



XI'AN HARMONIOUS NATURAL BIO-TECH CO.,LTD

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Certificate of Analysis

Product Name: Ceftriaxone sodium (Sterile, USP42)

Batch Number: HNB210316

Batch Quantity: 500kg

Manufacture Date: Mar., 16th,2021 Analysis Date: Mar., 16th,2021 Expiry Date: Mar., 15th,2023

Storage: Store in cool & dry place. Store in well-closed containers.

Shelf life: 24 Months when properly stored.

ITEMS OF ANALYSIS	SPECIFICATIONS	RESULT
Appearance	White to pale yellow crystalline powder, odorless	Complies
Assay by HPLC (dry base)	≥795µg/mg	925µg/mg
Identification	HPLC: Correspond to retention time of major peak in the chromatogram obtained from the reference solution	Complies
	IR	Complies
	Gives reaction of Sodium	Complies
Clarity	≤1# Clarity standard solution	0.5#
Water	8.0%~11.0%	10.5%
pH	6.0 ~ 8.0	7.02
Related Substances	Total Impurity: ≤ 1%	0.08%
Heavy metals	≤20ppm	Complies
Pyrogen	Should be conform with the standard	Complies
Crystallinity	Extinction level and birefringence should be present	Complies
Abnormal Toxicity	Should be conform with the standard	Complies
Sterility	Should be conform with the standard	Complies
Conclusion	Complied with the USP42 standard	

QC MANAGER:

王朝A

INSPECTOR:

杨恩送



ANALYST: 杜静