



**INTERNATIONAL JOURNAL OF
PHARMACEUTICAL SCIENCES**
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: <https://www.ijpsjournal.com>



Research Article

Analytical Method Development of Ambroxol HCL by UV Spectroscopy and Forced Degradation Study

Pratiksha Ghule*, Abhijeet Sonawane, Sanika Gorade, Sahil Hande, Gayatri Holkar, Anam Inamdar

VJSM'S Vishal Institute of Pharmaceutical Education and Research, Ale

ARTICLE INFO

Published: 01 May 2026

Keywords:

Ambroxol Hcl, UV Method Development, Forced Degradation, Stability Study.

DOI:

10.5281/zenodo.19950943

ABSTRACT

Ambroxol is a medication that assists in breaking down and thinning thick or sticky mucus in the lungs. It is primarily used to alleviate breathing difficulties caused by excessive mucus buildup. It is commonly included as the main active ingredient in cough remedies. It belongs to a class of compounds known as substituted benzylamines and is actually a metabolite of bromhexine. Bromhexine is synthesized in a laboratory and is derived from vasicine, a naturally occurring compound found in the *Adhatoda vasica* plant. Ambroxol aids in clearing mucus from the airways by enhancing the body's ability to move mucus, increasing the production of substances that maintain lung health, reducing inflammation, combating free radicals, and providing a mild numbing effect. The current study aims to create a simple, fast, and affordable method using UV spectrophotometry to measure the amount of ambroxol hydrochloride in both pure drug form and in tablets. This method uses methanol as the solvent and measures the absorption at a wavelength of 306 nm. It follows a single-point standardization technique. To check how stable the drug is, forced degradation tests were done under acidic and basic conditions. The method worked well, showing good accuracy, precision, and suitability for regular quality checks. A lot of breakdown was seen in the drug under both stress conditions, showing it is easily broken down by hydrolysis. The suggested UV method is easy to use, dependable, and can be used effectively for quality control and stability testing of ambroxol hydrochloride in medicine products.

INTRODUCTION

Ambroxol is a drug that breaks up phlegm, used in the treatment of respiratory diseases associated with viscid or excessive mucus. Ambroxol is often

administered as an active ingredient in cough syrup. It was patented in 1966 and came into medical use in 1979. Ambroxol, a substituted benzylamine, is an active metabolite of bromhexine, which is itself a synthetic derivative

***Corresponding Author:** Pratiksha Ghule

Address: VJSM'S Vishal Institute of Pharmaceutical Education and Research, Ale.

Email ✉: ghpratiksha777@gmail.com

Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.



of vasicine, the active principle extracted from the plant species *Adhatoda vasica*. Ambroxol is an expectorant exerting mucokinetic properties, mucociliary activity, stimulation of surfactant production, anti-inflammatory and antioxidative actions and the local anaesthetic effect. Ambroxol was discovered at and has been manufactured by Dr. Karl Thomae GmbH, a division of Boehringer Ingelheim. The ambroxol patent is expired and the drug is available as a generic product from many different companies. Ambroxol was originally developed by Boehringer Ingelheim as a OTC therapy for respiratory disorders related to excessive mucus.

Mechanism of Action:

Ambroxol assists in breaking down and thinning mucopolysaccharides, making mucus less sticky and easier to expel. It also promotes the production of surfactant in the lungs, which prevents mucus from adhering to the airway walls. Furthermore, it enhances the function of cilia, aiding in the more efficient removal of mucus and phlegm from the airways.

MEDICAL USES:

Ambroxol promotes mucus clearance, facilitates expectoration and eases productive cough allowing patients to breathe freely and deeply.

Ambroxol also provides pain relief in acute sore throat. Pain in sore throat is the hallmark of acute pharyngitis. Sore throat is usually caused by a viral infection. The infection is self-limited and the patient recovers normally after a few days.

Ambroxol is used in COPD, pneumonia, asthma, chest congestion, bronchitis.

