CERTIFICATE OF ANALYSIS

(Certificate No. KMP167011-01)

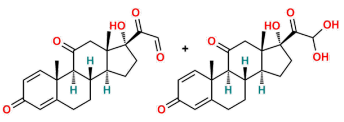
Release Date: 17/02/2025 **Re-test Date:** 16/02/2028

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