

Ipca Laboratories Limited

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CERTIFICATE OF ANALYSIS

Name of Product : Triamcinolone Acetonide EP		
Batch No. : TMCA/M/016/15	Batch Size : 21920 gm	
Mfg. Date : Apr-2015	A. R. No. : AVK/TMCA/071/15	
Exp. Date : Mar-2019	Date : 13/06/2015	
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.	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.	+116°
RELATED SUBSTANCES (BY HPLC)	Impurity- B : NMT 0.2 %	0.14 %
	Impurity- C : NMT 0.15 %	ND
	Unspecified Impurity : NMT 0.10 %	0.04 %
	Total Impurities : NMT 0.5 %	0.18 %
WATER	Maximum 2.0 %	1.5 %
ASSAY (BY HPLC)	97.5 % to 102.0 % on anhydrous substance.	99.6 %
ADDITIONAL TESTS		
A). Residual solvents	Methanol : NMT 3000 ppm Acetone : NMT 5000 ppm Methylene chloride: NMT 600 ppm	1811 ppm 45 ppm 79 ppm
B). Particle size (By Volume Basis)	70 % < 10 µ 99 % < 15 µ	6.61 µ 13.99 µ
REMARKS: The Product CONFORMS as per EP 8.0 / Party's Specifications.		
PREPARED BY NAME : NIMESH D PATEL DESIGNATION : QC SR CHEMIST DATE : 17/06/2015	CHECKED BY NAME : MAHESH G DUNNA DESIGNATION : QC ASST MANAGER DATE : 17/06/2015	APPROVED BY NAME : GAYATRI J VADVEKAR DESIGNATION : QA EXECUTIVE DATE : 17/06/2015

Analysis Report

Result Analysis Report

Sample Name:
TRIAMCINOLONE ACETONIDE

SOP Name:

Measured:

Wednesday, June 10, 2015 11:54:35 AM

Sample Source & type:

Measured by:
PS

Analysed:

Wednesday, June 10, 2015 11:54:36 AM

Sample bulk lot ref:
TMCA/M/016/15

Result Source:
Measurement

Particle Name:
Default

Accessory Name:
Scirocco 2000

Analysis model:
General purpose

Sensitivity:
Normal

Particle RI:
1.520

Absorption:
0.1

Size range:
0.020 to 2000.000 um

Obscuration:
3.79 %

Dispersant Name:
Dry dispersion

Dispersant RI:
1.000

Weighted Residual:
0.421 %

Result Emulation:
Off

Concentration:
0.03 %Vol

Span:
1.755

Uniformity:
0.532

Result units:
Volume

Specific Surface Area:
2.37 m²/g

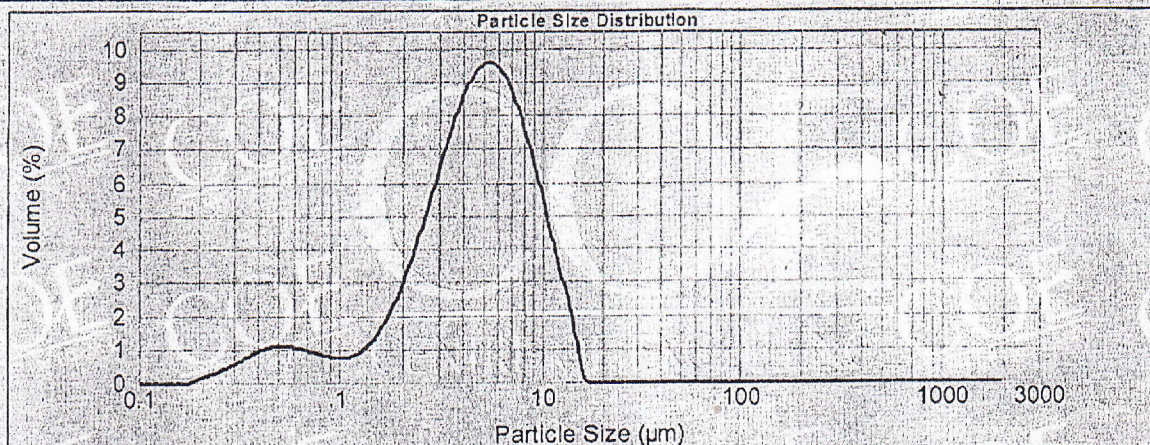
Surface Weighted Mean D[3,2]:
2.533 um

Vol. Weighted Mean D[4,3]:
5.256 um

D(1.00) : 15.72 um

D(0.99) : 13.99 um

d(0.1): 1.462 um D(0.80) : 7.83 um d(0.5): 4.741 um D(0.95) : 11.44 um d(0.9): 9.781 um



— TRIAMCINOLONE ACETONIDE, Wednesday, June 10, 2015 11:54:35 AM

Size (um)	Vol Under %	Size (um)	Vol Under %	Size (um)	Vol Under %	Size (um)	Vol Under %	Size (um)	Vol Under %	Size (um)	Vol Under %
0.010	0.00	0.105	0.00	1.095	8.23	11.482	95.10	120.225	100.00	1258.925	100.00
0.011	0.00	0.120	0.00	1.259	8.96	13.183	98.08	138.038	100.00	1445.440	100.00
0.013	0.00	0.138	0.00	1.445	9.91	15.136	99.84	158.489	100.00	1659.587	100.00
0.015	0.00	0.158	0.00	1.660	11.25	17.379	100.00	181.970	100.00	1905.451	100.00
0.017	0.00	0.182	0.00	1.905	13.18	19.953	100.00	208.930	100.00	2187.762	100.00
0.020	0.00	0.209	0.05	2.188	15.90	22.909	100.00	239.883	100.00	2511.886	100.00
0.023	0.00	0.240	0.23	2.512	19.59	26.303	100.00	275.423	100.00	2884.032	100.00
0.026	0.00	0.275	0.53	2.884	24.38	30.200	100.00	316.228	100.00	3311.311	100.00
0.030	0.00	0.316	0.98	3.311	30.25	34.674	100.00	363.078	100.00	3801.891	100.00
0.035	0.00	0.363	1.59	3.802	37.20	39.811	100.00	416.869	100.00	4365.150	100.00
0.040	0.00	0.417	2.37	4.365	45.02	45.700	100.00	478.630	100.00	5011.872	100.00
0.046	0.00	0.479	3.28	5.012	53.44	52.481	100.00	549.541	100.00	5754.399	100.00
0.052	0.00	0.550	4.25	5.754	62.00	60.256	100.00	630.957	100.00	6605.904	100.00
0.060	0.00	0.631	5.20	6.607	70.51	69.183	100.00	724.436	100.00	7585.775	100.00
0.069	0.00	0.724	6.08	7.586	78.34	79.433	100.00	831.764	100.00	8709.836	100.00
0.079	0.00	0.832	6.87	8.710	85.18	91.201	100.00	954.993	100.00	10000.000	100.00
0.091	0.00	0.965	7.55	10.000	90.82	104.713	100.00	1095.478	100.00		

Operator notes:

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Mastersizer 2000 Var. 5.31
Serial Number : MAL1007559

File name: DRY.MODE 2015.mea
Record Number: 426
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13/06/2015