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AND ADDRESS OF THE PARTY OF THE	SAI PRIMUS LIFE BIOTECH PVT LTD	Page 1 of 7
	Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009	No.: FPS: G13
SAI PRIMUS LIFE BIOTECH PVI UD	FINISHED PRODUCT SPECIFICATION	Revision No: 04
Title:	GENSET TABLETS (Cetirizine hydrochloride Tablet BP 10 mg)	Review Period: 3 Years
	Product Code: G13	Effective Date: 04/03/2020

01	GENERAL	Pharmacopoeia Reference	BP
02	Composition	Label Claim	
	Each film coated tablet contains:		
	Cetirizine Hydrochloride BP	10 mg	•
03	Shelf life	36 months	
04	Quantity of sample taken for analysis	Lubricated granules: 100 gm Bulk sample: 120'S (For complete analysis) Finished product: 12 X 10'S (For Physical parameter & Microbiological Limit Test only)	
05	Control sample	7 [3 X 10'S]	
06	Storage of Finished pack	Store in cool and dry place. Protect from ligh	nt and moisture.

	Prepared by	Checked by	Approved by
Designation	Executive-QC	Sr. Executive-QC	Manager-QC
Signature	Ph. M.	7.18	W
Date	04/03/2025	04/03/2025	0463/2025
Department: Quality C	Control	Date of Issue: 04/03/2025	





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AND THE PROPERTY OF THE PARTY O	SAI PRIMUS LIFE BIOTECH PVT LTD	Page 2 of 7
	Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate,	No.: FPS: G13
20 4	Villianur Commune, Puducherry-605009	
SAI PRIMUS LIFE	FINISHED PRODUCT SPECIFICATION	Revision No: 04
Title:	GENSET TABLETS	Review Period: 3 Years
(Cetirizine h	(Cetirizine hydrochloride Tablet BP 10 mg)	
Ŷ	Product Code: G13	Effective Date: 04/03/2023

BULK GRANULES SPECIFICATION

S.No.	TEST	LIMIT	METHOD
01	DESCRIPTION	White coloured granular powder.	Follow section I of Method of analysis
02	ASSAY (By HPLC)		Follow section XII of Method of analysis
	Each 118 mg Granules Contains:	* , * ***	
3	Cetirizine Hydrochloride BP-10 mg	Not less than 95.0% and Not more than 105.0%	

	Prepared by	Checked by	Approved by
Designation	Executive-QC	Sr. Executive-QC	Manager-QC
Signature	1t. N.	J. Carl	u
Date	04/08/2025	04/03/2025	0465/2025
Department: Quality Control		Date of Issue: 04/03/2027	_





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	Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009	No.: FPS: G13
SAI-PRIMUS LIFE BIOIECH PALUD	FINISHED PRODUCT SPECIFICATION	Revision No: 04
Title:	GENSET TABLETS (Cetirizine hydrochloride Tablet BP 10 mg)	Review Period: 3 Years
	Product Code: G13	Effective Date: 04103/2027

BULK PRODUCT SPECIFICATION

S.No.	TEST	LIMIT	METHOD
01	DESCRIPTION	White coloured, caplet shaped, uncoated tablet with break line on one side and plain on other side.	Follow section I of Method of analysis
02	AVERAGE WEIGHT	118.00 mg ± 5.0% (Limit: 112.10 mg to 123.90 mg)	Follow section III of Method of analysis
03	UNIFORMITY OF WEIGHT	NMT 2 tablets deviate by more than \pm 7.5 % and none deviates by more than \pm 15.0 % from the average weight.	Follow section IV of Method of analysis
04	DIMENSIONS Thickness Length Width	2.40 mm to 3.00 mm 9.80 mm to 10.20 mm 3.80 mm to 4.20 mm	Follow section V of Method of analysis
05	HARDNESS	NLT 2 Kg/cm ²	Follow section VI of Method of analysis
06	FRIABILITY	NMT 1.0 %	Follow section VII of Method of analysis
07	DISINTEGRATION TIME	Not more than 15 minutes	Follow section VIII of Method of analysis
08	DISSOLUTION By UV Cetirizine Hydrochloride BP-10 mg	Not less than 85.0 % of labeled amount	Follow section X of Method of analysis
09	ASSAY (By HPLC) Each Uncoated tablet contains: Cetirizine Hydrochloride BP-10 mg	Not less than 95.0% and Not more than 105.0%	Follow section XII of Method of analysis

