

Manufacturer Add:
Industrial Park in Wugong County,
Xianyang City, Shaanxi Province, China

www.fzbiotech.com
E-mail: sales@fengzusw.com
Tel.: 86-029-8129-4858

CERTIFICATE OF ANALYSIS

Product name	Hyoscine (Scopolamine) Hydrobromide		
Batch No	20170325	Quantity	10 KG
Mfg Date	Mar.25,2016	Release Date	Mar. 27,2016

Item	Method	Unit	Specification	Results
Description	Visual	White or almost white, crystalline crystals, freely soluble in water and soluble in ethanol (96%)	Must comply	Complies
Identification tests B. Infrared absorption spectra	Eur. Pharma 8 th Edition Method 2.2.24	Compares with the spectrum obtained with Hyoscine Hydrobromide (CRS)	Must comply	Complies
E. Reaction (a) of bromides	Eur. Pharma 8 th Edition Method 2.3.1	Gives positive reaction for bromides	Must comply	Complies
pH of Solution (S)	Eur. Pharma 8 th Edition Method 2.2.3		4.0-5.5	4.52
Specific Optical rotation on a Solution (S) as per monograph	Eur. Pharma 8 th Edition Method 2.2.7	Degrees	Negative 24° to Negative 27°	Negative 26.0°
Hyoscine and other related substances (byLC)	Eur. Pharma 8 th Edition Method 2.2.29			
Total impurities		% w/v	<0.7%	<0.7%
Water (on 0.20g)	Eur. Pharma 8 th Edition Method 2.5.12	% m/m	10.0-13.0 max.	10.85
Sulphated Ash (1.0g)	Eur. Pharma 8 th Edition Method 2.4.14	% m/m	0.1 maximum	<0.1

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Assay-potentiometric	Eur. Pharma 8 th Edition Method 2.2.20	% m/m	99.0-101.0	99.5
Residual Solvents	Eur. Pharma 8 th Edition Method 2.4.24			
a. Chloroform		mg/kg	60 max.	<60
Stability Testing		See Stability Testing Compliance Statement		



QC Manager: Liu Qiang