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CERTIFICATE OF ANALYSIS

Lot: 0020413

Name of Product : **Betamethasone Dipropionate EP**

Batch No : **BDP/M/004/13**

Batch size : 9400 gms.

Mfg. Date : Mar-2013

A.R.No. : AVK/BDP/009/13

Exp. Date : **Feb-2018**

Date : 11/03/2013

TEST	SPECIFICATION	RESULTS
CHARACTERS		
APPEREANCE	White or almost white crystalline powder.	White crystalline powder
SOLUBILITY	Practically insoluble in water; freely soluble in acetone and in methylene chloride, sparingly soluble in ethanol (96 percent).	Conforms
IDENTIFICATION	A). By UV: The absorbance measured at 419 nm is not more than 0.10. B). By IR.: Infrared spectrum of the sample is concordant to that of the standard. C). By TLC: Result A :The principal spot in each of the chromatograms obtained with the test solutions is similar in position, and size to the principal spot in the chromatogram obtained with the corresponding reference solution. Result B:-The principal spot in each of the chromatograms obtained with the test solution is similar in position, colour in daylight, fluorescence in ultraviolet light at 365 nm and size to the principal spot in the chromatogram obtained with the corresponding reference solution. The principal spot in each of the chromatograms obtained with the test solution (b) and reference solution (b) has an Rf value distinctly lower than that of the principal spot in each of the chromatograms obtained with the test solution (a) and reference solution (a). D). Add about 2 mg to 2 ml of sulphuric acid and shake to dissolve. Within 5 min, a deep reddish brown colour develops. Add the solution to 10 ml water and mix. The colour is discharged and a clear solution remains. E). The test solution is yellow and the blank is red.	0.04 Conforms Conforms Conforms Conforms Conforms
SPECIFIC OPTICAL ROTATION	+ 84° to + 88° On dried substance.	+ 86°
RELATED SUBSTANCES (BY HPLC)	Impurity C : NMT 0.5 % Impurity B : NMT 0.3 % Impurity H : NMT 0.3 % Impurity D : NMT 0.2 % Impurity E : NMT 0.2 % Impurity G : NMT 0.2 % Unspecified Impurity : NMT 0.1 % Total impurities : NMT 1.0 %	0.5 % 0.01% ND 0.01% 0.06% 0.2% 0.1% 0.95%
LOSS ON DRYING	Maximum 1.0%	0.4%
ASSAY (By HPLC)	97.0 % to 102.0 % of C ₂₈ H ₃₇ FO ₇ (On dried substance.)	99.7%
ADDITIONAL TEST		
A).Residual solvents	Methanol : NMT 3000 ppm Methylene chloride : NMT 600 ppm Pyridine : NMT 200 ppm DMF : NMT 880 ppm	427 ppm 100 ppm ND 398 ppm
B).Particle Size (By Number Basis)	100% < 10µm	7.20 µm

REMARKS: The sample CONFORMS as per **EP-7.4** specifications.

PREPARED BY
DATE : 06/04/2013

CHECKED BY
DATE : 06/04/2013

APPROVED BY
DATE : 06/04/2013