	Prepared by	Checked by	Approved by
Designation	Executive-QC	Sr. Executive-QC	Manager-QC
Signature	17.H.	J. Len J	Kr
Date	04/03/2025	04/03/2025	046312025
Department: Quality (Control	Date of Issue: 04/08/2005	





ACTION NO.	SAI PRIMUS LIFE BIOTECH PVT LTD	Page 4 of 7
571	Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009	No.: FPS: G13
SAI.PRIMUS LIFE BIDTECH PVI. UTD	FINISHED PRODUCT SPECIFICATION	Revision No: 04
Title:	GENSET TABLETS (Cetirizine hydrochloride Tablet BP 10 mg)	Review Period: 3 Years
-	Product Code: G13	Effective Date: 04/03/202

RELEASE SPECIFICATION

S.No.	TEST	LIMIT	METHOD
01	DESCRIPTION	White coloured, caplet shaped, film	Follow section I of
01	DESCRIPTION	coated tablet with break line on one side	Method of analysis
		and plain on other side.	Method of allarysis
02	IDENTIFICATION By IR	The infrared absorption spectrum of the	Follow section II of
"-	20 21 12 10 11 10 1 2 J	residue is concordant with the reference	Method of analysis
		spectrum of cetirizine hydrochloride.	Wielliod of analysis
03	AVERAGE WEIGHT	$120.00 \text{ mg} \pm 5.0\%$	Follow section III of
0.5	AVERAGE WEIGHT	(Limit: $114.00 \text{ mg to } 126.00 \text{ mg}$)	Method of analysis
- 50			<u> </u>
04	UNIFORMITY OF WEIGHT	NMT 2 tablets deviate by more than	Follow section IV of
		\pm 7.5 % and none deviates by more	Method of analysis
	\$ **	than \pm 15.0 % from the average weight.	
05	DIMENSIONS		Follow section V of
	Thickness	2.50 mm to 3.10 mm	Method of analysis
	Length	10.0 mm to 10.40 mm	
	Width	4.00 mm to 4.40 mm	- / /
06	HARDNESS	NLT 2 Kg/cm ²	Follow section VI of
			Method of analysis
07	DISINTEGRATION TIME	Not more than 30 minutes	Follow section VIII of
			Method of analysis
08	CONTENT UNIFORMITY		Follow section IX of
	By HPLC		Method of analysis
7	Cetirizine Hydrochloride BP-10 mg	NLT 85.0 % and NMT 115.0 % of	×
<u> </u>		labeled claim	
09	DISSOLUTION By UV		Follow section X of
-	Cetirizine Hydrochloride BP-10 mg	Not less than 85.0 % of labeled amount	Method of analysis
	,	т 1	2.200.00 01 0.000,000
10	RELATED SUBSTANCES		Follow section XI of
*	By HPLC		Method of analysis
	Impurity A	Not more than 0.3 %	
	Impurity B	Not more than 0.3 %	
	Impurity G	Not more than 0.3 %	***
	Single maximum unknown impurity	Not more than 0.2 %	
	Total impurities	Not more than 1.0 %	
¥		± 2	*

	Prepared by	Checked by	Approved by
Designation	Executive-QC	Sr. Executive-QC	Manager-QC
Signature	H. H.	J. Key	pe
Date	04/03/2025	04/03/2025	04/03/2025
Department: Quality (Control	Date of Issue: OH 103/2027	





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SAI PRIMUS LIFE BIOTECH PVT LTD	Page 5 of 7
	No.: FPS: G13
Villianur Commune, Puducherry-605009	1.00.225.025
FINISHED PRODUCT SPECIFICATION	Revision No: 04
*	
GENSET TABLETS	Review Period: 3 Years
(Cetirizine hydrochloride Tablet BP 10 mg)	
Product Code: G13	Effective Date: 04/03/200
	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009 FINISHED PRODUCT SPECIFICATION GENSET TABLETS (Cetirizine hydrochloride Tablet BP 10 mg)

