

CERTIFICATE OF ANALYSIS

Product Name	Triamcinolone Acetonide		
Reference Specification No.	FPS-087-00		
Batch No.	TREFB25001	A.R.No.	FP25QCD-0039
Batch Quantity	25.100 Kg	Mfg. Date	Jan-2025
Grade	EP-11.0	Retest Date	Dec-2029
Mfg. Lic. No.	G/25/2056	Released On	03/02/2025
Sr. No.	Test	Specification	Result
1.0	Characters Appearance	White or almost white, crystalline powder.	White crystalline powder
	Solubility	Practically insoluble in water, sparingly soluble in ethanol(96 percent)	Complies
2.0	Identification	A) By IR: The infra-red absorption spectrum of sample is concordant with to that of the standard. B) By HPLC: 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 standard.	Complies Complies
3.0	Specific optical rotation	Between +110° to +117° (On anhydrous basis).	+113.19°
4.0	Related substances (By HPLC)	Impurity B : NMT 0.20% w/w Impurity C : NMT 0.15% w/w Unspecified impurity : NMT 0.10% w/w Total impurities : NMT 0.50% w/w	0.12% Not Detected 0.06% 0.28%
5.0	Water	NMT 2.0 % w/w.	1.10%
6.0	Assay (By HPLC)	97.5 %w/w to 102.0 %w/w of C ₂₄ H ₃₁ FO ₆ (On anhydrous basis).	99.0%
Additional Tests:			
7.0	Particle Size	90% ≤ 10 μm	Complies
8.0	Residual solvents(By GC)	Methanol : NMT 3000 ppm Acetone : NMT 5000 ppm Methylene Chloride : NMT 600 ppm DIPE : NMT 5000 ppm Acetic Acid : NMT 5000 ppm	325 ppm 453 ppm Not Detected Not Detected Not Detected
Remark: The sample complies/ Does not comply with prescribed standard as per above specification.			
Prepared By:	Checked By:	Approved By:	
Sign./Date	Sign./Date	Sign./Date	
Name: Hitendra Chudavat	Name: Bunty Patel	Name: Milan Patel	
Designation : Executive -QC	Designation : Sr. Executive -QC	Designation : Asst. Manager-QC	

QCD-030/F01-01

Measurement Details

Operator Name Nilesh.Parmar
Sample Name 086AB015_270125_01
SOP File Name Triamcinolone Acetonide_1 mm.msop
Batch No. TREFB25001

Measurement Details

Analysis Date Time 27-01-2025 15:05:46
Measurement Date Time 27-01-2025 15:05:46
Result Source Measurement

