PROTOCOL	
Title	Analytical Method Verification Dissolution Protocol For Cetirizine Hydrochloride-10mg (Genset-10mg Tablet BP)
Protocol No.	AMVP/CET/002

ANALYTICAL METHOD VERIFICATION PROTOCOL FOR DISSOLUTION

Site Address: GENERIC HEALTHCARE PRIVATE LIMITED
R.S. No. 4/3, plot No. 33, Kurumbapet Industrial Estate,
Villianur Commune, Pondicherry- 605009

PROTOCOL	
Title	Analytical Method Verification Dissolution Protocol For Cetirizine Hydrochloride-10mg (Genset-10mg Tablet BP)
Protocol No.	AMVP/CET/002

1.0 INDEX

PROTOCOL	
Title	Analytical Method Verification Dissolution Protocol For Cetirizine Hydrochloride-10mg (Genset-10mg Tablet BP)
Protocol No.	AMVP/CET/002

2.0 PROTOCOL APPROVAL SHEET

Prepared By	:	Analytical Development
Name	:	R. SUBADHARSHINI
Signature	:	
Date	:	15/11/2023
Reviewed By	:	Analytical Development
Name	:	M. VINOTHINI
Signature	:	
Date	:	15/11/2023
Reviewed By	:	Quality Control
Name	:	A. VALLARASAN
Signature	:	
Date	:	15/11/2023
Approved By	:	Quality Assurance
Name	:	P. Stephen
Signature	:	
Date	:	15/11/23

PROTOCOL	
Title	Analytical Method Verification Dissolution Protocol For Cetirizine Hydrochloride-10mg (Genset-10mg Tablet BP)
Protocol No.	AMVP/CET/002

3.0 OBJECTIVE

To verify the method for the test of Dissolution of Genset-10mg (Cetirizine Hydrochloride Tablet BP) by UV.

4.0 GENERAL INFORMATION

METHOD REFERENCE	:	BP 2023
REASON FOR VERIFICATION	:	To verify the Dissolution test for Cetirizine HCl tablets as per British Pharmacopoeia

PROTOCOL	
Title	Analytical Method Verification Dissolution Protocol For Cetirizine Hydrochloride-10mg (Genset-10mg Tablet BP)
Protocol No.	AMVP/CET/002

5.0 DETAILS OF STANDARD, SAMPLES AND PLACEBO TO BE USED

Mention the name and Batch No., Potency of the reference/working std., Impurities Standard, test samples/placebo to be used during VERIFICATION (as applicable).

Name of Material	:	ID. No./Batch No./Control No.	:	Potency/ Purity	:	Valid Up to
Standard	:		:		:	
Placebo (If applicable)	:		:		:	
Sample	:		:		:	
Impurities	:		:		:	

PROTOCOL	
Title	Analytical Method Verification Dissolution Protocol For Cetirizine Hydrochloride-10mg (Genset-10mg Tablet BP)
Protocol No.	AMVP/CET/002

6.0 DETAILS OF INSTRUMENTS/EQUIPMENTS, COLUMN, SOLVENTS AND CHEMICALS TO BE USED:

INSTRUMENTS/EQUIPMENTS:

Ultra-violet spectrophotometer

Make: Shimadzu, Model: UV-1900

Analytical Balance

Make : Shimadzu, Model : AUW220D

pH Meter

Make: Eutech instruments, Model No: pH 700

Solvents and chemicals with grade:

Water (Purified water)

Working standard & Impurities Details

Cetirizine Hydrochloride (Working standard)

Dissolution

Make: Electro lab, Model No: TDT-08L

PROTOCOL	
Title	Analytical Method Verification Dissolution Protocol For Cetirizine Hydrochloride-10mg (Genset-10mg Tablet BP)
Protocol No.	AMVP/CET/002

7.0 DESCRIPTION OF ANALYTICAL METHOD

Dissolution parameters:

Medium	:	Water
Apparatus	:	Apparatus 2 (paddle)
Volume	:	900 ml
RPM	:	50
Temperature	:	37°C ± 0.5°C
Time	:	45 min

Preparation of Standard Solution:

Weigh accurately about 25 mg of Cetirizine HCl standard into a 100 mL volumetric flask. Add about 20 mL of Water, Sonicate to dissolve and make up to volume with Water. Further dilute 2ml of this solution to 100ml with water. (Conc.0.005 mg/ml)

Preparation of sample solution:

Perform the test on six tablets .Place the stated volume of dissolution medium of each vessels of the dissolution apparatus. Warm the dissolution medium at 37°C ± 0.5°C. Transfer 1 tablet in to the each vessel. Immediately operate the apparatus at specified speed. At the end of specified time interval, withdraw about required amount of aliquot from each specimen. Filter sufficient quantity of this solution through 0.45micron, Nylon syringe filter, dilute 5 ml of filtrate to 10ml with disso medium.(Conc 0.0055 mg/ml)

Spectrometer condition:

Detection : UV maximum wavelength at 230nm and at 260nm

Path length : 1 cm

System suitability requirement :

% Relative standard deviation for 6 replicate absorbance of standard should not be more than 5.0.