S.No.	TEST	LIMIT	METHOD
11	ASSAY (By HPLC)		Follow section XII of
	Each film coated tablet contains:		Method of analysis
	Cetirizine Hydrochloride BP-10 mg	Not less than 95.0% and	
		Not more than 105.0%	
12	MICROBIOLOGICAL LIMITS	,	Follow section XIII of
	Total Aerobic Microbial count	NMT 1000 CFU/g	Method of analysis
	Total Yeasts and mould counts	NMT 100 CFU/g	
	E. coli	Should be Absent/g	*
	Salmonella	Should be Absent/10g	4, 1, 1
	S. aureus	Should be Absent/g	
	P. aeruginosa	Should be Absent/g	of great

	Prepared by	Checked by	Approved by
Designation	Executive-QC	Sr. Executive-QC	Manager-QC
Signature	1f. N-4	3. Lend	W
Date	04/08/2025	04/03/2025	04/03/2025
Department: Quality Co	ontrol	Date of Issue: 01/03/2027	





P GREEN THROUGH	SAI PRIMUS LIFE BIOTECH PVT LTD	Page 6 of 7
	Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009	No.: FPS: G13
SAI PRIMUS LIFE BIOTECH PALLID	FINISHED PRODUCT SPECIFICATION	Revision No: 04
Title:	GENSET TABLETS (Cetirizine hydrochloride Tablet BP 10 mg)	Review Period: 3 Years
	Product Code: G13	Effective Date: OHIOBbox

SHELF LIFE SPECIFICATION

S.No.	TEST	LIMIT	METHOD
01	DESCRIPTION		METHOD
01	DESCRIPTION	White coloured, caplet shaped, film coated tablet with break line on one side	Follow section I of
		and plain on other side.	Method of analysis
02	AVERAGE WEIGHT	120.00 mg \pm 5.0%	Follow section III of
02	AVERAGE WEIGHT	(Limit: $114.00 \text{ mg to } 126.00 \text{ mg}$)	Method of analysis
			Method of analysis
03	HARDNESS	NLT 2 Kg/cm ²	Follow section VI of
			Method of analysis
04	DISINTEGRATION TIME	Not more than 30 minutes	Follow section VIII of
			Method of analysis
05	DISSOLUTION By UV		Follow section X of
	Cetirizine Hydrochloride BP-10 mg	Not less than 85.0 % of labeled amount	Method of analysis
06	RELATED SUBSTANCES .	er e	Follow section XI of
1 2	By HPLC		Method of analysis
	Impurity A	Not more than 0.3 %	
	Impurity B	Not more than 0.3 %	
11	Impurity G	Not more than 0.3 %	
	Single maximum unknown impurity	Not more than 0.2 %	
	Total impurities	Not more than 1.0 %	
07	ASSAY (By HPLC)		Follow section XII of
	Each film coated tablet contains:		Method of analysis
	Cetirizine Hydrochloride BP-10 mg	Not less than 95.0% and	in the second se
		Not more than 105.0%	
	, take the second of the second		
08	MICROBIOLOGICAL LIMITS		Follow section XIII of
	Total Aerobic Microbial count	NMT 1000 CFU/g	Method of analysis
· ·	Total Yeasts and mould counts	NMT 100 CFU/g	
	E.Coli	Should be Absent/g	
	Salmonella	Should be Absent/10g	
	S.aureus	Should be Absent/g	
	P.aeruginosa	Should be Absent/g	€ =

	Prepared by	Checked by	Approved by
Designation	Executive-QC	Sr. Executive-QC	Manager-QC
Signature	M.H.	J. bend	pu
Date	04/08/2025	04/03/2025	04to3/2025
Department: Quality (Control	Date of Issue: 04/03/2027	



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	Villianur Commune, Puducherry-605009	No.: FPS: G13	
SAI PRIMUS LIFE BIOTECH PVI LID	FINISHED PRODUCT SPECIFICATION	Revision No: 04	
Title:	GENSET TABLETS (Cetirizine hydrochloride Tablet BP 10 mg)	Review Period: 3 Years	
۲ .	Product Code: G13	Effective Date: 04/03/2025	

HISTORY

S. No.	Revision Number	Reason for Revision	
1	Revision No.: 00	New Specification No: G13	
2	Revision No.: 01	Periodic Revision	
3	Revision No.: 02	Revision reference to the change control CC/24/034.	
4	Revision No.: 03	Revision reference to the change control CC/24/087	
5	Revision No.: 04	Revision reference to the change control CC/25/051	

