



Hangzhou Huarong Pharm Co., Limited

No. 5 Yongfuqiao Road, Gongshu District, Hangzhou, Zhejiang Province, China.

TEL: 0086-571-86758373

FAX: 0086-571-81131109

CERTIFICATE OF ANALYSIS

Product :	INSULIN ASPART		
Cas No.:	116094-23-6	Batch No.:	AIA2022090003
Manufacturing Date:	2022.09.15	Retest Date:	2025.09.14

<u>检测项目 Items</u>	<u>规格 Specifications</u>	<u>检测结果 Results</u>
Retention time	Retention time of the major peak consistent with reference standard	Conforms
Peptide Mapping	Peptide Mapping consistent with reference standard	Conforms
Loss on drying	≤ 10.0%	2.4%
Residue on ignition	≤ 6.0% (dried substance)	1.2%
High molecular weight proteins	≤ 0.5%	0.1%
B28 iso Asp insulin aspart	≤ 1.0%	0.1%
A21 Asp insulin aspart, B3 Asp insulin aspart, B3 iso Asp insulin aspart	≤ 2.0%	0.2%
Total of other impurities	≤ 1.5%	0.1%
Microbial Enumeration Tests	≤ 300cfu/g	Conforms
Bacterial Endotoxins Test	≤ 10EU/mg	Conforms
Insulin aspart plus A21 Asp insulin aspart, B3 Asp insulin aspart, B3 iso Asp insulin aspart and B28 iso Asp insulin aspart	90.0%~104.0% (on the dried basis)	99.7%
Storage: Shade and seal, -20℃±5℃.		
Conclusion: According to USP 43, the result conforms to the regulations.		



审核 Review: Dr. Song

检测 Testing: Li Li