

# CERTIFICATE OF ANALYSIS

(Certificate No. KMM007001-01)

Release Date: 19/04/2024

Re-test Date: 18/04/2027

## Methylprednisolone EP Impurity D (Z-Isomer)

### Identification

**Chemical Name :**

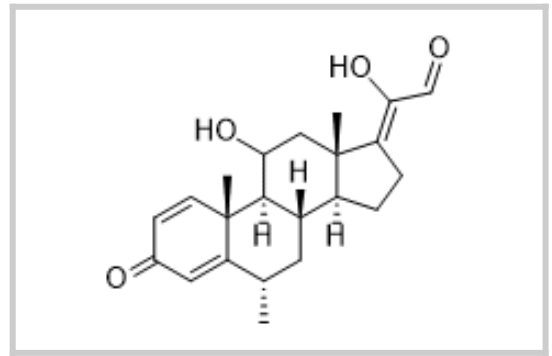
(Z)-11,20-dihydroxy-6a-methylpregna-1,4,17(20)-triene-3,21-dione

**CAT No.** : KMM007001

**CAS No.** : Not Available

**Molecular Formula** : C<sub>22</sub>H<sub>28</sub>O<sub>4</sub>

**Molecular Weight** : 356.46



### Analytical Information

**Batch No.** : METH-EPD-Z-073-179

**Description** : Off White Solid

**HPLC Purity** : 95.40 %

**Weight Loss By TGA** : 0.44 %

**% Potency** : 94.98 %

**Solubility** : ACN

**Mass** : Confirm

**IR** : Confirm

**<sup>1</sup>H NMR** : Confirm

**<sup>13</sup>C NMR** : Confirm

### Additional Information

**Long Term Storage** : Store at -20 deg. C for long term storage , Protect from Moisture and Light

**Shipping Condition** : Product is stable to be shipped at room temperature

**% Potency** = [100 - 0.44(Weight Loss By TGA)] x [95.40(HPLC Purity)]/100 = 94.98 %

**Recommendation** : Released

	Department	Name	Signature	Date
<b>Prepared By</b>	Analytical	Jignesh Patel		19/04/2024
<b>Reviewed &amp; Approved By</b>	Quality Control	Jatin Patel		19/04/2024

**Attachments** : COA, HPLC, MASS, <sup>1</sup>H NMR, <sup>13</sup>C NMR, IR and TGA