



AUROCHEM LABORATORIES (INDIA) PVT. LTD.

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WORKING STANDARD REPORT

Preparation Date	10/10/2017	Valid upto	10/10/2018
Manufacturer	Vaikunth Chemicals Pvt Ltd	Page no	1/1
Item Name	CETIRIZINE HYDROCHLORIDE BP	Mfg. Date	Oct 2015
Batch No	15 CTH 077	Exp. Date	Sep 2019
Storage condition	Store below 25°C	Quantity	500 mg
TEST		OBSERVATIONS	STANDARD
01.	Description	White powder,	White or Almost-white, powder.
02.	Solubility	Freely soluble in water, practically insoluble in acetone and in methylene chloride	Freely soluble in water, practically insoluble in acetone and in methylene chloride
03.	Identification		
A)	Light Absorption	0.366	Maxima at 231 nm : 0.359 to 0.381
B)	IR :	The Infrared absorption spectrum of substance is concordant with the IR spectrum obtained from Cetirizine Hydrochloride working standard.	The Infrared absorption spectrum of substance being examined should concordant with the IR spectrum obtained from Cetirizine Hydrochloride working standard.
C)		The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with reference solution.	The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with reference solution.
D)		A curdled, white precipitate is formed.	A curdled, white precipitate should formed.
04.	Appearance of solution	Solution S is clear and not more intensely coloured than reference solution BY7	Solution S is clear and not more intensely coloured than reference solution BY7
05.	pH	1.36	1.2 to 1.8
06.	Related Substances		
	Impurities A, B, C, D, E, F	Less than 0.15%	Not more than 0.15%
	Unspecified Impurity	Less than 0.10%	Not more than 0.10%
	Total Impurity	Less than 0.3 %	Not more than 0.3%
07.	Loss on drying	0.12%	Maximum 0.5 %
08.	Sulfated ash	0.05%	Maximum 0.2 %
09.	Assay : $C_{21}H_{25}ClN_2O_3 \cdot 2HCl$	99.19% on as such basis 99.31% on dried basis	99.0% to 100.5% on dried basis

In the opinion of undersigned the sample referred to above IS OF STANDARD QUALITY as defined in the Act and Rules made thereunder in above respect, as per BP & can be used as Working Standard.

ANALYSED BY	CHECKED BY
 10/10/2017	 10/10/2017



C7-2