PROTOCOL	
Title	Analytical Method Verification Dissolution Protocol For Cetirizine Hydrochloride-10mg (Genset-10mg Tablet BP)
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1) Calculated the content of Cetirizine hydrochloride by using following formula for 10mg ,

$$= \frac{Au}{As} \times \frac{Ws}{100} \times \frac{2}{100} \times \frac{900}{1} \times \frac{10}{5} \times \frac{P}{100} \times \frac{100}{LC}$$

Where,

Au = Absorbance of Cetirizine HCl obtained from sample solution.
As = Average absorbance of Cetirizine HCl BPCRS obtained from standard solution.
Ws = Weight of Cetirizine HCl working standard in mg
LC = Label claim(10mg)
P = Purity of Cetirizine hydrochloride working standard in %

8.0 PARAMETERS TO BE VERIFIED:

Following parameters shall be selected for VERIFICATION	
Sr. No.	**VERIFICATION Parameter**
1.	**Specificity (Selectivity)** i) Interference from Placebo (as applicable)
2.	**Precision** i) System precision ii) Method precision iii) Intermediate Precision
3.	**Accuracy (Recovery)**
4.	**STABILITY OF ANALYTICAL SOLUTION**
5.	**FILTER PAPER STUDY**

PROTOCOL	
Title	**Analytical Method Verification Dissolution Protocol For Cetirizine Hydrochloride-10mg (Genset-10mg Tablet BP)**
Protocol No.	**AMVP/CET/002**

9.0 DETAILS OF VERIFICATION PARAMETERS

9.1 SPECIFICITY (SELECTIVITY)

Interference from Placebo (As applicable)

"The specificity is the ability of an analytical procedure to measure accurately an analyte in presence of components that may be expected present in sample matrix".

Purpose:

To demonstrate that the placebo not interfering with the analyte Absorbance.

Preparation of standard solution

Weigh accurately about 25 mg of Cetirizine HCl standard into a 100 mL volumetric flask. Add about 20 mL of water, Sonicate to dissolve and make up to volume With water. Further dilute 2ml of this solution 100ml with water.

Preparation of Placebo:

Weigh and transfer 110 mg of placebo into 1000 mL volumetric flask. Add disso medium, sonicate for 15 minute with vigorously shaking to dissolve and make up to 900 volume with disso medium and Mix. Filter sufficient amount of this solution through 0.45 micron syringe filter .Further dilute 5 mL of filtered solution to 10 mL with disso medium.

Preparation of Cetirizine HCL + Placebo:

Weigh and transfer 110 mg of Placebo and 10 mg of Cetirizine HCl working standard into 1000 mL volumetric flask. Add 900ml disso medium, sonicate for 15 minute with vigorously shaking to dissolve and Mix. Filter sufficient amount of this solution through 0.45 micron syringe filter. Further dilute 5 mL of filtered solution to 10 mL with disso medium.

PROTOCOL	
Title	Analytical Method Verification Dissolution Protocol For Cetirizine Hydrochloride-10mg (Genset-10mg Tablet BP)
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Preparation of Sample solution :

Preparation of Sample Solution as per method precision

Study design:

Sequence shall be in following provisional manner.

S.No.	Description of solution	No. of absorbance
1	Blank (Diluent)	1
2	Standard preparation	1
3	Plain placebo	1
4	Placebo+ Cetirizine HCl Working standard	1
5	Sample solution -1(Genset-10mg)	1

Note:

Blank and placebo preparation shall be prepared by spiking of drugs at target concentration.

Acceptance criteria:

No significant interference due to blank and placebo.

