



## Certificate of Analysis-Pramipexole Hydrochloride

CAS: 104632-25-9

Batch Number: **FTF0241220** Batch Quantity: 5kg

Manufacture Date: Dec.18<sup>th</sup>,2024 Analysis Date: Dec.19<sup>th</sup>,2024 Certificate Date: Dec.20<sup>th</sup>,2024

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

Items	Standard	Results
Appearance	Visual Inspection-White to off-white crystalline powder	White to off-white powder
Identification	IR/UV Spectroscopy-Matches reference standard	Matches reference standard
Assay (Content)	HPLC-98.0%to 102.0%oflabeled amount	99.30%
Loss on Drying	Gravimetric Analysis at 105°C-Not more than 0.5%	0.40%
Residue on Ignition	Gravimetric Analysis -Not more than 0.1%	0.05%
Heavy Metals	AAS-Notmore than 20 ppm	7 ppm
Related Substances	HPLC-Individual impurity≤2.0%;total impurities≤5.0%	Individual:1.2%,Total: 3.5%
Microbial Limit	Culture Methods-Meets sterility requirements	Sterile,no microbial growth
Bacterial Endotoxins	LAL Test-Not more than 0.25 Endotoxin Units per mg	0.18 Endotoxin Units perr mg

Conclusion: Conform with enterprise specification.

QC MANAGER: **刘娟** INSPECTOR: **黄子烨**

