

**Ippca**

**Ippca Laboratories Limited**

A-17 Phase-I GIDC VAPI - 396195, Tel: 91 - 260 - 2401593, 2433097

**CERTIFICATE OF ANALYSIS**

Name of Product : Betamethasone Dipropionate EP		Batch size : 16450 gms.	
Batch No : BDP/N/003/11		A.R.No. : AVK/FP/256/11	
Mfg. Date : May-2011		Date : 06/05/2011	
Exp. Date : Apr-2016			
TEST	SPECIFICATION	RESULTS	
DESCRIPTION	White or almost white crystalline powder.	White powder	
SOLUBILITY	Practically insoluble in water, freely soluble in acetone and in methylene chloride; sparingly soluble in ethanol(96%).	Conforms	
IDENTIFICATION	<p>A). By UV: The absorbance of the specified solution measured at 419 nm is NMT 0.10.</p> <p>B). By IR: Infrared spectrum of the sample is concordant to that of the standard.</p> <p>C). By TLC: Result A :The principal spot in the chromatogram obtained with the test solution is similar in position, and size to the principal spot in the chromatogram obtained with reference solution (a).</p> <p>Result B:-The principal spot in the chromatogram 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 reference solution (a).</p> <p>D). By TLC : Result A : The principal spot in the chromatogram obtained with the test solution is similar in position, colour in daylight, fluorescence in ultraviolet at 365 nm and size to the principal spot in the chromatogram obtained with corresponding reference solution.</p> <p>Result B:- The principal spot in each of the chromatograms obtained with the test solution (b) and reference solution (b) has an R<sub>f</sub> value distinctly lower than that of the principal spots in each of the chromatograms obtained with the Test solution (a) and reference solution (a).</p> <p>E). The specified solution gives a deep reddish -brown colour develops. Add this solution to 10 ml water and mix. The colour is discharged and a clear solution remains.</p> <p>F). The test solution is yellow and the blank is red.</p>	<p>0.05</p> <p>Conforms</p> <p>Conforms</p> <p>Conforms</p> <p>Conforms</p> <p>Conforms</p> <p>Conforms</p>	
SPECIFIC OPTICAL ROTATION	+ 63° to + 70° On dried substance.	+ 67°	Conforms
RELATED SUBSTANCES (BY HPLC)	<p>Any Single impurity : 1.5 %</p> <p>One such impurity : 1.0 %</p> <p>Sum of all impurity : 2.5 %</p>	<p>0.50 %</p> <p>0.23 %</p> <p>1.21 %</p>	
LOSS ON DRYING	NMT 1.0% w/w.	0.4 %	
ASSAY (By UV)	97.0 % to 103.0 % of C <sub>22</sub> H <sub>31</sub> FO <sub>7</sub> (On dried substance.)	99.8%	
ADDITIONAL TEST			
Residual solvents	<p>Methanol : NMT 3000 ppm</p> <p>Methylene chloride : NMT 600 ppm</p> <p>Pyridine : NMT 200 ppm</p> <p>DMF : NMT 880 ppm</p>	<p>964 ppm</p> <p>95 ppm</p> <p>ND</p> <p>143 ppm</p>	
REMARKS: The sample CONFORMS as per EP-7.0 specifications.			

PREPARED BY  
DATE : 06/05/2011

CHECKED BY  
DATE : 06/05/2011

MANAGER QUALITY ASSURANCE  
DATE : 06/05/2011