

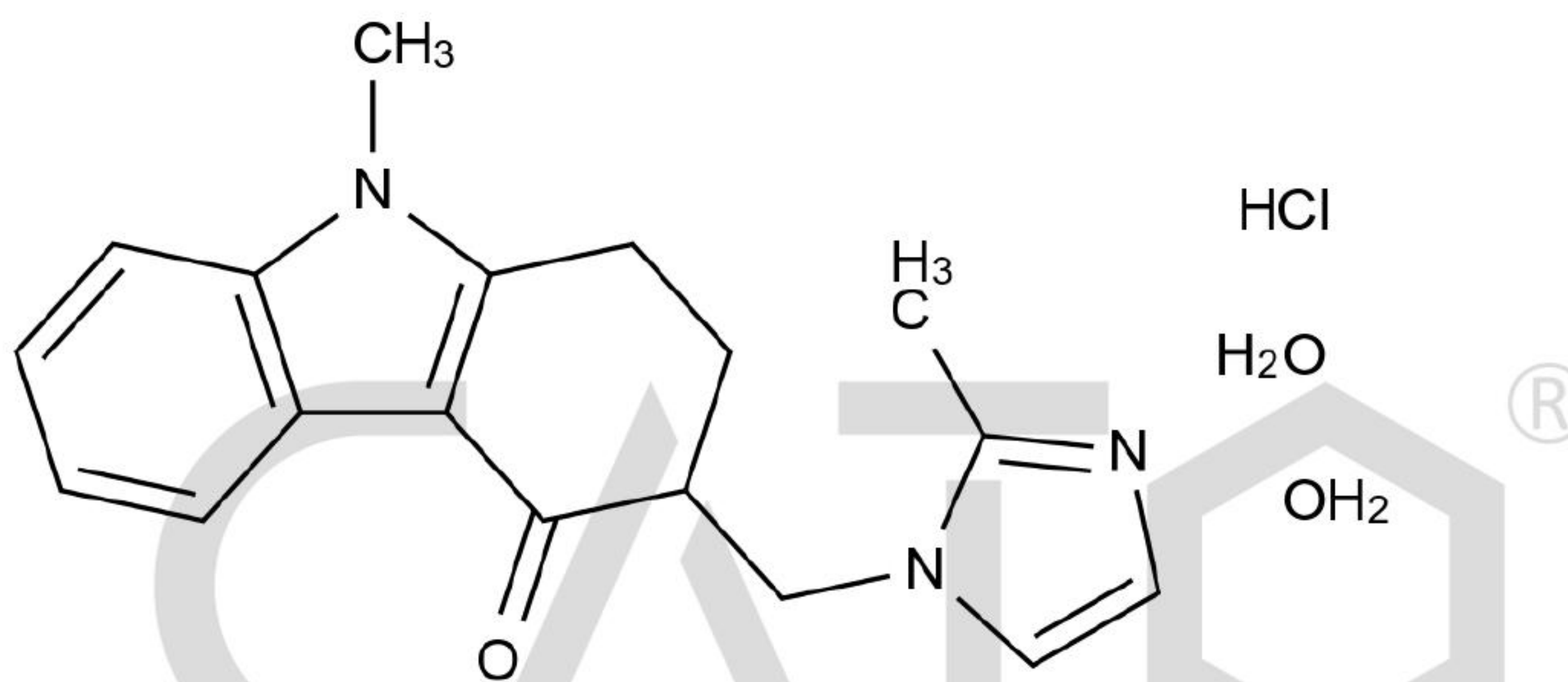
Certificate of Analysis

Reference Material & Standard

Product Name:	Ondansetron Hydrochloride Dihydrate	Catalogue Number:	CCAD302827
Synonyms:	N/A	Lot Number:	1220-RE-0055
CAS Number:	103639-04-9	Expiry Date:	Jan 21, 2028
Molecular Formula:	C ₁₈ H ₁₉ N ₃ O HCl 2*H ₂ O	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	293.36 36.46 2*18.02	Warning:	



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	99.677%
Water Content	Karl Fischer	9.7236%
Water Content(Free Water)		ND
Assay		99.7%
Uncertainty		±2.0%

Comment:

- The content of crystal water is 9.8507%.
- The calculation of the 100% method follows the formula (calculated on the non-dried basis):

$$\text{Assay (\%)} = (100\% - \text{Water Content(Free Water)}) * \text{Purity HPLC (\%)} / 100\%$$
 Water Content(Free Water) is considered as absolute effect, HPLC purity is considered as relative effect.
- 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:

Lisa

Aproved by General Manager:

David

Date: Jan 22, 2024

Date: Jan 22, 2024

Date: Jan 22, 2024

