



**QUALITY CONTROL DEPARTMENT**  
**Certificate of Analysis of Finished Product**

(Under Drug And Cosmetic Act. 1940 & The Rules There Under)

**Report No: TT/FG/207/24-25**

**Report Date: 27-07-2024**


Name of the product : BETASTAL injection 1ml  
Generic name : Betamethasone sodium phosphate Injection I.P  
Batch No. : BM415  
Batch Size : 100000  
Mfg. Date. : July-2024  
Exp. Date : June-2027  
Quantity of Sample : 100 Nos  
Date of Sampling : 12-07-2024  
Date of Commencement of analysis : 12-07-2024  
Date of Completion of analysis : 26-07-2024

TEST NAME	SPECIFICATION	OBSERVATION
Description:	A clear, colourless solution.	A clear, colourless solution
Identification:		
A.Maximum at 450nm	NMT0.1	Complies to IP specification
B.(By TLC )	The Chromatogram obtained with the test solution,reference solution(a) and reference solution (b) shows single principal spot with identical Rf values.	Complies to IP specification
C.Colour Reaction:	No Red colour is produced	Complies to IP specification
pH	8.0 to 9.0	8.52
Extractable Volume	NLT- 1.0ml/Ampoule	1.1 ml
Particulate matter	No visible particles	No visible particles
Related Substances	Ignore any peak with an area less than 0.05 times of the principal peak in the chromatogram obtained with reference solution (a) (0.1 percent )	Complies to IP specification
Appearance Of Solution	Betamethasone is not more intensely coloured than reference solutionBYS4	Complies to IP specification
Sterility Test	To comply as per IP	Complies
Assay		
Each ml contains :	3.7 mg to 4.3 mg	3.98mg
Beatamethasone Sodium Phosphate I.P Equivalent to Betamethasone 4mg	(92.5. % - 107.5%)	(98.50%)

**OBSERVATION:** In the opinion of the undersigned the sample referred to above is of **Standard Quality**/Not Standard Quality as in the act and the rules made there under for the reason given below.

**REMARKS :** COMPLIES AS PER IP WITH RESPECT TO THE ABOVE TESTS ONLY CARRIED OUT.

Analysed By:   
Date: 27/07/2024

Checked By:   
Date: 27/07/2024

Person In Charge of Testing  
Date:  27/07/2024

