



Certificate of Analysis-Gliclazide

CAS: 21187-98-4

Batch Number: FTF0240126 **Batch Quantity:** 160kg

Manufacture Date: Jan.24th,2024 **Analysis Date:** Jan.25th,2024 **Certificate Date:** Jan.26th,2024

Storage Store in cool & dry place. Store in well-closed containers.
Shelf life 3 years when properly stored.

Test	Specifications	Results of analysis
Appearance	White or almost white powder.	White powder
Solubility	Practically insoluble in water; freely soluble in methylene chloride; sparingly soluble in acetone; slightly soluble in ethanol(96 percent).	Meets the requirements
Identifications	The infrared absorption spectrum is concordant with that obtained with gliclazide CRS.	Meets the requirements
Impurity B (By HPLC)	≤2ppm	0.5ppm
Heavy metals	≤10ppm	<10ppm
	Impurity F ≤0.1%	Non-detected
Related substances (By HPLC)	Each unspecified impurity ≤0.10%	0.04%
	Sum of impurities other than F ≤0.2%	0.11%
Loss on drying	≤0.25%	0.11%
Sulfated ash	≤0.1%	0.03%
Residual solvents (By GC)	Ethyl acetate NMT 2500 ppm	265ppm
	N,N-Dimethylformamide NMT 880 ppm	Non-detected
Assay	99.0-101.0%, on dried basis.	100.0%

Conclusion: Conform with enterprise specification .

QC MANAGER: 刘娟 **INSPECTOR:** 黄子烨

