



## Certificate of Analysis

### Tirzepatide Base

<b>Product Name</b> : Tirzepatide Base	<b>Lot No.</b> : DL8673
<b>Mfg. Date</b> : Jan 29, 2025	<b>Exp. Date</b> : Jan 28, 2028
<b>M.F.</b> : C <sub>225</sub> H <sub>348</sub> N <sub>48</sub> O <sub>68</sub>	<b>M.W.</b> : 4813.45
<b>CAS No.</b> : 2023788-19-2	<b>Batch Qty</b> : 11546 g
<b>Sequence</b> : Tyr-Aib-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Tyr-Ser-Ile-Aib-Leu-Asp-Lys-Ile-Ala-Gln-Lys(PEG2-Ser-Gly-Ala-Pro-Pro-Pro-Ser	

TESTS	SPECIFICATIONS	RESULTS	
Appearance	White powder	White powder	
Solubility	Soluble in water or 50% aqueous acetonitrile	Conforms	
Mass (MS)	4813.45 ± 1.0	4812.78	
Amino Acid Composition (AAA)	Val	0.8 – 1.2	1.1
	Asp	1.6 – 2.4	2.0
	Tyr	1.6 – 2.4	2.2
	Lys	1.6 – 2.4	2.3
	Leu	1.6 – 2.4	2.2
	Thr	1.6 – 2.4	2.1
	Phe	1.6 – 2.4	2.3
	Ile	2.4 – 3.6	3.4
	Ser	4.0 – 6.0	5.5
	Ala	3.2 – 4.8	4.5
	Gly	3.2 – 4.8	4.4
	Glu	3.2 – 4.8	4.5
Pro	3.2 – 4.8	4.2	
Water Content (KF)	≤ 8.00%	2.20%	
pH (pH Tester)	5.0 – 8.0	7.2	
Ion Content (HPLC)	≤ 5.00%	1.20%	
Peptide Content (N%)	≥ 85.0%	93.1%	
Residual Solvents (GC)	Formaldehyde (GC)	Negative	Conforms
	Acetonitrile	≤ 410 ppm	< 410 ppm
	Dichloromethane	≤ 600 ppm	< 600 ppm
	N,N-Dimethylformamide	≤ 880 ppm	< 880 ppm
	Ethyl Ether	≤ 5000 ppm	Not Detected
	Pyridine	≤ 200 ppm	Not Detected
	Triisopropylsilane	≤ 1000 ppm	Not Detected
Peptide Purity (HPLC)	≥ 98.0%	99.5%	
Related Substances (HPLC)	Total Impurities	≤ 2.00%	0.50%
	Largest Single Impurity	≤ 1.00%	0.30%
Bacterial Endotoxins (USP)	≤ 10 EU/mg	< 10 EU/mg	
Microbial Limits (USP)	Total Aerobic Microbial Count	≤ 10 <sup>2</sup> CFU/g	< 20 CFU/g
	Total Yeast and Mold Count	≤ 10 <sup>2</sup> CFU/g	< 20 CFU/g
	<i>E. coli</i>	Negative	Conforms



TESTS	SPECIFICATIONS	RESULTS
Assay (On Anhydrous and Ion-Free Basis) (HPLC) (CP2020)	95.0 - 105.0%	100.9%
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. Distributed by Darmerica.		

Note: Analytical results transcribed from the original COA provided by Shaanxi MingDeRun PharmaTech Co., Ltd. (China); Lot No. TRBT20250129014.

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

	Name	Title	Signature	Date
Prepared by	Christina Boykin	Quality Supervisor		03/03/2025
Released by	Pietro Pazzetty	Quality Assistant		03/03/2025



## SAFETY DATA SHEET

### SECTION 1 – CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** Tirzepatide Base

**CAS#:** 2023788-19-2

**Supplier:**

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

### SECTION 2 – INGREDIENT INFORMATION

**Name:** Tirzepatide Base

**Purity:** ≥ 95.0%

### SECTION 3 – HAZARDS IDENTIFICATION

**Classification of the substance or mixture** - Not a hazardous substance or mixture.

**GHS Label elements, including precautionary statements** - Not a hazardous substance or mixture.

**Hazards not otherwise classified (HNOC) or not covered by GHS** - None

### SECTION 4 – FIRST AID MEASURES

**General advice:** Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

**If inhaled:** Move the victim into fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration and consult a doctor immediately. Do not use mouth to mouth resuscitation if the victim ingested or inhaled the chemical.

**In case of skin contact:** Rinse skin thoroughly with large amounts of water. Remove contaminated clothing and shoes and call a physician.

**In case of eye contact:** Remove any contact lenses, locate eye-wash station, and flush eyes immediately with large amounts of water. Separate eyelids with fingers to ensure adequate flushing. Promptly call a physician.

**If swallowed:** Rinse mouth with water. Call a doctor or Poison Control Center immediately. Never give anything by mouth to an unconscious person.

**Most important symptoms and effects, both acute and delayed:** The most important known symptoms and effects are described in the labeling (see section 11).

