

# **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.**

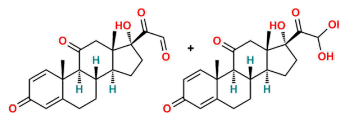
: 70522-55-3

**Molecular Formula**

: C<sub>21</sub>H<sub>24</sub>O<sub>5</sub> or C<sub>21</sub>H<sub>26</sub>O<sub>6</sub>

**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 %

**<sup>1</sup>H 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, <sup>1</sup>HNMR, IR and TGA