PROTOCOL	
Title	Analytical Method Verification Dissolution Protocol For Cetirizine Hydrochloride-10mg (Genset-10mg Tablet BP)
Protocol No.	AMVP/CET/002

9.2 PRECISION

"The Precision of an analytical procedure express the closeness of the agreement (Degree of factor) between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed condition. Precision may be considered repeatability and reproducibility"

9.2.1 System Precision

Purpose:

To establish the precision of the UV system being used for the analysis.

Preparation of Standard Solution:

Weigh accurately about 25 mg of Cetirizine HCl standard into a 100 mL volumetric flask. Add about 20 mL of water, Sonicate to dissolve and make up to volume With water. Further Dilute 2ml of this solution 100ml with water.

Study Design:

Sequence shall be in following provisional manner.

S.No.	Description of solution	No. of absorbance
1	Blank (Diluent)	1
2	Standard preparation	6

Acceptance criteria:

% RSD of analyte absorbance in six replicate standard should not be more than 2.0.

PROTOCOL	
Title	Analytical Method Verification Dissolution Protocol For Cetirizine Hydrochloride-10mg (Genset-10mg Tablet BP)
Protocol No.	AMVP/CET/002

9.2.2 Method Precision:

Purpose:

To establish the repeatability of test results obtained by the analytical method.

Preparation of Sample solution:

Perform the test on six tablets .Place the stated volume of dissolution medium of each vessels of the dissolution apparatus. Warm the dissolution medium at 37°C ± 0.5°C. Transfer 1 tablet in to the vessel. Immediately operate the apparatus at specified speed. At the end of specified time interval, withdraw about required amount of aliquot from each specimen. Filter sufficient quantity of this solution through 0.45micron, Nylon syringe filter, dilute 5 ml of filtrate to 10ml with disso medium.(Conc 0.0055 mg/ml)

Study design:

To demonstrate the method precision, analyze six sample preparations as per the methodology representing a single batch and determine the Dissolution for the same. Evaluate the method precision by computing the percentage and relative standard deviation of the Dissolution results.

S.No.	Description of solution	No. of absorbance
1	Blank (Diluent)	1
3	Standard preparation	1
4	Sample -1	1
5	Sample -2	1
6	Sample -3	1
7	Sample-4	1

8	Sample -5	1
9	Sample -6	1

Acceptance criteria:

% RSD for Dissolution of six preparations should not be more than 5.0.

9.2.3 Intermediate Precision (Ruggedness):

Purpose:

To demonstrate the reproducibility of test results obtained by the analytical method for the variability of instrument, column (different lot no) analyst and day. Analyse Six sample preparations as per the methodology representing a single batch and determine the Dissolution for the same. Evaluate the intermediate precision by computing the percentage and relative standard deviation of the dissolution results.

Preparation of Sample Solution as per method precision

S.No.	Description of solution	No. of absorbance
1	Blank (Diluent)	1
2	Standard preparation	1
3	Sample 1	1
4	Sample -2	1
5	Sample -3	1
6	Sample -4	1
7	Sample -5	1
8	Sample -6	1

PROTOCOL	
Title	Analytical Method Verification Dissolution Protocol For Cetirizine Hydrochloride-10mg (Genset-10mg Tablet BP)
Protocol No.	AMVP/CET/002

Acceptance criteria:

1) % RSD for Dissolution of six preparations should not be more than 5.0.
2) Cumulative % RSD for Dissolution of twelve preparations (i.e. method precision and intermediate precision) should not be more than 5.0.

9.3 ACCURACY(RECOVERY)

"The accuracy of an analytical method is the closeness of results obtained by that method to the true value. Accuracy may often be expressed as present recovery by the Dissolution of known, add amount of analyte".

Purpose:

To establish the accuracy of the analytical method in the specified range.

Preparation of Accuracy 100% solution:

Weigh and transfer 10 mg of cetirizine HCl working standard and 110 mg of placebo transfer into 1000 mL volumetric flask. Add disso medium, sonicate for 15 minute with Vigorously shaking to dissolve and make up to 900 volume with disso medium and Mix. Filter sufficient amount of this solution through 0.45 micron syringe filter. Further dilute 5 mL of filtered solution to 10 mL with water.

NOTE: Repeat the same procedure for accuracy 100 % solution another 2 Preparation of Sample Solution.

Preparation of Accuracy 50% solution:

To above the solution 100% dilute 5ml of the solution to 20 ml with water.

Preparation of Accuracy 150% solution:

Weigh and transfer 15 mg of cetirizine HCl working standard and 165 mg of placebo transfer into 1000 mL volumetric flask. Add disso medium, sonicate for 15 minute with vigorously shaking to dissolve and make up to 900 volume with disso medium and Mix. Filter sufficient amount of this solution through 0.45 micron syringe filter. Further dilute 5 mL of filtered solution to 10 mL with water.

