



MALLADI

DRUGS & PHARMACEUTICALS LIMITED

UNIT - 3

Factory: Plot No. 78 & 7C, SIPCOT Industrial Comptex, Ranipet, Vellore Dist. Tamil Nadu. Pin - 632 403. \$2:91-4172-244290 / 244653 Fax: 91-4172-244853

CERTIFICATE OF ANALYSIS

1. Name of the Product

Pseudoephedrine Hydrochloride BP/EP

Batch No.
 Quantity

513518

Quantity
 Date of Manufacture

1000 Kg Nov 2018

5. Retest Date

Oct 2023

S.No.	TEST	RESULT	LIMIT
1.	Characters a. Appearance	White crystalline powder.	White or almost white crystalline powder or colourless crystals.
	b. Solubility	Freely soluble in water and in ethanol (96%), sparingly soluble in methylene chloride.	Freely soluble in water and in ethanol (96%), sparingly soluble in methylene chloride.
	c. Melting point	184°C	It melts at about 184°C
2.	Identification A. Specific optical Rotation	Sample passes optical rotation	It complies with the test for specific optical rotation.
	B. [R D. Chloride	Sample spectrum matches with the standard spectrum Passes the test	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. Solution S gives reaction (a) of
			chlorides
3.	Appearance of solution	Solution S is clear and colourless	Solution S is clear and colourless
4.	Acidity or Alkalinity	Passes the test	Dilute 2ml of solution S to 10ml with carbon di- oxide free water R. Add 0.1ml of methyl red solution R

Prepared by S. Malathi – Q.C Date: Nov 21, 2018 Checked by K. Karthi - Q.A Date: Nov 21, 2018

Approved by
I. Charles -In- charge Q.C

and 0.1ml of 0.01M sodium hydroxide; the solution is yellow. Add 0.2ml of 0.01M hydrochloric

acid; the solution is red

Date: Nov 21, 2018

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(10) 2011



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3. Quantity $1000\,\mathrm{Kg}$

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S.No	TEST	RESULT	LIMIT
5.	Specific optical rotation (On dried basis)	+62.0°	Between +61.0° and +62.5°
6.	Related substances*	3730	
	A. Impurity A B. Any other impurity C. Sum of impurities	Below disregard limit Below disregard limit	Not more than 0.10% Not more than 0.10%
	other than impurity A	Below disregard limit	Not more than 0.50%
7.	Loss on drying	0.22%	Not more than 0.50%
8.	Sulphated ash	0.04%	Not more than 0.10%
9.	Assay (On dried basis)	99.9%	99.0% to 101.0%
10.	Residual solvents ** (In-house)		
	A. Methanol	7ppm	Not more than 100ppm
	B. Acetone C. Toluene	304ppm	Not more than 500ppm
	C. TOTUCHE	1ppm	Not more than 150ppm

^{*}Below disregard limit is 0.05% for impurity A and Any other impurity

Status: The sample referred above COMPLIES with BP 2018, EP 9.0 and In-house specification

Prepared by S. Malathi - Q.C Date: Nov 21, 2018

Checked by K. Karthi - Q.A Date: Nov 21, 2018 Approved by

I. Charles -In- charge Q.C

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