

QUALITY DIVISION
CERTIFICATE OF ANALYSIS

NAME OF THE PRODUCT : PROPRANOLOL HYDROCHLORIDE Ph. Eur.			
BATCH No.	: 24116PRRII	BATCH SIZE	: 579.50 Kgs.
MFG. DATE	: Oct. 2024	A.R. No.	: IBD - 244439
EXP. DATE	: Sep. 2029	DATE	: 09/11/2024
SPECIFICATION No. / REV. No.		: TS/API/PR/COS / 4.0	
CUSTOMER NAME / ITEM CODE		: NA	

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS	Appearance : A white or almost white powder.	White powder
	Solubility : Soluble in water and in ethanol (96%), practically insoluble in heptane	Conforms
IDENTIFICATION	1) Infrared absorption spectrum of sample and standard are concordant.	Conforms
	2) Conforms by reaction (a) of chlorides.	Conforms
APPEARANCE OF SOLUTION	The solution is clear and not more intensely coloured than intensity 6 of the range of reference solutions of the most appropriate colour.	Conforms
ACIDITY OR ALKALINITY	The solution is red. Add 0.4 ml of 0.01 M sodium hydroxide. The solution is yellow.	Conforms
RELATED SUBSTANCES (By HPLC)	Impurity A : NMT 0.10% Impurity B : NMT 0.10% Impurity C : NMT 0.10% Any Unspecified Impurity : NMT 0.10% Total Impurities : NMT 0.20%	BQL BQL Not Detected BDL BQL
LOSS ON DRYING (at 105°C)	NMT 0.5% w/w	0.26% w/w
SULPHATED ASH	NMT 0.1% w/w	0.07% w/w
ASSAY (By Titration)	99.0% - 101.0% of $C_{16}H_{22}ClNO_2$ (on dried basis)	99.9% (odb)
N-NITROSOPROPRANOLOL (By LC-MS/MS)	NMT 2.34 ppm	0.04 ppm
REMARKS : The above sample CONFORMS as per CEP 2002-026 - Rev 06 Specifications.		

Note : BDL - Below Detection Limit
BQL - Below Quantitation Limit

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METAPHARMACEUTICAL

N DE LOTE:

0960125



PREPARED BY

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MANAGER QUALITY CONTROL

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