

Ertugliflozin

Batch no Mf date

C060025071801 Jul 18 2025

Retest

Jul 17 2027

Molecular Structure

Molecular Formula

 $C_{22}H_{25}CIO_7$

Molecular Weight

436.88

CAS Registry Number

1210344-57-2

Sep 18 2025

<u>Tests</u>	Specifications		Results
Appearance Identification Specific rotation Residue on ignition Water	White to off-white soli IR, HPLC +5.0 ~ +10.0° ≤ 0.1% ≤ 0.5%	d	Off-white powder Positive +6.5° 0.06% 0.22%
Heavy metals Related substances	≤ 20 ppm Any single impurity	≤ 0.1%	< 20 ppm 0.02%
Residual solvents	Total impurities Methanol Ethanol Dichloromethane Tert-Butyl methyl ether Ethyl acetate Hexamethyldisiloxane Pyridine DMSO	≤ 1.0% ≤ 0.3% ≤ 0.5% ≤ 0.06% ≤ 0.5% ≤ 0.5% ≤ 0.1% ≤ 0.02% ≤ 0.5%	O. 10% Conforms Conforms Conforms Conforms Conforms Conforms Conforms Conforms Conforms
L-Pyroglutamic Acid Assay (HPLC)	21. 7 ~ 23. 9% 98. 0 ~ 102. 0%	- 3. 3%	22. 9% 99. 7%
Packaging & storage	Preserve in tight contai	ners and store in	- NO 201 10 10 10 10 10 10 10 10 10 10 10 10 1
Conclusion	Material complies with i	n-house standard	