PROTOCOL	
Title	Analytical Method Verification Dissolution Protocol For Cetirizine Hydrochloride-10mg (Genset-10mg Tablet BP)
Protocol No.	AMVP/CET/002

Study design:

To demonstrate the accuracy of the analytical method, prepare recovery samples by spiking known quantities of drug (at level 50%, 100% and 150% of targeted concentration) to placebo. Prepare the recovery samples in triplicate for each level.

Sequence shall be in following provisional manner

S.No.	Description of solution	No. of absorbance
1	Blank (Diluent)	1
2	Standard preparation	1
3	Blank (Diluent)	1
4	Level – 1 Set – 1 (50%)	1
5	Level – 1 Set – 2 (50%)	1
6	Level – 1 Set – 3 (50%)	1
7	Blank (Diluent)	1
8	Level – 2 Set – 1 (100%)	1
9	Level – 2 Set – 2 (100%)	1
10	Level – 2 Set – 3 (100%)	1
11	Blank (Diluent)	1
12	Level – 3 Set – 1 (150%)	1
13	Level – 3 Set – 2 (150%)	1

PROTOCOL	
Title	Analytical Method Verification Dissolution Protocol For Cetirizine Hydrochloride-10mg (Genset-10mg Tablet BP)
Protocol No.	AMVP/CET/002

14	Level – 3 Set – 3 (150%)	1

Acceptance criteria:

The mean % recovery at each level should be 95.0 to 105.0.

The Individual recover should be between 90.0% to 110.0%.

9.4 STABILITY OF ANALYTICAL SOLUTION:

Study design:

Prepare Standard and sample solution as per the methodology and store at room temperature. Chromatograph this solution at regular intervals for 48 hours by using same diluent. Calculate the % difference of analyte peak area for standard and sample preparations with that of initial. The study may be stopped if 2 consecutive failure of sample solution.

Preparation of Sample solution:

Place the stated volume of dissolution medium of each vessels of the dissolution Apparatus. Warm the dissolution medium at 37°C ± 0.5°C. Transfer 1 tablet in to the vessel Immediately operate the apparatus at specified speed. At the end of specified time Interval, withdraw about required amount of aliquot from each specimen. nylon filter sufficient quantity of this solution through 0.45 micron, Nylon syringe filter, dilute 5 ml of filtrate to 10 ml with water.

Sequence shall be in following provisional

S.No.	Description of solution	No. of absorbance
1	Blank (Diluent)	1

PROTOCOL	
Title	**Analytical Method Verification Dissolution Protocol For Cetirizine Hydrochloride-10mg (Genset-10mg Tablet BP)**
Protocol No.	**AMVP/CET/002**

2	Standard preparation (Initial)	1
3	Sample 1 (Initial)	1
4	Sample -2 (Initial)	1
5	Sample -3 (Initial)	1
6	Sample -4 (Initial)	1
7	Sample -5 (Initial)	1
8	Sample -6 (Initial)	1
9	Sample 1 (24 hours)	1
10	Sample -2 (24 hours)	1
11	Sample -3 (24 hours)	1
12	Sample -4 (24 hours)	1
13	Sample -5 (24 hours)	1
14	Sample -6 (24 hours)	1
15	Sample 1 (48 hours)	1

PROTOCOL	
Title	Analytical Method Verification Dissolution Protocol For Cetirizine Hydrochloride-10mg (Genset-10mg Tablet BP)
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16	Sample -2 (48 hours)	1
17	Sample -3 (48 hours)	1
18	Sample -4 (48 hours)	1
19	Sample -5 (48 hours)	1
20	Sample -6 (48 hours)	1

Acceptance criteria:

The sample and standard solution shall be considered stable for the final period till which the area difference between initial and next periodic interval should not be more than ±2%.

9.5 FILTER EVALUATION

Study design:

The filter paper study of the analytical method shall perform by filtering test solution through 0.45 µm Nylon, PVDF filter against that of unfiltered.

Preparation of Sample solution :

Place the stated volume of dissolution medium of each vessels of the dissolution Apparatus. Warm the dissolution medium at 37°C ± 0.5°C. Transfer 1 tablet in to the vessel Immediately operate the apparatus at specified speed. At the end of specified time Interval, withdraw about required amount of aliquot from each specimen. Filter sufficient quantity of this solution through 0.45 micron, nylon syringe filter, dilute 5 ml of filtrate to 10 ml with water.

