



METAPHARMACEUTICAL

N DE LOTE:

0220325

CERTIFICATE OF ANALYSIS

Corporate Office:

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MG Road, Sector 26
Gurugram 122002
Haryana, India

Unit 1:

55-56-57
HSIIDC Industrial Estate
Murthal, Sonipat
Haryana 131039
India

Product Name	Budesonide EP (Micronized)	Q.A.R No.	25118
Batch Number	6112024019	AR No.	BB-24110193
Manufacturing Date	November, 2024	S.O. No.	SO/24-25/0611
Retest Date	October, 2027	Quantity Supplied	500.0 g
CAS No.	51333-22-3	Date of Release	27/11/2024

CEP No. R1-CEP 2016-020-Rev 00

TEST	SPECIFICATION	RESULT
1. Appearance	White or almost white, crystalline powder.	White crystalline powder.
2. Solubility	Practically insoluble in water, Freely soluble in methylene chloride, sparingly soluble in alcohol (96 percent).	It is practically insoluble in water, Freely soluble in methylene chloride, sparingly soluble in alcohol (96 percent).
3. Identification		
A) By IR Absorption	The IR spectrum of the sample should be concordant with that of a similar preparation of Budesonide standard.	IR spectrum of sample concordant with standard.
B) By TLC	The principal spot of the test chromatogram should correspond to the principal spot of reference solution (a) at 254nm and 365nm.	The principal spot of the test chromatogram correspond with principal spot of reference solution (a) at 254nm and 365nm.
C) By Chemical	The colour should fade and a clear solution remains.	The fade colour observed and remain solution is clear.
D) By Chemical	The solution should turn blue.	Blue solution observed.
4. Loss on drying	Not more than 0.5%	0.19%
5. Epimer A (Second Peak)	40.0% to 51.0%	46.92%
6. Related Substances (By HPLC)		
Impurity A	Not more than 0.2%	Below Disregard Limit
Impurity D	Not more than 0.2%	Below Disregard Limit
Impurity K	Not more than 0.2%	Below Disregard Limit
Impurity L	Not more than 0.2%	0.06%
Unspecified impurities	Not more than 0.10%	0.07%
Total impurities	Not more than 0.5%	0.18%
7. Assay (By HPLC)	97.5% to 102.0% w/w (on dried basis)	99.72%
8. *Residual Solvents (By GCHS)		
Methanol	Not more than 1000 ppm	75 ppm
Dichloro Methane	Not more than 600 ppm	108 ppm
n-butylaldehyde	Not more than 150 ppm	8 ppm
Dimethyl formamide	Not more than 880 ppm	Not detected
Benzene	Not more than 2 ppm	Not detected

Prepared By
Sawan Saw
(Sr. Officer_QA)

Checked By
Sushil Rana
(Executive_QA)



Approved By
Shikhar Arora
(Asst. Manager_QA)

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CIN No.: U74899DL1993PTC056582

CORAL DRUGS PVT LTD

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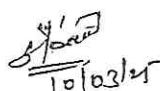
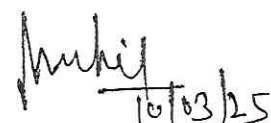
WEBSITE
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CERTIFICATE OF ANALYSIS

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CEP No. R1-CEP 2016-020-Rev 00

TEST	SPECIFICATION	RESULT
9. *Particle Size distribution (By Malvern Mastersizer)	D (0.1) Not more than 1.0 μ m	0.43 μ m
	D (0.5) Not more than 3.0 μ m	1.59 μ m
	D (0.9) Not more than 5.0 μ m	3.24 μ m

Remarks - The product complies with respect to EP specification & * indicates In-house specification.**Storage Condition**- Store protected from light.
Prepared By
Sawan Saw
(Sr. Officer_ QA)
Checked By
Sushil Rana
(Executive_ QA)
Approved By
Shikhar Arora
(Asst. Manager_ QA)

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PSD Analysis Report

Malvern Instrument



Measurement Details

Sample Name Average of 'Budesonide_6112024019_ (FG)'
 Analysis Date Time 25-11-2024 14:37:15
 Operator Name jitendra.kumar
 Particle Name Budesonide
 Particle Refractive Index 1.530
 Particle Absorption Index 0.010
 SOP File Name HydroMV.cfg
 Analysis Sensitivity Normal

Measurement Details

Analysis Model General Purpose
 Weighted Residual 1.23 %
 Laser Obscuration 14.26 %
 Concentration 0.0031 %
 Uniformity 0.531
 Span 1.768
 Result Source Averaged
 Dispersant Name Water
 Dispersant Refractive Index 1.330

