1520 P/1

CSPC INNOVATION PHARMACEUTICAL CO., LTD.

CERTIFICATE OF PRODUCT ANALYSIS

No.: REC-ZL-G6102 (03)

Product: Theophylline Batch No.: 2021612601 Quantity: 1000 kg

Analysis Standard: EP8.0 Analysis Date: 2016.12.25 Report Date: 2016.12.27

Manu. Date: 2016.12 Retest Date: 2020.11

Analysis Contents	Analysis Standards	Analysis Results
【Characters】		
Appearance	White or almost white crystalline powder	White crystalline powder
【Identification】		
B、Infrared absorption	Conforms to the Reference Spectrum	Pass
D、Loss on drying	See Tests	Pass
【Tests】		
Appearance of solution	clear、colourless	Pass
Acidity	Not more than 1.0 ml of 0.01M sodium hydroxide	Pass
Related substances		
- Each impurity A 、B、C、D	≤0.1%	<0.05%
- Any other impurity	≤0.1%	<0.05%
- Total impurities	≤0.5%	0.02%
Heavy metals	≤20ppm	<20ppm
Loss on drying	≤0.5%	0.09%
Sulphated ash	≤0.1%	0.05%
【Assay】	99.0～101.0%	99.8%

分析报告专用

Conclusion The above product conforms to EP8.0 requirement on Theophylline

Chief of Quality Analysis Dept: 刘俊爱 Rechecker: Reporter:

Address: No.48 shengxue Road, Luancheng County, Shi Jiazhuang City, Hebei Province, China

Tel: +86 311 85408618 +86 311 85408725 Fax: +86 311 85409463