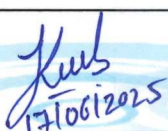
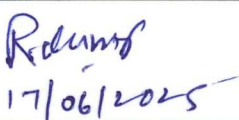
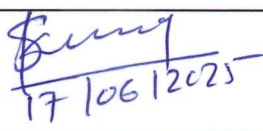


CERTIFICATE OF ANALYSIS

Product Name	Ambroxol HCL - IP
Mfg By	Paragon Organics
Cas No.	23828-92-4
Batch No.	PRG/AM/2506026
Date of Mfg.	Jun-2025
Date of Expiry	May-2030
Batch Qty.	729.20 Kg

Sr. No.	TEST	SPECIFICATION	RESULT
1.	Description	A white or yellowish crystalline powder	White crystalline powder
2.	Identification test by a) Infrared absorption spectrophotometry b) Reaction of chlorides	Compare the spectrum with that obtained with Ambroxol reference standard or with the reference spectrum of Ambroxol hydrochloride. The aqueous layer of substance with water and ammonia gives reaction of chlorides while acidifying with nitric acid.	Concordant Complies
3.	Solubility	Sparingly soluble in water, soluble in methanol, practically insoluble methylene chloride.	Complies
4.	pH (1 % w/v Solution in water)	4.5 to 6.0	5.20
5.	Heavy Metals (Method B)	Not more than 20 ppm	Less than 20 ppm
6.	Sulphated ash	Not more than 0.10 % w/w	0.013 % w/w
7.	Loss on drying	Not more than 0.50 % w/w	0.22 % w/w
8.	Related substance by HPLC a) Single max. impurity b) Total impurities	Not more than 0.50 % Not more than 1.00 %	0.005 % 0.008 %

Remark :- In the opinion of undersigned the material of the standard Quality as per IP

Prepared By	Checked By	Approved By
		

Format No.: F2-01, SOP/QCD/012-02

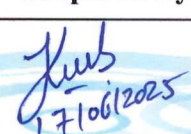
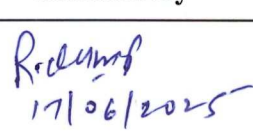
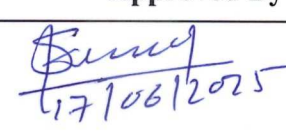
Page 1 of 2

CERTIFICATE OF ANALYSIS

Product Name	Ambroxol HCL - IP
Mfg By	Paragon Organics
Cas No.	23828-92-4
Batch No.	PRG/AM/2506026
Date of Mfg.	Jun-2025
Date of Expiry	May-2030
Batch Qty.	729.20 Kg

Sr. No.	TEST	SPECIFICATION	RESULT
9.	Assay by HPLC (On dried basis)	Not less than 99.0 % and not more than 101.0 % w/w	100.56 % w/w
10.	Additional Test		
10.1	Residual Solvent by GC-HSS		
	a) Methanol	Not more than 3000 ppm	194 ppm
	b) Isopropyl Alcohol	Not more than 5000 ppm	377 ppm
	c) Tetrahydrofuran	Not more than 720 ppm	ND
	d) Ethylene dichloride	Not more than 5 ppm	ND
	e) Toluene	Not more than 890 ppm	ND

Remark :- In the opinion of undersigned the material of the standard Quality as per IP

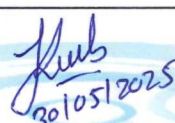
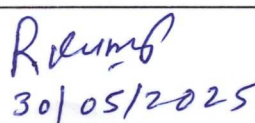
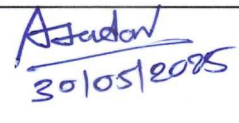
Prepared By	Checked By	Approved By
 17/06/2025	 17/06/2025	 17/06/2025

CERTIFICATE OF ANALYSIS

Product Name	Ambroxol HCL - BP/EP
Mfg By	Paragon Organics
CAS No.	23828-92-4
Batch No.	PRG/AM/2505024
Date of Mfg.	May-2025
Date of Expiry	Apr-2030
Batch Qty.	729.50 Kg

Sr. No.	TEST	SPECIFICATION	RESULT
1.	Description	A white or yellowish crystalline powder	White crystalline powder
2.	Identification test		
	a) UV-VIS spectrophotometry	Absorption maxima should be at 3.2 to 3.4 at 245 nm and 310 nm.	Complies
	b) Infrared Absorption Spectrophotometry	IR spectrum of the test sample should be concordant with that of reference standard spectrum.	Concordant
	c) Thin layer chromatography	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.	Complies
	d) Reaction of chloride	The filtrate gives reaction of chlorides.	Complies
3.	Solubility	Sparingly soluble in water, soluble in methanol, practically insoluble in methylene chloride.	Complies
4.	pH	4.5 to 6.0	5.23
5.	Appearance of solution	The solution is clear and not more intensely coloured than reference solution Y6.	Complies
6.	Sulphated ash	Not more than 0.10 % w/w	0.009 % w/w

Remark :- In the opinion of undersigned the material of the standard Quality as per BP/EP

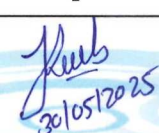
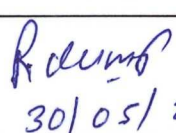
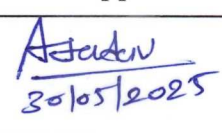
Prepared By	Checked By	Approved By
		

CERTIFICATE OF ANALYSIS

Product Name	Ambroxol HCL - BP/EP
Mfg By	Paragon Organics
CAS No.	23828-92-4
Batch No.	PRG/AM/2505024
Date of Mfg.	May-2025
Date of Expiry	Apr-2030
Batch Qty.	729.50 Kg

Sr. No.	TEST	SPECIFICATION	RESULT
7.	Loss on drying	Not more than 0.50 % w/w	0.23 % w/w
8.	Related substances by HPLC		
	a) Any other impurity	Not more than 0.10 %	0.010 %
	b) Total impurities	Not more than 0.30 %	0.018 %
9.	Assay by potentiometric titration (dried substance)	99.0 % to 101.0 % w/w	100.0 % w/w
10.	Additional Test		
	Residual Solvent by GC-HSS		
10.1	a) Methanol	Not more than 3000 ppm	199 ppm
	b) Isopropyl Alcohol	Not more than 5000 ppm	378 ppm
	c) Tetrahydrofuran	Not more than 720 ppm	ND
	d) Ethylene dichloride	Not more than 5 ppm	ND
	e) Toluene	Not more than 890 ppm	ND

Remark :- In the opinion of undersigned the material of the standard Quality as per BP/EP

Prepared By	Checked By	Approved By
 30/05/2025	 30/05/2025	 30/05/2025