

Sparxle

Atenolol



Certificate Of Analysis
ATENOLOL EP

Kopran

BATCH No.	ALU/P1404010	ANALYTICAL REPORT No.	MFG. DATE : APR. 2014
DISPATCH QTY.	: 10.00 kg	FPPA/140340	EXP. DATE : MAR. 2019

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. : 153.7°C B. UV abs. R : 1.18 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	ANGLE OF OPTICAL ROTATION	+0.0042°	+0.10° TO -0.10°
6	RELATED SUBSTANCES 1) Impurity B 2) Impurity F 3) Impurity G 4) Impurity I 5) Unspecified Impurity 6) Total Impurities	0.14 % 0.07 % Not Detected Not Detected 0.07 % 0.33 %	NMT 0.2%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	0.08 %	NMT 0.1 % w/w
9	LOSS ON DRYING	0.39 %	NMT 0.5 % w/w
10	ASSAY ON DRIED BASIS	99.37 %	99.0 % to 101.0 % of C ₁₄ H ₂₂ N ₂ O ₃

THIS PRODUCT CONFORMS TO EP

DATE: 16/05/2014

This batch is in conformity with Phann Eur & provisions of certificate of suitability RI-CEP 1998-017-Rev 03 granted to Kopran..

We hereby certify that we do not use organic solvent in our manufacturing process of Atenolol. Hence the residual solvent test is not performed.

PREPARED BY	CHECKED BY	APPROVED BY
S. D. Kamerkar Officer - QA	M. G. Sutar Asst. Manager - QC	Samir S. Sumbhe Manager - QA/QC

C. O. A. issued to : M/s. ACETO BV, THE NETHE

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CIN No. : L24230MH1958PLC011C

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Corresponde al lote de FAGRON:

14E 23-801

Director Técnico