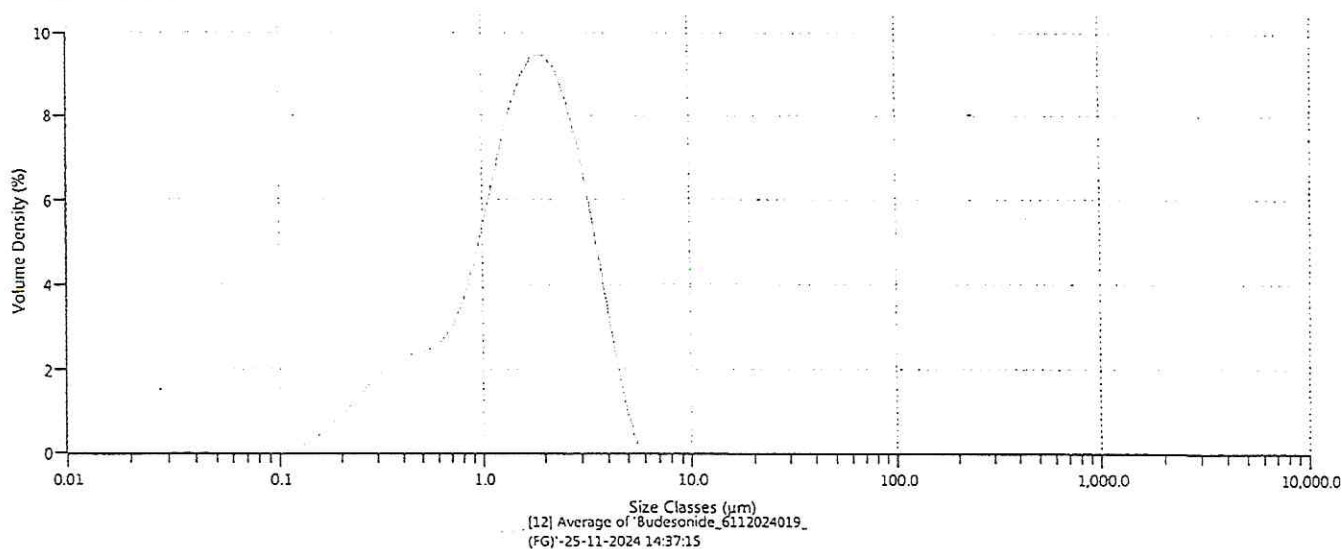
Analysis Result

D [3,2] 0.982 μm
 D [4,3] 1.74 μm
 Dv (5) 0.295 μm
 Dv (15) 0.586 μm
 Dv (25) 0.926 μm
 Dv (30) 1.07 μm
 Dv (40) 1.33 μm
 Volume Below (1) μm 27.44 %
 Volume Below (5) μm 99.71 %
 Volume Below (10) μm 100.00 %
 Volume Below (15) μm 100.00 %
 Volume Below (20) μm 100.00 %
 Volume Below (40) μm 100.00 %
 Volume Below (50) μm 100.00 %
 Volume Below (200) μm 100.00 %

Analysis Result

Dv (10) 0.426 μm
 Dv (20) 0.766 μm
 Dv (50) 1.59 μm
 Dv (70) 2.21 μm
 Dv (75) 2.40 μm
 Dv (80) 2.63 μm
 Dv (90) 3.24 μm
 Dv (95) 3.76 μm
 Dv (97) 4.05 μm
 Dv (98) 4.29 μm
 Dv (99) 4.56 μm
 Dv (99.5) 4.85 μm
 Dv (99.8) 5.06 μm
 Dv (99.9) 5.14 μm
 Dv (100) 5.21 μm

Frequency (compatible)



25/11/24



25/11/24

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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	Size (µm)	% Volume Under
0.0100	0.00	0.0771	0.00	0.594	15.24	4.58	99.10	35.3	100.00	272	100.00	2100	100.00
0.0114	0.00	0.0876	0.00	0.675	17.47	5.21	100.00	40.1	100.00	310	100.00	2390	100.00
0.0129	0.00	0.0995	0.00	0.767	20.03	5.92	100.00	45.6	100.00	352	100.00	2710	100.00
0.0147	0.00	0.113	0.00	0.872	23.15	6.72	100.00	51.8	100.00	400	100.00	3080	100.00
0.0167	0.00	0.128	0.08	0.991	27.07	7.64	100.00	58.9	100.00	454	100.00	3500	100.00
0.0189	0.00	0.146	0.28	1.13	31.95	8.68	100.00	66.9	100.00	516	100.00		
0.0215	0.00	0.166	0.62	1.28	37.84	9.86	100.00	76.0	100.00	586	100.00		
0.0244	0.00	0.188	1.16	1.45	44.62	11.2	100.00	86.4	100.00	666	100.00		
0.0278	0.00	0.214	1.93	1.65	52.09	12.7	100.00	98.1	100.00	756	100.00		
0.0315	0.00	0.243	2.95	1.88	59.96	14.5	100.00	111	100.00	859	100.00		
0.0358	0.00	0.276	4.22	2.13	67.90	16.4	100.00	127	100.00	976	100.00		
0.0407	0.00	0.314	5.71	2.42	75.55	18.7	100.00	144	100.00	1110	100.00		
0.0463	0.00	0.357	7.41	2.75	82.56	21.2	100.00	163	100.00	1260	100.00		
0.0526	0.00	0.405	9.25	3.12	88.60	24.1	100.00	186	100.00	1430	100.00		
0.0597	0.00	0.460	11.19	3.55	93.45	27.4	100.00	211	100.00	1630	100.00		
0.0679	0.00	0.523	13.18	4.03	96.94	31.1	100.00	240	100.00	1850	100.00		

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25/11/24



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