

CERTIFICATE OF ANALYSIS

(Certificate No. KME010098-01)

Release Date: 26/09/2023

Re-test Date: 25/09/2026

Empagliflozin Methyl Impurity

Identification

Chemical Name :

(2S,3R,4R,5S,6R)-2-(4-Chloro-3-(4-methoxybenzyl)phenyl)-6-(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol

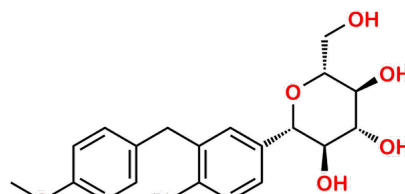
Alt. Name : Methoxy analog of Empagliflozin

CAT No. : KME010098

CAS No. : 333359-90-3

Molecular Formula : C₂₀H₂₃ClO₆

Molecular Weight : 394.8



Analytical Information

Batch No. : EMPA-METHYL-045-286

Description : Off White Solid

HPLC Purity : 98.93 %

Weight Loss By TGA : 3.89 %

% Potency : 95.08 %

Solubility : Acetonitrile

Mass : Confirm

IR : Confirm

¹H NMR : Confirm

Additional Information

Long Term Storage : Store at 2-8 deg. C for long term storage

Shipping Condition : Product is stable to be Shipped at Room Temperature

% Potency = [100 - 3.89(Weight Loss By TGA)] x [98.93(HPLC Purity)]/100 = 95.08 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		08/04/2025
Reviewed & Approved By	Quality Control	Ravi Patel		08/04/2025

Attachments : COA, HPLC, MASS, ¹HNMR, IR and TGA