**Indication of any immediate medical attention and special treatment needed:** Treat symptomatically.

### SECTION 5 – FIRE AND EXPLOSION DATA

**Extinguishing media:** Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

**Specific Hazards Arising from the Chemical:** During combustion, may emit irritant fumes.

**Fire Fighting:** As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

## SECTION 6 – ACCIDENTAL RELEASE MEASURES

**Personal Precautions:** Ensure adequate ventilation. Use personal protective equipment. Avoid breathing vapors, mist, or gas. Evacuate the danger area, observe emergency procedures, consult an expert.

**Environmental Precautions:** Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Avoid release into the environment.

**Methods and Materials for Containment and Cleaning Up:** Pick up and arrange disposal. Sweep up and shovel. Keep in suitable, closed containers for disposal.

## SECTION 7 – HANDLING AND STORAGE

**Handling:** Avoid inhalation, contact with eyes and skin. Avoid dust and aerosol formation. Use only in areas with appropriate exhaust ventilation.

**Storage:** Store in a sealed container in a fridge or freezer. Keep away from direct sunlight and sources of ignition.

## SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

**Ingredients with workplace control parameters:** Contains no substances with occupational exposure limit values.

**Appropriate engineering controls:** Ensure adequate ventilation. Provide accessible safety shower and eye wash station. Personal protective equipment.

**Respiratory protection:** Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

**Hand protection:** Handle with gloves.

**Eye protection:** Use face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

**Skin and body protection:** Impervious clothing.

**Hygiene measures:** General industrial hygiene practice.

**Control of environmental exposure:** Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

## SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance</b>	Powder
<b>Color</b>	White or off-white
<b>Odor</b>	No data available
<b>Odor Threshold</b>	No data available
<b>pH</b>	No data available
<b>Melting Point/Range</b>	No data available
<b>Boiling Point/Range</b>	No data available
<b>Flash Point</b>	No data available
<b>Evaporation Rate</b>	No data available
<b>Decomposition temperature</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Flammability or explosive limits</b>	No data available
<b>Upper</b>	No data available
<b>Lower</b>	No data available
<b>Vapor Pressure</b>	No data available

<b>Vapor Density</b>	No data available
<b>Relative Density</b>	No data available
<b>Specific Gravity</b>	No data available
<b>Water Solubility</b>	No data available
<b>Solubility</b>	No data available
<b>Partition coefficient; n-octanol/water</b>	No data available
<b>Autoignition Temperature</b>	No data available
<b>Decomposition Temperature</b>	No data available
<b>Viscosity</b>	No data available
<b>Explosive Properties</b>	No data available
<b>Oxidizing Properties</b>	No data available

## SECTION 10 – STABILITY AND REACTIVITY

**Reactivity:** No data available.

**Stability:** Stable under recommended storage conditions.

**Possibility of Hazardous Reactions:** No data available.

**Conditions to Avoid:** No data available.

**Incompatible Materials:** No data available.

**Hazardous Decomposition Products:** In the event of fire: see Section 5.

## SECTION 11 – TOXICOLOGICAL INFORMATION

### **Carcinogenicity:**

IARC: 1 - No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

NTP: No ingredient of this product presents at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product presents at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

### **Acute Toxicity:**

Oral: No data available

Inhalation: No data available

Dermal: No data available

No data available

**Skin corrosion/irritation:** No data available

**Serious eye damage/eye irritation:** No data available

**Respiratory or skin sensitization:** No data available

**Ingestion:** No data available

**Germ cell mutagenicity:** No data available

**Specific target organ toxicity - single exposure:** No data available

**Specific target organ toxicity - repeated exposure:** No data available

**Aspiration hazard:** No data available

**Reproductive toxicity:** No data available

**Additional Information:** No data available

**Signs and Symptoms of Exposure:** To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated

**Additional Information:** Not available

## SECTION 12 – ECOLOGICAL INFORMATION

<b>Toxicity:</b>	No data available.
<b>Toxicity, Ecology, general:</b>	No data available.
<b>Persistence and Degradability:</b>	No data available.
<b>Bioaccumulative Potential:</b>	No data available.
<b>Mobility in Soil:</b>	No data available.
<b>Results of PBT and vPvB Assessment:</b>	PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.
<b>Other Adverse Effects:</b>	No data available

## SECTION 13 – DISPOSAL CONSIDERATIONS

**Waste Disposal:** Waste must be disposed of in accordance with federal, state and local environmental control regulations.

## SECTION 14 – TRANSPORT INFORMATION

**DOT (US):** Not dangerous goods

**IMDG:** Not dangerous goods

**IATA:** Not dangerous goods

## SECTION 15 – OTHER REGULATORY INFORMATION

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

**For California State Only –** All users must follow Proposition 65 Procedures for any chemicals on the Prop. 65 Component List that may cause cancer, birth, or any other reproductive defects as per the guidelines.

## SECTION 16 – OTHER INFORMATION

**Created:** April 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.