AMBROXOL SIDE EFFECTS:

Nausea, Vomiting, Diarrhea, Gastrointestinal side effects, Skin rash, itching, Infections, Allergies, Upset stomach, Dizziness, Weakness, Dry mouth, Indigestion

AMBROXOL DOSAGE FORMS:

Adults: normal dosage from 30 mg (one tablet of Ambroxol) to 120 mg (4 tablets of Ambroxol) taken in 2 to 3 divided doses.

Children up to 2 years: half a teaspoonful Ambroxol syrup twice regular

Kids 2 to 5 years of age: half a teaspoon of Ambroxol syrup three times a day.

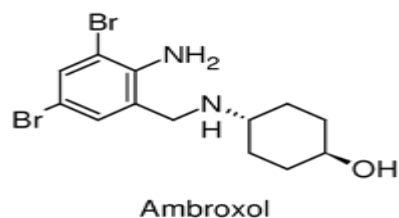
Children 5 years and older: one teaspoon of Ambroxol syrup 2-3 times a day.

BRAND NAMES:

- Muciclar (Italy)
- Mucosolvan
- Mucobrox (Spain)
- Bisolvon (Australia and Switzerland)
- Mucol
- Lasolvan
- Mucoangin
- Surbronic
- Brontex (Lithuanian)
- Ambro (Kazakhstan)
- Ambolar

DRUG PROFILE:

AMBROXOL HYDROCHLORIDE:



MOLECULAR FORMULA: C₁₃ H₁₈ Br 2 N₂O.HCL

CHEMICAL NAME: Trans-4-(2-amino-3,5-dibromobenzyl)amino Cyclohexanol hydrochloride

APPEARANCE: A white or almost white crystalline powder odorless or almost odorless.

SOLUBILITY: soluble in methanol, N, N – dimethyl formamide slightly soluble in water and ethanol practically insoluble in chloroform and benzene

STORAGE: ambroxol hydrochloride should be protected from light.

THERAPEUTIC CATEGORY: Expectorant: enhanced mucolytic

RESPIRATORY DISORDERS: Used in a variety of respiratory disorders including chronic bronchitis. Cystic fibrosis and infant respiratory distress syndrome. Also used in the treatment of cough

URICOSURIC ACTION: It also shows uricosuric effect. The minimum effective dose of lowering plasma uric acid concentrations was found to be between 250 mg and 500 mg daily given in 2 divided doses. Although these doses are much higher than those used to treat bronchopulmonary disease, doses as high as 1 gram daily were well tolerated.

DAILY DOSE: 30 to 120 mg has been given by mouth in 2 to 3 divided doses

ADVERSE EFFECT: hypersensitivity a report of contact allergy to Ambroxol.

MECHANISM OF ACTION: Ambroxol hydrochloride is a potent mucolytic and

mucokinetic capable of inducing bronchial secretion. It is particularly useful in it mucus plugs are present.

PHARMACOKINETICS:

Rapidly absorbed from the gastrointestinal tract and undergoes extensive first pass metabolism in the liver. It is widely distributed to body tissues. About 85% of the drug is excreted as metabolites. It has a terminal half-life of about 12 hours. It crosses the blood brain barrier and small amounts cross the placenta. Administration of Ambroxol hydrochloride by mouth to healthy subjects produce peak plasma concentration after about 1 hour. Only small amounts were excreted unchanged in the urine with a half-life of about 6.5 hours.

AMBROXOL INDICATION:

All forms of tracheobronchitis, emphysema with bronchitis, pneumoconiosis, chronic inflammatory pulmonary conditions, bronchiectasis, and bronchitis with bronchospasm asthma. During acute exacerbations of bronchitis it should be given with the appropriate antibiotic.

Brand Names: Mucosolvan and Mucoangin

Ambroxol is used for infections of the upper respiratory tract. It clears airways and eases cough. It enhances pulmonary surfactant production and stimulates ciliary activity. These actions result in improved mucus flow and transport (mucociliary clearance). Improvement of mucociliary clearance has been shown in clinical pharmacologic studies. Enhancement of fluid secretion and mucociliary clearance facilitates expectoration and eases cough.

