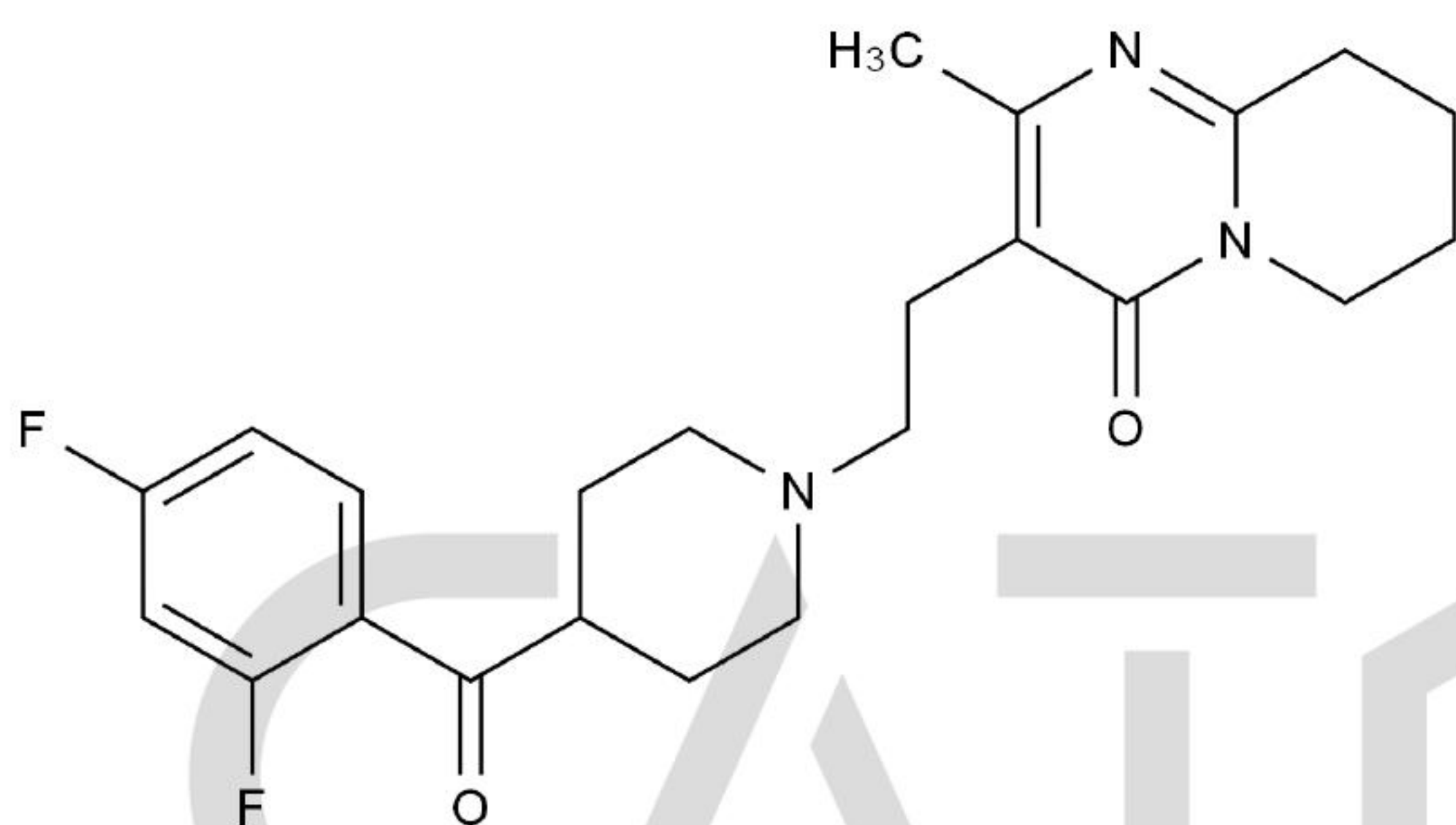


Certificate of Analysis

Reference Material & Standard

Product Name:	Risperidone EP Impurity H	Catalogue Number:	C4X-111113
Synonyms:	6-Methylrisperidone	Lot Number:	1230-RF-0023
CAS Number:	158697-67-7	Expiry Date:	Dec 25, 2027
Molecular Formula:	C ₂₃ H ₂₇ F ₂ N ₃ O ₂	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	415.48		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	98.137%
Water Content	Karl Fischer	0.14%
Residual Solvents	NMR	0.85% ethyl acetate
Assay		97.2%

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: Jan 03, 2025

Date: Jan 03, 2025

Date: Jan 03, 2025

