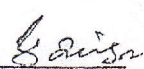
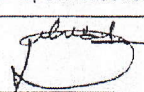
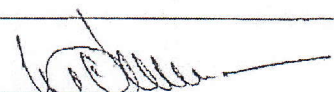


AVIK PHARMACEUTICAL LTD.

A-1/7 & A-1/8, Phase-1, GIDC, Vapi-396195. Tel: +91-260-2401593

Tele fax: +91-260-2433097 E-mail: avikpharma@avikpharma.com**CERTIFICATE OF ANALYSIS**

NAME OF PRODUCT : Clobetasol Propionate EP			
Batch No.	CLP/M/005/15	Batch Size	10420 gm
Mfg. Date	Mar.-2015	A. R. No.	AVK/CLP/024/15
Exp. Date	Feb.-2020	Released Date	16/03/2015
TESTS		SPECIFICATIONS	
Characters		RESULTS	
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.	+ 117°	
Related substances (By HPLC)	Impurity A: NMT 0.20 %	ND	
	Impurity B: NMT 0.30 %	0.06%	
	Impurity C: NMT 0.30 %	ND	
	Impurity D: NMT 0.50 %	ND	
	Impurity L: NMT 0.20 %	ND	
	Impurity M: NMT 0.20 %	ND	
	Impurity E: NMT 0.70 %	ND	
	Unspecified impurity : NMT 0.10 %	0.05%	
	Total impurities : NMT 2.0 %	0.16%	
Identified Impurities (By HPLC)	Betamethasone : NMT 0.15 %	ND	
	Impurity-G : NMT 0.15 %	ND	
	Impurity-K : NMT 0.15 %	ND	
	Impurity-I : NMT 0.15 %	ND	
	Impurity-J : NMT 0.15 %	ND	
	Betamethasone-17-Propionate-21-Tosylate : NMT 0.15 %	ND	
	Specified Unidentified Impurity(RRT about 0.7) : NMT 0.15%	0.05%	
Loss on drying	Maximum 0.5 % w/w	0.4%	
Sulphated ash	Maximum 0.10 %	0.06 %	
Assay (By HPLC)	97.0 % to 102.0 % of $C_{25}H_{32}ClFO_6$ (Dried substance).	99.8 %	
Additional tests			
A) Residual solvents	Methanol : NMT 3000 ppm	302 ppm	
	Methylene chloride : NMT 600 ppm	147 ppm	
	Dimethyl Formamide: NMT 880 ppm	32 ppm	
B) Partical Size (By Number Basis)	100% < 20 μ	14.24 μ	
Remarks: The sample CONFORMS as EP-8.0 Specifications.			
 PREPARED BY NAME : HETAL J DAIVAGNA DESIGNATION : QC SR.OFFICER DATE : 16/03/2015		 CHECKED BY NAME : MAHESH G DUNNA DESIGNATION : QC ASST MANAGER DATE : 16/03/2015	
		 APPROVED BY NAME : VINOD J PATEL DESIGNATION : QA/R MANAGER DATE : 16/03/2015	