



SWAPNROOP DRUGS & PHARMACEUTICALS

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CERTIFICATE OF ANALYSIS

Product Name	Betamethasone IP (Micronized)	CAS No:	378-44-9
Batch No.	2605001	Manufactured by	-
Date of Mfg.	MAY-2026	Date of Analysis	20/05/2026
Batch Quantity	-	Retest Date	APR2031

Sr No	Test	Acceptance Criteria	Results
1	Description	A white to creamy-white powder, odorless.	Complies
2	Solubility	Sparingly soluble in ethanol (95 per cent), very slightly soluble in chloroform, practically insoluble in water.	Complies
3	Identification by -IR	The IR absorption spectrum is concordant with the reference spectrum of Betamethasone IPRS/WS.	Complies
4	Identification by - TLC	The principal spot in the chromatogram obtained with the test solution should similar in color in daylight, in fluorescence in UV light at 365nm, position and size to the principle spot in the chromatogram obtained with reference solution (a) and the chromatogram obtained with reference solution (b) shows only one spot.	Complies
5	Specific Optical Rotation (On dried Basis)	Between +114.0° to +122.0°	+117.42°
6	Light Absorption	Between 0.37 to 0.40	0.389
7	Related Substance by HPLC Any Secondary Impurity	0.51 %	NMT 1.0 %
8	Related Substance by HPLC One such impurity	0.27 %	NMT 0.5 %
9	Related Substance by HPLC Total impurities	1.49 %	NMT 2.0 %
10	Sulphated Ash	NMT 0.1 % w/w	0.04 %
11	Loss on drying	NMT 0.5 % w/w	0.36 %
12	Assay by UV	Between 96.0 % and 104.0 % w/w (ODB)	98.39 %
13	Particle Size	Should be Micronized	Complies

Storage: Store in air tight container below room Temperature

Conclusion: Product Complies as per above Specifications

Prepared By  Sonali Nirmal Date: 23/05/2026	Checked by  Dadarao Kakde Date: 23/05/2026	Approved By  Nayna Nehete Date: 23/05/2026 
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