

Ertugliflozin

Batch no Mf date

C060024090201

Sep 02 2024

Retest

Sep 01 2026

Molecular Structure

Molecular Formula C₂₂H₂₅ClO₇

Molecular Weight 436.88

CAS Registry Number

1210344-57-2

Mar 06 2025

<u>Tests</u>	<u>Specifications</u>		<u>Results</u>
Appearance	White to off-white soli	d	White powder
Identification	IR, HPLC		Positive
Specific rotation	+5.0 ~ +10.0°		+6.5°
Residue on ignition			0. 02%
Water	≤ 0.5%		0. 12%
Heavy metals	≤ 20 ppm		< 20 ppm
Related substances	Any single impurity	≤ 0.1%	0. 04%
	Total impurities	≤ 1.0%	0. 14%
Residual solvents	Methanol	≤ 0.3%	Conforms
****	Ethanol	≤ 0.5%	Conforms
	Dichloromethane	≤ 0.06%	Conforms
	Tert-Butyl methyl ether	≤ 0.5%	Conforms
	Ethyl acetate	≤ 0.5%	Conforms
	Hexamethyldisiloxane	≤ 0.1%	Conforms
	Pyridine	≤ 0.02%	Conforms
	DMSO	≤ 0.5%	Conforms
L-Pyroglutamic Acid	21.7 ~ 23.9%		22. 1%
Assay (HPLC)	98.0 ~ 102.0%	Ψ	99. 7%
Packaging & storage	Preserve in tight containers and store in a dry place		
Conclusion	Material complies with in-house standard		