

CERTIFICATE OF ANALYSIS

Product : Betamethasone Sodium Phosphate **Manf. Date** : May 2023
Batch no. : BSP 001/0523 **Retest Date** : April 2028

Description	White, very hygroscopic powder (White to almost white powder, very hygroscopic)
Solubility	Complies (Freely soluble in water, slightly soluble in ethanol (96%), practically insoluble in methylene chloride)
Identification	Test A : IR (Concordant with EP standard) Test B : TLC (Complies with EP)
Appearance of solution	Complies (Test A : Solution S is clear) I) Clarity same as water OR II) Opalescence is NMT that of reference suspension 1 Complies (Test B : Solution S is not more intensely coloured than reference solution B ₇ (Method II))
pH	8.0 (7.5 to 9.0)
Specific Optical Rotation (1 % Solution in Water at 20° C)	+100° (+98° to +104° on anhydrous basis)
Related substances (By HPLC)	0.07 % (Single Impurity : NMT 2.0 %) Less than 0.05 % (Single Other Impurity: NMT 1.0 %) 0.07 % (Total Impurities: NMT 3.0 %)
Inorganic Phosphates	Complies (NMT 1.0%)
Water	6.3 % w/w (NMT 8.0 % w/w)
Assay	100.3 % w/w (NLT 96.0 % w/w and NMT 103.0 % w/w on anhydrous basis)
Residual solvents	Methanol : NMT 3000 ppm Acetone : NMT 5000 ppm Tetrahydrofuran : NMT 720 ppm Complies as per ICH guidelines

Analytical Chemist

HJH 25/08/23

Assoc. OC Manager



X 25/07/23

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<u>Additional Tests</u>	
Total Aerobic Microbial Count	<10 CFU/g (NMT 10 ³ CFU/g)
Total Combined Yeasts/Molds Counts	<10 CFU/g (NMT 10 ² CFU/g)
Pathogens:	
<i>Escherichia coli</i>	Absent (Absent)
<i>Salmonella</i>	Absent (Absent)
<i>Pseudomonas aeruginosa</i>	Absent (Absent)
<i>Staphylococcus aureus</i>	Absent (Absent)
<i>Clostridia</i>	Absent (Absent)
<i>Candida albicans</i>	Absent (Absent)
Bacterial Endotoxin	Less than 29.2 E.U./ mg (NMT 29.2 E.U/mg of Betamethasone)

Conclusion : Complies with EP 11

Analytical Chemist

H37 25/07/23

Assoc. QC Manager

