

杭州东瑞医药科技有限公司
HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.

CERTIFICATE OF ANALYSIS

Theophylline Anhydrous

Batch No.: DR20140520	Piece: 1000kg
Manufacture Date: 2014.05.20	Expiry Date: 2018.04

TESTS:

Items	Specification	Results
Appearance	A white, crystalline powder	Conforms
Identification	Positive reaction	Conforms
Acidity	50ml of solution S consumes 0.01mol/L NaOH \leq 1ml	Conforms
Appearance of solution	Clear , Colorless	Conforms
Related substance	Impurity A,B,C,D:each impurity <0.1% Any other impurity: each impurity <0.1% Total impurities <0.5%	Conforms
Heavy metals	\leq 20ppm	<20ppm
Loss on drying	\leq 0.5 %	0.13%
Sulphated ash	\leq 0.1 %	0.04%
Melting point	270~274°C	271.2~271.9°C
Assay	99.0~101.0%	99.4%

Conclusion: The results conform with the BP2012/USP35.



Analyst: Joe Yu Checker: Agnes Zhong QA.Manager: Sun Wenhui

Add:1018 Guangyin Building No.42 E. Fengqi Road, Hangzhou, 310012 China

Tel: +86-571- 85335020

E-mail: agnes@dawnraypharma.com

Fax: +86-571- 85335020

Website: <http://www.dawnraypharma.com/>