



AUROCHEM LABORATORIES (INDIA) PVT. LTD.

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WORKING STANDARD REPORT

Preparation Date		18/04/2017	Valid upto		18/04/2018
Manufacturer		S. S. Pharmachem	Page no		1/1
Item Name		AMBROXOL HYDROCHLORIDE BP	Mfg. Date		Apr 2016
Batch No		SAM/AMH/0416001	Exp. Date		Mar 2021
Storage condition		Store below 25°C	Quantity		500 mg
TEST		OBSERVATIONS		STANDARD	
01.	Description	A White, crystalline powder.		A White or yellowish, crystalline powder.	
02.	Solubility	Sparingly Soluble in water , Soluble in methanol , practically insoluble in methylene chloride.		Sparingly Soluble in water , Soluble in methanol , practically insoluble in methylene chloride.	
03.	Identification	A) Light Absorbtion: The solution exhibits maxima at same wavelength . Absorbance ratio : A245/A310 :3.35 B) The IR absorption spectra of the sample concordant with the reference spectrum of Ambroxol hydrochloride W.S. C) TLC: The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with the reference solution. D) A white, curdy precipitate is formed		A) Light Absorbtion: The solution exhibits maxima at same wavelength. Absorbance ratio : A245/A310 :3.2 TO 3.4 B) The IR absorption spectra of the sample concordant with the reference spectrum of Ambroxol hydrochloride W.S. C) TLC: The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with the reference solution. D) A white, curdy precipitate is formed	
04.	Appearance of Solution	The solution is clear and not more intensely coloured than reference solution Y ₆		The solution is clear and not more intensely coloured than reference solution Y ₆	
05.	pH	5.35		4.5 to 6.0	
06.	Related Substances	Any Impurity : Less than 0.1% Total Impurity :Less than 0.3% Less than 20ppm		Any Impurity : NMT 0.1% Total Impurity :NMT 0.3% Not more than 20ppm	
07.	Heavy Metals	0.28 %		Not more than 0.5%	
08.	Loss on drying	0.07 %		Not more than 0.1%	
09.	Sulphated Ash	99.39 % on as is basis 99.67 % on dried basis		99.0% to 101.0% on dried basis	
10.	Assay C ₁₃ H ₁₈ Br ₂ N ₂ O.HCl				

In the opinion of undersigned the sample referred to above IS OF STANDARD QUALITY as defined in the Act and Rules made thereunder in above respect, as per BP & can be used as Working Standard.

ANALYSED BY	CHECKED BY
 18/04/2017	 18/04/2017

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