Ipca Laboratories Limited

QUALITY ASSURANCE DEPARTMENT

CERTIFICATE OF ANALYSIS

Product : NIFEDIPINE Ph.Eur
Batch No. : 21019NFD1RA
Mfg Date : JUL.2021
Re-Test Date : JUN.2026
Batch Size : 457.000 Kg
Qty.for Dispatch : 1.000 Kg

Control No. : FP/00119/21
Date of Analysis : 31/07/2021
Analysed As per : Ph.Eur
Specification No : TS/BPC/NFD/CS/COS
Date of Report : 27/03/2023

Sr.No	TEST	RESULTS	LIMITS
1.	Description Appearance	Yellow crystalline powder	Yellow crystalline powder.
	Solubility	Complies	Practically insoluble in water, freely soluble in acetone, sparingly soluble in ethanol
2	Identification		
	By IR Spectrum	Complies	Infrared Absorption spectrum of sample and standard are concordant.
3.	Impurity D and other basic impurities	0.08 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	Not detected	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	0.04 %	Not more than 0.30%
5.	Loss on drying (at 105°C for 2 h)	0.20 %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	99.3 % w/w	98.0% to 102.0% of $C_{17}H_{18}N_2O_6$ (On dried substance)
8	Residual Solvent Methanol	1042 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/BPC/NFD/CS/COS

Analyst 27/03/2023

Approved by
Pinal Shah
Manager Q.C 27/03/2023

Reviewed By QA
Sign / Date 27/03/2023

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