END OF DOCUMENT

1 2 m	Prepared by	Checked by	Approved by
Designation	Executive-QC	Sr. Executive-QC	Manager-QC
Signature	17.H+	7-6-6	m
Date	04/03/2025	04/03/2025	04/03/2015
Department: Quality Control	- 1	Date of Issue: 04/03/2025	

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	SAI PRIMUS LIFE BIOTECH PVT LTD	Page 1 of 12
	Factory: R S No. 4/3, Plot No.33, Kurumbapet Industrial Estate,	No.: FPSTP: G13
SAI PRIMUS LIFE	Villianur Commune, Puducherry-005009 FINISHED PRODUCT STANDARD TEST PROCEDURE	Revision No: 04
Title:	GENSET TABLETS (Cetirizine hydrochloride Tablet BP 10 mg)	Review Period: 3 Years
	Product Code: G13	Effective Date: 0H 03/202

METHOD OF ANALYSIS

SECTION - I

DESCRIPTION: (By Visual Inspection)

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

SECTION - II

IDENTIFICATION By IR

Shake a quantity of the powdered tablets containing 50 mg of Cetirizine Hydrochloride with 20 mL of absolute ethanol, filter (Whatman GF/C is suitable), evaporate the filtrate and dry the residue at 60° for 1 hour. The infrared absorption spectrum of the residue.

SECTION-III

AVERAGE WEIGHT

Weigh 20 tablets and note down weight in g. Determine the average weight.

Report the result of average weight in mg.

	Weight of 20 tablets in g		
Average weight =		- x 1000 = _	mg
	20		

SECTION - IV

UNIFORMITY OF WEIGHT

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

×	Prepared by	Checked by	Approved by
Designation	Executive-QC	Sr. Executive-QC	Manager-QC
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Date	04/03/2025	04/03/2025	046312025
Department: Quality		Date of Issue: 04/03/2025	

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		Page 2 of 12
	Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate,	No.: FPSTP: G13
	Villianur Commune, Puducherry-605009 FINISHED PRODUCT STANDARD TEST PROCEDURE	Revision No: 04
Title:	GENSET TABLETS	Review Period: 3 Years
Ψ.	(Cetirizine hydrochloride Tablet BP 10 mg) Product Code: G13	Effective Date: 04/03/20



SECTION - V

DIMENSIONS

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

SECTION - VI

HARDNESS

Take 10 tablets randomly from sample drawn for analysis. Place one tablet diagonally in between the space provided in the hardness tester. Operate the instrument for tablet hardness tester. Note down the reading when tablet breaks. Repeat the test for remaining 9 tablets and record the values in kg/cm². Express the results as the minimum and maximum values in kg/cm².

SECTION - VII

FRIABILITY

Weigh accurately about 6.5 g of tablets note down the mass in grams (a). Place weighed tablets in friability test apparatus and operate the instrument as per SOP for tablet friability test apparatus, for 100 rotations. After completion of test collect the tablets from the sample collector carefully. Remove broken particles, chipped pieces

(if any) by means of gentle brushing. Weigh the tablet and record the mass in grams (b).

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Designation	Executive-QC	Sr. Executive-QC	Manager-QC
Signature	14. H4	J. Keyl	M sala is
Date	04/03/2025	04/03/2028	04/03/2025
Department: Quality	Control	Date of Issue: 04/03/2027	





	SAI PRIMUS LIFE BIOTECH PVT LTD	Page 3 of 12
7.122	Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate,	No.: FPSTP: G13
4	Villianur Commune, Puducherry-605009 FINISHED PRODUCT STANDARD TEST PROCEDURE	Revision No: 04
Title:	GENSET TABLETS (Cetirizine hydrochloride Tablet BP 10 mg)	Review Period: 3 Years
	Product Code: G13	Effective Date: 04 103/202

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

Calculate the percentage as follows:

Calculation

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

a

SECTION - VIII

DISINTEGRATION TIME

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

SECTION - IX

ASSAY AND CONTENT UNIFORMITY By HPLC

Chromatographic Condition:

Column	:	C18, 250 mm × 4.6 mm, pa (Phenomenex Luna C18 (2)	cked with octadecyl silyl silica gel (5 μm) column is suitable) or equivalent
Flow rate	:	1.0 mL/min	
Wavelength	;	230 nm	A STATE OF THE STA
Injection volume	:	20 μL	
Column Oven	;	30°C	
Temperature			

