

Ipca Laboratories Limited

QUALITY ASSURANCE DEPARTMENT

CERTIFICATE OF ANALYSIS

Product : NIFEDIPINE Ph.Eur	Control No. : FP/00119/21
Batch No. : 21019NFD1RA	Date of Analysis : 31/07/2021
Mfg Date : JUL.2021	Analysed As per : Ph.Eur
Re-Test Date : JUN.2026	Specification No : TS/BPC/NFD/CS/COS
Batch Size : 457.000 Kg	Date of Report : 08/05/2023
Qty. for Dispatch : 3.000 Kg	

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	ND	Not more than 0.10%
	Impurity B	ND	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 ₂ O 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

08/05/2023

Approved by
Pinal Shah
Manager Q.C

08/05/2023

Reviewed By QA

Sign / Date.....

08/05/2023

Ipca Laboratories Ltd.

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