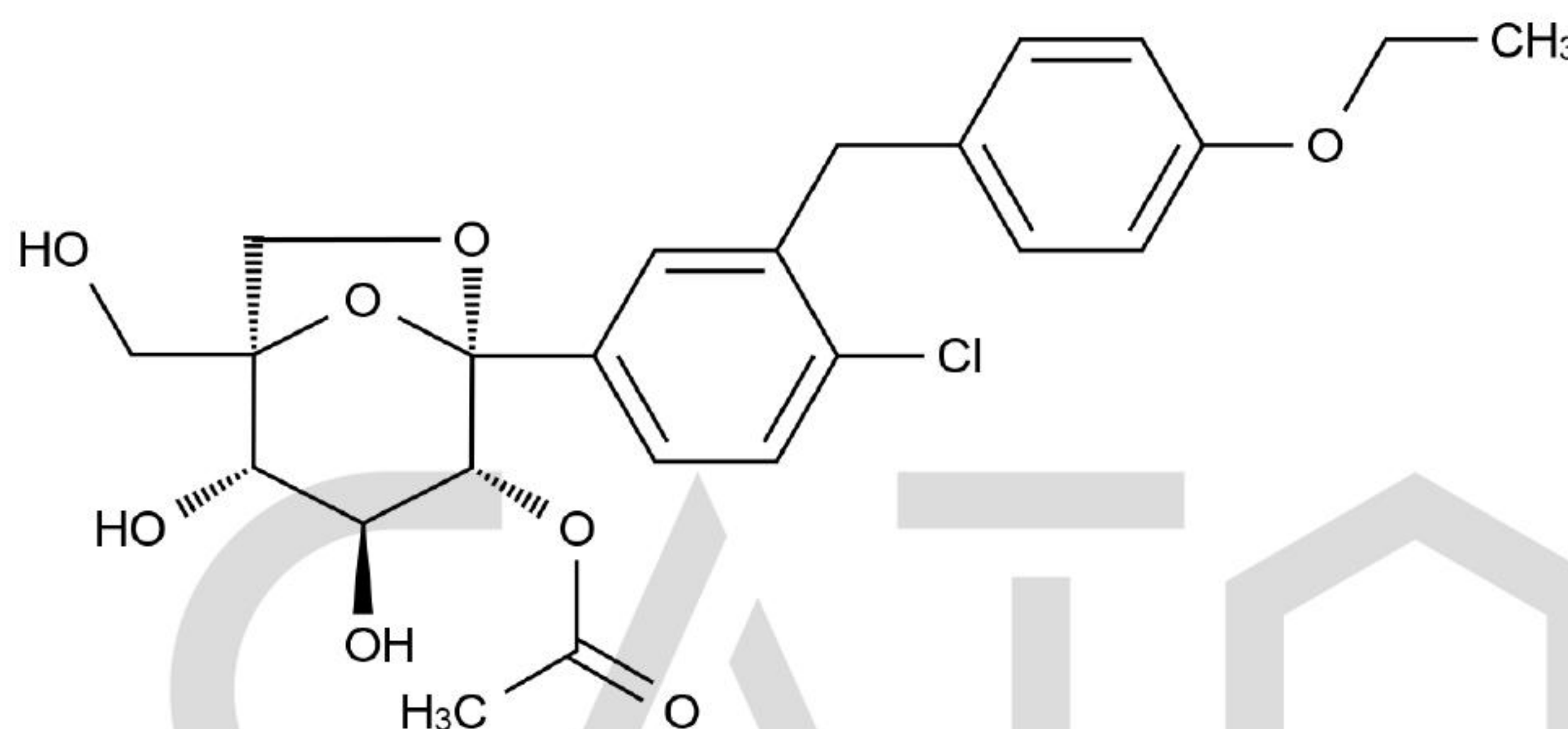


Certificate of Analysis

Reference Material & Standard

Product Name:	Ertugliflozin impurity 19	Catalogue Number:	C4X-301119
Synonyms:	N/A	Lot Number:	0717-RG-0030
CAS Number:	N/A	Expiry Date:	Nov 07, 2028
Molecular Formula:	C ₂₄ H ₂₇ ClO ₈	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	478.92		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&UV&HNMR	Confirmed
Purity	HPLC	99.662%
Water Content	Karl Fischer	0.42%
Residual Solvents	NMR	0.42% ethyl acetate and 0.74% dichloromethane
Assay		98.1%

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: Jul 17, 2025

Date: Jul 17, 2025

Date: Jul 17, 2025

