

R# 14567  
 RI 0638  
 8-10-22

# Xinfa Pharmaceutical Co., Ltd.

East of Huangdian Village Kenli, Dongying Shandong, 257500

## Certificate of Analysis

<b>Product</b>	<b>Thiamine Mononitrate</b>	Ref. Standard:	USP 43
		Batch / Lot #	210310X032
CAS # (Active) :	532-43-4	MFG Date	03/10/2021
Formula (Active):	C <sub>12</sub> H <sub>17</sub> N <sub>5</sub> O <sub>4</sub> S	Retest Date	03/09/2024
PAT Item # :	30-8210	Batch Size	1000 KG
Country of Origin :	CHINA	Pack Size	25 KG / Carton

Distributed by PAT Vitamins

Analysis Contents	Specification	Methods	Results
DESCRIPTION	White to creamy white powder	Visual	Conform
IDENTIFICATION	Positive	USP 43	Positive
PARTICLE SIZE			Not Tested
BULK DENSITY			Not Tested
TAPPED DENSITY			Not Tested
APPEARANCE OF SOLUTION	Meets requirement	USP	Pass
PH	6.0 ~ 7.5	USP 43	7.3
CHLORIDE	≤ 300 PPM	BP	< 300 PPM
HEAVY METAL	≤ 10 PPM	BP	< 10 PPM
ARSENIC	≤ 3 PPM	AAS	< 3 PPM
CADMIUM	≤ 0.3 PPM	AAS	< 0.3 PPM
LEAD	≤ 0.5 PPM	AAS	< 0.5 PPM
MERCURY	≤ 0.1 PPM	AAS	< 0.1 PPM
RESIDUAL SOLVENTS	Ethanol ≤ 0.50%	GC	< 0.50%
	Methanol ≤ 0.50%	GC	< 0.50%
RELATED SUBSTANCES	Within limit	USP	Conform
LOSS ON DRYING (%)	≤ 1.00%	USP 43	0.13%
RESIDUE ON IGNITION	≤ 0.20%	USP 43	0.10%
CHOMATOGRAPHIC PURITY	≤ 1.00%	USP 43	< 1.00%
ASSAY (on dried basis)	98.00% ~ 102.00%	USP 43	99.40%
<b>MICROBIOLOGY</b>			
TOTAL PLATE COUNT	≤ 1,000 CFU / Gram	CP	< 1000 CFU / Gram
YEAST & MOLD	≤ 100 CFU / Gram	CP	< 100 CFU / Gram
COLIFORMS	≤ 10 CFU / Gram	CP	< 10 CFU / Gram
E. COLI	≤ 10 CFU / Gram	CP	Negative
STAPH. AUREAUS	Negative	CP	Negative
SALMONELLA	Negative	CP	Negative

**CONCLUSION** The above product conforms to listed standard(s)

QC Department	Verified by: K.Y	Analyst: J.J.
	Date: 06/14/2021	Date: 06/14/2021