

Ipca Laboratories Limited

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Lot: 0131015

CERTIFICATE OF ANALYSIS

Name of Product : Triamcinolone Acetonide EP		Batch Size : 21920 gm
Batch No. : TMCA/M/016/15		
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.	99.5 %
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:
TMCAM/016/15

Result Source:
Measurement

Particle Name:
Default

Accessory Name:
Sirocco 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

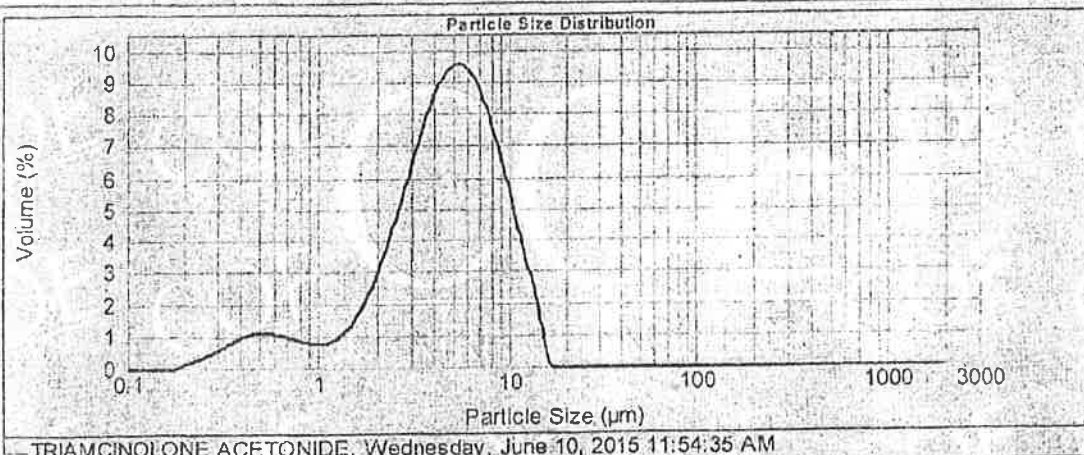
Specific Surface Area:
2.37 m²/g

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(D.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



Size (um)	Vol Under %	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	0.100	0.00	1.000	8.20	11.400	65.10	120.225	100.00	1226.925	100.00		
0.011	0.00	0.120	0.00	1.200	8.96	13.183	68.00	138.000	100.00	1445.440	100.00		
0.013	0.00	0.150	0.00	1.445	9.51	15.135	99.64	158.400	100.00	1659.597	100.00		
0.015	0.00	0.180	0.00	1.800	11.25	17.370	100.00	181.970	100.00	1905.451	100.00		
0.017	0.00	0.210	0.00	2.100	13.18	19.953	100.00	208.900	100.00	2187.762	100.00		
0.020	0.00	0.250	0.00	2.500	15.00	22.909	100.00	239.885	100.00	2511.606	100.00		
0.023	0.00	0.300	0.00	3.000	16.99	26.330	100.00	275.423	100.00	2864.032	100.00		
0.026	0.00	0.360	0.00	3.600	19.28	30.230	100.00	316.226	100.00	3311.311	100.00		
0.030	0.00	0.450	0.00	4.500	24.38	34.674	100.00	363.076	100.00	3801.694	100.00		
0.035	0.00	0.540	0.00	5.400	30.25	39.811	100.00	416.890	100.00	4355.150	100.00		
0.040	0.00	0.660	0.00	6.600	37.20	45.730	100.00	478.630	100.00	5011.872	100.00		
0.046	0.00	0.810	0.00	8.100	45.02	52.481	100.00	549.541	100.00	5754.329	100.00		
0.052	0.00	1.000	0.00	10.000	63.44	60.256	100.00	630.957	100.00	6605.924	100.00		
0.060	0.00	1.200	0.00	12.000	62.01	69.183	100.00	724.436	100.00	7765.778	100.00		
0.069	0.00	1.445	0.00	14.445	70.51	78.433	100.00	851.704	100.00	8700.635	100.00		
0.079	0.00	1.800	0.00	18.000	78.34	91.201	100.00	954.993	100.00	10000.000	100.00		
0.091	0.00	2.100	0.00	21.000	85.16	104.713	100.00	1095.478	100.00				
		2.500	0.00	25.000	90.82								

Operator notes:

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Mastersizer 2000 Ver: 5.31
Serial Number : MAL1007559

File name: DRY MODE 2015.mxi
Record Number: 426
10 Jun 2015 11:55:43 AM

13/06/2015