

12/07/2024

Ipca Laboratories Limited

QUALITY ASSURANCE DEPARTMENT

CERTIFICATE OF ANALYSIS

Product : NIFEDIPINE Ph.Eur
 Batch No. : 23011NFD1RA
 Mfg Date : MAY.2023
 Re-Test Date : APR.2028
 Batch Size : 474.500 Kg
 Qty. for Dispatch : 5.000 Kg

Control No. : FP/00274/23
 Date of Analysis : 06/06/2023
 Analysed As per : Ph.Eur
 Specification No : TS/API/NFD/COS
 Date of Report : 07/06/2024

Sr.No	TEST	RESULTS	LIMITS
1.	Description Appearance Solubility	Yellow crystalline powder Complies	Yellow crystalline powder. Practically insoluble in water, freely soluble in acetone, sparingly soluble in anhydrous ethanol
2	Identification By IR Spectrum	Complies	Infrared Absorption spectrum of sample and standard are concordant.
3.	Impurity D and other basic impurities	0.07 ml	Not more than 0.48 ml of 0.1 M Perchloric acid is required (0.14%)
4.	Related substances (by HPLC)		
	Impurity A	Not detected	Not more than 0.10%
	Impurity B	0.01%	Not more than 0.10%
	Impurity C	Not detected	Not more than 0.10%
	Any Unspecified impurity	0.01 %	Not more than 0.10%
	Total impurities	0.05 %	Not more than 0.30%
5.	Loss on drying (at 105°C for 2 h)	0.21 %w/w	Not more than 0.5% w/w
6.	Sulphated Ash	0.06 % w/w	Not more than 0.1% w/w
7	Assay	99.8 % w/w	98.0% to 102.0% of $C_{17}H_{18}N_2O_6$ (Dried substance)
8	Residual Solvent Methanol	235 ppm	Not more than 3000 ppm
9.	2-Nitrobenzaldehyde content	< 2.1 ppm	Not more than 8 ppm

Remarks: Conforms to Ph.Eur Specification TS/API/NFD/COS, Ver.No.6.0

Analyst


 07/06/2024

Reviewed By QA

Sign / Date


 07/06/2024

 Approved by
 Pinal Shah
 Manager Q.C


 07/06/2024

Ipca Laboratories Ltd.

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