/01/2021

Revision History

Version 1 1/23/2021 2:23:15 PM IST User SRIRAM Created method 'GENSET_RS_FP_IM'. IM

Method Version Summaries

	Method Name	Method Type	Method Comments	Method Date	Method Modified User	Method Locked
1	GENSET_RS_FP_IM	Instrument	IM	1/23/2021 2:23:15 PM IST	SRIRAM	No

Method Version Summaries

	Method Id	Old Id	Method Version	Source S/W Info
1	3935		1	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2404097152

Analysed by:
Date : 23/01/2021

Checked by:
Date : 23/01/2021

Empower 3

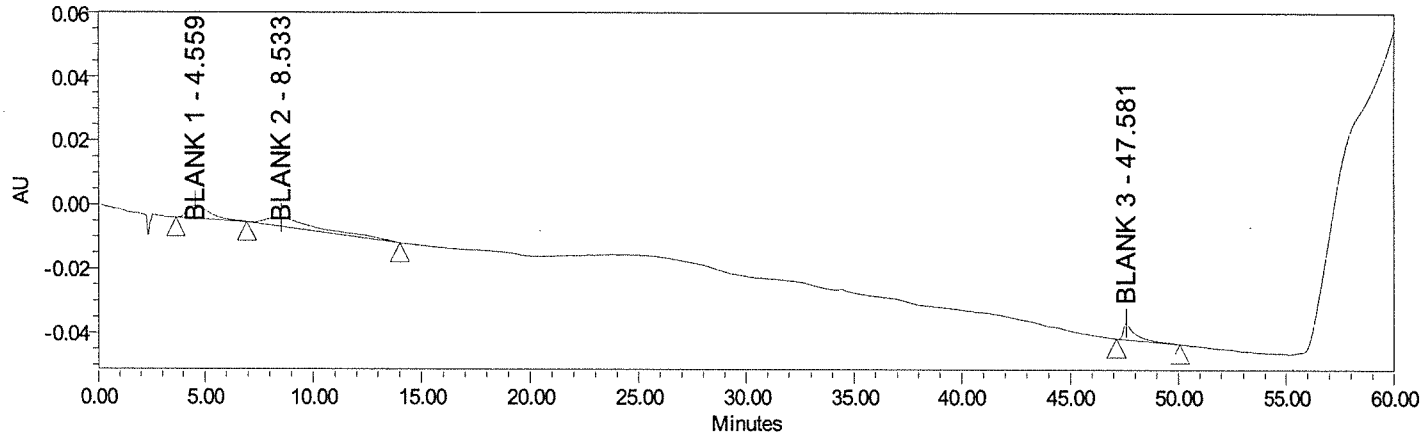
CHROMATOGRAPHIC DATA

SAI PRIMUS LIFE BIOTECH PVT LTD

SAMPLE INFORMATION

Sample Name:	RS BLANK	Acquired By:	SRIRAM
Sample Type:	Unknown	Sample Set Name:	23012021 GENSET RS FP
Vial:	1	Acq. Method Set:	GENSET RS FP MSET
Injection #:	1	Processing Method	GENSET RS BLANK PM
Injection Volume:	20.00 ul	Channel Name:	2487Channel 1
Run Time:	60.0 Minutes	Proc. Chnl. Descr.:	2487Channel 1
Date Acquired:	1/23/2021 3:14:32 PM IST		
Date Processed:	1/24/2021 2:12:37 PM IST		

Auto-Scaled Chromatogram



Peak Results

	Name	RT	Area
1	BLANK 1	4.559	283056
2	BLANK 2	8.533	474974
3	BLANK 3	47.581	199650

Analysed by: MM
Date : 24/01/2021

Checked by: BL
Date : 27/01/2021

Reported by User: SRIRAM (SRIRAM)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 4600
Page: 1 of 1

Project Name: 2021\QC_HPL_002\JAN-2021
Printed Date 1/24/2021
Printed Time 5:18:08 PM A

