

**CERTIFICATE OF ANALYSIS****(Finish Product)****Product Name** : AMBROXOL HYDROCHLORIDE Ph.Eur**Batch No** : AMX/40050620**A.R No.** : FP20/00575**Mfg Date** : JUN-20**Expiry/Retest Date** : MAY-25**Approved Qty** : 2110.60 Kg**Date of Analysis** : 04.07.20

Sr No.	Test	Specifications	Results
1	Description	White or yellowish, crystalline powder	White crystalline powder
2	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.
3	First Identification: B), D) B) IR D) By Chloride test	The IR absorption spectrum of Ambroxol Hydrochloride is concordant with that of spectrum of obtained from standard. Gives reaction of chlorides.	The IR absorption spectrum of Ambroxol Hydrochloride is concordant with that of spectrum of obtained from standard. Gives reaction of chlorides.
4	Appearance of solution	Solution S is clear and not more intensely coloured than reference solution Y6.	Complies
5	pH	Between 4.5 to 6.0	5.052
6	Related Substances by HPLC ➤ Unspecified Impurities ➤ Total impurities	NMT : 0.10 % NMT : 0.3 %	ND ND
7	Heavy metals	NMT : 20 ppm	Less than 20 ppm
8	Loss on drying	NMT : 0.5 % w/w	0.18 %w/w
9	Sulfated ash	NMT : 0.1 % w/w	0.07 %w/w
10	Assay (on dried basis)	99.0 % to 101.0 %w/w	99.7 %w/w

Prepared by		Checked by		Approved by	
Sign		Sign		Sign	
Date	04.07.20	Date	04.07.20	Date	04.07.20
Name	Vishnu Patel	Name	Pranav Desai	Name	Kinshuk Dube
Designation/ Department	Dy.Manager Quality Control	Designation/ Department	Asst.Manager Quality Control	Designation/ Department	Manager Quality Assurance



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11	Residual solvents* ➤ Methanol ➤ THF ➤ Toluene	NMT : 3000 ppm NMT : 720 ppm NMT : 890 ppm	254 ppm ND ND
ADDITIONAL TEST			
12	Bacterial Endotoxins*	NMT : 3.4 IU/mg	Less than 3.4 IU/mg
13	Microbiological Control* ➤ Total Aerobic Microbial count ➤ Total Yeasts and Moulds Count ➤ Salmonella SP ➤ Escherichia Coli ➤ Pseudomonas Aeruginosa ➤ Staphylococcus Aureus	NMT: 100 CFU/g NMT: 10 CFU/g Absent/10g Absent/g Absent/g Absent/g	< 10 CFU/g < 10 CFU/g Absent Absent Absent Absent

Remarks: The product **conforms** as per Specification No: FPS/AMX/05/01.

"*" Indicates in house method

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Date	04.07.20	Date	04.07.20	Date	04.07.20
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Designation/ Department	Dy.Manager Quality Control	Designation/ Department	Asst.Manager Quality Control	Designation/ Department	Manager Quality Assurance