



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

Certificate of Analysis-Nevirapine

CAS: 129618-40-2

Batch Number: FTF0231226 **Batch Quantity:** 100kg

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.

Test Items		Specifications	Results
Characters	Description	White to off-white, odorless to nearly odorless, crystalline powder.	Off-white, odorless, crystalline powder
	Solubility	Slightly soluble, practically insoluble in water.	Conform
Identification	A: The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay.		Conform
	B: Infrared absorption spectrophotometry: corresponds to the reference standard.		Conform
Water	≤0.2%		<0.1%
Residue on ignition	≤0.1%		<0.1%
Heavy metals	≤0.001%		<0.001%
Related substances (HPLC)	**Impurity A≤0.2%		N.D
	**Impurity B≤0.2%		<LOQ(LOQ:0.04%)
	**Impurity C≤0.2%		<LOQ(LOQ:0.04%)
	Any other individual unspecified impurity≤0.1%		0.07%
	Total impurities≤0.6%		0.07%
Assay (HPLC)	98.0 %~102.0 % (calculated on anhydrous basis)		99.72%
Residual solvents (GC)	Ethanol≤3000ppm		N.D

Conclusion: Conform with enterprise specification .

QC MANAGER: 刘娟 **INSPECTOR:** 黄子烨