Empower 3 SOFTWARE

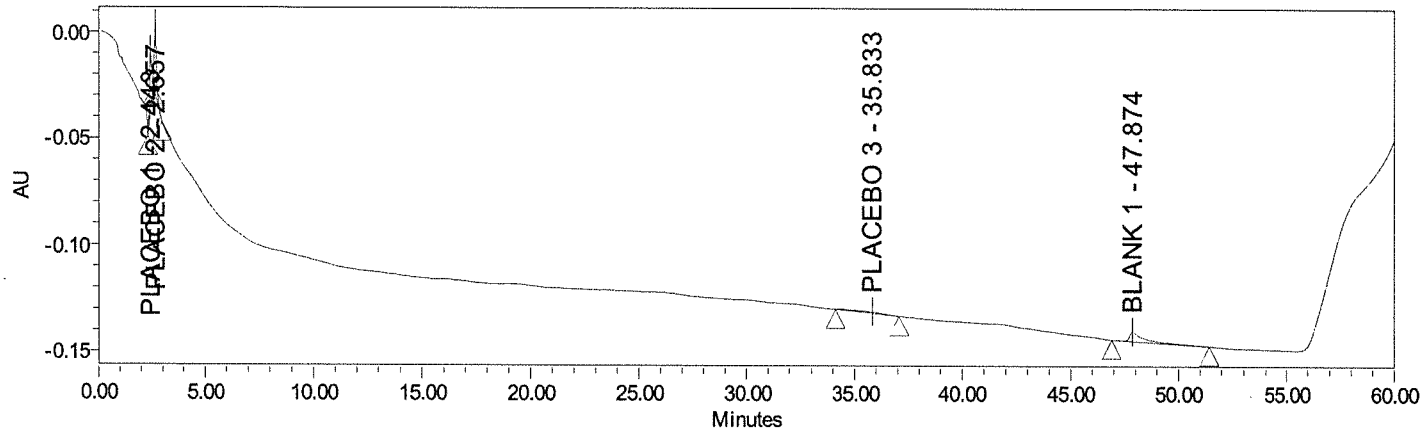
CHROMATOGRAPHIC DATA

SAI PRIMUS LIFE BIOTECH PVT LTD

SAMPLE INFORMATION

Sample Name:	RS PLACEBO	Acquired By:	SRIRAM
Sample Type:	Unknown	Sample Set Name:	23012021 GENSET RS FP
Vial:	2	Acq. Method Set:	GENSET RS FP MSET
Injection #:	1	Processing Method	GENSET RS PLACEBO PM
Injection Volume:	20.00 ul	Channel Name:	2487Channel 1
Run Time:	60.0 Minutes	Proc. Chnl. Descr.:	2487Channel 1
Date Acquired:	1/23/2021 4:16:12 PM IST		
Date Processed:	1/24/2021 2:23:09 PM IST		

Auto-Scaled Chromatogram



Peak Results

	Name	RT	Area
1	PLACEBO 1	2.443	201550
2	PLACEBO 2	2.657	203914
3	PLACEBO 3	35.833	77149
4	BLANK 1	47.874	212027

Analysed by: 24/01/2021
Date :

Checked by: BP
Date : 27/01/2021

Reported by User: SRIRAM (SRIRAM)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 4600
Page: 1 of 1

Project Name: 2021\QC_HPL_002\JAN-2021
Printed Date 1/24/2021
Printed Time 5:18:43 PM A

