METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

011-TDS-ENG-2025

LIRAGLUTIDE		
DESCRIPTION DCI: LIRAGLUTIDE	DESCRIPTION DOE: LIRAGLUTIDA	
CAS Nº: 204656-20-2	EC Nº: 810-818-7	AEMPS CODE: 8323A
MOL. WEIGHT: 3751,2	MOL. FORMULA: C172H265N43O51	ARTICLE CODE: 011

ATTRIBUTES	SHOULD BE
Appearance	White or off-white powder or loose lump
Hygroscopicity	Hygroscopic, the hygroscopicity should be not less than 2% and less than 15%
Solubility	Freely soluble in water, 10mmol/L phosphate buffer, and 0.1mol/L sodium hydroxide solution
Specific optical rotation	- 15º / - 25º
Identification HPLC	Complies
Monoisotopic weight	3748.4 Da - 3749.4 Da
Peptide mapping	Complies
pH	8.2 - 9.2
Water	=< 8.0 %
Clarity of solution	=< 2 NTU
Color of solution	Colorless
Residual solvents	
Methanol	=< 3000 ppm
Acetonitrile	=< 410 ppm
Pyridine	=< 200 ppm
Isopropyl alcohol	=< 5000 ppm
Dichloromethane	=< 600 ppm
N-Metilpirrolidona	=< 530 ppm
N,N-Dimethylformamide	=< 880 ppm
Amino acid analysis	
Asp	0.9 - 1.1
Ser	2.4 - 3.0
Glu	4.5 - 5.5
Gly	3.6 - 4.4
His	0.9 - 1.1
Arg	1.8 - 2.2
Thr	1.8 - 2.2
Ala	3.6 - 4.4
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
Anions	

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ATTRIBUTES	SHOULD BE
Acetate ion	=< 0.5 %
Phosphate ion	=< 0.1 %
Carbonate ion	=< 0.4 %
Trifluoroacetate ion	=< 0.1 %
Ammonium ion	=< 0.2 %
Sodium ion	=< 3.0 %
Elemental impurities	
Pd	=< 1.0 ppm
Ni	=< 10.0 ppm
Macromolecular impurities	=< 0.5 %
Related substances	
Impurity M	=< 0.15 %
Impurity C	=< 0.15 %
Impurity D	=< 0.15 %
Impurity F	=< 0.25 %
Impurity G	=< 0.15 %
Impurity H	=< 0.25 %
Impurity I	=< 0.10 %
Impurity J	=< 0.10 %
Impurity K	=< 0.25 %
Impurity L	=< 0.15 %
Impurity N	=< 0.15 %
Impurity O	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 2.0 %
Bacterial endotoxines	=< 10 EU/mg
Microbiology	
TAMC	=< 100 CFU/g
TYMC	=< 50 CFU/g
Assay	
Peptide content	85.0 % - 100.0 %
Assay	95.0 % - 103.0 %

COMPLIES WITH

Manufacturer's Specifications

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STORAGE

Store in a cool place. Keep the container tightly closed, in a dry and well-ventilated place.

REMARKS

Liraglutide 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.