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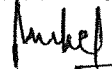
CERTIFICATE OF ANALYSIS

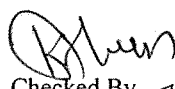
Product Name	Triamcinolone Acetonide (Micronized)	Q.A.R No.	22250
Batch Number	6702022005	AR No.	BB-22050082
Manufacturing Date	May, 2022	S.O. No.	SO/22-23/0068
Retest Date	April, 2025	Quantity Supplied	40.0 kg
Date of receipt	25/05/2022	Date of release	30/05/2022
CEP No.	R0-CEP 2017-167-Rev 00		

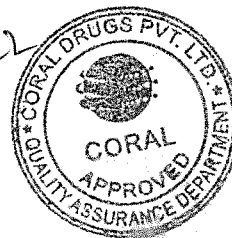
TEST	SPECIFICATION	RESULT
1. Appearance	White or almost white, crystalline powder.	White, crystalline powder.
2. Solubility	Practically insoluble in water, sparingly soluble in Ethanol (96%).	It is practically insoluble in water, sparingly soluble in Ethanol (96%).
3. Identification		
A) By IR	IR spectrum of sample should be concordant with that of the standard spectrum.	IR spectrum of sample is concordant with that of the standard spectrum.
B) By TLC	The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with reference solution (a).	The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with reference solution (a).
C) By HPLC	In the test of Assay, the principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (c).	In the test of Assay, the principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (c).
D) By Chemically	Compare the colour of the solution to that of a blank prepared in the same manner. The test solution should be yellow and the blank should be red.	The colour of the solution and blank is compared. The test solution is yellow and the blank is red.
4. Specific optical rotation	+110° to +117° (anhydrous substance)	+ 113.60°
5. Water (By KF)	Not more than 2.0%	1.58%
6. Related Substances (By HPLC)		
Impurity 'B'	Not more than 0.2%	0.08%
Impurity 'C'	Not more than 0.15%	0.05%
Unspecified impurity	Not more than 0.10%	0.08%
Total impurities	Not more than 0.5%	0.22%
7. Assay (By HPLC)	97.5% to 102.0% (anhydrous substance)	99.85%
8. *Residual Solvent (By GCHS)		
Methanol	Not more than 1000 ppm	125 ppm
Acetone	Not more than 1000 ppm	96 ppm
Methylene Chloride	Not more than 150 ppm	2 ppm
Benzene	Not more than 2 ppm	Not detected
9. **Particle Size Distribution (By Malvern Mastersizer)	D(0.99) Not more than 10 µm	8.58 µm

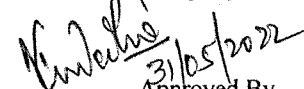
Remarks - The product complies with respect to current Ph. Eur. 10.0 specifications, * indicates In-house specification & ** indicates party specification.

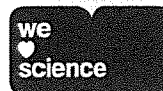
Storage Condition- Protected from light.

Prepared By 
Sushil Rana
(Jr. Executive_QA) 31/05/22


Checked By 31/05/22
Kamal Ahuja
(Sr. Executive_QA)




31/05/2022
Approved By
Pradeep Kudeshia
(Manager_QA)



PSD Analysis Report

Malvern Instrument

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Measurement Details

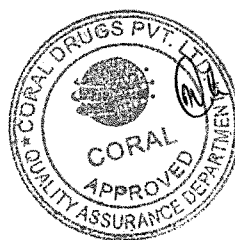
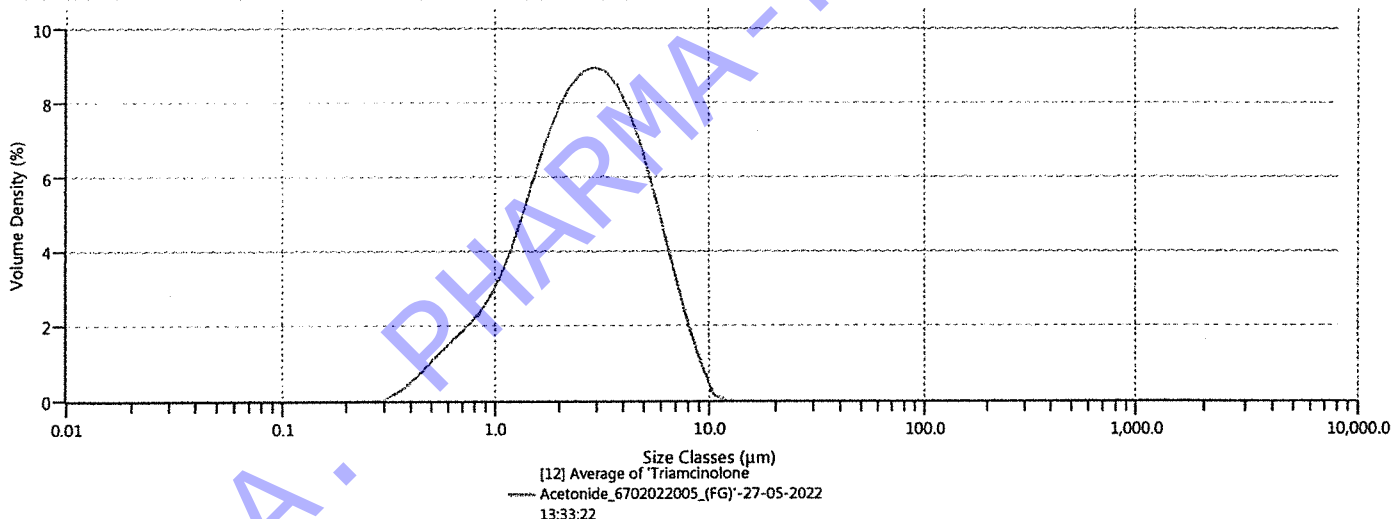
Analysis Date Time 27-05-2022 13:33:22
Operator Name amittiwari
Sample Name Average of 'Triamcinolone Acetonide_6702022005_(FG)'
SOP File Name HydroMV.cfg
Particle Name Triamcinolone Acetonide
Particle Refractive Index 1.588
Particle Absorption Index 0.010
Analysis Model General Purpose
Weighted Residual 1.12 %
Laser Obscuration 12.38 %
Concentration 0.0030 %
Uniformity 0.547
Span 1.789
Result Source Averaged
Dispersant Name Water
D [4,3] 3.05 µm

