

# HUAZHONG PHARMACEUTICAL CO.,LTD.

NO. 71 WEST CHUNYUAN ROAD, XIANGYANG CITY, HUBEI PROVINCE, CHINA

## CERTIFICATE OF ANALYSIS

PRODUCT NAME: THIAMINE MONONITRATE 98% DC

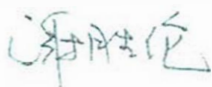
BATCH NO. : K

QUANTITY:400kg

DATE: NOV.05,2016

ITEMS	Customer's Specification	Results
Description:	A white free-flowing, granular powder With a slight meat-like or yeasty odor.	Conforms
Indentification:	IR Absorption spectrophotometry Chemical reaction	<b>Positive</b>
Assay:	97.0%~99.0% of Thiamine Mononitrate (calculated on a dry basis)(2%-3%HPMC)	98.5%
Loss on Drying:	1.0%Max	0.2%
Sieve analysis:	NLT 100% through a USS#10 NLT 95% through a USS#14 NMT 30% through a USS#100	100.0% 99.0% 19.7%
Bulk density:	NLT 0.50g/ml	0.56g/ml
Tapped density:	NLT 0.60g/ml	0.63g/ml
PH:	6.5-7.5	7.0
Chloride:	0.06%Max	Conforms
Residue on ignition	0.20%Max	0.06%
Heavy metals	≤20ppm	Conforms
Microbial limits:	Salmonella: Negative;E.coli:Negative Coliforms: 1CFU/g Max. Standard plate count: 1,000CFU/g Max Mold & Yeast: 100CFU/gm Max.	Negative Conforms Conforms Conforms
Manufacturing Date:	OCT.29,2016	
Expiration Date:	OCT.28,2019	

APPROVED:



INSPECTOR: MA SHAOCHEN



0107651

## RAPPORT D'ANALYSE DES MATIÈRES PREMIÈRES

Code No.: T-013 ✓

Spéc. approuvées par l'Assurance Qualité 2013/08/20

ré-évaluation ✓

NOM DU PRODUIT: Thiamine Mononitrate D.C. 98% (MFR)

NO. DE RÉCEPTION: 2017-04-05 ✓

FOURNISSEUR: Cambrian Solutions Inc ✓

MANUFACTURIER: Hubei Huazhong ✓

LOT DU FOURNISSEUR: 2017-04-05 ✓

NO. DE LOT DU MAN.: 2017-04-05 ✓

DATE D'EXPIRATION: 2019-11-03 ✓

PAYS D'ORIGINE: Chine ✓

DATE DE RÉ-ANALYSE: N/A

QUANTITÉ REÇUE: 16 x 25 Kg ✓

RÉFÉRENCE: USP, méthode interne

## CATÉGORIE:

DESCRIPTION	SPÉCIFICATION	OBSERVATION
COULEUR:	Blanc à blanc crème	Conforme £ ✓
ODEUR:	Légère odeur caractéristique	Conforme £ ✓
FORME:	Poudre cristalline ou granuleuse	Poudre granuleuse £ ✓

ANALYSES	MÉTHODE	SPÉCIFICATIONS	RÉSULTATS
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IDENTIFICATION:

Test C	USP	Positive	Conforme £ ✓
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<u>PERTE DE POIDS:</u>	USP	≤ 1.0%	0.6 % £ ✓
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<u>ESSAI:</u> (sur base sèche)	SOP.MP.095	96.0 - 100.0%	99.6 % £ ✓
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Tel quel	Calcul	À rapporter	99.0 % £ ✓
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	Calcul (Essai Tel quel X 10)	À rapporter	990 ✓
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<u>SOLVANTS RÉSIDUELS:</u>	USP <467>	Rencontre les normes USP	Conforme ‡ ✓
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RÉVISÉ PAR: <i>Annel QS</i>	DATE: 2017-04-05	REJETÉ <input type="checkbox"/>
COMMENTAIRE: @ Produit certifié en ré-évaluation ✓ £ Analysé par Laboval ✓ ‡ Se référer à la lettre de solvants résiduels ci-jointe ✓		APPROUVÉ <input checked="" type="checkbox"/>
		PAR: <i>Annel QS</i> <sup>QC MP 2017-04-05</sup> Superviseur Laboratoire Matières Premières
		DATE: 2017-04-05
		APPROUVÉ PAR: <i>Annel QS</i> Assurance Qualité
ANALYSTE: NC	DATE: 2017-03-27	DATE: 2017-04-05
		DATE: 2017-04-05

### Certificat d'analyses

Client: *Farm. Lab. 4470 St. J.*  
*ATKINS PHARMACEUTICALS INC.*  
*1000 St. Jacques*  
*St. J.*

Att: *J. Kousha*

Fax: *514-354-4470*

Produit: Thiamine Mononitrate D.C. 98% (MFR)

Code: T-013 ✓

Date: 2017-04-04

CA: *150211*

PO: *104470*

Req: *104470*

Lot: *104470*

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Tests	Spécifications	Résultats	Méthodes
<b>Description</b>			
Couleur	Blanc à blanc crème	Conforme ✓	Organoleptique
Forme	Poudre cristalline ou granuleuse	Poudre granuleuse ✓	Organoleptique
Odeur	Légère odeur caractéristique	Conforme ✓	Organoleptique
<b>Identification</b>			
C	Positive	Conforme ✓	USP, Édition courante
Perte au séchage	≤ 1.0%	0.6 % ✓	USP, Édition courante
<b>Teneur par HPLC</b>			
Thiamine mononitrate (Vitamine B1)	96.0 - 100.0%(sur base sèche)	99.6 % ✓	MP.095 ✓
<b>Teneur par calcul</b>			
Thiamine mononitrate (Vitamine B1)	À rapporter (tel quel)	99.0 % ✓	Calculs ✓

Vérifié par:

*Karim Kousha*  
Karim Kousha, Ph. D.

Approuvé par:

*Fred Bakshi*  
Fred Bakshi, B. Sc.

*REC# 241358*  
*2017-04-05*

HUAZHONG PHARMACEUTICAL CO.,LTD.

NO. 71 WEST CHUNYUAN ROAD, XIANGYANG CITY, HUBEI PROVINCE, CHINA

CERTIFICATE OF ANALYSIS

PRODUCT NAME: THIAMINE MONONITRATE 98% DC

BATCH NO. : 165 2017-03-27 QUANTITY:400kg

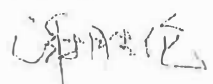
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Loss on Drying:	1.0%Max	0.4%
Sieve analysis:	NLT 100% through a USS#10 NLT 95% through a USS#14 NMT 30% through a USS#100	100.0% 99.7% 22.0%
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Tapped density:	NLT 0.60g/ml	0.68g/ml
PH:	6.5-7.5	7.2
Chloride:	0.06%Max	Conforms
Residue on ignition	0.20%Max	0.06%
Heavy metals	≤20ppm	Conforms
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Manufacturing Date: NOV.04,2016

Expiration Date: NOV.03,2019 ✓

APPROVED:



INSPECTOR: MA SHAOCHEN