

**CERTIFICATE OF ANALYSIS**

**Product** : Betamethasone Acetate **Manf. Date** : July 2023  
**Batch no.** : BAC 001/0723 **Retest Date** : June 2028

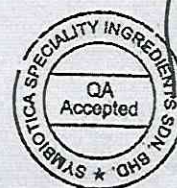
|                                                                       |                                                                                                                                                                                                                                              |
|-----------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Description</b>                                                    | White, crystalline powder<br>(White or almost white, crystalline powder)                                                                                                                                                                     |
| <b>Solubility</b>                                                     | Complies (Practically insoluble in water, freely soluble in acetone, soluble in ethanol (96%) and in methylene chloride)                                                                                                                     |
| <b>Identification</b>                                                 | Test B : IR - Concordant with EP standard)<br>Test C : TLC - Complies with EP                                                                                                                                                                |
| <b>Specific Optical Rotation</b><br>(1 % Solution in Dioxan at 20 °C) | +123 ° (+120 ° to +128 ° on anhydrous basis)                                                                                                                                                                                                 |
| <b>Water</b>                                                          | 0.6 % w/w ( NMT 4.0% w/w)                                                                                                                                                                                                                    |
| <b>Related substances</b>                                             | Less than 0.05 % ( Impurity A : NMT 0.5 % )<br>Less than 0.05 % ( Impurity B : NMT 0.5 % )<br>Less than 0.05 % ( Impurity C : NMT 0.5 % )<br>Less than 0.05 % ( Impurity D: NMT 0.5 % )<br>Less than 0.05 % (Total impurities : NMT 1.25 % ) |
| <b>Assay</b>                                                          | 99.6 % w/w<br>( NLT 97.0 % w/w and NMT 103.0 % w/w on anhydrous basis )                                                                                                                                                                      |
| <b>Residual solvents</b>                                              | Acetonitrile : NMT 410 ppm<br>Pyridine: NMT 200 ppm<br>Complies as per ICH guidelines                                                                                                                                                        |

**Conclusion** : Complies with EP 11

**Analytical Chemist**

*afh*  
11/09/23

**QC Manager**



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11/09/23