



Kopran

Certificate Of Analysis ATENOLOL EP

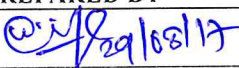
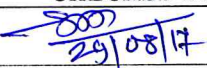
BATCH No. : ALU/P1707012	ANALYTICAL REPORT No.	MFG. DATE : JUL.2017
DISPATCH QTY. : 425.00 Kg	FPPA/170739	EXP.DATE : JUN.2022

SR. No.	TESTS	RESULTS	SPECIFICATIONS
1	APPEARANCE	A white powder	White or almost white powder
2	SOLUBILITY	Complies	Sparingly soluble in water, soluble in ethanol, slightly soluble in methylene chloride.
3	IDENTIFICATION	A. M. P. : 153.8°C B. UV abs. R : 1.17 C. IR : Complies D. TLC : Complies	A) Melting range: 152 to 155°C B) By UV (Ratio of absorbance between 1.15 to 1.20) C) By I.R. D) By TLC
4	APPEARANCE OF SOLUTION	Clear and not more intensely coloured than degree 6	Solution S is clear & not more intensely coloured than degree 6 of the range of reference solutions of the most appropriate colour
5	OPTICAL ROTATION at 20°C	+0.005°	+0.10° TO -0.10°
6	RELATED SUBSTANCES 1) Impurity B 2) Impurity F 3) Impurity G 4) Impurity I 5) Impurity J 6) Unspecified Impurity 7) Total Impurities	0.11 % BDL BDL BDL BDL BDL 0.11 %	NMT 0.2%w/w NMT 0.15%w/w NMT 0.15%w/w NMT 0.15%w/w NMT 0.15%w/w NMT 0.10%w/w NMT 0.5%w/w
7	CHLORIDE	Complies	NMT 0.1 % w/w
8	SULPHATED ASH	0.07 %	NMT 0.1 % w/w
9	LOSS ON DRYING	0.31 %	NMT 0.5 % w/w
10	ASSAY ON DRIED BASIS	100.03 %	99.0 % to 101.0 % of C ₁₄ H ₂₂ N ₂ O ₃
11	ADDITIONAL TESTS		
11.1	BULK DENSITY 1. Tapped 2. Untapped	0.51 g/cc 0.34 g/cc	Informative Informative
11.2	PARTICLE SIZE BY (Sieve Test)	Complies	100% Below 375µm

THIS PRODUCT CONFORMS TO EP

DATE: 29/08/2017

This batch is in conformity with Pharm Eur & provisions of certificate of suitability R1-CEP 1998-017-Rev 05
Granted to Kopran.

PREPARED BY	CHECKED BY	APPROVED BY
 V.K. Ghadge Sr. Executive - QA	 M. G. Sutar Manager - QC	 P. M. Sheth Sr. Manager - QC

Date of Sampling – 20th July 2017

Date of Analysis – 21st July 2017



KOPRAN RESEARCH LABORATORIES LIMITED

K-4/4, Additional MIDC, At/Post : Birwadi, Tal : Mahad, Dist : Raigad, Pin 402 302, Maharashtra - India.
Tel.: (02145) 251101 - 04 • Fax.: (02145)251100. CIN - U24230 MH 1986 PLC 040601.

Registered Office : Parijat House, 1076, Dr. E. Moses Road, Worli, Mumbai - 400 018. P.B.No.: 9917
Tel.: (022) 4266 4444 • Fax.: (022) 2405 0362 Website: www.kopran.com