

Specification Sheet

PRODUCT: THIAMINE HYDROCHLORIDE

DATE: 2024.1.9

SPECIFICATION: BP2022/USP43/EP10.0/FCC10

PACKING: 25KG PER DRUM

SHELF LIFE: 3YEARS

EXAMINATION ITEMS

INDEX OF QUALITY

Appearance

White Crystals or almost white Crystalline Powder

Identification

(1) should be positive reaction

(2) consistent with the reference IR spectra

PH

2.7– 3.3

Appearance of Solution

Clear, no more colour than reference solution Y7 or GY7

Sulphates

≤300ppm

Limit of Nitrate

No brown ring is produced at the junction of the 2 layers

Lead

≤2 ppm

Cadmium

≤1.0ppm

Mercury

≤0.1 ppm

Arsenic

≤1.0 ppm

Water

≤5.0%

Residual on ignition

≤0.1%

Absorbance of solution

≤0.025

Residual solvents

Ethanol ≤5000ppm Methanol ≤3000ppm

Related substances (Disregard limit 0.05%)

-Impurity A

≤0.15%

-Impurity B

≤0.3%

-Impurity C

≤0.15%

-Any impurity

≤ 0.1%

-Total impurities

≤ 0.5%

-Chromatographic purity

≤ 1.0%

Assay

98.5 – 101.0%

MICROBIAL

S. Aureus

Negative

Salmonella

Negative

E.Coli

Negative

Total Plate count

≤1000 cfu/g

Yeast and Mould

≤100 cfu/g

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