

NANJING SUNNY PHARMATECH CO., LTD.
 NO.1704 SHUANGLONG AVENUE, NANJING, CHINA
 TEL: +86-25-86189919/29 FAX: +86-25-86189616
 E-MAIL: Brian@sunny-pharma.cn

Certificate of Analysis

Product Name	NEOTAME	Quantity	1000Kg
Manufacture Date	2024.03.22	Expire Date	2029.03.21
Batch Number	NSS230322A	Issue Date	2024.03.22

Item	Specification	Test result
Characters	white or almost white powder	white powder
Infrared Spectrum	To match with the working standard	Complies
Assay (On anhydrous basis)	97.0%~102.0%	99.32%
N-[N-(3,3-Dimethylbutyl)-L-α-aspartyl]-L-phenylalanine	$\leq 1.5\%$	0.16%
Lead	$\leq 1\text{mg/kg}$	0.03mg/kg
Other Related Substances	$\leq 2.0\%$	0.21%
Specific Rotation	$-43.4^{\circ} \sim -40.0^{\circ}$	-41.2°
Water	$\leq 5.0\%$	4.35%
Sulfated ash	$\leq 0.2\%$	0.00%
PH, 0.5% solution	5.0~7.0	5.3
Melting Point	81~84°C	83°C
Total Aerobic Plate Count	<250cfu/g	Complies
Coliforms	<10mpn/g	Complies
Fungi	<100cfu/g	Complies
Solubility (25°C)	>95g per 100g of ethanol	Complies
	~1.26g per 100g of water	Complies

Conclusion Conforms to USP42 /FCC 11
Storage Store in well-closed containers in a cool, dry place
Shelf Life 5 years when properly stored

SURVEYOR: LIYONG

CHIEF INSPECTOR: LIHONG



THANK YOU FOR YOUR BUSINESS