Optical Properties

Dv (10) 0.992 µm
Dv (20) 1.44 µm
Dv (50) 2.64 µm
Dv (70) 3.73 µm
Dv (75) 4.09 µm
Dv (80) 4.51 µm
Dv (90) 5.72 µm
Dv (95) 6.74 µm
Dv (97) 7.44 µm
Dv (98) 7.92 µm
Dv (99) 8.58 µm
Dv (99.5) 9.18 µm
Dv (99.8) 9.62 µm
Dv (100) 11.1 µm

Volume Below (1) µm 10.17 %
Volume Below (5) µm 84.71 %
Volume Below (10) µm 99.96 %
Volume Below (20) µm 100.00 %
Volume Below (40) µm 100.00 %
Volume Below (50) µm 100.00 %
Volume Below (200) µm 100.00 %

Frequency (compatible)



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PSD Analysis Report

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Result											
Size (µm)	% Volume Under	Size (µm)	% Volume Under	Size (µm)	% Volume Under	Size (µm)	% Volume Under	Size (µm)	% Volume Under	Size (µm)	% Volume Under
0.0100	0.00	0.0995	0.00	0.991	9.97	9.86	99.95	98.1	100.00	976	100.00
0.0114	0.00	0.113	0.00	1.13	12.70	11.2	100.00	111	100.00	1110	100.00
0.0129	0.00	0.128	0.00	1.28	16.10	12.7	100.00	127	100.00	1260	100.00
0.0147	0.00	0.146	0.00	1.45	20.32	14.5	100.00	144	100.00	1430	100.00
0.0167	0.00	0.166	0.00	1.65	25.41	16.4	100.00	163	100.00	1630	100.00
0.0189	0.00	0.188	0.00	1.88	31.31	18.7	100.00	186	100.00	1850	100.00
0.0215	0.00	0.214	0.00	2.13	37.89	21.2	100.00	211	100.00	2100	100.00
0.0244	0.00	0.243	0.00	2.42	44.96	24.1	100.00	240	100.00	2390	100.00
0.0278	0.00	0.276	0.00	2.75	52.34	27.4	100.00	272	100.00	2710	100.00
0.0315	0.00	0.314	0.00	3.12	59.82	31.1	100.00	310	100.00	3080	100.00
0.0358	0.00	0.357	0.14	3.55	67.21	35.3	100.00	352	100.00	3500	100.00
0.0407	0.00	0.405	0.45	4.03	74.29	40.1	100.00	400	100.00		
0.0463	0.00	0.460	1.01	4.58	80.81	45.6	100.00	454	100.00		
0.0526	0.00	0.523	1.84	5.21	86.53	51.8	100.00	516	100.00		
0.0597	0.00	0.594	2.93	5.92	91.27	58.9	100.00	586	100.00		
0.0679	0.00	0.675	4.29	6.72	94.94	66.9	100.00	666	100.00		
0.0771	0.00	0.767	5.88	7.64	97.54	76.0	100.00	756	100.00		
0.0876	0.00	0.872	7.74	8.68	99.14	86.4	100.00	859	100.00		

Signature

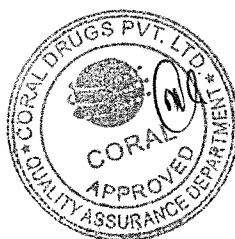
Record Number

Sample Name Signature State

Signatory Signature Date

12 Average of 'Triamcinolone Acetonide_6702022005_(FG)'

Unsigned



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