

# Savan Group

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## TYPICAL ANALYSIS / SPECIFICATION

PRODUCT : BETAMETHASONE VALERATE  
SHELF LIFE : FOUR YEARS SUBJECT TO CORRECT STORAGE

Test	Observation	Specification
Description	White powder	White to practically white powder
Melting range	192.0 <sup>0</sup> C – 193.0 <sup>0</sup> C	About 192.0 <sup>0</sup> C
Solubility	Complies	Practically insoluble in water, freely soluble in acetone, in methylene chloride and in chloroform, soluble in alcohol, slightly soluble in benzene and in ether.
Identification	Complies	IR: The IR spectrum of the sample agrees with IR spectrum of the standard
chromatogram	Complies	TLC: The principal spot in the chromatogram obtained with the test solution should be similar in position, colour in daylight, fluorescence in ultra-violet light at 365nm and size to the principal spot in the chromatogram obtained with reference solution(a).
Specific optical rotation	+78.12 <sup>0</sup>	+75.00 <sup>0</sup> to +82.00 <sup>0</sup>
Loss on drying	0.30%	NMT 0.50%
Residue on ignition	0.065%	NMT 0.200% (as per USP)
Chromatographic purity USP		
Any individual impurity	0.42%	NMT 1.00%
Total impurities	0.89%	NMT 2.00%
Related substances USP		
Single impurity	0.50%	NMT 1.50%
Any other impurity	0.37%	NMT 1.00%
Total impurities	1.08%	NMT 3.00%
Assay (By HPLC) USP)	99.24%	Between 97.00 to 103.00% (ODB as per USP)
Assay (By UV) USP)	99.47%	Between 97.00 to 103.00% (ODB as per USP)
<b>IN-HOUSE TESTS</b>		
Residual solvents		
Acetone	Not detected	NMT 5000 ppm
Ethyl acetate	Not detected	NMT 5000 ppm
Methylene chloride	Not detected	NMT 600 ppm
Particle size	Complies	100% <20 microns

**Observation: Material complies as per BP & USP**