

## Savan Group

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### TYPICAL ANALYSIS / SPECIFICATION

PRODUCT : BECLOMETHASONE DIPROPIONATE  
SHELF LIFE : FOUR YEARS SUBJECT TO CORRECT STORAGE

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TEST	RESULT	SPECIFICATIONS
Description	White crystalline powder	White or almost white crystalline powder
Solubility	Complies	To comply
Identification	Complies	To comply
Melting point	209 <sup>0</sup> C	About 210 <sup>0</sup> C
Specific optical rotation	+92.40 <sup>0</sup>	+88.0 <sup>0</sup> to +94.0 <sup>0</sup>
Absorbance at 238 nm	295	284 to 302
Related substances	Complies	To comply
1. Beclomethasone 17 propionate	0.32%	
2. Beclomethasone 21 propionate	0.38%	
3. Other total impurities	0.29%	
Residue on ignition	0.05%	NMT 0.10%
Loss on drying	0.32%	NMT 0.50%
Assay (by HPLC)	98.75%	96.0% to 103.0% (ODB)
<b>Residual impurities</b>	<b>Test</b>	<b>Limits</b>
Acetone	390 ppm	NMT 1000 ppm
Dichloromethane	240 ppm	NMT 400 ppm
<b>Micronised</b>	<b>Conforms</b>	<b>Less than 5µm</b>

**CONCLUSION: MATERIAL CONFORMS TO BP/USP**