

14J13-B08

Director Técnico

CERTIFICATE OF ANALYSIS

No.:

Date: Sept.12,2014

Quantities and Descriptions

ATROPINE SULFATE EP8.0

	Standard	Results
Batch no.:		APS1404001
Quantity:		10KG
Appearance:	White crystalline powder	Conforms
Identification:		
A:Optical rotation	Meets the requirement	Conforms
B:Infrared absorption	Conforms with the spectrum of RS	Conforms
C:Chemical reaction	Meets the requirement	Conforms
D:Chemical reaction	Should be positive	Positive
E:The reaction of sulfates	Should be positive	Positive
F:The reaction of alkaloids	Should be positive	Positive
PH(Acidity):	4.5 - 6.2	6.0
Optical rotation:	-0.50 - -0.05°	-0.001°
Infrared absorption:	Conforms with spectrum of RS	Conforms with RS
Chemical reaction:	Meets the requirements	Conforms
Chemical reaction:	Should be positive	Positive
The reaction of sulphates:	Should be positive	Positive
The reaction of alkaloids:	Should be positive	Positive
Water:	2.0% - 4.0%	3.2%
Solubility: Very soluble in water, freely soluble in ethanol(96%)		Conforms
Sulphated ash:	Not more than 0.1%	0.02%
Related compounds:	Meets the requirements	Conforms
	Impurities A 0.2% Max.	No detection
	Impurities B 0.2% Max.	No detection
	Impurities C 0.2% Max.	No detection
	Impurities D 0.2% Max.	No detection
	Impurities E 0.3% Max.	No detection
	Impurities F 0.2% Max.	No detection
	Impurities G 0.2% Max.	No detection
	Impurities H 0.3% Max.	No detection
	Unspecified Impurities 0.10% Max.	No detection
	Total Impurities 0.5% Max.	No detection
Acetone (Residual solvent impurities):	Not more than 0.25%	No detection
Assay(anhydrous substance):	99.0 - 101.0%	99.2%
Mfg/Expiry date:	April 10, 2014/April 09,2016	

This is to certify that we, the undersigned, have instructed tested the quantity of the

above mentioned goods and found the results as follows:

Corresponding to the requirement of EP8.0

Manufacturer: Minsheng Group Shaoxing Pharmaceutical Co., Ltd.