

Lot: 0140615

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CERTIFICATE OF ANALYSIS

Name of Product : Betamethasone Dipropionate EP		
Batch No : BDP/M/005/15	Batch size : 19260 gm	
Mfg. Date : Feb.-2015	A.R.No. : AVK/BDP/031/15	
Exp. Date : Jan.-2020	Date : 11/03/2015	
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%).	Conforms
IDENTIFICATION	A). By UV: The absorbance measured at 419 nm is NMT 0.10. B). By IR.: The Infrared absorption spectrum of the test sample is concordant to that of the standard. C). By TLC: Result A : The principal spot in each 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 solutions 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 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). The colour of solution is discharged and a clear solution remains. E). The test solution is yellow and the blank is red.	0.09 Conforms Conforms Conforms Conforms Conforms
SPECIFIC OPTICAL ROTATION	+ 84° to + 88° On dried substance.	+ 86°
RELATED SUBSTANCES (BY HPLC)	Impurity B : NMT 0.3 % Impurity C : NMT 0.5 % Impurity D : NMT 0.2 % Impurity E : NMT 0.2 % Impurity G : NMT 0.2 % Impurity H : NMT 0.3 % Unspecified impurity : NMT 0.1 % Total impurities : NMT 1.0 %	ND 0.44 % ND ND ND ND ND 0.44 %
Identified Impurities (By HPLC)	Betamethasone (Impurity A) : NMT 0.15 % 9β, 11β- Epoxy Betamethasone Dipropionate (Impurity-F) : NMT 0.15 %	ND ND
LOSS ON DRYING	Maximum 1.0% w/w.	0.5 %
ASSAY (By HPLC)	97.0 % to 102.0 % of C ₂₆ H ₃₇ FO ₇ (On dried substance.)	99.0 %
ADDITIONAL TEST A).Residual solvents	Methanol : NMT 3000 ppm Methylene chloride : NMT 600 ppm Triethylamine : NMT 320 ppm Tetrahydrofuran : NMT 720 ppm Dimethyl formamide : NMT 880 ppm	148 ppm 225 ppm ND 15 ppm 297 ppm
B).Particle Size (By Number Basis)	100% < 10µm	5.90 µm

REMARKS: The sample CONFORMS as per EP-8.0/ Party's Specifications.

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