



ANUH PHARMA LTD.

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CERTIFICATE OF ANALYSIS

Product Name : Betamethasone Valerate EP 07 Micronised
Batch No. : APL/128/B-12 Batch Qty. : 3.00 Kg (3 x 1.0 Kg)
Mfg. Date : 02/2012 Exp. Date : 01/2016
A.R. No. : AFP/028/2012

Sr. No.	Tests	Observations	Limits
1	Character- Appearance	White powder. Melting point : 194°C	White or almost white; crystalline powder. It melt at about 192°C, with decomposition
2	Solubility	Practically insoluble in water, freely soluble in acetone & in methylene chloride, soluble in ethanol (96%)	Practically insoluble in water, freely soluble in acetone & in methylene chloride, soluble in ethanol (96%)
3	Identification Test A & B	Complies	As per EP
4	Specific optical rotation on dried basis	+79.18°	+ 77.0° to + 83.0°
5	Related substances Impurity-A Impurity-I Impurity-C Impurity-H Impurity-E Impurity-G Unspecified impurity Total impurities	N.D. N.D. N.D. N.D. 0.05% N.D. 0.092% 0.15%	Not more than 0.7% Not more than 0.15% Not more than 0.15% Not more than 0.15% Not more than 0.3% Not more than 0.3% Not more than 0.10% Not more than 1.5%
6	Loss on drying	0.24%	Maximum 0.5%
7	Assay on dried basis	99.65%	97.0% to 103.0%
8	Particle Size	Complies Complies	99.0% <25 microns 90.0% <10 microns

Remarks: The sample complies as per EP 07 Specification.

Tested by DMH
Date 22/02/2012

Checked by
Date

22/02/2012



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