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De Ref 369/14/R

SHANGHAI SHENGXIN MEDICINE CHEMICAL CO., LTD.
ADDRESS: DONGJING TOWN SONGJIANG BOROUGH SHANGHAI,
CHINA.

QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS

Name of Product : Bromhexine Hydrochloride EP7 (Page 1 of 1)			
CAS No.		611-75-6	Grade
Batch No.		2141300011	Batch Quantity
Mfg. Date		07-03-2013	Expiry Date
Inspection Lot No.		040000111186	Date of Release
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	Complies	IR Spectrum of sample conforms to that of Bromhexine Hydrochloride Working Reference Standard.
	A) By IR Spectrophotometer		
	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 ₆ .
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 Nov 01)

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