

Certificate of Analysis

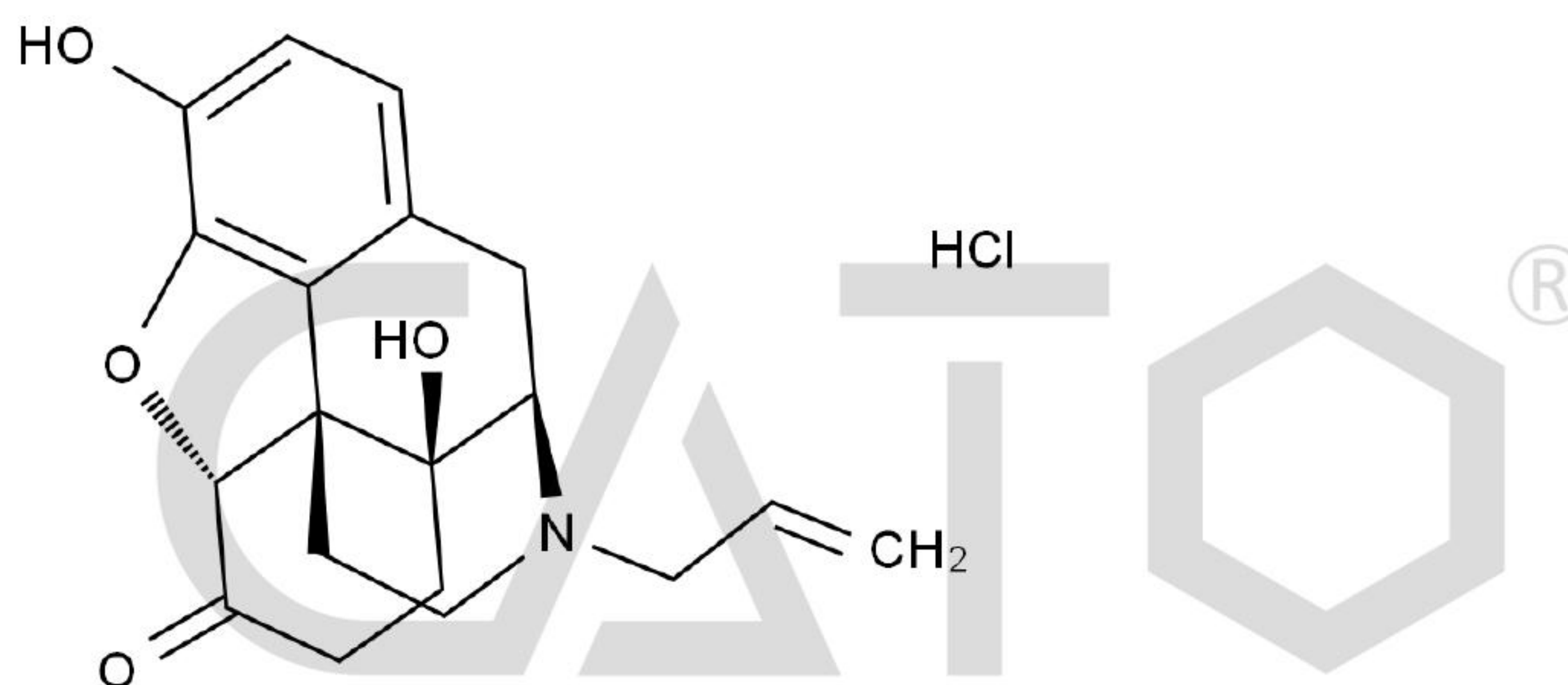
Reference Material & Standard

Product Name:	Naloxone Hydrochloride	Catalogue Number:	CCAD301768
Synonyms:	N/A	Lot Number:	0617-RD-0052
CAS Number:	357-08-4	Expiry Date:	May 13, 2030
Molecular Formula:	C ₁₉ H ₂₁ NO ₄ HCl	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	327.37 36.46	Shipping Condition:	Shipping with Ice Packs

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	100.000%
Loss on Drying	TGA	8.7560%
Assay		91.2%
Uncertainty		±1.0%

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:

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Date: May 14, 2026

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