



Ipca Laboratories Limited

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CERTIFICATE OF ANALYSIS

Name of Product: Triamcinolone-Acetonide EP		
Batch No. : TMCA/M/024/13		Batch Size : 32200 gm
Mfg. Date : Jun-2013		A. R. No. : AVK/TMCA/089/13
Exp. Date : May-2017		Date : 01/07/2013
TESTS	SPECIFICATIONS	RESULTS
CHARACTERS		
Appearance	White or almost white crystalline powder.	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.	+113°
RELATED SUBSTANCES (BY HPLC)	Impurity- B : NMT 0.20 % Impurity- C : NMT 0.15 % Unspecified Impurity : NMT 0.10 % Total Impurities : NMT 0.50 %	0.09 % ND 0.05 % 0.14 %
WATER	Maximum 2.0 %	1.6 %
ASSAY (BY HPLC)	97.5 % to 102.0 % on anhydrous substance.	99.8 %
ADDITIONAL TESTS		
A). Residual solvents	Methanol : NMT 3000 ppm Acetone : NMT 5000 ppm Methylene chloride: NMT 600 ppm Isopropyl Ether: NMT 5000 ppm	1622 ppm ND 101 ppm 7 ppm
B). Particle size (By Volume Basis)	70 % < 10 µ 99 % < 15 µ	6.52 µ 14.12 µ
REMARKS: The Product CONFORMS as per EP 7.5 / Party's specifications.		
PREPARED BY DATE : 31/07/2013	CHECKED BY DATE : 31/07/2013	APPROVED BY DATE : 31/07/2013