PROTOCOL	
Title	Analytical Method Verification Dissolution Protocol For Cetirizine Hydrochloride-10mg (Genset-10mg Tablet BP)
Protocol No.	AMVP/CET/002

Sequence shall be in following provisional manner.

S.No.	Description of solution	No. of absorbance
1	Blank (Diluent)	1
2	Standard preparation (Initial)	1
3	Sample 1 Unfiltered (Centrifuge)	1
4	Sample -2 Unfiltered (Centrifuge)	1
5	Sample -3 Unfiltered (Centrifuge)	1
6	Sample -4 Unfiltered (Centrifuge)	1
7	Sample -5 Unfiltered (Centrifuge)	1
8	Sample -6 Unfiltered (Centrifuge)	1
9	Sample 1 Filter Set 1 (0.45µm Nylon Syringe filter)	1
10	Sample -2 Filter Set 1 (0.45µm Nylon Syringe filter)	1
11	Sample -3 Filter Set 1 (0.45µm Nylon Syringe filter)	1
12	Sample -4 Filter Set 1 (0.45µm Nylon Syringe filter)	1

PROTOCOL	
Title	**Analytical Method Verification Dissolution Protocol For Cetirizine Hydrochloride-10mg (Genset-10mg Tablet BP)**
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13	Sample -5 Filter Set 1 (0.45µm Nylon Syringe filter)	1
14	Sample -6 Filter Set 1 (0.45µm Nylon Syringe filter)	1
15	Sample 1 Filter Set 2 (0.45µm PVDF Syringe filter)	1
16	Sample -2 Filter Set 2 (0.45µm PVDF Syringe filter)	1
17	Sample -3 Filter Set 2 (0.45µm PVDF Syringe filter)	1
18	Sample -4 Filter Set 2 (0.45µm PVDF Syringe filter)	1
19	Sample -5 Filter Set 2 (0.45µm PVDF Syringe filter)	1
20	Sample -6 Filter Set 2 (0.45µm PVDF Syringe filter)	1

Acceptance criteria:

The % area difference of filter solution should not differ ±2.0 against that of unfiltered.

PROTOCOL	
Title	Analytical Method Verification Dissolution Protocol For Cetirizine Hydrochloride-10mg (Genset-10mg Tablet BP)
Protocol No.	AMVP/CET/002

10.0 ABBREVATION:

mg	:	Milligram
S.No	:	Serial Number
ml	:	Milliliter
%	:	Percentage
ID	:	Identification
API	:	Active pharmaceutical ingredient
HPLC	:	High performance liquid chromatography
B.NO	:	Batch number
mm	:	Millimeter
µm	:	Micrometer
min	:	Minutes
°C	:	Degree centigrade
nm	:	Nanometer
RSD	:	Relative standard deviation
µl	:	Micro liter
HCL	:	Hydrochloric acid
NaoH	:	Sodium Hydroxide
H2O2	:	Hydrogen Peroxide

PROTOCOL	
Title	Analytical Method Verification Dissolution Protocol For Cetirizine Hydrochloride-10mg (Genset-10mg Tablet BP)
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11.0CONCLUSION

12.0REVISION HISTORY

Ver. #	Effective Date	HISTORY OF REVISIONS	
		Reason for change	Summary of change
00			

Report	
Title	Analytical Method Verification Dissolution Report For Genset_10mg (Cetirizine hydrochloride Tablet BP)
Report No.	AMVR/CET/002

ANALYTICAL METHOD VERIFICATION REPORT FOR DISSOLUTION

Site Address: GENERIC HEALTHCARE PRIVATE LIMITED
R.S. No. 4/3, plot No. 33, Kurumbapet Industrial Estate,
Villianur Commune, Pondicherry- 605009

Report	
Title	Analytical Method Verification Dissolution Report For Genset_10mg (Cetirizine hydrochloride Tablet BP)
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1.0 INDEX

Report	
Title	Analytical Method Verification Dissolution Report For Genset_10mg (Cetirizine hydrochloride Tablet BP)
Report No.	AMVR/CET/002

2.0 REPORT APPROVAL SHEET

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Signature	:	AV
Date	:	29/11/2023
Approved By	:	Quality Assurance
Name	:	R. Stephen
Signature	:	
Date	:	29/11/23

Report	
Title	Analytical Method Verification Dissolution Report For Genset_10mg (Cetirizine hydrochloride Tablet BP)
Report No.	AMVR/CET/002

3.0 OBJECTIVE

To verify the method for the test Dissolution of Genset-10mg (Cetirizine hydrochloride tablet BP) by UV.