Empower 3

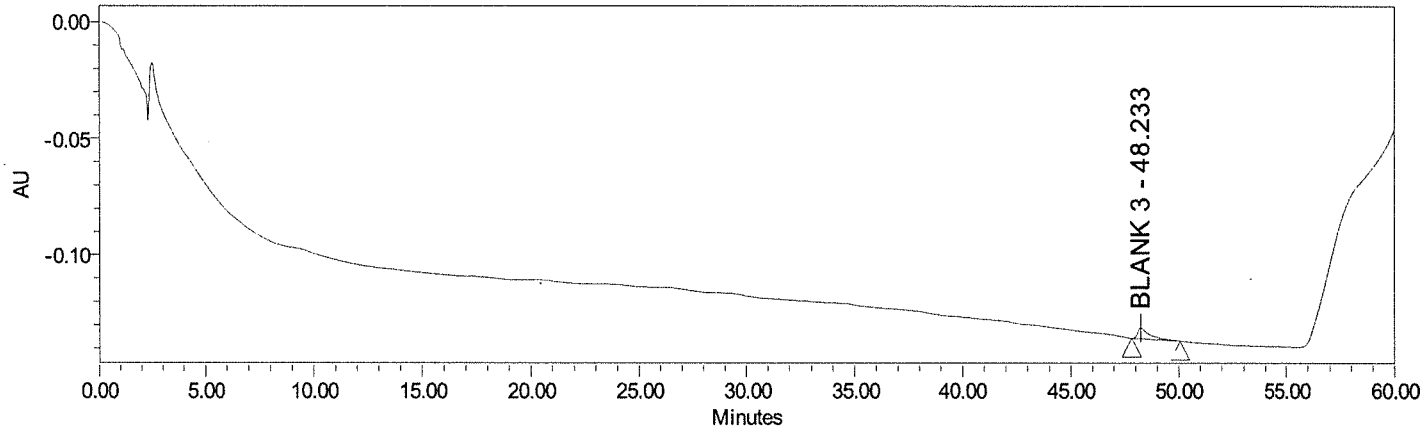
CHROMATOGRAPHIC DATA

SAI PRIMUS LIFE BIOTECH PVT LTD

SAMPLE INFORMATION

Sample Name:	RS BLANK	Acquired By:	SRIRAM
Sample Type:	Unknown	Sample Set Name:	23012021 GENSET RS FP
Vial:	3	Acq. Method Set:	GENSET RS FP MSET
Injection #:	1	Processing Method	GENSET RS BLANK PM
Injection Volume:	20.00 ul	Channel Name:	2487Channel 1
Run Time:	60.0 Minutes	Proc. Chnl. Descr.:	2487Channel 1
Date Acquired:	1/23/2021 5:17:54 PM IST		
Date Processed:	1/24/2021 2:13:18 PM IST		

Auto-Scaled Chromatogram



Peak Results

	Name	RT	Area
1	BLANK 1	4.559	
2	BLANK 2	8.533	
3	BLANK 3	48.233	178533

Analysed by: RRM
Date : 24/01/2021

Checked by: RR
Date : 27/01/2021

Reported by User: SRIRAM (SRIRAM)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 4600

Project Name: 2021\QC_HPL_002\JAN-2021
Printed Date 1/24/2021
Printed Time 5:19:06 PM A