Overdosage:



No symptoms of overdosage have been reported in man to date. If they occur, symptomatic treatment should be provided. Administration of ambroxol together with antibiotics (amoxicilline, cefuroxime, erythromycin, and doxycycline) leads to higher antibiotic concentration in the lung tissue. No clinically relevant unfavorable interaction with other medications have been reported

Physical And Chemical Properties of Ambroxol Hydrochloride (API):

Test	Results	Specifications as per IP 2018
Description	A white crystalline Powder	A white or yellowish crystalline powder
Solubility	complies	Soluble in Methanol, Sparingly soluble in water, Practically insoluble in Dichloromethane
Identification		
Identification A	complies	Test A: IR Absorption Spectrum of Test Sample should be concordant to that of similarly recorded spectrum of WRS/ CRS of Ambroxol Hcl
Identification B	Complies	Test B : The Filtrate gives reaction of chlorides
pH	5.69	Between 4.5-6.0
Any Impurity	Below detection Limit	NMT 0.5%
Total Impurities	Below detection Limit	NMT 1.0%
Heavy metals	Less than 20 ppm	NMT 20ppm
Sulfated Ash	0.04%	NMT 0.1%
Loss on Drying	0.14%	NMT 0.5%

Literature Survey:

1. Mrs.M.Sumithra et al,

Analytical method development and validation of Ambroxol hydrochloride by UV spectroscopy and force degradation study (Research Journal of Pharmacy and Technology), 2016, 9(7),

Page.no -794-800.

Spectroscopic method: UV

Wavelength: 306 nm

UV method: Calibration curve method.

2. Padmavathi P.Prabhu et al,

Method development and validation for the estimation of Ambroxol Hcl in Pharmaceutical dosage form (International Journal of Pharmaceutical Sciences and research), 2018, vol 9(6),

Page.no- 2550-2553.

Spectroscopic method: UV

Wavelength: 537.2 nm and 438.4 nm

UV method: Calibration curve method.

3. Gopi Patel et al,

Simultaneous estimation of Azithromycin and Ambroxol Hcl in combined dosage form by RP-HPLC method (Journal of Chemical and Pharmaceutical research), 2018, vol 10(5),

Page.no.-142-147

Spectroscopic method: HPLC

Wavelength: 215 nm

Column: C18



Mobile Phase: KH_2PO_4 (pH 5.0 adjusted with 1% Orthophosphate acid: Methanol 60:40%V/V)).

Temperature: Ambient

Injection volume: 20 μl

Flow rate: 1.0 ml/Min

4. Balaji P

Formulation development of stable ambroxol Hcl syrup and Comparative evaluation with marketed samples.

Need of Work:

1. Spectroscopic methods are large group of analytical methods that are based on atomic and molecular spectroscopy.
2. The aim is to develop simple and validated method for qualitative analysis of Ambroxol Hcl.
3. To develop rapid, sensitive and specific spectroscopic method for qualitative estimation of Ambroxol Hcl in bulk and dosage form
4. The single point procedure involves the measurement of the absorbance of sample solution and of standard solution of reference substance.
5. By reducing the experimental requirements to only one data point, the single point method offers the advantages of simplicity and speed often with little loss in accuracy

Aim and Objectives:

AIM: Analytical Method Development of Ambroxol Hydrochloride by UV- Spectroscopy

and Forced Degradation Study and detection Stability.

OBJECTIVE:

- To develop simple, sensitive and accurate spectroscopic method development of Ambroxol HCL by using Single Standard Method by UV- Spectrophotometer.
- To Method development is based on analytical chemistry, which includes methodologies to identify, separate and quantify the chemical components of medicinal compounds.
- To perform stability study and degradation of Ambroxol HCL

Plan of Work:

Method development of Ambroxol Hcl and force degradation studies was performed by following method

- Spectroscopic method: UV
 - UV method: Single point standardisation method
1. Literature survey
 2. Selection of method of qualitative analysis of Ambroxol Hcl
 3. Collection of drug (API and Marketed formulation)
 4. Testing of Physical and Chemical parameters
 5. Selection of Spectroscopic method
- Single point standardisation method
 - Selection of solvent



- Wavelength selection
- Determination of absorbance
- Observations and calculation

6. Force degradation studies

- Alkali degradation
- Acid degradation

7. Results and conclusion

Chemicals and Instrument:

1. API details:

The API was obtained from ANUH PHARMA LTD. 3-A, Shivsagar Estate, North Wing, Dr. Annie Besant Road, Worli Mumbai-400018, and India

2. Marketed formulation details:

Mucolite (Ambroxol Hcl 30 mg) was obtained from Morya Medical, Alephata.

