

NANYANG TIANHUA PHARMACEUTICAL CO., LTD.
WANGCUN, WOLONG DISTRICT, NANYANG, HENAN, CHINA

Certificate of analysis

Batch No.: 20150901

Date of manufacture: 20150914

Exp.Date: 20200913

Analysis Date: 20150914

Report Date: 20150914

Produced by: Nanyang Tianhua Pharmaceutical Co., Ltd.

Product: Bethanechol Chloride

Quantity: 100kg

Test Result: Come up to standard

Apply standard: USP34

Character: White crystalline powder; absorb water easily in moist air.

Solubility: Freely soluble in water; soluble in ethanol (95%); practically insoluble in ether and in chloroform.

Identification:

A: Meet the requirements of standard

B: Meet the requirements of standard

C: Meet the requirements of standard

D: Meet the requirements of standard

pH: 6.2 (standard:5.5-6.5).

Loss on drying: 0.2% (standard: not more than 1.0%)

Residue on ignition: 0.03% (standard: not more than 0.1%)

Heavy metals: <0.003% (standard: the limit is 0.003%)

Related compounds:

2-hydroxypropyltrimethyl ammonium: 0.3% (standard: not more than 1.0%)

Any other impurity: 0.05% (standard: not more than 0.10%)

Total impurities: 0.6% (standard: not more than 1.5%)

Chloride content: 18.1% (standard: 17.7-18.3%)

Residual ethanol solvent: 0.03% (standard: not more than 0.5%)

Assay:

It contains 99.9% of C₇H₁₇ClN₂O₂ calculated on the dried basis (standard: 98.0-101.5%)

Analyst: Qin xiangjun

秦向君

Checker: Wu Yingfen

吴应芬

Supervisor: Zhu Junli

朱俊丽

NANYANG TIANHUA PHARMACEUTICAL CO., LTD.

张俊