



西安菲斯弗生物科技有限公司

Xi'an Faithful Biological Technology Co., Ltd.

Certificate of Analysis-Fexofenadine hydrochloride

CAS: 153439-40-8

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 ITEM	SPECIFICATION	RESULTS
Appearance	White or almost white micro-crystalline powder	White powder
Solubility	Insoluble in the water and me'thanol	Complies
Identification	By IR, to match with the standard.	Complies
The retention time of major peak of the sample solution corresponds to the standard		Complies
Related substance	Individual impurity: Not more than0.1%	0.03%
Total impurities: Not more than 0.5%	0.08%	Complies
Residue on ignition	Not more than 0.2%	0.01%
Loss on drying	Not more than 1.0%	0.15%
Heavy metal	Not more than 20ppm	< 20ppm
Assay (on anhydrous basis)	98%-101%	99.78%

Conclusion: Conform with enterprise specification .

QC MANAGER: 刘娟 **INSPECTOR:** 黄子烨