Empower 3

RSD REPORT

SAI PRIMUS LIFE BIOTECH PVT LTD

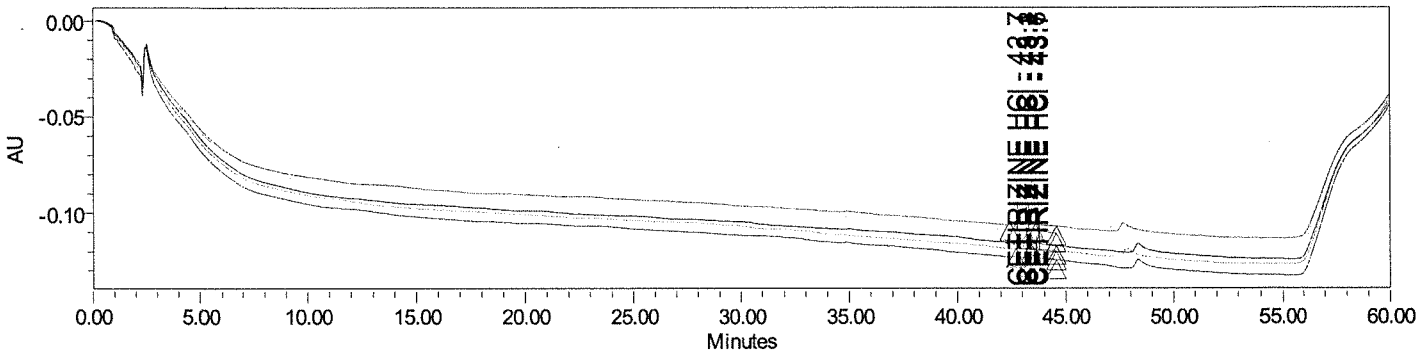
SAMPLE INFORMATION

Sample Name:	RS_STANDARD	Acquired By:	SRIRAM
Sample Type:	Unknown	Sample Set Name:	23012021 GENSET RS FP
Vial:	4	Acq. Method Set:	GENSET_RS_FP_MSET
Injection #:	1, 6, 2, 4, 5, 3	Processing Method	GENSET_RS STD_PM
Injection Volume:	20.00 ul	Channel Name:	2487Channel 1
Run Time:	60.0 Minutes	Proc. Chnl. Descr.:	2487Channel 1

Date Acquired: 1/23/2021 6:19:37 PM IST, 1/23/2021 7:21:18 PM IST, 1/23/2021 8:22:56 PM IST, 1/23/2021 9:24:35 PM IST, 1/23/2021 10:26:16 PM IST, 1/23/2021 11:28:00 PM IST

Date Processed: 1/24/2021 2:25:49 PM IST, 1/24/2021 2:25:50 PM IST

Auto-Scaled Chromatogram



Peak Name: CETIRIZINE HCl

	Injection	Peak Name	RT	Area	USP Plate Count	USP Tailing
1	1	CETIRIZINE HCl	43.644	87004	107914	1.9
2	2	CETIRIZINE HCl	43.185	92844	98878	2.5
3	3	CETIRIZINE HCl	43.767	88007	118460	1.8
4	4	CETIRIZINE HCl	43.718	85839	74113	1.8
5	5	CETIRIZINE HCl	43.278	91036	93095	2.1
6	6	CETIRIZINE HCl	42.780	90342	101957	1.9
Mean			43.396	89179	99069	2.0
Std. Dev.			0.385	2664.322		
% RSD			0.9	3.0		

Analysed by: Date : 24/01/2021

Checked by: Date : 27/01/2021

Reported by User: SRIRAM (SRIRAM)
Report Method: RSD REPORT SYSTEM
Report Method ID 1522
Page: 1 of 1

Project Name: 2021\QC_HPL_002\JAN-2021
Printed Date 1/24/2021
Printed Time 5:19:32 PM A

