



西安菲斯弗生物科技有限公司
Xi'an Faithful Biological Technology Co., Ltd.

Certificate of Analysis-Zafirlukast

CAS: 107753-78-6

Batch Number: FTF0231226 **Batch Quantity:** 60kg

Manufacture Date: Dec.24th,2023 **Analysis Date:** Dec.25th,2023 **Certificate Date:** Dec.26th,2023

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

Items	Standard	Results
Description	Off-white to pink powder	Light pink powder
Solubility	Freely soluble in methanol and ethanol,practically insoluble in acetonitrile	Complies
Identification	Retention time of the sample should be concordant to the retention time of working standard	Complies
	IR absorption spectrum of the sample must be concordant with that of a similar preparation of montelukast sodium working standard /reference standard.	Complies
Loss on drying	≤1.0%	0.35%
Sulphated Ash	≤0.2%	0.04%
Heavy metals	≤20ppm	<20ppm
Relative substances (HPLC)	Total impurity:≤1.0%	0.8%
Assay(on dried basis)	98.0% ~ 102.0%	99.5%
Conclusion:It complies to prescribed enterprise standard		

QC MANAGER: 刘娟

INSPECTOR: 黄子烨

