

Certificate of Analysis

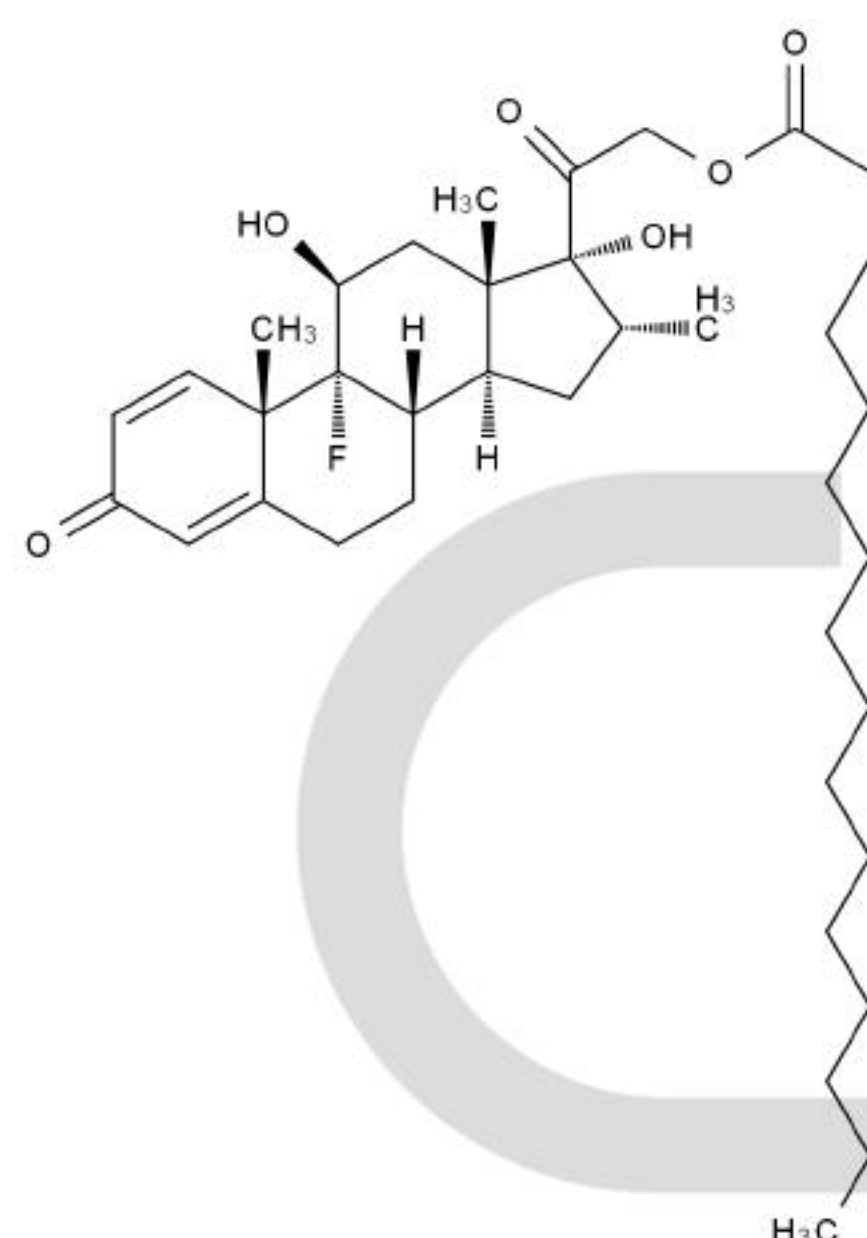
Reference Material & Standard

Product Name:	Dexamethasone 21-Palmitate	Catalogue Number:	CCAD301954
Synonyms:	N/A	Lot Number:	0308-RF-0064
CAS Number:	14899-36-6	Expiry Date:	Mar 12, 2028
Molecular Formula:	C ₃₈ H ₅₉ FO ₆	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	630.87	Shipping Condition:	Shipping with Ice Packs

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Yellow Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	98.922%
Loss on Drying	TGA	0.3892%
Assay		98.5%
Uncertainty		±2.0%

Comment:

1. The calculation of the mass balance method follows the formula (calculated on the non-dried basis):

$$\text{Assay (\%)} = (100\% - \text{Loss on Drying}) * \text{Purity HPLC (\%)} / 100\%$$

Loss on Drying is considered as absolute effect, HPLC purity is considered as relative effect.

2. The uncertainty values are the expanded uncertainty and represent an estimated standard deviation equal to the positive square root of the total variation of the uncertainty of components. A normal distribution is assumed and a coverage factor of K=2 is chosen using approximately a 95% confidence level.

Signature:

Prepared by:

Nice

Reviewed by:

Koi

Approved by General Manager:

David

Date: Mar 13, 2024

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