

6e. 050312

Ipca

Ipca Laboratories Limited

A-1/7 Phase-I GIDC VAPI - 390195, Tel: 91 - 260 - 2401593, 2433097

CERTIFICATE OF ANALYSIS

Name of Product: **Triamcinolone Acetonide EP**

Batch No.: **TMCA/M/004/12**

Batch Size: **17240 gm**

Mfg. Date: **Feb - 2012**

A. R. No.: **AVK/FP/158/12**

Exp. Date: **Jan - 2016**

Date: **13/03/2012**

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS		
Appearance	A White or almost white crystalline powder.	A 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 TLC: The principal spot in each of the Chromatogram obtained with test is similar in position and size to the principal spots in each of the chromatograms obtained with the corresponding reference solution. The principal spot in the chromatograms obtained with test solution (b) and reference solution (b) has an Rf value distinctly higher than that of the principal spot in the chromatograms obtained with test solution (a) and reference solution (a).	Conforms
	D) The test solution is yellow and the blank is red.	Conforms
SPECIFIC OPTICAL ROTATION	+ 100° to + 107° on anhydrous substance.	+104°
RELATED SUBSTANCES (BY HPLC)	Impurity- A : NMT 0.25 % Total Impurities : NMT 0.50 %	0.04 % 0.22 %
WATER	Maximum 2.0 %	1.2 %
ASSAY (BY UV)	97.0 % to 103.0 % on anhydrous substance.	99.3 %
ADDITIONAL TESTS		
A). Residual solvents	Methanol : NMT 3000 ppm Acetone : NMT 5000 ppm Methylene chloride: NMT 600 ppm Isopropyl Ether: NMT 5000 ppm	1476 ppm 50 ppm 21 ppm 2 ppm
B). Particle size (By Volume Basis)	100 % < 10 µ	8.81 µ
REMARKS: The Product CONFORMS as per EP 7.0 specifications.		
PREPARED BY DATE: 13/03/2012	CHECKED BY DATE: 13/03/2012	APPROVED BY DATE: 13/03/2012