METAPHARMACEUTICAL IND SL
Josep Plà, 163, 2n 5a / Tel. 933 089 976 / info@metapharmaceutical.com

TECHNICAL DATA SHEET

46433121-TDS-ENG-2025

SEMAGLUTIDE		
DESCRIPTION DCI: SEMAGLUTIDE	DESCRIPTION DOE: SEMAGLUTIDA	
CAS Nº: 910463-68-2	EC Nº: 691-729-9	AEMPS CODE: 9375A
MOL. WEIGHT: 4113,58	MOL. FORMULA: C187H291N45O59	ARTICLE CODE: 46433121

ATTRIBUTES	SHOULD BE
Appearance	The substance is white or off-white powder or loose mass.
Hygroscopicity	Hygroscopic
Solubility	Freely soluble in water, very slightly soluble in ethanol
Identification HPLC	Complies
MS Identification	Complies
Peptide mapping	Complies
pH	7.0 - 9.0
Water	=< 8.0 %
Clarity of solution	=< 2 NTU
Solution color	Colorless solution
Residual solvents	
Acetonitrile	=< 0.041 %
Sulfates	=< 0.15 %
Sodium ion	=< 3.0 %
Macromolecular impurities	=< 0.3 %
Amino acid analysis	
Asp	0.9 - 1.1
Ser	2.4 - 3.3
Glu	4.5 - 5.5
Gly	3.6 - 4.4
His	0.9 - 1.1
Aib	0.7 - 1.3
Arg	1.8 - 2.2
Thr	1.8 - 2.2
Ala	2.7 - 3.3
Tyr	0.9 - 1.1
Val	1.8 - 2.2
Lys	0.9 - 1.1
Ile	0.9 - 1.1
Leu	1.8 - 2.2
Phe	1.8 - 2.2
Trp	Detected
Related substances	
Impurity A	=< 0.10 %
Impurity B	=< 0.15 %
Impurity C	=< 0.3 %

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ATTRIBUTES	SHOULD BE
Impurity D	=< 0.15 %
Impurity F	=< 0.10 %
Impurity G	=< 0.10 %
Impurity H	=< 0.10 %
Unknown largest single impurity	=< 0.10 %
Total impurities	=< 1.5 %
Bacterial endotoxines	< 10 EU/mg
Microbiological control	
TAMC	=< 100 CFU/g
TYMC	=< 50 CFU/g
Assay	0.76 - 1.00mg API/mg Semaglutide

COMPLIES WITH

Manufacturer's Specifications

STORAGE

Keep the container tightly closed, in a dry place at a -20ºC. Protected from air and light.

REMARKS

Semaglutide is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.