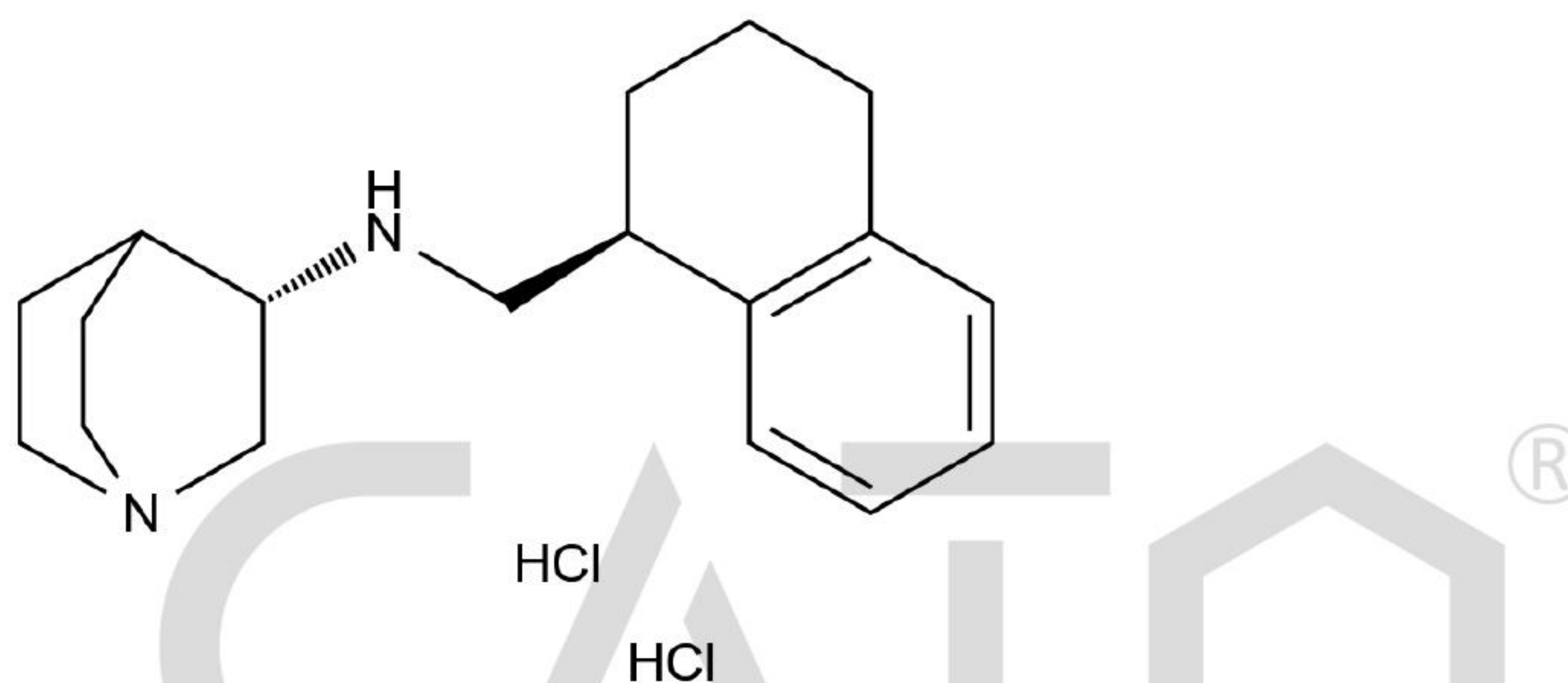


Certificate of Analysis

Reference Material & Standard

Product Name:	Palonosetron Impurity 12 DiHCl	Catalogue Number:	C4X-110512
Synonyms:	N/A	Lot Number:	0303-RG-0053
CAS Number:	177793-80-5(free base)	Expiry Date:	Dec 25, 2027
Molecular Formula:	C ₁₈ H ₂₆ N ₂ 2*HCl	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	270.41 2*36.46		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Off-White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	97.627%
Water Content	Karl Fischer	3.07%
Residual Solvents	NMR	Not detected in NMR
Assay		94.6%

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

Approved by General Manager:

David

Date: Mar 04, 2025

Date: Mar 04, 2025

Date: Mar 04, 2025