,	Prepared by	Checked by	Approved by
Designation	Executive-QC	Sr. Executive-QC	Manager-QC
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Date	04/03/2025	04/03/2025	offosloss
Department: Quality		Date of Issue: 04/03/2027	





	SAI PRIMUS LIFE BIOTECH PVT LTD	Page 4 of 12
2000	Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate,	No.: FPSTP: G13
	Villianur Commune, Puducherry-605009 FINISHED PRODUCT STANDARD TEST PROCEDURE	Revision No: 04
SAI PRIMUS LIFE Title:	GENSET TABLETS	Review Period: 3 Years
	(Cetirizine hydrochloride Tablet BP 10 mg) Product Code: G13	Effective Date: 04103 200

Preparation of Buffer Solution:

Weight accurately 0.34 gm of Potassium Dihydrogen Orthophosphate into 1000 mL of water. Sonicate to dissolve and adjust to pH 1.5 ± 0.05 with Orthophosphoric acid.

Preparation of Mobile Phase:

Mix 700 mL of Buffer Solution and 300 mL of Acetonitrile. Filter through 0.45-micron membrane filter and degas.

Preparation of Solution-3:

Weight accurately about 2 mg of Impurity standard BPCRS and transfer into a 10 mL volumetric flask. Add about 5 mL of mobile phase, sonicate with intermediate shaking to dissolve and dilute up to the volume with mobile phase. (Concentration: 0.2 mg/mL)

Preparation of Solution-2:

Weight Accurately and transfer about 20 mg of Cetirizine hydrochloride working standard into 100 mL volumetric flask. Add about 50 mL of mobile phase, sonicate with intermediate shaking to dissolve and dilute up to the volume with mobile phase. Further dilute 10 mL of this solution to 100 mL with mobile phase. (Conc.0.02 mg/mL)

Preparation of Solution-1 Sample Powder:

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

Preparation of Solution-1:

Weight accurately and transfer about 240 mg of powdered sample (equivalent to 20 mg Cetirizine hydrochloride) into 100 mL volumetric flask. Add about 70 mL of mobile phase, shake for 15 minutes with to dissolve, cool and dilute up to the volume with mobile phase. Filter sufficient quantity of this solution through 0.45 µm nylon syringe filter and inject. Further dilute 10 mL of this solution to 100 mL with mobile phase and inject.

Note: Prepare sample solution in duplicate.

Preparation of Sample solution CU:

Weigh 10 random tablets individually and transfer them into ten 100 mL volumetric flask containing 10 mL of

	Prepared by	Checked by	Approved by
Designation ————————————————————————————————————	Executive-QC	Sr. Executive-QC	Manager-QC
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Signature	04/03/2025	04/03/2025	04/03/1025
Date Department: Quality (Date of Issue: 04/03/2025	-



		Page 5 of 12 No.: FPSTP: G13
SAI PRIMUS LIFE	Villianur Commune, Puducherry-605009 FINISHED PRODUCT STANDARD TEST PROCEDURE	Revision No: 04
Title:	GENSET TABLETS (Cetirizine hydrochloride Tablet BP 10 mg)	Review Period: 3 Years
	Product Code: G13	Effective Date: 04/03/202

water. Keep as it is until the complete dispersion of tablets. Add 50 mL of mobile phase, sonicate for 10 minutes with intermediate shaking and dilute up to the volume with mobile phase. Filter sufficient quantity of this solution through 0.45µ nylon syringe filter and further dilute 5 mL of this solution to 25 mL with mobile phase.

Procedure:

Equilibrate the chromatographic system with mobile phase till a stable baseline is obtained. Separately inject equal volumes (20 µL) of solutions as per Sequence of injections into the chromatograph and record the peak area responses for the major peaks and check for the System suitability requirements.

Sequence of Injections:

S. No	Solution type	No. of injections
1.	Blank	1 -
2.	Solution 3	1 . 1.
3.	Solution 2	5
4.	Solution 1-1	1
5.	Solution 1-2	1
6.	Bracketing Solution 2 - I	I in the state of
7.	Content Uniformity solution 1-5	1
8.	Bracketing Solution 2 - 2	1
9.	Content Uniformity solution 6-10	1.
10.	Bracketing Solution 2 - 2	1

Note: Bracketing standards may vary as per In-House SOP.

