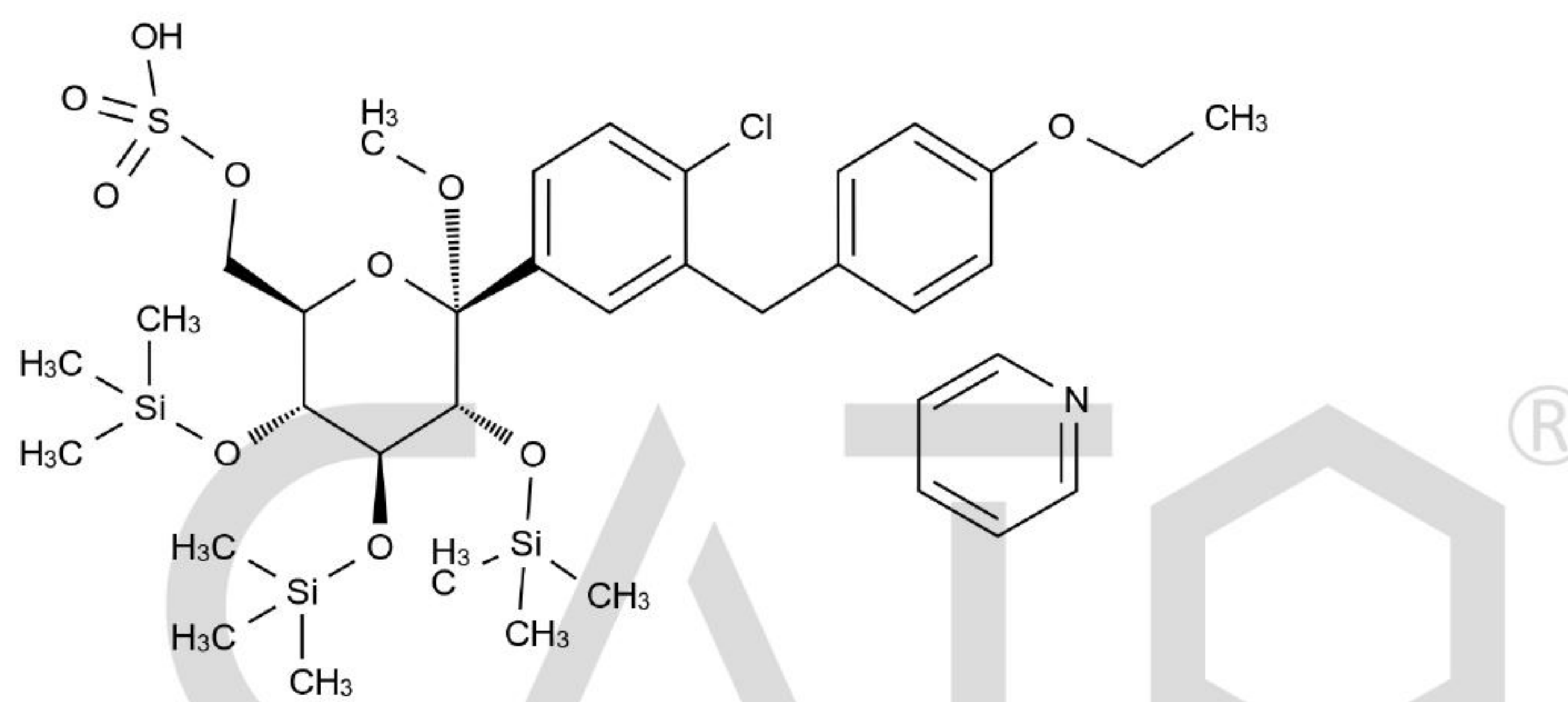


Certificate of Analysis

Reference Material & Standard

Product Name:	Ertugliflozin impurity 13 Pyridine salt	Catalogue Number:	C4X-301113
Synonyms:	N/A	Lot Number:	0731-RF-0043
CAS Number:	1528636-36-3	Expiry Date:	Jul 23, 2027
Molecular Formula:	C ₃₁ H ₅₁ ClO ₁₀ Si ₃ C ₅ H ₅ N	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	735.51 79.10		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Off-White Sticky Solid
Identification	HRMS&HNMR	Confirmed
Purity	HPLC	97.811%
Water Content	Karl Fischer	2.87%
Residual Solvents	NMR	0.26% ethyl acetate and 0.89% dichloromethane
Assay		93.9%

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:

Hinlam

Approved by General Manager:

David

Date: Aug 01, 2024

Date: Aug 01, 2024

Date: Aug 01, 2024

