



ENVEE DRUGS
PVT. LTD.

CERTIFICATE OF ANALYSIS

Reg. Off. & Works : N.H. No. 8, DUMRAL - 387 355 Tal. : Nadiad, Dist. : Kheda (Gujarat) India
 Phone : +91-268-2559595 / 2559275 / 2559795 Fax No. : +91-268-2558095
 Email : qc@enveelab.com, enveelab@hotmail.com Web Site : www.enveelab.com

QUALITY CONTROL DEPARTMENT

Material Name :	Betamethasone Di Propionate	Batch No.	EV/BD-373/19
Grade :	BP/EP	Mfg Date :	08.03.20
Molecular Formula :	$C_{28}H_{37}FO_7$	Exp. Date :	07.03.24
Molecular Weight :	504.6	Release Date :	15.03.20
A.R.No :	F/381/19		

TEST	OBSERVATIONS	SPECIFICATIONS
1 - Description or appearance :	White crystalline powder	White or almost white, crystalline powder.
2 - Solubility :	Complies	Practically insoluble in water, freely soluble in acetone & in methylene chloride, sparingly soluble in ethanol (96 %).
3 - Identification Test(s) :	Complies	A. Absorbance at 419 nm
	Complies	B. IR Test
	Complies	C. TLC
	Complies	D. Chemical
	Complies	E. Chemical
4 - Specific optical rotation :	+86.5°	+84.0° to +88.0°
5 - Related Substances :	0.14%	Impurity B : NMT 0.3%
	0.42%	Impurity C : NMT 0.5%
	ND	Impurity D : NMT 0.2%
	0.13%	Impurity E : NMT 0.2%
	ND	Impurity G : NMT 0.2%
	0.19%	Impurity H : NMT 0.3%
	ND	Un specified impurities : NMT 0.1%
	0.88%	Total Impurities : NMT 1.0%
6 - Loss on Drying :	0.42%	NMT 1.0%
7 - Assay (ODB) :	98.8%	97.0 % to 102.0 %
8 - Residual Solvent :	Complies	MDC : NMT 600 ppm
	Complies	Pyridine : NMT 200 ppm
	Complies	Methanol : NMT 3000 ppm
9 - Particle Size :	Complies	100% less than 20 microns

- The above sample is complies as per BP/EP.

Prepared By : Q.C Officer
 Sign : 
 Name : Chhota Singh
 Date : 15/03/2020

Checked By : Q.C Manager
 Sign : 
 Name : Anand Paul
 Date : 15/3/20