Empower 3 SOFTWARE

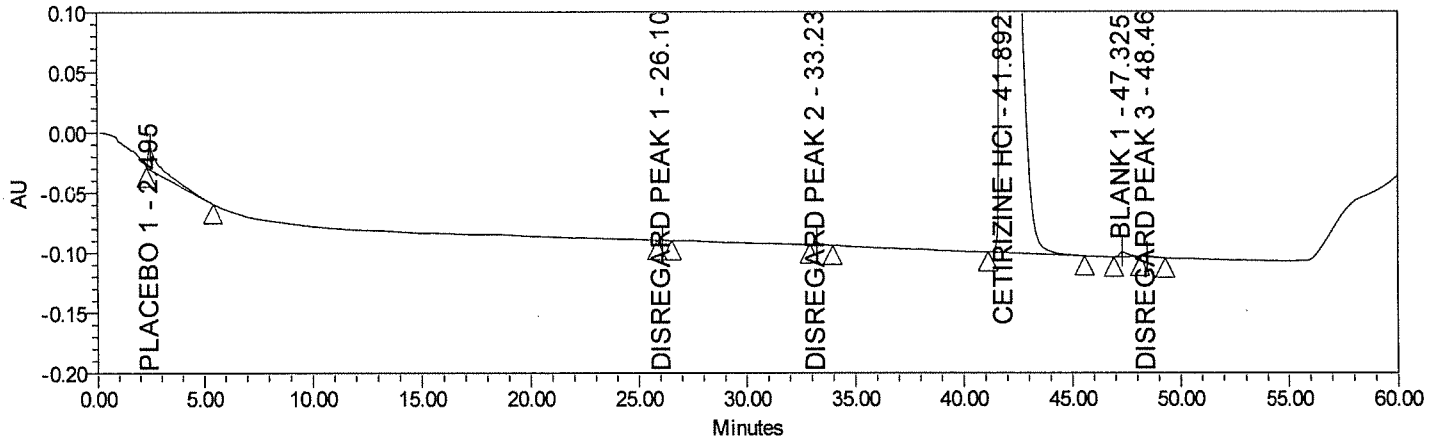
CHROMATOGRAPHIC DATA

SAI PRIMUS LIFE SCIENCES PVT LTD

SAMPLE INFORMATION

Sample Name:	GENSET_GF210101_TS		Acquired By: SRIRAM
Sample Type:	Unknown	Sample Set Name	23012021_GENSET_RS_FP
Vial:	5	Acq. Method Set:	GENSET_RS_FP_MSET
Injection #:	1	Processing Method	GENSET_RS_GF210101_TS_PM
Injection Volume:	20.00 ul	Channel Name:	2487Channel 1
Run Time:	60.0 Minutes	Proc. Chnl. Descr.:	2487Channel 1
Date Acquired:	1/24/2021 12:29:45 AM IST		
Date Processed:	2/2/2021 10:21:56 AM IST		

Auto-Scaled Chromatogram



Peak Results

	Name	RT	Area	% Area
1	PLACEBO 1	2.495	806010	1.87
2	DISREGARD PEAK 1	26.103	10087	0.02
3	DISREGARD PEAK 2	33.236	38741	0.09
4	CETIRIZINE HCl	41.892	42118613	97.67
5	BLANK 1	47.325	117991	0.27
6	DISREGARD PEAK 3	48.463	30224	0.07

Analysed by: RM
Date : 02/02/2021

Checked by: PL
Date : 02/02/2021

Reported by User: SRIRAM (SRIRAM)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 5090
Page: 1 of 1

Project Name: 2021\QC_HPL_002\JAN-2021
Printed Date 2/2/2021
Printed Time 10:22:25 AM

Empower 3

RSD REPORT

SAI PRIMUS LIFE BIOTECH PVT LTD

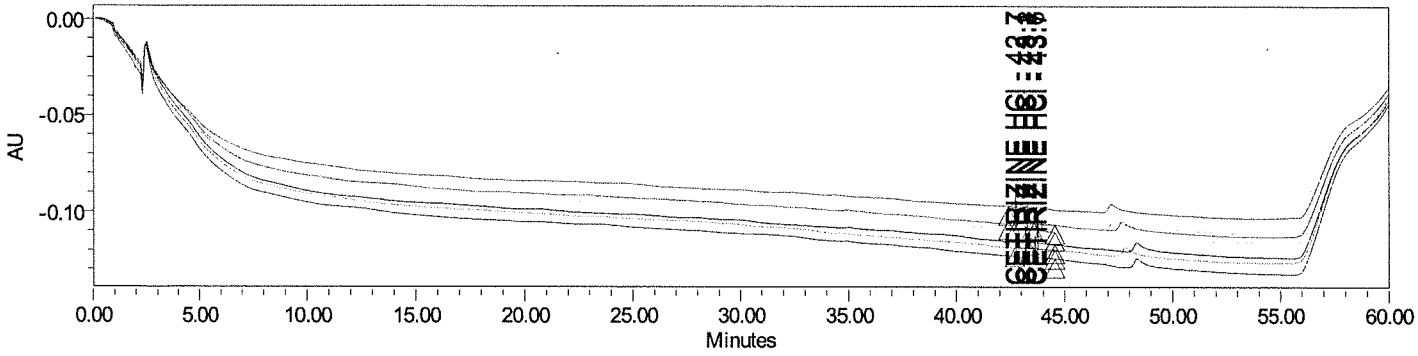
SAMPLE INFORMATION

Sample Name:	RS_STANDARD, RS_BKT_STD	Acquired By:	SRIRAM
Sample Type:	Unknown	Sample Set Name:	23012021 GENSET RS FP
Vial:	4	Acq. Method Set:	GENSET_RS_FP_MSET
Injection #:	1, 6, 2, 4, 5, 3	Processing Method	GENSET_RS STD_PM
Injection Volume:	20.00 ul	Channel Name:	2487Channel 1
Run Time:	60.0 Minutes	Proc. Chnl. Descr.:	2487Channel 1

