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De Ref 369/14/R

SHANGHAI SHENGXIN MEDICINE CHEMICAL CO., LTD.  
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CHINA.

QUALITY CONTROL DEPARTMENT  
CERTIFICATE OF ANALYSIS

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Name of Product : Bromhexine Hydrochloride EP7			
CAS No.	611-75-6	Grade	EP
Batch No.	2141300011	Batch Quantity	300.050 Kg.
Mfg. Date	07-03-2013	Expiry Date	07-02-2018
Inspection Lot No.	040000111186	Date of Release	22-03-2013
Sr. No.	Test	Observation	Specification
1.	Appearance	Almost white, crystalline powder.	White or almost white, crystalline powder.
2.	Solubility	Complies	Very slightly soluble in water, slightly soluble in alcohol and in methylene chloride.
3.	Identification A) By IR Spectrophotometer	Complies	IR Spectrum of sample conforms to that of Bromhexine Hydrochloride Working Reference Standard.
	B) By TLC	Complies	The principal spot in the chromatogram obtained with test solution is similar in position and size to the principal spot in the chromatogram obtained with reference solution.
	C) By chemical test	Complies	A brownish-yellow colour develops in the lower layer.
	D) By reaction of primary Aromatic amines	Complies	The solution gives the reaction of primary aromatic amines.
	E) By reaction (a) of chloride	Complies	The solution gives the reaction (a) of chlorides.
4.	Appearance of Solution	Complies	The solution is clear and not more intensely coloured than reference solution Y <sub>6</sub> .
5.	Related Substances (By HPLC)		
	Any one Impurity	0.11 %	Not more than 0.2 %
	Any other Impurity	Below disregard limit*	Not more than 0.1 %
	Total Impurities	0.11 %	Not more than 0.3 %
6.	Loss on drying	0.37 % w/w	Not more than 1.0 % w/w
7.	Sulfated ash	0.07 % w/w	Not more than 0.1 % w/w
8.	Assay by potentiometer (On dried basis)	99.8 % w/w	Not less than 98.5 % w/w and not more than 101.5 % w/w
9.	ADDITIONAL TEST		
	Residual Solvent (By GC-MS)		
	• Methanol	250 ppm	NMT 3000 ppm
	• Ethyl Acetate	31 ppm	NMT 5000 ppm

\* Disregard limit is 0.05%

Remark: The above sample Complies / Does not comply with the prescribed standards of quality with respect to above tests as per EP7 Specification No. FP/SPS/BRH/001 (Rev. 01)

Prepared By <u>Shun</u> 22-03-2013	Checked By <u>Q.A.</u> 22-03-2013	Approved By <u>Q.A.</u> 10 SEP 2015
Head Q.C.	Head Q.C.	Head Q.A.