

Certificate of Analysis

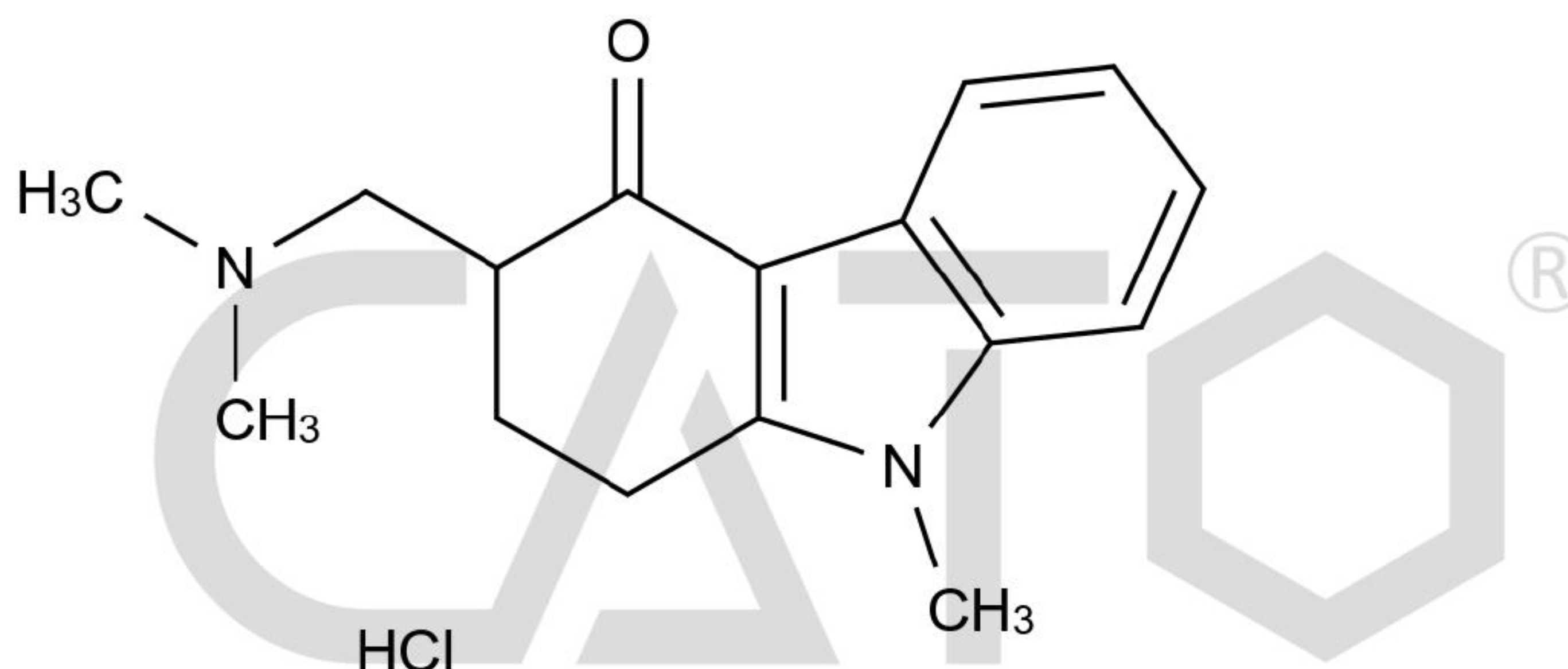
Reference Material & Standard

Product Name:	Ondansetron EP Impurity A	Catalogue Number:	CP106580
Synonyms:	N/A	Lot Number:	1020-RE-0006
CAS Number:	119812-29-2	Expiry Date:	Jun 30, 2030
Molecular Formula:	C ₁₆ H ₂₀ N ₂ O HCl	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	256.34 36.46	Shipping Condition:	Shipping with Ice Packs

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	99.423%
Water Content	Karl Fischer	0.81%
Residual Solvents	NMR	Not detected in NMR
Assay		98.6%

Comment:

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

Assay (%) = (100% - Water Content - Residual Solvents) * Purity HPLC (%) / 100%

Water Content and Residual Solvents are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Koi

Reviewed by:

Lisa

Approved by General Manager:

David

Date: Jul 01, 2026

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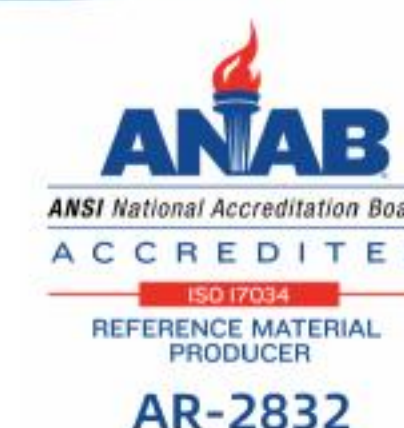
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