

Analysis Date: 03-08-2023 **Re-test Date:** 03-08-2026

HYDROCORTISONE EP IMPURITY I

Identification

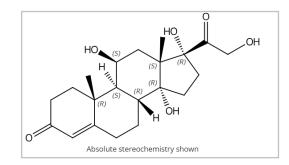
Chemical Name : 11β,14,17,21-Tetrahydroxypregn-4-ene-3,20-dione

CAT No : ALL-H04159

CAS No : 103795-84-2

Molecular Formula : C21H30O6

Molecular Weight : 378.46



IR Analysis

: Confirm

Analytical Information

Batch Code : ALL-H04159 HPLC Purity : 94.44 %

Solubility : USP Diluent / EP Diluent (MEOH) Potency : 92.35 %

Appearance of Product: Off White Solid Mass: Confirm

Long Term Storage : -20°C

Weight Loss By TGA : 1.344 % 1HNMR : Confirm

Residue Of Ignition : 0.861 %

Additional Information

% **Potency** = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =

 $[100 - (1.344 + 0.861) \times 94.44]/100 = 92.35 \%$

Recommendation : Released

| | Department | Name | Signature |
|--------------------------|------------|------------------------------------|-----------|
| Prepared and Reviewed by | Analytical | Mr.Vipul Khadase Jr. Executive | |
| Approved By | QA&QC | Dr. Ashish Keche Director QA&QC | |

Attachment : HPLC, Mass, 1H NMR, IR, TGA

Shipping Condition : All Product are stable to be shipped at room temperature, unless

otherwise specified