Date Acquired: 1/23/2021 6:19:37 PM IST, 1/23/2021 7:21:18 PM IST, 1/23/2021 8:22:56 PM IST, 1/23/2021 9:24:35 PM IST, 1/23/2021 10:26:16 PM IST, 1/23/2021 11:28:00 PM IST.

Date Processed: 1/24/2021 2:25:49 PM IST, 1/24/2021 2:25:50 PM IST

Auto-Scaled Chromatogram



Peak Name: CETIRIZINE HCl

	Injection	Peak Name	RT	Area	USP Plate Count	USP Tailing
1	1	CETIRIZINE HCl	43.644	87004	107914	1.9
2	1	CETIRIZINE HCl	42.735	89302	91992	1.9
3	2	CETIRIZINE HCl	43.185	92844	98878	2.5
4	3	CETIRIZINE HCl	43.767	88007	118460	1.8
5	4	CETIRIZINE HCl	43.718	85839	74113	1.8
6	5	CETIRIZINE HCl	43.278	91036	93095	2.1
7	6	CETIRIZINE HCl	42.780	90342	101957	1.9
Mean			43.301	89196	98058	2.0
Std. Dev.			0.431	2432.629		
% RSD			1.0	2.7		

Analysed by: Date : 24/01/2021

Checked by: Date : 27/01/2021

Reported by User: SRIRAM (SRIRAM)
Report Method: RSD REPORT SYSTEM
Report Method ID: 1522
Page: 1 of 1

Project Name: 2021\QC_HPL_002\JAN-2021
Printed Date 1/24/2021
Printed Time 5:20:46 PM A

MICROBIOLOGICAL TEST REPORT

Name of Product:	Grenset tablet				
Type of Product:	Finished Product				
Batch No./ Lot No.	GF210101	**Quality Control A.R. No.**	FP/050121/03		
Microbiology A.R. No.	MA/0121/0032	**Mfg. Date**	Jan-2021	**Exp.Date**	DEC-2023
Date of Receipt	05/01/2021	**Date of test**	05/01/2021	**Date of Completion**	12/01/2021

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

Analysed by: D.Dhanaraj Date: 05/01/2021	Reported by: D.Dhanaraj. Date: 12/01/2021	Checked by: Date: 12/01/2021

Media and Accessories used:

Autoclave Id. No: MB/ALE/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	01/01/2021	MS-21-0003	MP/21/0001
2	BSC-Peptone	04/01/2021	MS-21-0007	MP/21/0021
3	SCDA	05/01/2021	MS-21-0010	MP/21/0023
4	SDA	05/01/2021	MS-21-0010	MP/21/0024
5	MCB	05/01/2021	MS-21-0009	MP/21/0025
6	MCA	04/01/2021	MS-21-0007	MP/21/0020
7	RVSE	NA	NA	NA
8	XLDA	04/01/2021	NA	MP/21/0019
9	MSA	01/01/2021	MS-21-0003	MP/21/0006
10	CA	01/01/2021	MS-21-0003	MP/21/0005
11	GN Broth		NA	
12	XLDA			
13	EE Broth			
14	VRBGA			

D. Dhanraj 05/01/2021

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

Media Mfg.: HiMedia **Media Lot No:** CQ1625 **Expiry at:** 01/2022

Note: GN broth (Readymade form):

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

S. No.	Temperature	Incubator Id. No.
1	30-35^{0}C	MB/BOT/002
2	20-25^{0}C	MB/BOD/001
3	42-44^{0}C	MB/BOI/003

LAF Id. No: MB/LAF/001 **BSC Id. No:** MB/BSC/001

a) Sample Preparation.