3. Chemical and Solvents:

Sr. No.	Name	Collection source
1	Methanol	Ag Traders
2	Hcl	Thermosil
3	NaoH	Sahyadri scientific suppliers

4. Instruments used :

UV- VISIBLE SPECTROPHOTOMETER:

UV-Vis Spectroscopy (or Spectrophotometry) is a quantitative technique used to measure how much a chemical substance absorbs light. This is done by measuring the intensity of light that passes through a sample with respect to the intensity of light through a reference sample or blank.

Types of Spectrophotometers

Single Beam

- Double beam
- Split beam

Principle:

The Principle of UV-Visible Spectroscopy is based on the absorption of ultraviolet light or visible light by chemical compounds, which results in the production of distinct spectra. Spectroscopy is based on the interaction between light and matter.

When matter absorbs ultraviolet radiation, the electrons present in it undergo excitation. This causes them to jump from a ground state (an energy state with a relatively small amount of energy associated with it) to an excited state (an energy state with a relatively large amount of energy associated with it). It is important to note that the difference in the energies of the ground state and the excited state of the electron is always equal to the amount of ultraviolet radiation or visible radiation absorbed by it.

Beer's Law:

It States that the intensity of beam of parallel monochromatic radiation decreases exponentially with the number of absorbing molecules. In other words, absorbance is proportional to the concentration.

Lambert's Law:

It states that the intensity of beam of parallel monochromatic radiations decreases exponentially as it passes through a medium of homogenous thickness. A combination of these two laws yields the Beer-Lambert law.

Beer-Lambert Law:



When a beam of monochromatic light is made incident on a solution that contains a substance that absorbs the monochromatic light, the rate at which the intensity of the beam decreases along the thickness of the solution is directly proportional to the concentration of the absorbing substance in the solution and is also directly proportional to the intensity of the incident monochromatic radiation.

Formula:

$$A = \epsilon cl$$

A	Absorbance	
ϵ	Molar absorption coefficient	$M^{-1}cm^{-1}$
C	Molar concentration	M
l	optical path length	cm

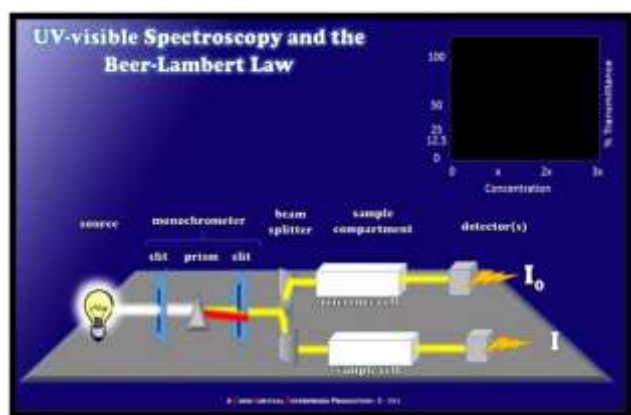


Fig. UV-Spectrophotometer

General requirements:

Volumetric flask, pipette, beakers, stirrer, mortar pestle, weighing balance, Funnel, Measuring cylinder, etc.

Experimental work:

1. Selection of method of qualitative analysis of Ambroxol Hcl
2. Collection of drug (API and Marketed formulation)

- The API is obtained from ANUH PHARMA LTD. 3-A, Shivsagar Estate, North Wing, Dr. Annie Besant Road, Worli Mumbai-400018, India
- The Marketed Formulation (Dr.Reddy's Laboratories, Mucolite (Ambroxol Hcl 30 mg) was obtained from Morya Medical, Alephata)

PREPARATION OF SOLUTION

1) Preparation of Standard Ambroxol HCL Solution:

Weigh the 30mg Ambroxol HCL and dissolve in 30ml Methanol to form the 1000ppm solution. Then withdraw 10 ml of solution and dilute upto 100ml with distilled water to form 100ppm solution. Again withdraw 10ml of solution from it and dilute upto 100ml to form 10ppm solution.

