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Lot: 0040313

CERTIFICATE OF ANALYSIS

Name of Product : Triamcinolone Acetonide EP

Batch No. : TMCA/M/008/13

Batch Size : 11620 gm

Mfg. Date : Feb-2013

A. R. No. : AVK/TMCA/024/13

Exp. Date : Jan-2017

Date : 16/03/2013

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.	Conforms
	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).	Conforms
	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).	Conforms
	D) The test solution is yellow and the blank is red.	Conforms
SPECIFIC OPTICAL ROTATION	+ 110° to + 117° on anhydrous substance.	+114°
RELATED SUBSTANCES (BY HPLC)	Impurity- B : NMT 0.20 %	0.15 %
	Impurity- C : NMT 0.15 %	ND
	Unspecified Impurity : NMT 0.10 %	0.06 %
	Total Impurities : NMT 0.50 %	0.21 %
WATER	Maximum 2.0 %	0.7 %
ASSAY (BY HPLC)	97.5 % to 102.0 % on anhydrous substance.	99.9 %
ADDITIONAL TESTS		
A). Residual solvents	Methanol : NMT 3000 ppm Acetone : NMT 5000 ppm Methylene chloride: NMT 600 ppm Isopropyl Ether: NMT 5000 ppm	1883 ppm 4 ppm 65 ppm 10 ppm
B). Particle size (By Number Basis)	99 % < 10 µ	2.10 µ

REMARKS: The Product CONFORMS as per EP 7.5 / Party's specifications.

PREPARED BY

DATE : 16/03/2013

CHECKED BY

DATE : 16/03/2013

APPROVED BY

DATE : 16/03/2013