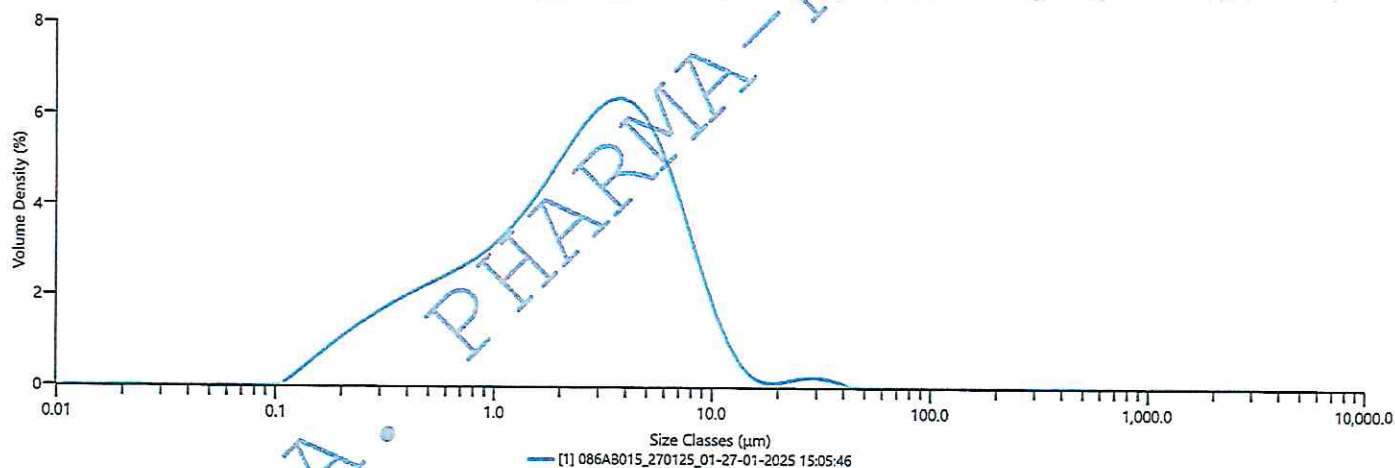
Analysis

Particle Name Triamcinolone Acetonide
Particle Refractive Index 1.520
Particle Absorption Index 0.100
Dispersant Name Dry dispersion
Dispersant Refractive Index 1.000
Scattering Model Mie
Analysis Model General Purpose
Weighted Residual 0.48 %
Laser Obscuration 0.64 %

Result

Concentration 0.0001 %
Span 2.700
Uniformity 0.903
Specific Surface Area 5391 m²/kg
D [3,2] 1.11 µm
D [4,3] 3.37 µm
Dv (10) 0.420 µm
Dv (50) 2.48 µm
Dv (75) 4.61 µm
Dv (80) 5.24 µm
Dv (90) 7.13 µm
Dv (95) 8.96 µm
Dv (99) 15.1 µm
Dv (100) 40.0 µm

Frequency (compatible)



086AB015

Instrument Serial No: MAL1243336

21CFR Mode: Active

Record Number: 1

Created: 27-01-2025 15:05

Printed: 27-01-2025 15:33



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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	Size (µm)	% Volume Under	Size (µm)	% Volume Under
0.0100	0.00	0.0597	0.00	0.357	7.89	2.13	44.51	12.7	98.54	76.0	100.00	454	100.00	2710	100.00
0.0114	0.00	0.0679	0.00	0.405	9.52	2.42	49.02	14.5	98.94	86.4	100.00	516	100.00	3080	100.00
0.0129	0.00	0.0771	0.00	0.460	11.26	2.75	53.85	16.4	99.11	98.1	100.00	585	100.00	3500	100.00
0.0147	0.00	0.0876	0.00	0.523	13.12	3.12	58.94	18.7	99.18	111	100.00	666	100.00		
0.0167	0.00	0.0995	0.00	0.594	15.08	3.55	64.21	21.2	99.25	127	100.00	756	100.00		
0.0189	0.00	0.113	0.00	0.675	17.16	4.03	69.54	24.1	99.37	144	100.00	859	100.00		
0.0215	0.00	0.128	0.19	0.767	19.36	4.58	74.79	27.4	99.54	163	100.00	976	100.00		
0.0244	0.00	0.146	0.56	0.872	21.70	5.21	79.80	31.1	99.73	186	100.00	1110	100.00		
0.0278	0.00	0.166	1.11	0.991	24.20	5.92	84.40	35.3	99.90	211	100.00	1260	100.00		
0.0315	0.00	0.188	1.84	1.13	26.89	6.72	88.45	40.1	100.00	240	100.00	1430	100.00		
0.0358	0.00	0.214	2.74	1.28	29.81	7.64	91.84	45.6	100.00	272	100.00	1630	100.00		
0.0407	0.00	0.243	3.81	1.45	33.01	8.68	94.50	51.8	100.00	310	100.00	1850	100.00		
0.0463	0.00	0.276	5.03	1.65	36.51	9.86	96.46	58.9	100.00	352	100.00	2100	100.00		
0.0526	0.00	0.314	6.39	1.88	40.33	11.2	97.76	66.9	100.00	400	100.00	2390	100.00		

Signature

Record Number	Sample Name	Signature State	Signatory	Signature Date
1	086AB015_270125_01	Approved	INTERVEIN\Nilesh.Parmar	27-01-2025 15:06:46 +05:30
		Locked	INTERVEIN\nirav.gandhi	27-01-2025 15:17:03 +05:30

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