

Name of the Product : **TRIHXYPHENIDYL HYDROCHLORIDE USP**

Batch No. : HTXCPS002

Date of manufacture : JULY 2024

Quantity : 100.0kgs (25.0kgs x 4)

Date of Expiry : JUNE 2029

Nature of Packing : HDPE DRUMS

C E R T I F I C A T E O F A N A L Y S I S

S.No	TEST	RESULTS	SPECIFICATION
1.	Description	White, Crystalline powder. , having not more than a very faint odor.	White or slightly off-white, crystalline powder, having not more than a very faint odor.
2.	Solubility	Soluble in alcohol and in chloroform; slightly soluble in water	Soluble in alcohol and in chloroform; slightly soluble in water
3.	Melting Point	251.3 ⁰ C, with decoposition	About 250 ⁰ C, with decomposition.
4.	IDENTIFICATION TESTS		
	A. IR spectrum	Complies	The positions and the relative sizes of the bands in the spectrum of the sample and the reference spectrum shall be concordant.
	B. Test for chlorides	Complies with test for chlorides	Shall comply the test.
5.	pH (1% w/v Solution)	5.65	Between 5.2 to 6.2
6.	Related substances by HPLC Impurity A Unspecified impurities Total impurities	Not detected 0.02% 0.04%	Not more than 0.5% Not more than 0.10% of each impurity Not more than 0.5%
7.	Loss on Drying at 105 ⁰ C	0.21%	Not more than 0.5%
8.	Residue on ignition	0.03%	Not more than 0.1%
9.	ASSAY by HPLC (dried basis)	99.8%	Not less than 98.0 % and Not more than 102.0%
RESULT : The sample complies with prescribed standards as per USP			

Analyst

Date: 29-08-2024

QC In Charge

Date: 29-08-2024

HARIKA DRUGS PRIVATE LIMITED

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Butuh penyesuaian
terlampir

STANDARISASI CERTIFICATE OF ANALYSIS API PRODUK

No	Nama Bahan	Manufaktur	Referensi pada CoA Manufaktur saat ini	Referensi pada CoA yang diusulkan	Penyesuaian Parameter			Nomor SPBB	Keterangan
					Parameter yang Dihilangkan	Parameter yang Ditambah	Parameter yang direvisi		
1	Trihexyphenydl HCL	Harika Drugs	USP	USP47/ FI VI		Identifikasi C (waktu retensi) USP 47 logam berat ≤ 20 bpj (FI VI)		RD.02-SBA/110.04	Penyesuaian CoA dari Manufacterur

Diperiksa Oleh

Disetujui Oleh,


15/10/24
Koordinator QC


15/10/24
Koordinator TS


15/11/24
Koordinator QA


Manajer QA