4.0 GENERAL INFORMATION

METHOD REFERENCE	:	BP 2023
REASON FOR VERIFICATION	:	To verify the Dissolution test for Genset-10mg as per British Pharmacopoeia.

Report	
Title	Analytical Method Verification Dissolution Report For Genset_10mg (Cetirizine hydrochloride Tablet BP)
Report No.	AMVR/CET/002

5.0 DETAILS OF STANDARD, SAMPLES AND PLACEBO TO BE USED

Mention the name and Batch No., Potency of the reference/working std., Impurities Standard, test samples/placebo to be used during Verification (as applicable).

Name of Material	:	ID. No./Batch No./Control No.	:	Potency/ Purity	:	Valid Up to
Standard Cetirizine hydrochloride	:	WS No: WS/CET/003	:	99.60 %	:	14/07/2024
Placebo (If applicable)	:	Not Applicable	:	Not Applicable	:	Not Applicable
Sample Genset-10mg	:	G18231112	:	COA Attached	:	Not Applicable

Report	
Title	Analytical Method Verification Dissolution Report For Genset_10mg (Cetirizine hydrochloride Tablet BP)
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6.0 DETAILS OF INSTRUMENTS/EQUIPMENTS,COLUMN,SOLVENTS AND CHEMICALS TO BE USED:

INSTRUMENTS/EQUIPMENTS:

Ultra-violet spectrophotometer

Make: Shimadzu, Model: UV-1900

Analytical Balance

Make : Shimadzu, Model : AUW220D

pH Meter

Make: Eutech instruments, Model No: pH 700

Solvents and chemicals with grade:

Water (Purified water)

Working standard & Impurities Details

Cetirizine Hydrochloride (Working standard)

Dissolution

Make: Electro lab, Model No: TDT-08L

Report	
Title	Analytical Method Verification Dissolution Report For Genset_10mg (Cetirizine hydrochloride Tablet BP)
Report No.	AMVR/CET/002

7.0 DESCRIPTION OF ANALYTICAL METHOD

Dissolution parameters:

Medium	:	Water
Apparatus	:	Apparatus 2 (paddle)
Volume	:	900 ml
RPM	:	50
Temperature	:	37°C ± 0.5°C
Time	:	45 min

Preparation of Standard Solution:

Weigh accurately about 25 mg of Cetirizine HCl standard into a 100 mL volumetric flask. Add about 20 mL of Water, sonicate to dissolve and make up to volume with Water. Further dilute 2 ml of this solution to 100 ml with water. (Conc.0.005 mg/ml)

Preparation of sample solution:

Place the stated volume of dissolution medium of each vessels of the dissolution apparatus. Warm the dissolution medium at 37°C ± 0.5°C. Transfer 1 tablet in to the vessel. Immediately operate the apparatus at specified speed. At the end of specified time interval, withdraw about required amount of aliquot from each specimen. Filter sufficient quantity of this solution through 0.45micron, Nylon syringe filter, dilute 5 ml of filtrate to 10ml with disso medium.(Conc 0.0055 mg/ml)

Spectrometer condition:

Detection : UV maximum wavelength at 230nm and at 260nm

Path length : 1 cm

System suitability requirement :

% Relative standard deviation for 5 replicate absorbance of standard should not be more than 2.0.

Report	
Title	Analytical Method Verification Dissolution Report For Genset_10mg (Cetirizine hydrochloride Tablet BP)
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1) Calculated the content of Cetirizine hydrochloride by using following formula for 10mg ,

$$= \frac{Au}{As} \times \frac{Ws}{100} \times \frac{2}{100} \times \frac{900}{1} \times \frac{10}{5} \times \frac{P}{100} \times \frac{100}{LC}$$

Where,

Au = Absorbance of Cetirizine HCl obtained from sample solution.
As = Average absorbance of Cetirizine HCl WS obtained from standard solution.
Ws = Weight of Cetirizine HCl working standard in mg
LC = Label claim(10mg)
P = Purity of Cetirizine hydrochloride working standard in %

