

METAPHARMACEUTICAL

N DE LOTE:

0180625



11/06/2025

Ipca Laboratories Limited

QUALITY ASSURANCE DEPARTMENT

CERTIFICATE OF ANALYSIS

Product : NIFEDIPINE Ph.Eur
Batch No. : 24010NFD1RA
Mfg Date : AUG.2024
Re-Test Date : JULY.2029
Batch Size : 455.120 Kg
Qty. for Dispatch : 10.000 Kg

Control No. : FP/00362/24
Date of Analysis : 23/08/2024
Analysed As per : Ph.Eur
Specification No : TS/API/NFD/COS
Date of Report : 01/05/2025

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 anhydrous ethanol
2	Identification		
	By IR Spectrum	Complies	Infrared Absorption spectrum of sample and standard are concordant.
3.	Impurity D and other basic impurities	0.28 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)	0.21 %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	99.3 % w/w	98.0% to 102.0% of C ₁₇ H ₁₈ N ₂ O ₆ (Dried substance)
8	Residual Solvent Methanol	499 ppm	Not more than 3000 ppm
9.	2-Nitrobenzaldehyde content	Not detected	Not more than 8 ppm

Remarks: Conforms to Ph.Eur Specification TSAPI/NFD/COS Ver 6.0

Analyst

01/05/2025

Approved by

Pinal Shah

Manager Q.C.

01/05/2025

Reviewed By QA

Sign / Date

01/05/2025

Ipca Laboratories Ltd.

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