

Certificate Of Analysis

ATENOLOL EP

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BATCH No. : AL/P1211222	ANALYTICAL REPORT No. FPPA/120692	MFG. DATE : NOV - 2012
BATCH QTY : 660.00 Kg		EXP. DATE : OCT - 2017

SR No.	TESTS	RESULTS	SPECIFICATIONS
1	DESCRIPTION	Almost 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 O. UV abs. R : 1.19 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	Complies	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	+0.0012°	+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 % Not Detected 0.08 % Not Detected 0.05 % 0.27 %	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	0.34 %	NMT 0.5 % w/w
10	ASSAY ON DRIED BASIS	99.33 %	99.0 % to 101.0 % of C ₁₄ H ₂₂ N ₂ O ₃

THIS PRODUCT CONFORMS TO EP

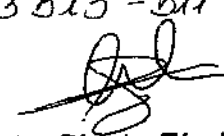
DATE : 11/01/2013

PREPARED BY	CHECKED BY	APPROVED BY
 11/01/13 D. S. Pangarkar Officer - QA	 11/01/13 P. M. Sheth Manager - QC	 11/01/13 P. Anand Kumar Sr. Manager - QA

C. O. A. issued to : Aceto BV Netherland.

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

13 B13 - B11


26.9.13 Director Técnico S.



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