

Certificate of Analysis

Reference Material & Standard

Product Name:	Fluoxetine EP Impurity B	Catalogue Number:	C4X-13522
Synonyms:	N/A	Lot Number:	0707-RG-0155
CAS Number:	23580-89-4	Expiry Date:	Jul 07, 2028
Molecular Formula:	C ₁₀ H ₁₅ N	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	149.23	Warning:	



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Colourless Liquid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	98.791%
Water Content	Karl Fischer	1.2183%
Assay		97.6%

Comment:

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

Assay (%) = (100% - Water Content) * Purity HPLC (%) / 100%

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

Signature:

Prepared by:

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Reviewed by:

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Approved by General Manager:

David

Date: Jul 09, 2025

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