2) Preparation of Test Ambroxol HCL Solution:

Take 10 tablets of Ambroxol HCL of 30mg labelling and calculate the average weight of 1 tablet which is 208mg (0.208gm). Add this weight of 208mg powder in 30ml Methanol to form the 1000ppm solution. Then withdraw 10 ml of solution and dilute upto 100ml with distilled water to form 100ppm solution. Again withdraw 10ml of solution from it and dilute upto 100ml to form 10ppm solution.

PROCEDURE:

- Preparation of Standard stock solution of 10 PPM
- Preparation of Test stock solution of 10 PPM
- Measurement of absorbance using UV-Spectrophotometer at 306nm.

- Calculation of content Uniformity
- Formula : Content Uniformity (C.U) = $\text{TEST} / \text{STD} \times 100$
- $C_{\text{test}} = \text{Abs Test} \times C_{\text{std}} / \text{Abs std}$

Where,

Abs = Absorbance

C= Concentration

Std= standard

Assay Method for Ambroxol HCL (100mg):

Test Preparation:

Calculate Average Weight of Tablet containing 693.33mg dissolve in 100ml methanol and prepare upto 10ppm solution and take the absorbance by using UV Spectrophotometer.

Standard Preparation:

Take 100mg of Ambroxol HCL, dissolve in 100ml Methanol and prepare upto 10ppm solution. Take the Absorbance by using UV Spectrophotometer.

Procedure:

- Preparation of Standard stock solution of 10 PPM
- Preparation of Test stock solution of 10 PPM
- Measurement of absorbance using UV-Spectrophotometer at 306nm.
- Calculation of content Uniformity
- Formula : Content Uniformity (C.U) = $\text{TEST} / \text{STD} \times 100$
- $C_{\text{test}} = \text{Abs Test} \times C_{\text{std}} / \text{Abs std}$

Where,

Abs = Absorbance

C= Concentration

Std= standard

Study of acid degradation Ambroxol Hydrochloride by UV spectroscopy method:

Standard Preparation (stress) Ambroxol hydrochloride was transferred to volumetric flask and dissolved methanol to achieve a concentration of 1mg/mL. After 30mins, an aliquot solution was diluted with 1N hydrochloric acid to get a final concentration of 100mcg/mL. The solution was scanned in the UV region

And the maximum absorbance was recorded at 306 nm. The same procedure was repeated for 60mins, and 90mins time interval.

Test Preparation (stress) Ambroxol hydrochloride tablets were powdered and weighed and then transferred into volumetric flask and dissolved methanol to achieve a concentration of 1mg/mL. After 30mins, an aliquot solution was diluted with 1N hydrochloric acid to get a final concentration of 100mcg/mL. The solution was scanned in the UV region and the maximum absorbance was recorded at 306 nm. Repeated for 60mins, and 90mins time's interval.

Blank Preparation: A blank preparation of Hydrochloric acid (1N) solution was prepared in a similar manner. The procedure was repeated thrice. After the stipulated time, the absorption of the resulting solution showed maxima 306nm against reagent blank treated in the same way. Three such determinations were made and the assay value was estimated the obtained values are concurrent.



Study of alkali degradation Ambroxol Hydrochloride by UV spectroscopy method:

Standard Preparation (stress) Ambroxol hydrochloride 10mg was transferred to volumetric flask and dissolved methanol to achieve a concentration of 1mg/mL. After 30mins, an aliquot solution was diluted with distilled with 0.1M Sodium hydroxide to get a final concentration of 100mcg/mL. The solution was scanned in the UV region and the maximum absorbance was recorded at 306nm. The same procedure was repeated for 60mins, and 90mins time interval.