Take 2.0045 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 2.0049 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 NA 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.

TAMC & TYMC :

Tested for	Incubation details		Incubated on		Observed on		Done by	Observed by
	Temp. (^{0}C)	Duration (days)	Date	Time	Date	Time		
TAMC	30-35	3-5	05/01/2021	18:10	10/01/2021	13:39	05/01/2021	10/01/2021
TYMC	20-25	5-7	05/01/2021	18:15	12/01/2021	14:05	05/01/2021	12/01/2021

Enrichment :

Tested for	Incubation details		Incubated on		Observed on		Done by	Observed by
	Temp. (^{0}C)	Duration (hours)	Date	Time	Date	Time		
Pre enrichment for *E. coli*, *P. aeruginosa*, *S. aureus*	30-35	18-24	05/01/2021	18:10	06/01/2021	13:54	05/01/2021	06/01/2021
Pre enrichment for *Salmonella abony* & *Shigella* Species	30-35	18-24	05/01/2021	18:10	06/01/2021	13:54	05/01/2021	06/01/2021
Enterobacteria gram negative	30-35	24-48	—	—	NA	—	—	—

05/01/2021

Test for Specified Microorganisms:

1. ***E. coli*:** Transfer 1 ml of enrichment sample to 100 ml of Mac Conkey broth and incubate at 42-44^{0}C for 24-48 hrs. After incubation, subculture on Mac Conkey agar and incubate at 30-35^{0}C for 18-72 hrs.
2. ***Salmonella* sp.:** Transfer 0.1 ml of enrichment sample to 10 ml of Rappaport vassiliadis salmonella enrichment broth and incubate at 30-35^{0}C for 24-48 hrs. After incubation subculture on Xylose lysine deoxycholate agar and incubate at 30-35^{0}C for 24-48 hrs.
3. ***Pseudomonas aeruginosa*:** Subculture on plate of cetrimide agar and incubation at 30-35^{0}C for 18-72 hrs.

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

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 in100 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		
E. coli	MCB	42 -44	24 – 48	06/01/2021	15:38	08/01/2021	14:05	D.Dhar 08/01/2021	D.Dhar 08/01/2021
	MCA	30 -35	18 – 72	08/01/2021	16:10	11/01/2021	14:01	D.Dhar 08/01/2021	D.Dhar 11/01/2021
Salmonella Species.	RVSE	30 -35	24 –48	06/01/2021	15:34	08/01/2021	14:11	D.Dhar 06/01/2021	D.Dhar 08/01/2021
	XLDA	30 -35	24 – 48	08/01/2021	16:10	10/01/2021	13:39	D.Dhar 08/01/2021	A.Ch 10/01/2021
S. aureus	MSA	30 -35	18 –72	06/01/2021	15:34	09/01/2021	13:55	D.Dhar 06/01/2021	D.Dhar 09/01/2021
P. aeruginosa	CA	30 -35	18 –72	06/01/2021	15:34	09/01/2021	13:55	D.Dhar 06/01/2021	D.Dhar 09/01/2021
Shigella Species.	GN	30-35	24-48						
	XLDA	30-35	24-48						
Enterobacteria gram negative	VRBGA	30-35	18-24						

NA

D.Dhar 06/01/2021

Observation:

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

Calculation:

TAMC: Average Count X Dilution factor= 01 Countx10= 10 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	NA	NA	NA	NA

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. _____ as per IP/BP/USP/IHS.

