



Certificate of Analysis
Bremelanotide Acetate

Product Name : Bremelanotide Acetate	Lot No. : DL8470
Mfg. Date : Nov 16, 2024	Exp. Date : Nov 15, 2027
M.F. : C ₅₂ H ₇₂ N ₁₄ O ₁₂	M.W. : 1085.23
CAS No. : 1607799-13-2	Batch Qty : 629 g
Sequence : Ac-Nle-Asp-His-D-Phe-Arg-Trp-Lys-OH · CH ₃ CO ₂ H	

TESTS	SPECIFICATIONS		RESULTS
Appearance	White or off-white powder		White powder
Identification (MS)	1025.16 ± 1		1026.03
Solubility	Soluble in water		Complies
Amino Acid Composition (HPLC)	Arg	0.9 – 1.1	1.0
	Phe	0.9 – 1.1	0.9
	His	0.9 – 1.1	1.1
	Asp	0.9 – 1.1	0.9
	Trp	0.9 – 1.1	1.0
	Lys	0.9 – 1.1	1.1
	Nle	0.8 – 1.2	1.1
Water (KF)	≤ 8.0%		3.0%
Acetic Acid (HPLC)	≤ 15.0%		5.8%
Peptide Content (N%)	≥ 80.0%		89.7%
Residual Solvent (GC)	Formaldehyde	Absent	Absent
	Acetonitrile	≤ 410ppm	< 410 ppm
	Ethyl Ether	≤ 5000ppm	Not Detected
	Dichloromethane	≤ 600ppm	< 600 ppm
	Pyridine	≤ 200ppm	Not Detected
	N,N-Dimethylformamide	≤ 880ppm	< 880 ppm
	Triisopropylsilane	≤ 1000ppm	Not Detected
Peptide Purity (HPLC)	≥ 98.0%		99.6%
Related Substances (HPLC)	Total Impurities	≤ 2.0%	0.4%
	Largest Single Impurity	≤ 1.0%	0.1%
Assay (HPLC) (Anhydrous, Acetic Acid Free Basis) (CP2020)	95.0 – 105.0%		99.7%
Bacterial Endotoxins (USP2022)	≤ 10EU/mg		< 10EU/mg
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

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.
 Disclaimer: This is a bulk ingredient that requires pharmacy compounding. The buyer is liable for any finished product patent infringement.
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Note: Analytical results transcribed from the original COA provided by Xi'an XinFengYi Pharmaceutical Technology Co., Ltd. (China); Lot No. 241116-BLM095.

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

	Name	Title	Signature	Date
Prepared by	Luz Guevara	Quality Assistant		12/10/2024
Released by	Pietro Pazzetty	Quality Assistant		12/10/2024



SAFETY DATA SHEET

SECTION 1 – CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Bremelanotide Acetate

CAS# 1607799-13-2

Supplier:

Darmerica
4380 Oakes Road, Unit 800
Davie, FL 33314, USA
Tel: 954-530-6597

SECTION 2 – INGREDIENT INFORMATION

Name: Bremelanotide Acetate

Purity: ≥ 95.0%

SECTION 3 – HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Harmful if swallowed.

Potential Health Effects:

The toxicological properties of this material have not been investigated. Use appropriate procedures to prevent opportunities for direct contact with the skin or eyes and to prevent inhalation. Compound is Non-hazardous, Non-Toxic/Non-Flammable.

SECTION 4 – FIRST AID MEASURES

Eyes: Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids.

Skin: Flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.

Ingestion: Do NOT induce vomiting. If conscious and alert, rinse mouth and drink 2-4 cupfuls of milk or water.

Inhalation: Remove from exposure and move to fresh air immediately.

SECTION 5 – FIRE AND EXPLOSION DATA

General Information: As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear. During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion.

Extinguishing Media: In case of fire, use water, dry chemical, chemical foam, or alcohol-resistant foam.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

General Information: Use proper personal protective equipment as indicated in Section 8.

Spills/Leaks: Clean up spills immediately, observing precautions in the Protective Equipment section. Sweep up, then place into a suitable container for disposal

SECTION 7 – HANDLING AND STORAGE

Handling: Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Avoid contact with eyes, skin, and clothing. Avoid ingestion and inhalation.

Storage: Store in a sealed container.

SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: Use adequate general or local exhaust ventilation to keep airborne concentrations below the permissible exposure limits. Use process enclosure, local exhaust ventilation, or other engineering controls to control airborne levels.

Eyes: Wear safety glasses and chemical goggles if splashing is possible.

Skin: Wear appropriate protective gloves and clothing to prevent skin exposure.

Clothing: Wear appropriate protective clothing to minimize contact with skin.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Appearance Form: white powder
Odour: Characteristic
Odour Threshold No data available
pH No data available
Melting point/freezing point No data available
Initial boiling point and boiling range No data available
Flash point No data available
Evaporation rate No data available
Flammability (solid, gas) No data available
Upper/lower flammability or explosive limits No data available
Vapour pressure No data available
Vapour density No data available
Relative density No data available
Water solubility No data available
Auto-ignition temperature No data available
Decomposition temperature No data available
Viscosity No data available
Explosive properties No data available

SECTION 10 – STABILITY AND REACTIVITY

Stability: Stable under recommended storage conditions.

Conditions to be avoided: Humidity, Sunshine and High Temperature.

Substances to be avoided: Strong oxidizing agents; strong bases; strong acids.

Hazardous decomposition products: Acid and Base

SECTION 11 – TOXICOLOGICAL INFORMATION

N/A

SECTION 12 – ECOLOGICAL INFORMATION

No ecological problems expected, if product is handled and used with care and attention.

SECTION 13 – DISPOSAL CONSIDERATIONS

Dissolve or mix material with a suitable combustible solvent and incinerate in a chemical incinerator equipped with an afterburner and scrubber. Material should be disposed of in keeping with all local and national legislation. Packaging should be disposed of in keeping with all local and national legislation. Handle contaminated containers as product.

SECTION 14 – TRANSPORT INFORMATION

DOT Not regulated TDG Not regulated IATA Not regulated IMDG/IMO Not regulated

SECTION 15 – OTHER REGULATORY INFORMATION

The format refers to SDS requirements ANSI (American National Standards Institute) and International Standards organization (ISO).

SECTION 16 – OTHER INFORMATION

Created: December 2018

Last Modified: June 2023

Important Notice:

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Darmerica shall not be liable for any damages resulting from handling or from contact with the above product.