



Ipca Laboratories Limited

A-1/7 & A-1/8, Phase-1, GIDC, Vapi-396195. Tel: +91-260-2401593
 Tele fax: +91-260-2433097 E-mail: avikpharma@avikpharma.com

CERTIFICATE OF ANALYSIS

Name of Product : Triamcinolone Acetonide EP		Batch Size : 21630 gm
Batch No. : TMCA/M/038/14		A. R. No. : AVK/TMCA/126/14
Mfg. Date : Aug-2014		Date : 11/09/2014
Exp. Date : Jul-2018		
TESTS	SPECIFICATIONS	RESULTS
CHARACTERS		
Appearance	White or almost white crystalline powder.	Almost White crystalline powder
Solubility	Practically insoluble in water; sparingly soluble in ethanol (96 %).	Conforms
IDENTIFICATION	A) By IR: IR spectra of the sample are concordant to that of the standard. B) By TLC: The principal spot in the chromatogram obtained with test solution is similar in position and size to the principal spot in the chromatogram obtained with reference solution (a). C) By HPLC: The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the chromatogram obtained with reference solution (c). D) The test solution is yellow and the blank is red.	Conforms Conforms Conforms Conforms
SPECIFIC OPTICAL ROTATION	+ 110° to + 117° on anhydrous substance.	+115°
RELATED SUBSTANCES (BY HPLC)	Impurity- B : NMT 0.20 % Impurity- C : NMT 0.15 % Unspecified Impurity : NMT 0.10 % Total Impurities : NMT 0.50 %	0.18% ND 0.03% 0.21%
WATER	Maximum 2.0 %	1.6 %
ASSAY (BY HPLC)	97.5 % to 102.0 % on anhydrous substance.	99.8 %
ADDITIONAL TESTS		
Residual solvents	Methanol : NMT 3000 ppm Acetone : NMT 5000 ppm Methylene chloride: NMT 600 ppm	2301 ppm 27 ppm 342 ppm
B). Particle size (By Volume Basis)	70 % < 10 µ 99 % < 15 µ	5.02 µ 12.19 µ
REMARKS: The Product CONFORMS as per EP 8.0 / Party's Specifications.		
PREPARED BY NAME: <i>Hetal J. Desai</i> DESIGNATION: <i>S.E. Officer</i> DATE: <i>24/09/2014</i>	CHECKED BY NAME: <i>Mahesh D. Desai</i> DESIGNATION: <i>Asst Manager</i> DATE: <i>24/09/2014</i>	APPROVED BY NAME: <i>Vinod J. Patel</i> DESIGNATION: <i>P. A. Manager</i> DATE: <i>24/09/2014</i>