Sample Preparation (stress) Ambroxol hydrochloride granules were weighed and transferred to volumetric flask and dissolved methanol to achieve a concentration of 1mg/mL. After 30mins, an aliquot solution was diluted with 0.1M Sodium hydroxide to get a final concentration of 100mcg/mL. The solution was scanned in the UV region and the maximum absorbance was recorded at 306nm. The same procedure was repeated for 60mins, and 90mins time interval.

Blank Preparation: A blank preparation of 0.1 M Sodium Hydroxide solution was prepared in a similar manner. The procedure was repeated thrice. After the stipulated time, the absorption of the resulting solution showed maxima 306nm against reagent blank treated in the same way. Three such determinations were made and the assay value was estimated the obtained values are concurrent.

Results:

Table for Assay method for Ambroxol Hcl for single tablet

Sr. No	Test	Concentration (PPM)	Absorbance at 306nm
1	Standard	10	0.0602
2	Test	9.65	0.0624

Table for Assay method for Ambroxol Hcl for Approx. 3-4 tablet

Sr. No.	Test	Concentration (PPM)	Absorbance at 306nm
1	Standard	10	0.0530
2	Test	10.64	0.0564

Table for Assay method for Ambroxol Hcl for Single tablet

Sr. No	Test	Concentration (PPM)	Absorbance at 306nm	Content Uniformity (%)
1	Standard	10	0.0602	96.47%
2	Test	9.65	0.0624	

The content uniformity for Ambroxol Hcl for single tablet was found to be 96.47%

Table for Assay method for Ambroxol Hcl for 3-4 tablet

Sr.no	Test	Concentration (PPM)	Absorbance at 306nm	Content Uniformity (%)
1	Standard	10	0.0530	93.97%
2	Test	10.64	0.0564	

The content uniformity for Ambroxol Hcl for single tablet was found to be 93.97%

Table No. Acid Degradation Study of Interday



Stress condition	Time in minutes	Absorbance (nm)		% concentration		Remarks
		Test	Std	Test	Std	
HCL(1N) Acid Hydrolysis	30	0.534	0.572	57.53%	66.03%	Degradation observed
	60	0.503	0.560	54.01%	64.23%	Degradation observed
	90	0.420	0.462	51.44%	61.19%	Degradation observed

The Acid degradation study for interday was performed for Standard and Test for 30,60,90 minutes and the degradation was observed.

Table Acid Degradation Study of Intraday

Stress condition	Time in hours	Absorbance (nm)		% concentration		Remarks
		Test	Std	Test	Std	
HCL(1N) Acid Hydrolysis	24	0.641	0.662	55.50%	62.34%	Degradation observed
	48	0.585	0.591	53.20%	60.40%	Degradation observed
	72	0.512	0.530	49.30%	57.03%	Degradation observed

The Acid degradation study for intraday was performed for Standard and Test for 24, 48, 72 hours. And the degradation was observed.

Table Alkali Degradation Study of Interday

Stress condition	Time in minutes	Absorbance (nm)		% concentration		Remarks
		Test	Std	Test	Std	
Sodium Hydroxide (0.1M) Alkali Hydrolysis	30	0.654	0.614	85%	77.52%	Degradation observed
	60	0.602	0.593	80.63%	73.30%	Degradation observed
	90	0.530	0.491	76.50%	70.25%	Degradation observed

The Alkali Degradation study for interday was performed for Standard and Test for 30, 60, 90 minutes and the degradation was observed.

Table Alkali Degradation Study of Intraday

Stress condition	Time in hours	Absorbance (nm)		% concentration		Remarks
		Test	Std	Test	Std	
Sodium Hydroxide (0.1M) Alkali Hydrolysis	24	0.603	0.593	70.04%	67.35%	Degradation observed
	48	0.585	0.572	65.30%	61.30%	Degradation observed
	72	0.542	0.533	59.45%	56.45%	Degradation observed

The Alkali Degradation study for intraday was performed for Standard and Test for 24, 48, 72 hours. And the degradation was observed.

