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## **Technical Data Sheet**

USP monograph/USP<731><731>

## Vitamin B12 Cyanocobalamin 97-102% P.

#### PRODUCT INFORMATION

Ph Eur. /. BP Oriain China Standard 005439-01178-9380 Use Cosmetic and Food Submission Code

INCI CYANOCOBALAMIN Quality **GMP** Parmaceutucal

CAS 68-19-9 Carrier None

ITEM SPECIFICATION METHOD Assay 97.0%~102.0% USP monograph Dark red crystals or amorphous or crystalline red powder Characters Visual method Identification A UV: The absorption spectrum exhibits USP monograph maxima at 278±1nm,361±1nm,and 550

+2nm 278+1nm 361+1nm 550+2nm A361 nm/A278nm :1.70~1.90 A361 nm/A550nm :3.15~3.40

Identification B Cobalt: Meets USP requirements USP monograph Identification C HPLC: The retention time of the major-peak USP monograph of the sample solution corresponds to that

of the standard solution.

Loss on drying ≤10.0%

Related substances Total impurities ≤3.0% USP monograph

> 7β,8β - Lactocyanocobalamin ≤1.0% 34-Methylcyanocobalamin ≤2.0% 8-Epi-cyanocobalamin ≤1.0% Any othter unidentified impurity and 50-Carboxycyanocobalamin ≤0.5%

Acetone ≤5000ppm In house /(GC) SOP-QC-001-04-05

## STATEMENTS

Food Quality and Safety According to Reg. (EC) 178/2002

Contaminants According to Reg. (EC) 1881/2006 and amendments Residual Solvents According to Dir. (EC) 2009/32 and amendments Pesticides According to Reg. (EC) 396/2005 and amendments

Microbiology Bacterial Count: TAMC-Bacteria <1,000 cfu/g, TYMC <100 cfu/g

GMO Not Detectable, GMO Free According to Reg. (EC) 1829/2003 and 1830/2003 and amendments

ETO ETO free Vegan Vegan

No ionization or other radiation is permitted According to Dir. (EC) 1999/2 and 1999/3 and amendments Irradiation

BSE/TSE Risk Free BSE/TSE

Allergen free according to Reg. (EC) 1169/2011 Nanomaterials Absent According to Reg. (EC) 1169/2011 Absent According to Reg. (EC) 2022/63 Titanium dioxide

Packaging According to Reg. (EC) Nr. 10/2011 and 1935/2004

Regulatory (for production) GMP, ISO 9001, ISO 14001, ISO 45001

HALAL and KOSHER Conform

**CMR Status** according to Cosmetics Regulation (EC) 1223/2009

Mineral oil Free Palm (kernel) oil Free

# STORAGE AND HANDLING

Storage Store in a well-closed container away from moisture and direct sunlight

Shelf Life 5 years if sealed and properly stored

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