System suitability requirement:

- 1. The Resolution between the peaks of Cetirizine hydrochloride and Impurity B obtained with impurity standard solution should not less than 1.5.
- 2. The tailing factor for the peak of Cetirizine hydrochloride obtained with standard solution should not more than 2.0:

Approved by	Checked by	Prepared by	
Manager-QC	Sr. Executive-QC	Executive-QC	Designation
M	J. Kery	P.H.	
04/01/2015	04/03/2025	04/03/2025	
		04 03 19025	Signature Date Department: Quality C





	SAI PRIMUS LIFE BIOTECH PVT LTD	Page 6 of 12
	Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate,	No.: FPSTP: G13
	Villianur Commune, Puducherry-605009 FINISHED PRODUCT STANDARD TEST PROCEDURE	Revision No: 04
Title:	GENSET TABLETS (Cetirizine hydrochloride Tablet BP 10 mg)	Review Period: 3 Years
*	Product Code: G13	Effective Date: 04/03b

- 3. The column efficiency for the peak of Cetirizine hydrochloride obtained in the chromatogram of standard solution should not less than 2000.
- 4. The % RSD for the peak area response of Cetirizine Hydrochloride peak obtained with the replicate injections of standard solution should not more than 2.0.
- 5. The % RSD for the peak area response of Cetirizine Hydrochloride peak obtained with the replicate injections of standard solution and bracketing standard solution should not more than 2.0.

Calculation: (% Assay)

1) Calculate the content of Cetirizine Hydrochloride by using following formula,

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

2) Calculation: (% Content / Tab):

Were,

A = Peak area response of Cetirizine hydrochloride peak obtained from the sample solution

B = Average peak area response of Cetirizine hydrochloride peak obtained with replicate injection standard Solution

W1 = Weight of Cetirizine hydrochloride working standard in mg

W2 = Weight of sample in mg

Av = Average weight of sample in mg

LC = Label claim

P = Purity of Cetirizine hydrochloride working standard on as is basis in %

Prepared by	Checked by	Approved by
Executive-QC	Sr. Executive-QC	Manager-QC
H.H.	J-kenpl	Kr
04/03/2025	04/03/2022	0403/2025
	Executive-QC	Executive-QC Sr. Executive-QC 17.4 J- terp 04/03/2025 04/03/2025



	SAI PRIMUS LIFE BIOTECH PVT LTD	Page 7 of 12
15 15 15 15 15 15 15 15 15 15 15 15 15 1	Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate,	No.: FPSTP: G13
	Villianur Commune, Puducherry-605009	
	FINISHED PRODUCT STANDARD TEST PROCEDURE	Revision No: 04
SAI PRIMUS LIFE BIOTECH DVT LID		
Title:	GENSET TABLETS	Review Period: 3 Years
7100	(Cetirizine hydrochloride Tablet BP 10 mg)	
	Product Code: G13	Effective Date: 04/03/2023

SECTION - X

DISSOLUTION (By UV):

Dissolution Parameters:

Medium	:	Water ·
Volume	:	900 mL
Apparatus	•	Apparatus Type II (Paddle)
RPM		50
Temperature		37°C .
Time	:	45 minutes

Preparation of Solution-2:

Weight Accurately and transfer about 25 mg of Cetirizine hydrochloride working standard into a 100 mL volumetric flask. Add about 20 mL of water, sonicate to dissolve and dilute up to the mark with water. Further dilute 2 mL of this solution to 100 mL with water. (Conc.0.0050 mg/mL)

Preparation of Solution-1:

Place the stated volume of dissolution medium in each vessel of the dissolution apparatus. Equilibrate the dissolution medium at $37^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$. Transfer 1 tablet in to each vessel. Immediately operate the apparatus at specified speed. At the end of specified time interval, withdraw 10 mL of aliquot from each specimen. Filter through 0.45μ nylon syringe filter. Dilute 5 mL of this solution to 10 mL with dissolution medium.

(Conc.0.0056 mg/mL)

(Aliquot withdrawal Position: - from the midway zone between the top surface of dissolution medium and top of rotating paddle and 1 cm away from vessel wall.)

Note: Carry out dissolution test on six tablets.

