



Ipca Laboratories Limited

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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	<p>A) By IR: IR spectra of the sample are concordant to that of the standard.</p> <p>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).</p> <p>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).</p> <p>D) The test solution is yellow and the blank is red.</p>	<p>Conforms</p> <p>Conforms</p> <p>Conforms</p> <p>Conforms</p>
SPECIFIC OPTICAL ROTATION	+ 110° to + 117° on anhydrous substance.	+115°
RELATED SUBSTANCES (BY HPLC)	<p>Impurity- B : NMT 0.20 %</p> <p>Impurity- C : NMT 0.15 %</p> <p>Unspecified Impurity : NMT 0.10 %</p> <p>Total Impurities : NMT 0.50 %</p>	<p>0.18%</p> <p>ND</p> <p>0.03%</p> <p>0.21%</p>
WATER	Maximum 2.0 %	1.6 %
ASSAY (BY HPLC)	97.5 % to 102.0 % on anhydrous substance.	99.8 %
ADDITIONAL TESTS		
Residual solvents	<p>Methanol : NMT 3000 ppm</p> <p>Acetone : NMT 5000 ppm</p> <p>Methylene chloride: NMT 600 ppm</p>	<p>2301 ppm</p> <p>27 ppm</p> <p>342 ppm</p>
B). Particle size (By Volume Basis)	<p>70 % < 10 µ</p> <p>99 % < 15 µ</p>	<p>5.02 µ</p> <p>12.19 µ</p>
REMARKS: The Product CONFORMS as per EP 8.0 / Party's Specifications.		
<p><i>[Signature]</i></p> <p>PREPARED BY NAME : <i>Heber J. Derosa</i> DESIGNATION : <i>SE Office</i> DATE : <i>24/09/2014</i></p>	<p><i>[Signature]</i></p> <p>CHECKED BY NAME : <i>Manish Datta</i> DESIGNATION : <i>Asst Manager</i> DATE : <i>24/09/2014</i></p>	<p><i>[Signature]</i></p> <p>APPROVED BY NAME : <i>Vinod J. Patel</i> DESIGNATION : <i>Asst. Manager</i> DATE : <i>24/09/2014</i></p>