WPS-02-6

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CERTIFICATE OF ANALYSIS
(Working Standard)

Name of the sample	OLOPATADINE HYDROCHLORIDE USP		
Lot Number	WS/O-05.14		
Date of analysis	Oct 10, 2014	**Date of retest**	Oct 09, 2015

Sr. No.	Test(s)	Specification(s)	Result(s)
01.	Description	White crystalline powder.	White crystalline powder. Complies
02.	Solubility	Very soluble in formic acid; sparingly soluble in water; very slightly soluble in dehydrated alcohol	Complies
03.	Identification A. Infrared Absorption	The infrared absorption spectrum of the preparation of test sample exhibits maxima only at the same wavelengths as that of a similar preparation of USP Olopatadine Hydrochloride reference standard / working standard.	Positive
	B. HPLC	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay	Positive
	C. Chlorides	A white, curdy precipitate that is insoluble in nitric acid but is soluble in a slight excess of 6N ammonium hydroxide	Positive
04.	Organic Impurities α-Hydroxy Olopatadine Olopatadine *E*-isomer Any other individual Impurity Total impurities	 Not more than 0.2% Not more than 0.1% Not more than 0.1% Not more than 0.25%	 0.034% Not detected 0.033% 0.095%
05.	pH	Between 2.0 and 4.0	2.61
06.	Loss on drying	Not more than 0.3%	0.21%
07.	Assay	Not less than 98.0% and not more than 102.0% of $C_{21}H_{23}NO_3 \cdot HCl$, calculated on the dried basis	99.6%

Remarks : The working standard of Olopatadine Hydrochloride WS/O-05.14, evaluated against reference standard F0J014, complies as per USP specification.

Prepared By	Checked By	Approved By
Analyst Jayashree Ghatkar Date: Oct 10, 2014	Sr. Manager Mr. Vijay Shetty Date: Oct 10, 2014	Sr. General Manager Dr. Dhanraj Amin Date: Oct 10, 2014

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AUTHORISED C. O. A.
Sign Apr 22, 2015