

CERTIFICATE OF ANALYSIS

(Certificate No. KMP167004-01)

Release Date: 14/11/2024

Re-test Date: 14/11/2026

Prednisone

Identification

Chemical Name :

17,21-Dihydroxypregna-1,4-diene-3,11,20-trione (as per EP and USP) ; Prednisone

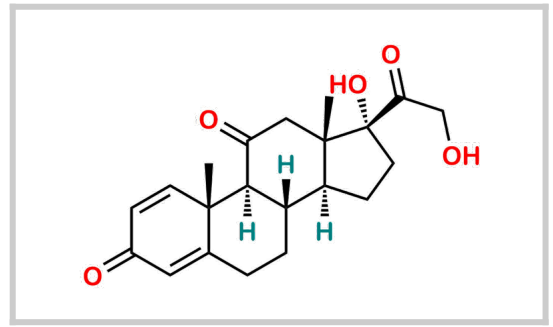
Alt. Name : Prednidone ; Apo-Prednisone ;
Ancortone

CAT No. : KMP167004

CAS No. : 53-03-2

Molecular Formula : C₂₁H₂₆O₅

Molecular Weight : 358.4



Analytical Information

Batch No. : U70VB

Description : White Solid

HPLC Purity : 99.42 %

Weight Loss By TGA : 0.40 %

% Potency : 99.02 %

Solubility : Methanol

Mass : Confirm

IR : Confirm

¹H NMR : Confirm

Additional Information

Long Term Storage : Room Temperature

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

% Potency = [100 - 0.40(Weight Loss By TGA)] x [99.42(HPLC Purity)]/100 = 99.02 %

Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 18/11/2024 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 18/11/2024 |

Attachments : COA, HPLC, MASS, ¹H NMR, IR and TGA