



绍兴民生医药有限公司

Minsheng Group Shaoxing Pharmaceutical Co., Ltd.

Add:315 Tanggong Road, Paojiang Industrial Zone, Shaoxing, China

CERTIFICATE OF ANALYSIS

No.: OC923WRM083

Date: APR.18,2013

Quantities and Descriptions

ATROPINE SULFATE EP7.0

Standard

Results

APS1303001

4KG

Conforms

Batch no.:

Quantity:

Appearance:

White crystalline powder

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

5.5

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%

0.06%

Related compounds:

Meets the requirements

Conforms

Impurities A 0.2% Max.

0.15%

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.

0.15%

Acetone (Residual solvent impurities)

Not more than 0.25%

No detection

Assay(anhydrous substance):

99.0 - 101.0%

99.5%

Mfg/Expiry date: 绍兴民生医药有限公司 March 27, 2013/March 26, 2015

MINSHENG GROUP

SHAOXING PHARMACEUTICAL CO., LTD.

This is to certify that we, the undersigned, have inspected/tested the quality of the

above mentioned goods and found the results as follows:

Corresponding to the requirement of EP7.0

Manufacturer:Minsheng Group Shaoxing Pharmaceutical Co., Ltd.

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

13F05- B08

Director Técnico S.

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