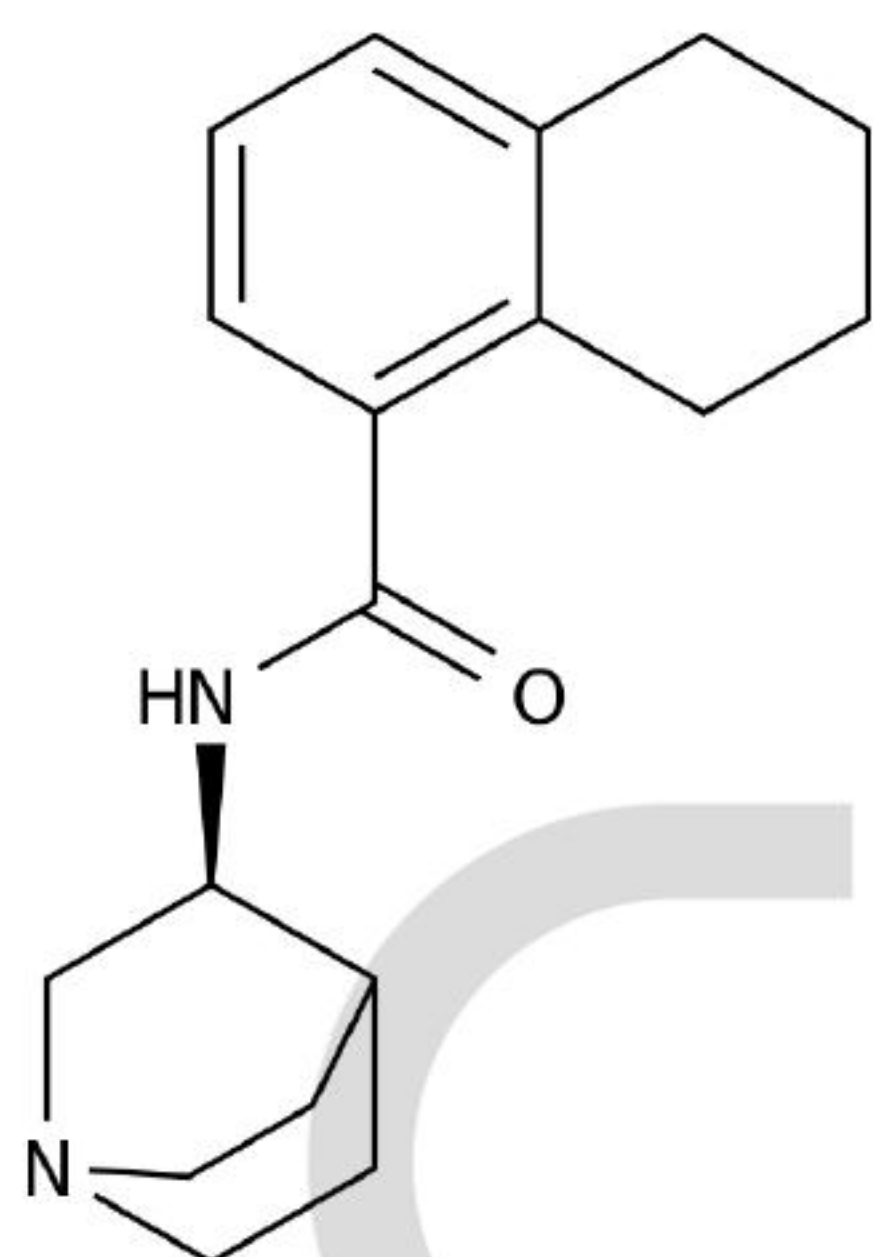


Certificate of Analysis

Reference Material & Standard

Product Name:	Palonosetron Impurity 15	Catalogue Number:	C4X-110515
Synonyms:	N/A	Lot Number:	1229-RE-0015
CAS Number:	135729-78-1	Expiry Date:	Dec 25, 2026
Molecular Formula:	C ₁₈ H ₂₄ N ₂ O	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	284.40		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	98.732%
Water Content	Karl Fischer	0.42%
Residual Solvents	NMR	0.41% ethyl acetate
Assay		97.9%

Comment:

The calculation of the 100% 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:

Lily

Reviewed by:

Hin Lam

Aproved by General Manager:

David

Date: Dec 29, 2023

Date: Dec 29, 2023

Date: Dec 29, 2023