Instrument parameters for US-Vis Spectrophotometer:

Detection wavelength: 230 nm and 260 nm

	Prepared by	Checked by	Approved by
Designation	Executive-QC	Sr. Executive-QC	Manager-QC
Signature	H. H.	They	m
Date	04/03/2025	04/03/2025	0462/2015
Department: Quality Co	ontrol	Date of Issue: 04/03/2027	





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	Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate,	No.: FPSTP: G13
SAI PRIMUS LIFE	Villianur Commune, Puducherry-605009 FINISHED PRODUCT STANDARD TEST PROCEDURE	Revision No: 04
Title:	GENSET TABLETS (Cetirizine hydrochloride Tablet BP 10 mg)	Review Period: 3 Years
a •-	Product Code: G13	Effective Date: 04/03/2021

Path length: 1 cm

Cuvette: Quartz

Procedure:

Measure the absorbance of Standard and sample solution in water at the maximum wavelengths at 230 nm and 260 nm using dissolution medium in reference cell and calculate the difference between two readings (Δ A) for each measurement.

Calculation:

Calculate the content of Cetirizine hydrochloride by using following formula,

% Dissolution =
$$\frac{Au}{As} \times \frac{Ws}{100} \times \frac{2}{100} \times \frac{900}{LC} \times \frac{10}{5} \times P$$

Were,

Au = Absorbance of Cetirizine hydrochloride obtained from sample solution.

As = Average absorbance of Cetirizine hydrochloride BPCRS obtained from standard solution.

Ws = Weight of Cetirizine hydrochloride working standard in mg.

LC = Label claim

P = % Potency of Cetirizine hydrochloride on as is basis.

SECTION - XI

RELATED SUBSTANCES (By HPLC):

Chromatographic Condition:

Column type		C18, 250 mm × 4.6 mm, packed with octadecyl silyl silica gel (5 µm) (Phenomenex Luna C18 (2) column is suitable) or equivalent	
Flow rate	:	1.0 mL / minute	

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Department: Quality	Control	Date of Issue: 04/03/2025	





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		No.: FPSTP: G13
SAI PRIMUS LIFE	FINISHED PRODUCT STANDARD TEST PROCEDURE	Revision No: 04
Title:	GENSET TABLETS (Cetirizine hydrochloride Tablet BP 10 mg)	Review Period: 3 Years
	Product Code: G13	Effective Date: 04/03/2015

Detector wavelength	:	230 nm	
Column oven temperature	:	30 °C	
Injection volume	:	20 μL	
Diluent	:	Mobile phase-A	

Preparation of Mobile Phase-A:

Mix 170 mL of Acetonitrile and 830 mL of water previously adjusted pH to 1.5 ± 0.05 with orthophosphoric acid. Filter and Degas.

Preparation of Mobile phase-B:

Mix 350 mL of Acetonitrile and 650 mL of water previously adjusted pH to 1.5 ± 0.05 with orthophosphoric acid. Filter and Degas.

Gradient Program:

Time (mins)	Mobile phase A	Mobile phase B	Comment
0 - 50	100 → 0	0 → 100	Linear gradient
50 - 53	0	100	Isocratic
53 - 54	0 →100	100 →0	Linear gradient
54 - 60	100	0	Re - equilibration

Preparation of Placebo solution:

Weight accurately and transfer about 220mg of placebo (equivalent to 20 mg Cetirizine hydrochloride) into 20 mL volumetric flask. Add about 10 mL of diluent, shake for dissolve and dilute up to the volume with diluent. Filter sufficient quantity of this solution through 0.45μ nylon filter.

Preparation of solution-4:

Weight accurately about 2 mg of Impurity standard BPCRS and transfer into a 10 mL volumetric flask. Add about 5 mL of diluent, sonicate with intermediate shaking to dissolve and dilute up to the volume with diluent. (Concentration: 0.2 mg/mL)

Preparation of Solution-2:

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Department: Quality (Control	Date of Issue: 04/03/2027	





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- 5 TO 10 TO	Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate,	No.: FPSTP: G13
SAI PRIMUS LIFE	Villianur Commune, Puducherry-605009 FINISHED PRODUCT STANDARD TEST PROCEDURE	Revision No: 04
Title:	GENSET TABLETS (Cetirizine hydrochloride Tablet BP 10 mg)	Review Period: 3 Years
× 36	Product Code: G13	Effective Date: 04/03/20

Dilute 1 mL of solution-1 in to 100 mL with diluent. Further dilute 10 mL of this solution to 50 mL of with diluent. (Concentration:0.002 mg/mL)

Preparation of Solution-3:

Dilute 5 mL of solution-2 to 10 mL with diluent. (concentration:0.001 mg/mL).

