



1P04000029

MALLADI

DRUGS & PHARMACEUTICALS LIMITED

UNIT - 3

Factory : Plot No. 7B & 7C, SIPCOT Industrial Complex,
Ranipet, Vellore Dist. Tamil Nadu. Pin - 632 403.

☎ : 91-4172-244290 / 244653 Fax : 91-4172-244853

CERTIFICATE OF ANALYSIS

1. Name of the Product : Pseudoephedrine Hydrochloride BP/EP
2. Batch No. : 513518
3. Quantity : 1000 Kg
4. Date of Manufacture : Nov 2018
5. Retest Date : Oct 2023

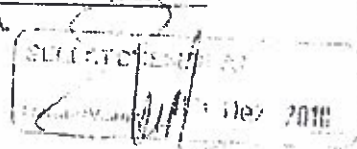
S.No.	TEST	RESULT	LIMIT
1.	Characters		
	a. Appearance	White crystalline powder.	White or almost white crystalline powder or colourless crystals.
	b. Solubility	Freely soluble in water and in ethanol (96%), sparingly soluble in methylene chloride.	Freely soluble in water and in ethanol (96%), sparingly 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. IR	Sample spectrum matches with the 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.
	D. Chloride	Passes the test	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 and 0.1ml of 0.01M sodium hydroxide; the solution is yellow. Add 0.2ml of 0.01M hydrochloric acid; the solution is red

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
Date: Nov 21, 2018

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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*		
	A. Impurity A	Below disregard limit	Not more than 0.10%
	B. Any other impurity	Below disregard limit	Not more than 0.10%
	C. Sum of impurities 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	304ppm	Not more than 500ppm
	C. Toluene	1ppm	Not more than 150ppm

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

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

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

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