

1902000131

Location: CTO Unit: VI

Dr.Reddy's

CERTIFICATE OF ANALYSIS

Product Name	: NARATRIPTAN HYDROCHLORIDE	Specification No.	: S-08-NH-USP/05
Batch No.	: AFL11008837		: #S-08-NH-IH-01/00
Batch Quantity	: 2.680 Kg	Date of Manufacture	: November-2018
A.R.No.	: 040001128432	Retest Date	: October-2023
Reference	: USP	Version No.	: 00
Customer Name	: Laboratorio Chile S.A.	Date of Analysis	: 16 th January 2019
Storage conditions	Preserve in tight containers at 25°C (77°F) Excursions allowed between 15°C and 30°C (59° and 86°F)		
S.No.	Test	Specification	Result
1.0	Description	White to pale yellow solid	Pale yellow solid
2.0	Identification		
2.1	By IR	The absorption maxima in the spectrum obtained with the sample preparation, correspond in position and relative intensity to those in the spectrum obtained with a similar preparation of standard.	Matches with standard spectrum
2.2	By HPLC	The retention time of the major peak of the sample corresponds to that of the retention time of the standard.	Complies
2.3	Test for Chlorides	To respond to the test for chlorides	Complies
3.0	Solubility	Freely soluble in DMSO; Slightly soluble in Methanol, and Sparingly soluble in water	Complies
4.0	Water by KF	Not more than 0.50%w/w	0.09% w/w
5.0	Residue on ignition	Not more than 0.10% w/w	0.06% w/w
6.0	Heavy metals	Not more than 0.002%	Less than 0.002%
7.0	Related substances by HPLC		
	Impurity-1 at RRT 0.96	Not more than 0.15%	Less than LOQ(0.04%)
	Impurity-2 at RRT 1.12	Not more than 0.15%	Not detected
	Impurity-3 at RRT 1.18	Not more than 0.15%	0.03%
	Any unknown individual impurity	Not more than 0.10%	0.02%
	Total impurities	Not more than 1.0%	0.06%
8.0	Assay by HPLC (on anhydrous and solvent free basis)	Not less than 98.0%w/w and Not more than 101.0%w/w	99.3% w/w
9.0	Hydrochloric acid content by potentiometric titration (On anhydrous basis)	Not less than 9.6%w/w and Not more than 10.0%w/w	9.8 % w/w
10.0	Residual solvents by GC		
	Methanol	Not more than 1000 ppm	Below Limit of Detection(8.3 ppm)
	Dichloromethane	Not more than 300 ppm	Not detected
	Ethyl Acetate	Not more than 500 ppm	Not detected
	Toluene	Not more than 500 ppm	Not detected
*11.0	Particle size by malvern		
	d(0.1)	Not more than 10 µm	1 µm
	d(0.5)	Not more than 30 µm	8 µm
	d(0.9)	Not more than 80 µm	18 µm

The product conforms to above specification * Customer requirement # Particle size by malvern method reference

Impurity-1 : 1,1-dimethyl-4-[5-(2-methyl sulfamoyl ethyl)-1H-3-indolyl] hexahydro pyridinium chloride.

Impurity-2: 3-(1-methyl-4-piperidyl)-5-methyl Sulfamoyl ethyl-1H-2-indole carboxylic acid mono hydrochloride

Impurity-3 : 1-methyl-4-[5-(2-methyl sulfamoyl ethyl)-1H-3-indolyl]-hexahydro-1-pyridinium salt

Compiled By :

Checked By :

Approved By :

Date :

Date :

Date :

Address: Factory : Dr.Reddy's Laboratories Ltd., CTO Unit-VI, APIC Industrial Estate, I.D.A., Pydibhimasaram,

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