

Certificate of Analysis

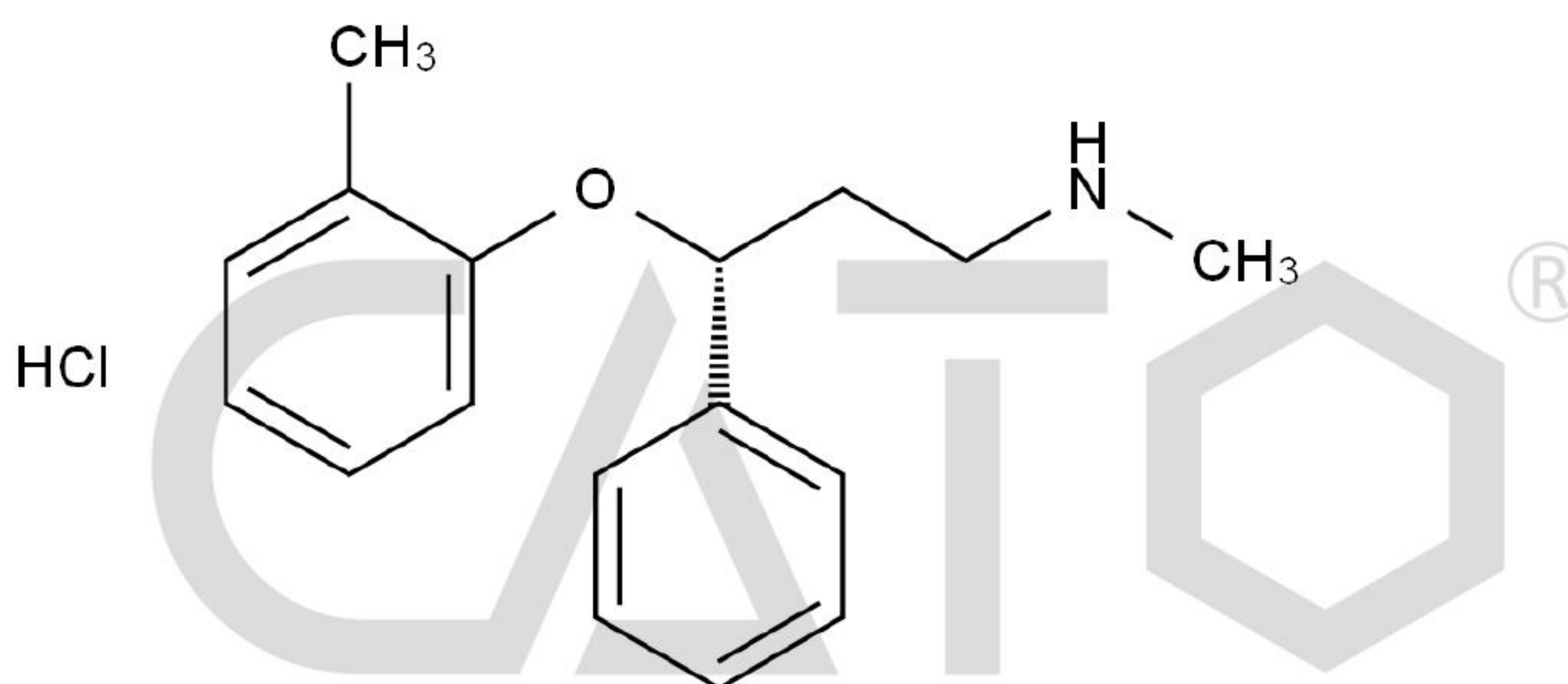
Reference Material & Standard

Product Name:	Atomoxetine hydrochloride	Catalogue Number:	CCAD302118
Synonyms:	N/A	Lot Number:	0424-RD-0030
CAS Number:	82248-59-7	Expiry Date:	Apr 25, 2026
Molecular Formula:	C ₁₇ H ₂₁ NO HCl	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	255.35 36.46	Shipping Condition:	Shipping with Ice Packs

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Powder
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.927%
Water Content	Karl Fischer	0.4410%
Assay		99.5%
Uncertainty		±2.0%

Comment:

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

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

Water Content is considered as absolute effect, HPLC purity is considered as relative effect.

2. The uncertainty values are the expanded uncertainty and represent an estimated standard deviation equal to the positive square root of the total variation of the uncertainty of components. A normal distribution is assumed and a coverage factor of K=2 is chosen using approximately a 95% confidence level.

Signature:

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Approved by General Manager:

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Date: Apr 26, 2022

Date: Apr 27, 2022

Date: Apr 27, 2022



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