

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.

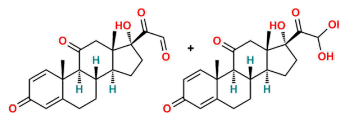
: 70522-55-3

Molecular Formula

: C₂₁H₂₄O₅ or C₂₁H₂₆O₆

Molecular Weight

: 356.412 (Aldehyde) ; 374.43 (Dihydroxy)



Analytical Information

Batch No.

: P167011-091-220

Solubility

: ACN : Water (1:1)

Description

: Off White Solid

Mass

: Confirm

HPLC Purity

: 95.69 %

IR

: Confirm

Weight Loss By TGA

: 3.28 %

¹H NMR

: Confirm

% Potency

: 92.55 %

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