

TLC PHARMACEUTICAL STANDARDS

Certificate of Analysis

Certificate No.: 20230614011

Compound Name:	Semaglutide-d8		
Synonyms:	L-histidyl-2-methylalanyl-L- α -glutamylglycyl-L-threonyl-L-phenylalanyl-L-threonyl-L-seryl-L- α -aspartyl-L-valyl- d_8 -L-seryl-L-seryl-L-tyrosyl-L-leucyl-L- α -glutamylglycyl-L-glutaminyl-L-alanyl-L-alanyl- N^6 -[N -(17-carboxy-1-oxoheptadecyl)-L- γ -glutamyl-2-[2-(2-aminoethoxy)ethoxy]acetyl-2-[2-(2-aminoethoxy)ethoxy]acetyl]-L-lysyl-L- α -glutamyl-L-phenylalanyl-L-isoleucyl-L-alanyl-L-tryptophyl-L-leucyl-L-valyl-L-arginylglycyl-L-arginyl-Glycine		
TLC Catalogue Number:	PS-189038		
CAS Number:	910463-68-2 (non-labelled)		
Molecular Weight:	4121.69		
Molecular Formula:	C ₁₈₇ H ₂₈₃ D ₈ N ₄₅ O ₅₉	al la l	
Source:	TLC Pharmaceutical Standards		
Source Lot No.:	5646-034A12		
Storage Conditions:	Store at 2-8 °C		
Solubility:	Solution of Water and Acetonitrile, DMSO		

Test Description	Specifications	Results	
Visual Description	White to off-white solid	Conforms	
Identification			
IR	Conforms to structure	Conforms	
MS	Conforms to structure	Conforms	
¹H NMR	Conforms to structure	Conforms	
Elemental Analysis	Conforms to structure	Conforms	
Purity (HPLC)	Not less than 90.0%	95.1%	
Impurity (HPLC)	RT 8.66, 1.22%; RT 9.22, 0.67%; RT 12.80, 1.58%		
Isotopic Enrichment	Not less than 98.0% 99.5%		
Water Content (KF)	N/A	6.4%	
Residual Solvents (NMR)	No residual solvent		
Assay (%)	Not less than 85.0%	89.0%	
Recommendation:	Release.		

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		06 115 12025
Approved by:	Quality Assurance	Kand.	06/15/2023

Attachments: HPLC, IR, MS and NMR spectra.

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