Analysed by: Dishaq Date: 05/01/2021	Reported by: Dishaq Date: 12/01/2021	Checked by: Date: 12/01/2021

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 Sign/Date: 30/12/2020
		No.: F/QCGN/003/01	
	GOOD LABORATORY PRACTICES	Revision No.: 00	
TITLE:	ANALYTICAL DATA SHEET	Review Period: 02 years	
		Effective Date: 18/05/19	

Product Name:- Grensel-tabs

Batch No:- GTF210101

Diss. std

Cetirizine Hcl Assay STD

Assay GTF210101

Assay Sp-I

01/02/2021

Assay Sp-II GTF210101

05/01/2021

05/01/2021

05/01/2021

RS STD

RS TS

Placebo

23/01/2021

23/01/2021

23/01/2021

Analysed by:
Date: 24/01/2021

Checked by:
Date: 27/01/2021

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 FINISHED PRODUCT	Format No: F/QCGN/022/08

Product Name	:	Genset (Cetirizine hydrochloride Tablet BP 10 mg)			
A.R.No.	:	BS/270221/03			
Batch No.	:	GF210216	Batch Size	:	30.0 L
Mfg. Date	:	Feb-2021	Exp. Date	:	Jan-2024
Sampling Date	:	27.02.2021	Sample Qty	:	120 Tablets
Analysis Date	:	27.02.2021	Release Date	:	12.03.2021

S.No.	TEST	RESULTS	LIMITS
01.	Description	White coloured, caplet shaped, film coated tablet with break line on one side and plain on other side	White coloured, caplet shaped, film coated tablet with break line on one side and plain on other side
02.	Identification By IR	Complies	The infrared absorption spectrum of the residue is concordant with the reference spectrum of cetirizine hydrochloride.
03.	Average weight of tablets	120.70 mg	120.00 mg ± 5.0 % (114.00 mg to 126.00 mg)
04.	Uniformity of weight	+2.73 % to -2.23 %	Not more than 2 of the individual weights deviate from the average weight by more than ± 7.5 % and none deviate by more than ± 15 % .
05.	Dimensions:		
	Thickness	Min 2.78 mm / Max 2.82 mm / Avg. 2.79 mm	2.50 mm to 3.10 mm
	Length	Min 10.16 mm / Max 10.18 mm / Avg. 10.16 mm	9.90 mm to 10.30 mm
	Width	Min 4.11 mm / Max 4.14 mm / Avg. 4.12 mm	3.90 mm to 4.30 mm
06.	Hardness	3.78 kg/cm^2	NLT 3.0 kg/cm^2
07.	Disintegration time	05 minutes 12 seconds	Not more than 30 minutes
08.	Content Uniformity:		
	Cetirizine Hydrochloride BP -10 mg	Min 99.72 % / Max 104.10 % / Avg. 101.93 %	Not less than 85.0 % and Not more than 115.0 % of labeled claim.
09.	Dissolution:		
	Cetirizine Hydrochloride BP -10 mg	Min 95.56 % / Max 101.86 % / Avg. 98.88 %	Not less than 85.0 % of labeled amount.
10.	Related substances:		
	Impurity A	Not Detected	Not more than 0.3 %
	Impurity B	Not Detected	Not more than 0.3 %
	Impurity G	Not Detected	Not more than 0.3 %

	Tested By	Checked By	Approved By
Sign			
Name	Dhiviya	Ramesh	Vallarasan
Date	12/03/2021	12/03/2021	12/03/2021

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	Format No: F/QCGN/022/08

Product Name	:	**Genset (Cetirizine hydrochloride Tablet BP 10 mg)**			
A.R.No.	:	**BS/270221/03**			
Batch No.	:	**GF210216**	**Batch Size**	:	**30.0 L**
Mfg. Date	:	**Feb-2021**	**Exp. Date**	:	**Jan-2024**
Sampling Date	:	**27.02.2021**	**Sample Qty**	:	**120 Tablets**
Analysis Date	:	**27.02.2021**	**Release Date**	:	**12.03.2021**

	Single maximum unknown impurity	Not Detected	Not more than 0.2 %
	Total impurities	Not Detected	Not more than 1.0 %
11.	**Assay: Each Filmcoated tablet contains:**		
	Cetirizine Hydrochloride BP -10 mg	101.03 %	Not less than 95.0 % and Not more than 105.0 %
12.	**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	Dhiviya	Ramesh	Vallarasan
Date	12/03/2021	12/03/2021	12/03/2021