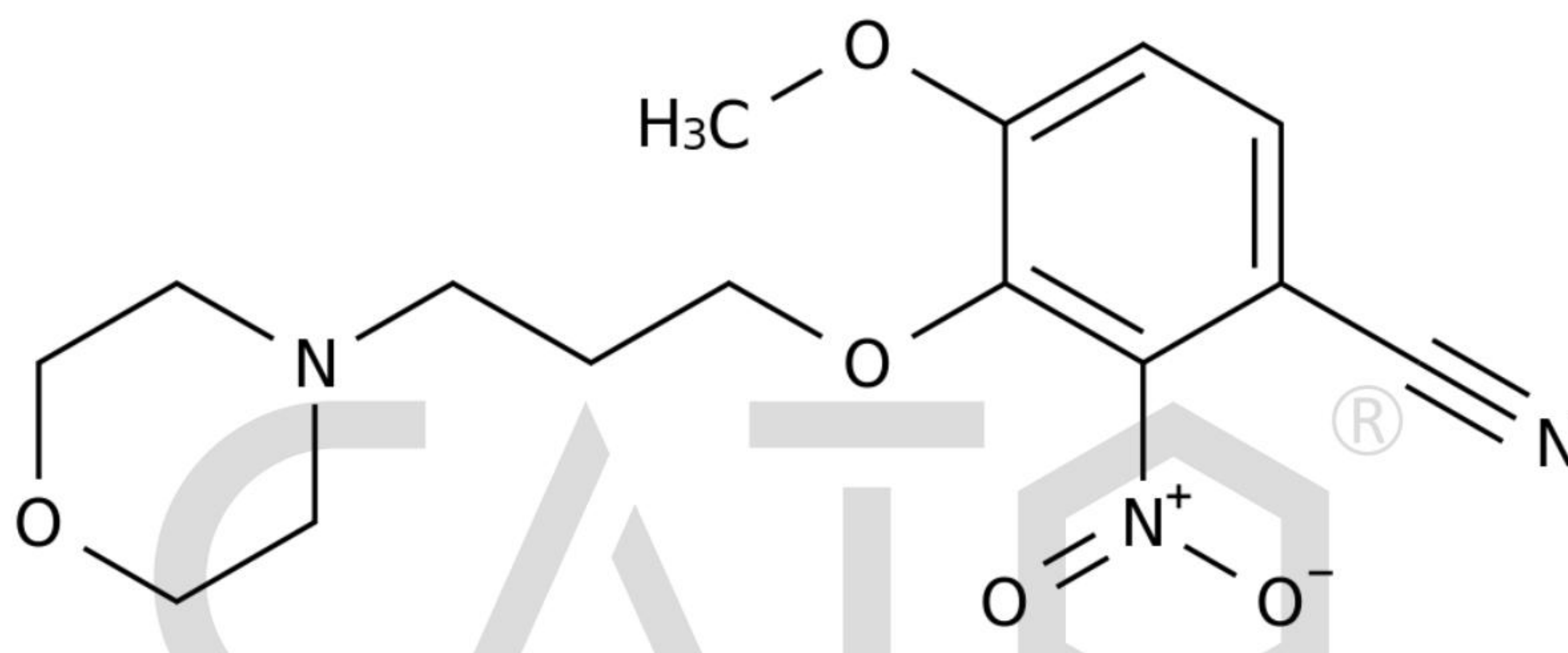


Certificate of Analysis

Reference Material & Standard

Product Name:	Gefitinib Impurity 48	Catalogue Number:	C4X-111748
Synonyms:	N/A	Lot Number:	0113-RG-0072
CAS Number:	1006378-06-8	Expiry Date:	May 30, 2027
Molecular Formula:	C ₁₅ H ₁₉ N ₃ O ₅	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	321.33		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Yellow Oil
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	98.799%
Water Content	Karl Fischer	0.33%
Residual Solvents	NMR	0.38% acetonitrile and 0.53% dimethylformamide
Assay		97.6%

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:

Lisa

Approved by General Manager:

David

Date: Jan 13, 2025

Date: Jan 13, 2025

Date: Jan 13, 2025

