

CERTIFICATE OF ANALYSIS

(Certificate No. KMP167011-01)

Release Date: 17/02/2025

Re-test Date: 16/02/2028

Prednisone EP Impurity C

Identification

Chemical Name :

17-Hydroxy-3,11,20-trioxopregna-1,4-dien-21-al (as per EP) ; 17,21,21-Trihydroxy-pregna-1,4-diene-3,11,20-trione

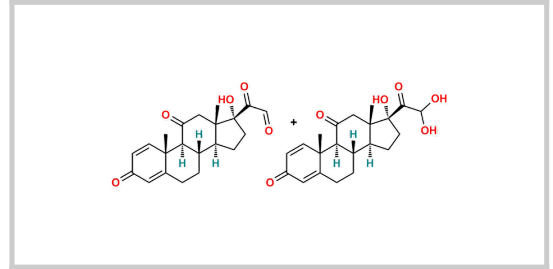
Alt. Name : Prednisone-21-aldehyde + 17,21,21-Trihydroxy-pregna-1,4-diene-3,11,20-trione

CAT No. : KMP167011

CAS No. : 70522-55-3

Molecular Formula : C₂₁H₂₄O₅ or C₂₁H₂₆O₆

Molecular Weight : 356.412 (Aldehyde) ; 374.43 (Dihydroxy)



Analytical Information

Batch No. : P167011-091-220

Description : Off White Solid

HPLC Purity : 95.69 %

Weight Loss By TGA : 3.28 %

% Potency : 92.55 %

Solubility : ACN : Water (1:1)

Mass : Confirm

IR : Confirm

¹H NMR : Confirm

Additional Information

Long Term Storage : Store at 2-8 deg. C for long term storage

Shipping Condition : Product is stable to be Shipped at Room Temperature

% Potency = [100 - 3.28(Weight Loss By TGA)] x [95.69(HPLC Purity)]/100 = 92.55 %

Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 18/02/2025 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 18/02/2025 |

Attachments : COA, HPLC, MASS, ¹HNMR, IR and TGA