



NuCare<sup>™</sup>  
Pharmaceuticals, Inc.

# NuCare Pharmaceuticals, Inc.

622 W. Katella Ave. 92867

NDC:83821-202-07(25g per bottle)

NDC:83821-202-08(100g per bottle)

COA-TIR-HANX-REV1

## Tirzepatide API

Product	<u>Tirzepatide</u>	Batch	<u>C01829/C01831</u>
Grade	<u>API for Injection</u>	Quantity	<u>3850.0g</u>
Mfg Date	<u>2025-02-23</u>	Retest Date	<u>2027-02-22</u>
Test Date	<u>2025-03-04</u>	Standard	<u>In-house</u>
Package	Double layer polyethylene bag, Single layer aluminum-plastic film bag		
Storage conditions:	Tight container, protected from light. For less than 6 months storage, store in refrigerator (2°C to 8°C). For more than 6 months storage, store in freezer ( -25°C to -10°C).		

Test Item	Acceptance Criteria	Test Result
Description	White or off-white powder	Meet the requirements
Solubility	Soluble in water and 50% aqueous acetonitrile	Meet the requirements
Chromatographic Identification	The retention time of the major peak of the Sample Solution should correspond to that of the Standard Solution, as obtained in the Assay.	Meet the requirements
Average Molecular Weight	4813.45±1.0 Da	4812.65 Da
pH	6.0 – 9.0	7.6
Peptide Content	NLT 85.0%	96.9%
Assay	95.0%~105.0% (Anhydrous ,Sodium-ion, ammonium-ion and phosphate-ion free)	100.6%
Chromatographic Purity	NLT 98.0%	99.4%
Related Substances	Maximum unknown single impurity NMT 0.5%	0.3%
	Total impurities should be NMT 2.0%	0.6%
Water Content	NMT 8.0%	1.0%



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Test Item	Acceptance Criteria	Test Result
Acetic acid	NMT 0.1%	ND
TFA	NMT 0.1%	ND
Sodium Content	Sodium ion NMT 3.0%	1.4%
	Methanol NMT 3000 ppm	49ppm
	Acetonitrile NMT 410 ppm	4ppm
	N,N-Dimethylformamide NMT 880 ppm	ND
Residual Solvents	Isopropanol NMT 5000 ppm	19ppm
	Methylene NMT 600 ppm	ND
	triethylamine NMT 320 ppm	ND
	Tert-butyl methyl ether NMT 5000 ppm	191ppm
Bacterial Endotoxins	less than 10 EU per mg	<0.5 EU/mg
Microbial Limit	The total aerobic bacteria count should be NMT 1000 cfu/g	<10 cfu/g



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Test Item	Acceptance Criteria	Test Result
	Total Yeasts and Molds count does not exceed 100 cfu/g	< 10 cfu/g
	Total E.coli count does not detect in 1 gram sample	ND

**Conclusion** This product complies with Enterprise Standard. Distributed by NuCare Pharmaceuticals, Inc.

Note: Analytical results transcribed from the original COA provided by Nanjing Hanxin Pharmaceutical Tech Co., Ltd. (China) Batch No: HXTZ250223.

Prepared By: Isaac Ramirez Released By: Adriana Prado Date: 05/05/2025

