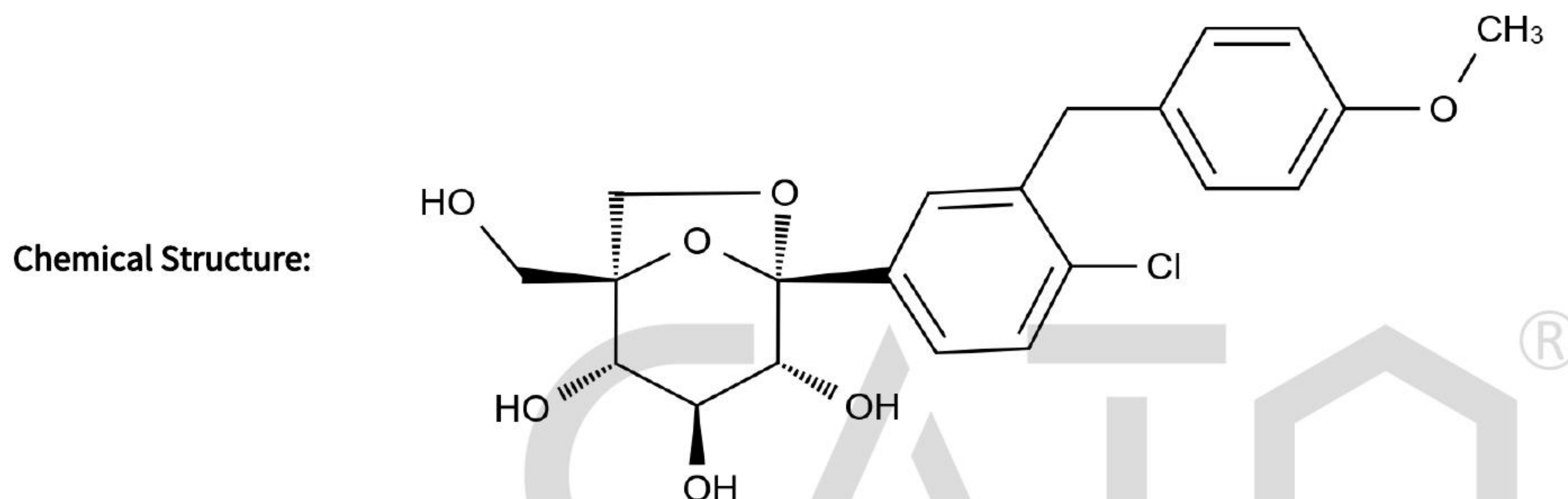


Certificate of Analysis

Reference Material & Standard

Product Name:	Ertugliflozin impurity 18	Catalogue Number:	C4X-301118
Synonyms:	N/A	Lot Number:	0929-RF-0035
CAS Number:	1210344-55-0	Expiry Date:	Sep 23, 2027
Molecular Formula:	C ₂₁ H ₂₃ ClO ₇	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	422.86		



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.923%
Water Content	Karl Fischer	0.78%
Residual Solvents	NMR	2.21% ethyl acetate and 1.46% dichloromethane
Assay		95.5%

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: Sep 29, 2024

Date: Sep 29, 2024

Date: Sep 29, 2024