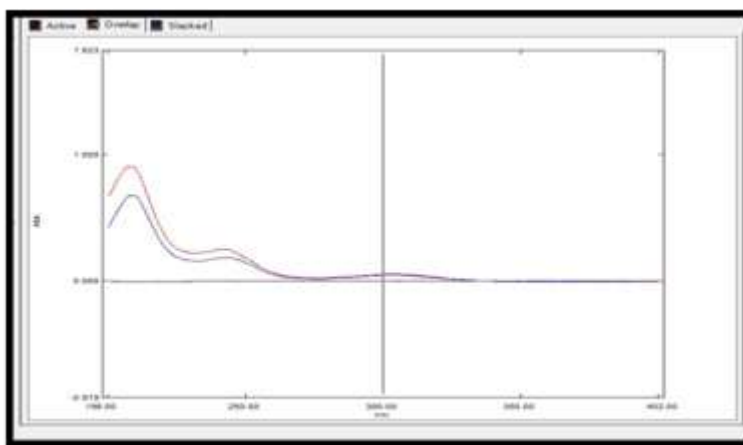


Fig.1.1 Absorbance of Ambroxol Hcl for Single Tablet at 306 nm.

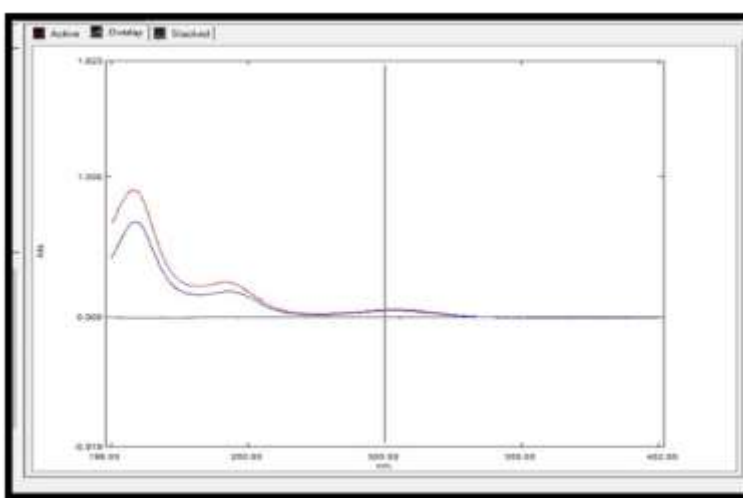


Fig.1.2 Absorbance of Ambroxol Hcl for 3-4 Tablet At 306 nm.

Testing of Physical and Chemical parameters

- **Ruggedness:** Ruggedness is a measure of reproducibility of test results under the variation in conditions normally expected from laboratory to laboratory and analyst to analyst. Ruggedness is normally expressed as the lack of influence on test results of operational and environmental variables of the analytical method. Ruggedness is a measure of reproducibility of test results under normal, expected operational conditions from laboratory to laboratory and from analyst to analyst".
- **Robustness:** Robustness is the evaluation of an analytical method wherein the results

obtained are found to be reliable even when performed in a slightly varied condition. It is the ability of a method to remain unaffected when slight variations are applied. Robustness is the capacity of a method to remain unaffected by small, deliberate variations in method parameters; a measure of the reliability of a method. Robustness should be evaluated in late development, or early in the method validation process.

- **Accuracy:** Accuracy of the method was confirmed by the recovery studies. To the preanalysed formulation a known quantity of raw material of Ambroxol hydrochloride was

added in 6 concentration and recovery process are followed as per the quantification process.

- **Precision;** the repeatability of the developed method was confirmed by the precision analysis. The intermediate precision of the method was confirmed by intraday and interday analysis i.e. the analysis of formulation was repeated three time in the same day and on three successive days. For this process Ambroxol hydrochloride 30mg was used.
- **Solubility:** 1mg Ambroxol HCl was dissolved in 100ml of different solvents like water methylene chloride, ethanol and ether separately and was tested for solubility as per BP 2000.
- **Determination of λ_{max} :** A solution of Ambroxol HCl containing the concentration 10 $\mu\text{g/ml}$ was prepared in 0.1N HCl and UV spectrum was taken using Shimadzu UV double beam spectrophotometer. The solution was scanned in the range of 200 to 400 nm.
- **Determination of Average Weight:** Average weight of 10 Tablets of Ambroxol HCL was weighed by using Analytical Weigh Balance and its average weight was found to be 208.3mg.

