



TEMAD CO.
(ACTIVE PHARMACEUTICAL INGREDIENTS)
Quality Control Department
Certificate of Analysis

METAPHARMACEUTICAL

N DE LOTE:

0060825

[Signature]
07/08/2025

Product Name: Naltrexone Hydrochloride API (EP)		
Lab No.: AV.3.115	Batch No.: NAH4030802	Analysis Date: 8 Jun. 2025
Mfg. Date: 26 May 2025	Exp. Date: 26 May 2030	QC Code: 66647
Methods Reference: EP11.0		
Packaging and Storage: In an airtight container. Protected from light.		

Tests	Specification	Results	Pass✓ / Fail✗
Appearance	white or almost white powder, very hygroscopic.	Conforms	✓
Solubility	Freely soluble in water, slightly soluble in ethanol (96 per cent), practically insoluble in methylene chloride.	Conforms	✓
Identification	A: IR Infrared absorption spectrophotometry	Conforms	✓
	B: It gives reaction (a) of chlorides.	Conforms	✓
Appearance of solution	Solution S is clear and not more intensely coloured than reference solution Y ₆ or B ₆ .	Conforms	✓
Acidity or alkalinity	Not more than 0.2 mL of 0.02 M sodium hydroxide or 0.02 M hydrochloric acid is required to change the colour of the indicator.	Conforms	✓
Specific Optical rotation	-187 to -195 (anhydrous substance)	-189	✓
Related substances	Impurity C:	Not more than 0.2%	0.1 % ✓
	Impurity D:	Not more than 0.2%	0.1 % ✓
	Impurity E:	Not more than 0.2%	0.15% ✓
	Impurity F:	Not more than 0.2%	0.01 % ✓
	Impurity G:	Not more than 0.2%	Not detected ✓
	Impurity A:	Not more than 0.1%	Not detected ✓
	Impurity B:	Not more than 0.1%	Not detected ✓
	Impurity H:	Not more than 0.1%	Not detected ✓
	Impurity I:	Not more than 0.1%	Not detected ✓
	Impurity J:	Not more than 0.1%	Not detected ✓
	Any other impurities:	Not more than 0.1%	0.03 % ✓
	Total:	Not more than 1.0%	0.5 % ✓
Ethanol	Maximum 3.0%	0.35 %	✓
Water	Maximum 10.0%	1.3 %	✓
Sulfated ash	Maximum 0.1%	0.06 %	✓
Assay	98.0 per cent to 102.0 per cent (anhydrous substance).	100.2 %	✓
Residual solvents	DMF	Not more than 880 ppm	Not detected ✓
	Chloroform	Not more than 60 ppm	Not detected ✓

Analyzed by: M. Hosseini Q.C. Expert	Approved by: Dr. S. Dini Q.C. Manager	Authorized by: Dr. M. Ramin Qualified Person	Approved <input checked="" type="checkbox"/>
Date:	Date:	Date:	Rejected <input type="checkbox"/>
			Hold <input type="checkbox"/>