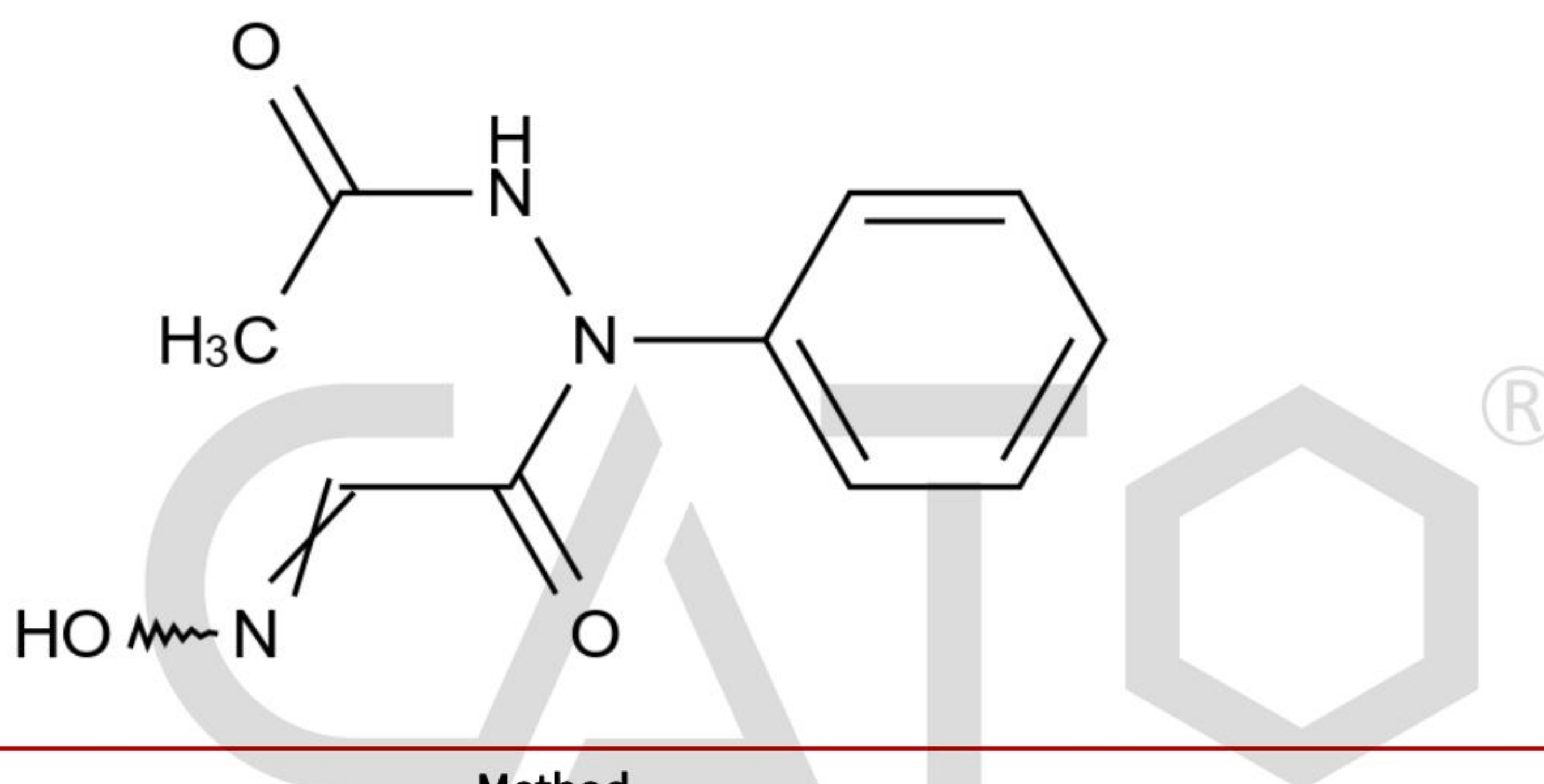


Certificate of Analysis

Reference Material & Standard

Product Name:	Granisetron Impurity 11(Mixture of Z and E Isomers)	Catalogue Number:	C4X-197011
Synonyms:	N/A	Lot Number:	0202-RF-0004
CAS Number:	123704-98-3	Expiry Date:	Jan 22, 2027
Molecular Formula:	C10H11N3O3	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	221.21		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Off-White Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	95.7722%
Water Content	Karl Fischer	5.70%
Residual Solvents	NMR	Not detected in NMR
Assay		90.3%

Comment:

The calculation of the 100% method follows the formula (calculated on the non-dried basis):

$\text{Assay (\%)} = (100\% - \text{Water Content} - \text{Residual Solvents}) * \text{Purity HPLC (\%)} / 100\%$

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

Signature:

Prepared by:

Lily

Reviewed by:

Hinlam

Aproved by General Manager:

David

Date: Feb 04, 2024

Date: Feb 04, 2024

Date: Feb 04, 2024

