

# Certificate of Analysis

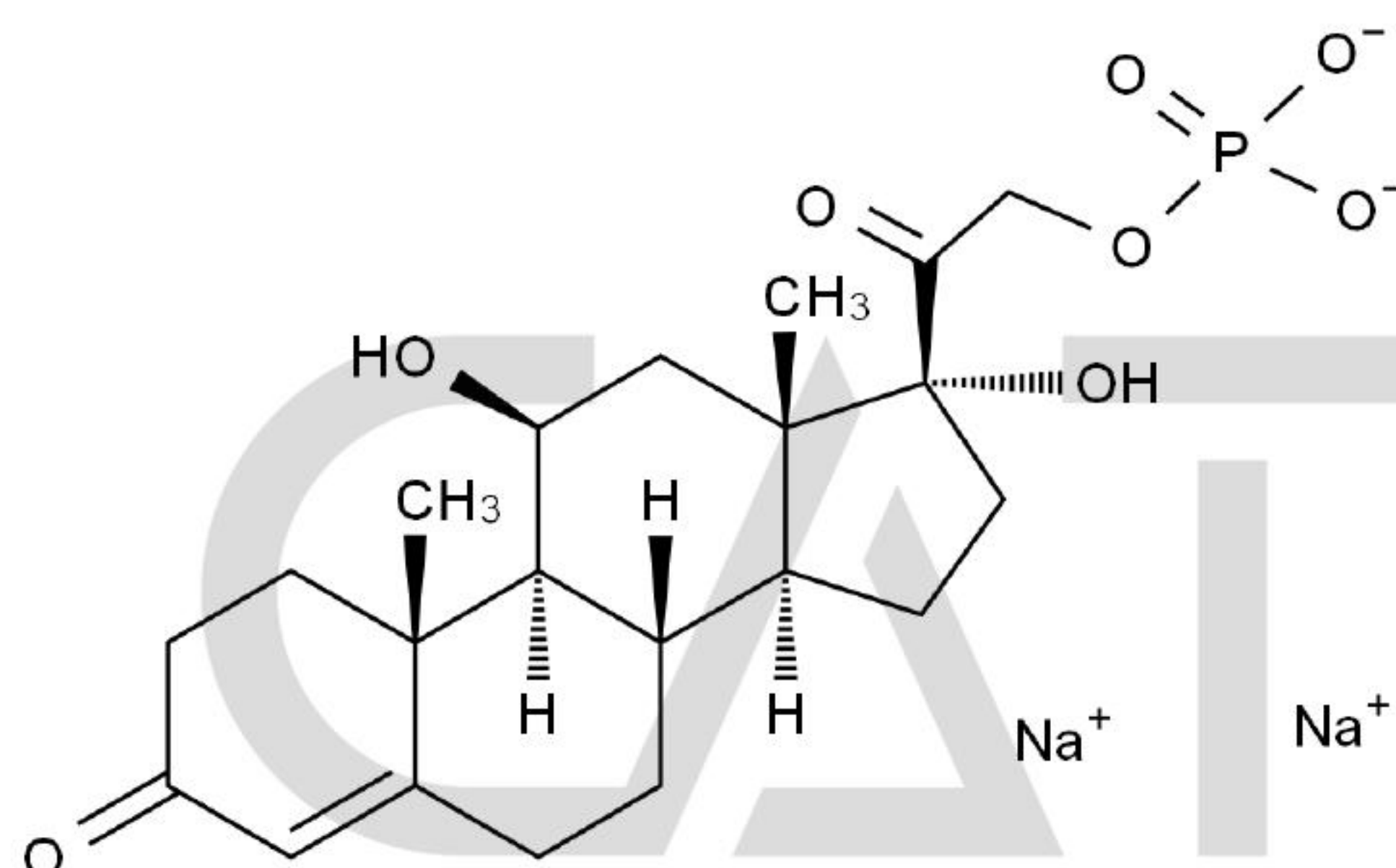
## Reference Material & Standard

|                           |                                                       |                            |                                           |
|---------------------------|-------------------------------------------------------|----------------------------|-------------------------------------------|
| <b>Product Name:</b>      | Hydrocortisone Sodium Phosphate                       | <b>Catalogue Number:</b>   | CCAD301942                                |
| <b>Synonyms:</b>          | N/A                                                   | <b>Lot Number:</b>         | 0721-RE-0063                              |
| <b>CAS Number:</b>        | 6000-74-4                                             | <b>Expiry Date:</b>        | Jul 30, 2027                              |
| <b>Molecular Formula:</b> | C <sub>21</sub> H <sub>29</sub> O <sub>8</sub> P 2*Na | <b>Storage:</b>            | -20°C±5°C Protected from light and Sealed |
| <b>Molecular Weight:</b>  | 440.42 2*22.99                                        | <b>Shipping Condition:</b> | Shipping with Ice Packs                   |

**Warning:**



**Chemical Structure:**



| Test Items     | Method            | Results     |
|----------------|-------------------|-------------|
| Appearance     | Visual inspection | White Solid |
| Identification | LCMS&HNMR         | Confirmed   |
| Purity         | HPLC              | 97.179%     |
| Loss on Drying | TGA               | 7.4823%     |
| Assay          |                   | 89.9%       |
| 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:

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Reviewed by:

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Approved by General Manager:

*David*

Date: Jul 31, 2023

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