8.0 PARAMETERS TO BE VERIFIED:

Following parameters shall be selected for Verification	
Sr. No.	**VERIFICATION Parameter**
1.	**Specificity (Selectivity)** i) Interference from Blank and Placebo (as applicable)
2.	**Precision** i) System precision ii) Method precision iii) Intermediate Precision
3.	**Accuracy (Recovery)**
4.	**STABILITY OF ANALYTICAL SOLUTION**
5.	**FILTER PAPER STUDY**

Report	
Title	Analytical Method Verification Dissolution Report For Genset_10mg (Cetirizine hydrochloride Tablet BP)
Report No.	AMVR/CET/002

9.0 DETAILS OF VERIFICATION PARAMETERS

9.1 SPECIFICITY (SELECTIVITY)

Interference from blank and placebo

Study Design:

Blank, standard, placebo and placebo spiked with analyte and sample were analyzed as per the method to examine the interference of blank and placebo with Genset.

System suitability parameters are tabulated in Table 1.

Table 1: System suitability

System Suitability Parameter	Limit	Observed Result
% RSD	NMT 2.0	0.355

Table 2: Specificity

S.No.	Description of solution	230nm	260nm
1	Blank (Diluent)	Nil	Nil
2	Standard preparation	0.166	0.007
3	Placebo	Nil	Nil
4	Placebo+ Cetirizine HCl Working standard	0.200	0.018
5	Sample -1(Genset-10mg)	0.201	0.014

Report	
Title	Analytical Method Verification Dissolution Report For Genset_10mg (Cetirizine hydrochloride Tablet BP)
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Results and Conclusion:

From the Blank and Placebo peaks are not interfere with Genset sample within specified limits. Hence method is selective and specific.

9.2 PRECISION

"The Precision of an analytical procedure express the closeness of the agreement (Degree of factor) between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed condition. Precision may be considered repeatability and reproducibility"

9.2.1 System Precision

Study design:

Six replicate absorbance of standard preparation into the UV system. The absorbance for Genset along with % RSD are tabulated in Table 3.

Acceptance criteria:

% RSD of area of analyte peak in Six replicate standard absorbance should not be more than 2.0.

Table 3: System precision

S.No	Absorbance reading
1	0.154
2	0.154
3	0.154
4	0.155

Report	
Title	Analytical Method Verification Dissolution Report For Genset_10mg (Cetirizine hydrochloride Tablet BP)
Report No.	AMVR/CET/002

5	0.155
6	0.155
Mean	0.155
% RSD	0.355

Results and Conclusion:

The results are well within the acceptance criteria and the % RSD observed for the replicate absorbance indicates the system precision of UV system used.

9.2.2 Method Precision:

Study Design:

Six dissolution unit preparations of sample were analyzed as per the method. The dissolution of Genset is calculated. The results are tabulated in Table 4.

Acceptance criteria:

% RSD for dissolution of six test units should not be more than 5.0.

Table 4: Method precision for Genset

No. of Preparation	% Dissolution of Cetirizine hydrochloride
1	98.84
2	99.43
3	102.96
4	102.37

Report	
Title	Analytical Method Verification Dissolution Report For Genset_10mg (Cetirizine hydrochloride Tablet BP)
Report No.	AMVR/CET/002

5	98.25
6	94.13
Mean	99.33
% RSD	3.21

Results and Conclusion:

The results are well within the acceptance criteria and the % RSD observed for dissolution values indicates the precision of the analytical method.

9.2.3 Intermediate Precision (Ruggedness):

Study summary:

Six dissolution unit preparations of sample are analyzed as per the method by different analyst using different instrument and different column on different day. The dissolution of Cetirizine hydrochloride is calculated. The results are tabulated in Table 5 and cumulative results are tabulated in Table 6.

Acceptance criteria:

1) %RSD for dissolution of six test units should not be more than 5.0.
2) Cumulative % RSD for dissolution of twelve sample preparations of (method and intermediate precision) should not be more than 5.0.

Table 5: Intermediate precision for Cetirizine hydrochloride

Dissolution Jars	Dissolution of Cetirizine hydrochloride
1	99.52

Report	
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Report No.	AMVR/CET/002

2	103.43
3	102.31
4	102.31
5	100.64
6	102.87
Mean	101.85
% RSD	1.45

The Cumulative results of Method Precision and Intermediate Precision are tabulated in Table 6

Table 6: Cumulative % RSD for Cetirizine hydrochloride

Parameter	Dissolution of Cetirizine hydrochloride
Method Precision	98.84
	99.43
	102.96
	102.37
	98.25
	94.13
Intermediate Precision	99.52

Report	
Title	Analytical Method Verification Dissolution Report For Genset_10mg (Cetirizine hydrochloride Tablet BP)
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	103.43
	102.31
	102.31
	100.64
	102.87
Mean	100.59
% RSD	2.69

Result and Conclusion:

The results are well within the acceptance criteria and the % RSD observed for dissolution indicates the precision of the method.