CONCLUSION

In this study a simple, precise, accurate and sensitive UV- spectroscopy methods were developed for the Single standard method estimation of ambroxol hydrochloride in bulk and in tablet dosage a form. The proposed method was successfully applied for the determination of Ambroxol hydrochloride in bulk and Pharmaceutical formulations (Tablets). Additives and impurities commonly present in the dosage

forms but did not show any interference in the proposed method..The values are complies all the limit as per ICH guidelines. The forced acid and alkali degradation study of ambroxol hydrochloride was studied by UV spectroscopy at various time interval (30mins, 60mins, 90mins) & (24hrs, 48hrs, 72hrs) it is observed that the drug ambroxol hydrochloride is degrading. The Ambroxol HCL was under a forced degradation study for interday and intraday results were given remark as “Degradation”. Therefore the drug ambroxol hydrochloride has to be stored under such condition where the possibility of acid and alkali hydrolysis does not arise.

REFERENCES

1. Ambroxol. In: Wikipedia [Internet]. Available from: <https://en.wikipedia.org/wiki/Ambroxol>
2. Ambroxol. Drugs.com [Internet]. Available from: <https://www.drugs.com/ambroxol.html>
3. Ambroxol hydrochloride. PubChem, National Library of Medicine [Internet]. Available from: <https://pubchem.ncbi.nlm.nih.gov/compound/Ambroxol-hydrochloride>
4. Balaji P. Formulation development of stable Ambroxol HCl syrup and comparative evaluation with marketed samples. Project Report. Reg No. 26114502.
5. Indian Pharmacopoeia Commission. Indian Pharmacopoeia. Vol. 1. Ghaziabad: IPC; 2018. p. 221, 1197.
6. Sumithra M, et al. Analytical method development and validation of Ambroxol hydrochloride by UV spectroscopy and forced degradation study. Res J Pharm Technol. 2016;9(7):794–800.
7. Prabhu PP, et al. Method development and validation for the estimation of Ambroxol HCl



- in pharmaceutical dosage form. *Int J Pharm Sci Res.* 2018;9(6):2550–2553.
8. Patel G, et al. Simultaneous estimation of azithromycin and Ambroxol HCl in combined dosage form by RP-HPLC method. *J Chem Pharm Res.* 2018;10(5):142–147.
 9. Beckett AH, Stenlake JB, editors. *Practical Pharmaceutical Chemistry*. 4th ed. Vol. 1 & 2. p. 281.
 10. Chatwal GR, Anand SK. *Instrumental Methods of Chemical Analysis*. Himalaya Publishing House; p. 2.1, 2.112, 2.149.
 11. Tom J. UV-Vis spectroscopy: principle, strengths and limitations and applications. *Technology Networks* [Internet]. 2021 Jun 30 [cited 2022 May 3]. Available from: <https://www.technologynetworks.com/analysis/articles/uv-vis-spectroscopy-principle-strengths-and-limitations-and-applications-349865>
 12. Chemsurvival. UV-Vis spectroscopy [Video]. YouTube; 2014 Sep 29. Available from: <https://www.youtube.com/watch?v=wxrAELeXlek>
 13. Doredla NR, Yengisetty B, Bojjagani R, Madasu SV. Method development and validation of forced degradation studies of pioglitazone hydrochloride using UV spectroscopy. *Int J PharmTech Res.* 2012;4(4):1750–1757.
 14. Hamrapurkar P, Patil P, Desai M, Phale M, Pawar S. Stress degradation studies and development of a validated stability-indicating assay method for determination of diacerein in presence of degradation products.

HOW TO CITE: Pratiksha Ghule, Abhijeet Sonawane, Sanika Gorade, Sahil Hande, Gayatri Holkar, Anam Inamdar, Analytical Method Development of Ambroxol HCL by UV Spectroscopy and Forced Degradation Study, *Int. J. of Pharm. Sci.*, 2026, Vol 4, Issue 5, 1-13. <https://doi.org/10.5281/zenodo.19950943>

