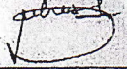


AVIK PHARMACEUTICAL LTD.

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CERTIFICATE OF ANALYSIS

NAME OF PRODUCT : Clobetasol Propionate EP			
Batch No.	CLP/M/008/14	Batch Size	9900gm
Mfg. Date	July-2014	A. R. No.	AVK/CLP/037/14
Exp. Date	June-2019	Released Date	01/08/2014
TESTS		SPECIFICATIONS	
RESULTS			
Characters			
Appearance	White or almost white, crystalline powder.		White, crystalline powder
Solubility	Practically in soluble in water, freely soluble in acetone, sparingly soluble in ethanol. (96 %).		Conforms
Identification	By IR: Infrared absorption spectrum of the sample is concordant to that of the standard.		Conforms
Specific optical rotation	+ 112 to +118 on dried substances.		+ 115°
Related substances (By HPLC)	Impurity A: NMT 0.20 %		ND
	Impurity B: NMT 0.30 %		0.07%
	Impurity C: NMT 0.30 %		ND
	Impurity D: NMT 0.50 %		0.03%
	Impurity L: NMT 0.20 %		ND
	Impurity M: NMT 0.20 %		ND
	Impurity E: NMT 0.70 %		ND
	Unspecified impurity : NMT 0.10 %		0.07%
Total impurities : NMT 2.0 %		0.17%	
Identified organic impurities	Betamethasone-17-Propionate-21-Tosylate : NMT 0.15 %		ND
Loss on drying	Maximum 0.5 % w/w		0.3 %
Sulphated ash	Maximum 0.10 %		0.03 %
Assay (By HPLC)	97.0 % to 102.0 % of $C_{25}H_{32}ClFO_5$ (Dried substance).		99.3 %
Additional tests			
A) Residual solvents	Methanol : NMT 3000 ppm		1951 ppm
	Methylene chloride : NMT 600 ppm		281 ppm
	Dimethyl Formamide: NMT 880 ppm		ND
B) Particle Size (By Number Basis)	100% < 20 μ		11.37 μ
Remarks: The sample CONFORMS as EP-8.0 / Party's Specifications.			
 PREPARED BY NAME: Dharmesh - Patel DESIGNATION: Executive DATE: 08/08/2014		 CHECKED BY NAME: Mahesh Purna DESIGNATION: Asst. Manager DATE: 08/08/2014	
		 APPROVED BY NAME: Vinod J. Patel DESIGNATION: Q.A. Manager DATE: 08/08/2014	

