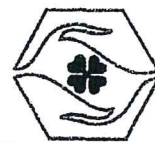


FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

15116-BU

Director Técnico

Certificate Of Analysis ATENOLOL EP



Kopran

BATCH No. : AL/P1508131	ANALYTICAL REPORT No.	MFG. DATE : AUG.2015
DISPATCH QTY. : 10.00 Kg	FPPA/150750	EXP. DATE : JUL.2020

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	-0.010°	+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	0.17 % 0.07 % BDL BDL 0.08 % 0.32 %	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	0.26 %	NMT 0.5 % w/w
10	ASSAY ON DRIED BASIS	99.86 %	99.0 % to 101.0 % of C ₁₄ H ₂₂ N ₂ O ₃
11	ADDITIONAL TEST		
11.1	RESIDUAL SOLVENT'S 1. METHANOL	Not Detected	NMT 1000ppm

THIS PRODUCT CONFORMS TO EP 8

DATE: 28/08/2015

PREPARED BY	CHECKED BY	APPROVED BY
28/08/15	28/08/15	28/08/15
S. D. Kamerkar	M. G. Sutar	P. M. Shteh
Sr. Officer - QA	Asst. Manager - QC	Sr. Manager - QC

C. O. A. issued to: M/s. Polydrug Laboratories P. Ltd.



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