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MALLADI

DRUGS & PHARMACEUTICALS LIMITED, UNIT-3

Factory : Plot No. 7B & 7C, SIPCOT Industrial Complex,
Ranipet, Vellore Dist. Tamil Nadu. Pin - 632 403.
Ph. : 91-4172-244290 / 244653 Fax : 91-4172-244853



CERTIFICATE OF ANALYSIS

1. Name of the Product : Pseudoephedrine Hydrochloride USP
2. Batch No : 503416
3. Quantity : 1000 Kg
4. Date of Manufacture : Mar 2016
5. Retest Date : Feb 2021

S.No.	TEST	RESULT	LIMIT
1.	Description	Fine, White crystalline powder, having a faint characteristic odour.	Fine, white to off-white crystals or powder, having a faint characteristic odour.
2.	Solubility	Very soluble in water, freely soluble in alcohol, slightly soluble in chloroform	Very soluble in water, freely soluble in alcohol, slightly soluble in chloroform
3.	Identification. A. Infrared absorption	Complies with standard spectrum.	The Infrared absorption spectrum of the preparation of the test specimen exhibits maxima only at the same wavelengths as that of a similar preparation of the working standard.
	B. Chloride	Passes the test	A solution of it responds to the tests for chloride
4.	Melting range or temperature Class I	183°C to 184°C	Between 182°C and 186°C, but the range between beginning and end of melting does not exceed 2°C
5.	Optical rotation at 25°C	+61.8°	Between +61.0° and +62.5°
6.	pH	5.2	Between 4.6 and 6.0
7.	Loss on drying	0.17%	Not more than 0.50%
8.	Residue on Ignition	0.05%	Not more than 0.10%
9.	Assay by HPLC	99.4%	Not less than 98.0% and Not more than 102.0% of $C_{10}H_{15}NO.HCl$ calculated on dried basis
10	Organic impurities by HPLC a) Sum of Impurities	0.01%	Not more than 2.0%

Prepared by
R. Suresh - Q.C
Date: Mar 29, 2016

Checked by
V. Jeevarajan - Q.A
Date: Mar 29, 2016

Approved by
P. Kumaran - In-charge Q.C
Date: Mar 29, 2016

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Datum/Visum: 11 April 2016

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S.No.	TEST	RESULT	LIMIT
11	Residual solvents * (In-house) A. Methanol B. Acetone C. Toluene	Not detected 186ppm 2ppm	Not more than 100ppm Not more than 500ppm Not more than 150ppm
12.	Particle size (In-House)	100%	Not less than 99% w/w should pass through ASTM sieve#20

*Other solvents are not used or known to be produced during manufacture or purification processes.

Status: The sample referred above COMPLIES with USP 38 and In-house specification

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