



Certificate of Analysis

Tesamorelin Acetate

Product Name : Tesamorelin Acetate
Mfg. Date : Mar 22, 2024
M.F. : $C_{223}H_{370}N_{72}O_{69}S$
CAS No. : 901758-09-6
Sequence : N-(trans-3-hexenoyl)-Tyr-Ala-Asp-Ala-Ile-Phe-Thr-Asn-Ser-Tyr-Arg-Lys-Val-Leu-Gly-Gln-Leu-Ser-Ala-Arg-Lys-Leu-Leu-Gln-Asp-Ile-Met-Ser-Arg-Gln-Gln-Gly-Glu-Ser-Asn-Gln-Glu-Arg-Gly-Ala-Arg-Ala-Arg-Leu-NH₂ · CH₃COOH

Lot No. : DL8213
Exp. Date : Mar 21, 2027
M.W. : 5195.90
Batch Qty : 415 g

TESTS	SPECIFICATIONS		RESULTS
Appearance	White or almost white crystalline powder		White crystalline powder
Solubility	Soluble in water		Conforms
Mass (MS)	5135.85 ± 1		5135.6
Amino Acid Composition (AAA)	Val	0.9 – 1.1	1.0
	Met	0.9 – 1.1	1.0
	Ile	1.8 – 2.2	2.1
	Tyr	1.8 – 2.2	2.0
	Ala	4.5 – 5.5	5.1
	Asp	3.6 – 4.4	4.0
	Phe	0.9 – 1.1	1.0
	Ser	3.6 – 4.4	4.1
	Arg	5.4 – 6.6	6.0
	Lys	1.8 – 2.2	2.1
	Leu	4.5 – 5.5	5.1
	Gly	2.7 – 3.3	3.1
	Glx	6.3 – 7.7	6.9
	Thr	0.9 – 1.1	1.1
Acetic Acid Content (HPLC)	≤ 15.0%		7.00%
Water Content (KF)	≤ 10.0%		5.70%
Microbial Tests (USP2022)	Total Aerobic Microbial Count	≤ 10 ² CFU/g	< 20 CFU/g
	Total Yeast and Mold Count	≤ 10 ² CFU/g	< 20 CFU/g
	<i>E. coli</i>	Absent	Absent
Bacterial Endotoxin (USP2022)	≤ 10 EU/mg		< 10 EU/mg
Peptide Content (N%)	≥ 80.0%		87.4%
Assay (On Anhydrous And Acetic-Acid Free Basis) (HPLC) (CP2020)	95.0 – 105.0%		99.1%
Peptide Purity (HPLC)	≥ 98.0%		99.2%
Related Substances (HPLC)	Total Impurities	≤ 2.00%	0.80%
	Largest Single Impurity	≤ 1.00%	0.80%
Conclusion: The product is a synthetic peptide and meets the In-House specifications. Long Term Storage: Store in a sealed container at 2°C - 8°C in the fridge or in the freezer. Distributed by Darmerica.			

Note: Analytical results transcribed from the original COA provided by Chengdu Weihual Pharmaceutical Technology Co., Ltd. (China); Lot No.: WHT-09/20240322/10.

Based on the review of above information, the lot stands released.

	Name	Title	Signature	Date
Prepared by	Kamlesh Mistry	Quality Manager		07/18/2024
Released by	Pietro Pazzetty	Quality Assistant		07/18/2024