



XI'AN HARMONIOUS NATURAL BIOTECHNOLOGY CO.,LTD

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Certificate of Analysis

Batch No.: HNB220303

Product Name: **CYPROHEPTADINE HYDROCHLORID**

CAS No.: 10592-13-9

Manufacture Date:Mar.,03th,2022 Analysis Date: Mar.,04th,2022 Expiry Date: Mar.,02nd,2022

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

Shelf life: 24 Months when properly stored.

ITEMS OF ANALYSIS	SPECIFICATIONS	RESULT
Appearance	White to slightly yellow, odorless or practically odorless, crystalline powder.	White Crystalline Powder
Identification	IR: The infrared absorption spectrum of the potassium bromide dispersion of the sample exhibits maxima only at the same wavelengths as that of a similar preparation of Cyproheptadine Hydrochloride reference standard	Complies
	HPLC: The retention time of the cyproheptadine peak of the sample solution corresponds to that of the standard solution, as obtained in the test for organic impurities	Complies
	A saturated solution gives reaction of chlorides	Complies
Solubility	Freely soluble in methanol, sparingly soluble in chloroform, sparingly soluble in alcohol, slightly soluble in water practically insoluble in ether.	Complies
Fluorescence Test	To comply	Complies
Residue of Ignition	≤ 0.1%	0.07%
Sulphated Ash	≤ 0.1%	0.08%
Light-absorbing	At 490nm ≤ 0.07	0.04
Organic Impurities by HPLC	Cyproheptadine related compound C: ≤ 0.15%	Not detected
	Amitriptyline related compound B ≤ 0.15%	Not detected
	Cyproheptadine related compound A ≤ 0.15%	0.05%
	Any individual unknown Impurity ≤ 0.1%	0.05%
	Total impurities ≤0.5%	0.13%
Acidity	NMT 0.15 ml of 0.01 M sodium Hydroxide is	0.1ml
Water Determination	7.0% to 9.0%	8.5%
Residual Solvents	Methanol ≤300ppm	163ppm
	O-rylene ≤2170ppm	Not detected
	Isopropyl alcohol ≤5000ppm	24ppm
	Toluene ≤890ppm	Not detected
	Tetrahydrofuran ≤720ppm	Not detected
	Chloroform ≤60ppm	Not detected
Assay (Dry based)	98.5%~100.5%	100.2%
Conclusion	Complies with the USP40 standard	

QC MANAGER:

王翠娟

INSPECTOR:

杨思远

