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UNIMAX LABORATORIES PVT. LTD.

MFGRS & EXPORTERS OF: Specialised API Products (Exclusively Corticoid-Steroids)

QUALITY ASSURANCE DEPARTMENT CERTIFICATE OF ANALYSIS

Product Name	BETAMETHASONE DIPROPIONATE USP		Page 1 of 1
Batch No	BDP/1115003 .	A. R. No.	UL/FP/012/15-16
Batch size	15.0 Kg	Released on	23/06/2015
Mfg. Date	MAY-2015	Expiry Date	APRIL-2020

Sr. No.	TEST	SPECIFICATIONS	Results.			
1	Description	White to cream white, odorless powder.	White odorless powder.			
2	Solubility	Insoluble in water, freely soluble in acetone & chloroform. Sparingly soluble in alcohol.	Complies			
	First identification					
3	A) Infrared Absorption Spectrophotometry	The sample spectrum should be concordant with the Betamethasone Dipropionate CRS/WS.	Complies			
3	B) BY TLC	The RF value of the principle spot obtained from the test solution corresponds to that obtained from the Standard solution.	Complies			
4	Specific optical rotation (On dried basis)	+63° to +70°	+64.80°			
5	Loss on drying	NMT 1.0%	0.27 %			
6	Residue on ignition	NMT 0.2%	0.02 %			
7	Chromatographic purity (BY HPLC) i)Any individual impurity ii) Total impurity	NMT 1.0% NMT 2.0%	0.57 % 1.55 %			
8	Assay (BY HPLC) (On dried basis)	NLT 97.0 to NMT 103.0%	99.91 %			

CONCLUSION: In opinion of the undersigned, the above mentioned product **COMPLIES** as per USP 36 and Additional test Specification.

Storage condition: Preserve In Tight, Light resistant Container.

131	Prepared By	Verified By	Approved By
Sign & Date	Pada 14/10/15	14/m/15	Jely 14/10/15
Name	Mr.Rakesh Kadam	Mr. Hemant Zambare	Mr. S.V.Padwal
Designation	QC Executive	QA Manager	CQA Manager