9.3 ACCURACY(RECOVERY)

Study Design:

Known quantity of Cetirizine hydrochloride working standard are spiked with placebo at three different levels (at level of 50%, 100% and 150% of targeted concentration).

Prepared the recovery samples in triplicate for each level and absorbance only one reading for each sample. The samples are analyzed as per the proposed method. The results are tabulated in Table 7 & 8 for Cetirizine hydrochloride respectively to demonstrate the accuracy of the method.

The mean % recovery at each level for Cetirizine hydrochloride should be 95.0 to 105.0.

%RSD for each level and overall RSD should not be more than 5.0%

Report	
Title	Analytical Method Verification Dissolution Report For Genset_10mg (Cetirizine hydrochloride Tablet BP)
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Table 7: Accuracy for Cetirizine hydrochloride

Recovery level	Sample No.	% Recovery	Mean	% RSD
50 %	1	98.93	99.44	1.16
	2	100.76		
	3	98.64		
100 %	1	98.35	97.90	0.56
	2	97.29		
	3	98.06		
150 %	1	98.95	98.47	0.44
	2	98.12		
	3	98.32		
% Overall RSD				0.97

Result and Conclusion:

All the results are well within the acceptance criteria and results indicate that the method is accurate and precise.

Report	
Title	Analytical Method Verification Dissolution Report For Genset_10mg (Cetirizine hydrochloride Tablet BP)
Report No.	AMVR/CET/002

9.4 STABILITY OF ANALYTICAL SOLUTION:

Study design:

Sample solution:

Sample preparation is prepared as per the proposed method and absorbance the system initially and at various time intervals and data tabulated in Table 9.

Table 9: Stability of sample solution for Cetirizine hydrochloride

Time in hours	Average Dissolution % of Sample	Absolute % Difference
Initial	99.33	Not applicable
24	98.14	1.19
48	99.13	0.20

The sample solution shall be considered stable for the final period till which the area difference between initial and next periodic interval should be not more than ±2%.

Results and conclusions:

The Standard solution and Sample solution was stable upto 48 hours at room temperature.

9.5 FILTER PAPER STUDY:

Study design:

The filter paper study of analytical method is performed by filtering test solution through 0.45µm Nylon membrane filter against that of unfiltered centrifuged sample. The results are tabulated in Table 10.

Report	
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Table 10: Filter paper study for Sample solution of Cetirizine Hydrochloride

Filter study	Average Dissolution % of Sample	% difference from unfiltered sample
FILTER SET-II (0.45µm NYLON FILTER)	99.33	Not applicable
FILTER SET-II (0.45µm PVDF FILTER)	99.33	0.00
UNFILTERED SAMPLE (CENTRIFUGED)	99.62	-0.29

Acceptance criteria:

The % difference on filter solution should not differ ± 2.0 against that of unfiltered (centrifuged) sample.

Results and conclusions:

The % difference on filtered sample (0.45 µm Nylon) membrane within limit against that of unfiltered (centrifuged) sample.

Report	
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10.0 ABBREVATION:

mg	:	Milligram
S.No	:	Serial Number
ml	:	Milli liter
%	:	Percentage
ID	:	Identification
API	:	Active pharmaceutical ingredient
HPLC	:	High performance liquid chromatography
B.NO	:	Batch number
mm	:	Millimeter
µm	:	Micrometer
min	:	Minutes
°C	:	Degree centigrade
nm	:	Nanometer
RSD	:	Relative standard deviation
µl	:	Micro liter
HCL	:	Hydrochloric acid
NaoH	:	Sodium Hydroxide
H2O2	:	Hydrogen Peroxide

Report	
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11.0 CONCLUSION:

Verification studies have been conducted for Dissolution of Cetirizine hydrochloride tablets for the parameters of specificity, method precision, Intermediate precision, accuracy and Filter paper study and solution stability by using the proposed method. The data is complied and found satisfactory with the analytical method for all the parameters analysed. Hence it is concluded that the method can be used for regular analysis.

12.0 REVISION HISTORY

Ver. #	Effective Date	HISTORY OF REVISIONS	
		Reason for change	Summary of change
00	24.01.2024	New Report prepared.	New Report prepared