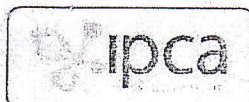


Lot: 0101214



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CERTIFICATE OF ANALYSIS

Name of Product : Triamcinolone Acetonide EP	
Batch No. : TMCA/M/038/14	Batch Size : 21630 gm
Mfg. Date : Aug-2014	A. R. No. : AVK/TMCA/126/14
Exp. Date : Jul-2018	Date : 11/09/2014

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: Hitesh J. Desai DESIGNATION: S.E. 0185022 DATE: 24/09/2014	 CHECKED BY NAME: Mahesh D. Desai DESIGNATION: Asst Manager DATE: 24/09/2014	 APPROVED BY NAME: Vinod J. Patel DESIGNATION: P. A. Manager DATE: 24/09/2014
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