Preparation of Solution-1:

Take accurately 20 tablets and triturate to fine powder with mortar & pestle. Weight accurately and transfer 240 mg of sample powder (equivalent to 20 mg Cetirizine hydrochloride) into 20 mL of volumetric flask. Add about 10 mL of diluent, shake for dissolve and dilute up to the volume with diluent. Filter sufficient quantity of this solution through 0.45 µm nylon syringe filter.

Procedure:

Equilibrate the chromatographic system with mobile phase till a stable baseline is obtained. Separately inject equal volumes (20 μ l) of solutions as per Sequence of injections into the chromatograph and record the peak area responses for the major peaks and check for the System suitability requirements.

Sequence of injection:

Solution type	No. of injections
Blank	1
Placebo	1
Blank	1
Solution-4	1
Blank	1 2
Solution-1	1.
Solution-2	
Solution-3	1
Blank	1865 - 1
	Blank Placebo Blank Solution-4 Blank Solution-1 Solution-2 Solution-3

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and a	SAI PRIMUS LIFE BIOTECH PVT LTD	Page 11 of 12
	Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate,	No.: FPSTP: G13
	Villianur Commune, Puducherry-605009 FINISHED PRODUCT STANDARD TEST PROCEDURE	Revision No: 04
SAI PRIMUS LIFE JOSECH SVELID Title:	GENSET TABLETS	Review Period: 3 Years
2 K	(Cetirizine hydrochloride Tablet BP 10 mg) Product Code: G13	Effective Date: 04/03/202

Identify any peaks corresponding to impurity-A, impurity-B and impurity-G using solution-(4) and the chromatogram supplied with cetirizine impurity standard BPCRS.Multiply the area of any peak corresponding to impurity-A by a correction factor of 0.7.

Disregard any peak with an area less than the area of the principal peak in the chromatogram obtained with solution (3) (0.1%)

System suitability requirement:

The Resolution between the peaks of Cetirizine hydrochloride and cetirizine impurity-B obtained with impurity standard solution should be not less than 1.5.

Calculation:

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

$$= \frac{A}{B} \times \frac{W1}{20} \times \frac{1}{100} \times \frac{10}{50} \times \frac{20}{W2} \times \frac{Av}{LC} \times \frac{P}{100} \times 100 \times CF$$

2)Calculate the % Unknown impurity by using following formula,

$$= \frac{A}{B} \times \frac{W1}{20} \times \frac{1}{100} \times \frac{10}{50} \times \frac{20}{W2} \times \frac{Av}{LC} \times \frac{P}{100} \times 100$$

Were,

A = Peak area response of known / Unknown impurity obtained from the sample solution.

B = Peak area response of cetirizine Hydrochloride peak obtained with solution (2).

W1 = Equivalent weight of Cetirizine hydrochloride in mg

W2 = Weight of sample in mg

Av = Average weight of sample in mg

P = % Purity of Cetirizine Hydrochloride working standard on as is basis.

CF = Correction Factor (For impurity A = 0.7)

CF = Correction Factor (Prepared by	Checked by	Approved by
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	Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate,	No.: FPSTP: G13
SAI PRIMUS LIFE	Villianur Commune, Puducherry-605009 FINISHED PRODUCT STANDARD TEST PROCEDURE	Revision No: 04
Title:	GENSET TABLETS (Cetirizine hydrochloride Tablet BP 10 mg)	Review Period: 3 Years
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Total impurities = Sum of all known impurities & unknown impurities

SECTION - XII ASSAY (By HPLC)

Refer to ASSAY AND CONTENT UNIFORMITY (SECTION-IX)

SECTION-XIII

MICROBIOLOGICAL LIMITS

Refer to SOP No. QCMB 006.

HISTORY

S. No.	Revision Number	Reason for Revision	
1	Revision No.: 00	New STP No: FPSTP: G13	
2	Revision No.: 01	Periodic Revision	
3	Revision No.: 02	Revision reference to the change control CC/24/034.	
. 4	Revision No.: 03	Revision reference to the change control CC/24/087	
5	Revision No.: 04	Revision reference to the change control CC/25/051	

END OF DOCUMENT

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