Spectrophotometric Determination of Loratadine in Bulk and Pharmaceutical Dosage Form

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ABSTRACT:

PURPOSE-The present work was to develop a simple, accurate, cost effective and reproducible UV spectrophotometric method for the estimation of Loratadine in bulk and pharmaceutical dosage form.

METHOD-Spectrophotometric determination of both the marketed formulation and standard loratadine solution was performed by using 0.1N MethanolicHCl as solvent at 275nm. Simultaneously the parameters are validated sequentially.

RESULTS-An absorption maximum was found to be at 275 nm. The percentage recovery of Loratadine ranged from 99.982 to 101.4908% in pharmaceutical dosage form. The developed method was validated with respect to Linearity, Accuracy (% Recovery), Precision (Inter Day & Intra Day), Limit of Detection (LOD), Limit of Quantitation (LOQ). Beer's law was obeyed in the concentration range of 2-10 µg/mL having line equation Y= 0.099x + 0.0812 with correlation coefficient of 0.999 and the range was within the acceptance limit according to ICH guidelines. .

CONCLUSION- The above results of the present study revealed that the developed method was accurate and all the validation parameters were found to be within the limits.

Key Words:*Loratadine, UV spectrophotometry, 0.1N Methanolic HCL, Method development, Validation.*

1. INTRODUCTION

1.1. ANALYTICAL CHEMISTRY

Analytical chemistry (1-2)is defined as the science and art of determining thecomposition of material in terms of the elements of compounds contained. It involves theapplication of a range of techniques and methodologies to obtain and assess qualitative,quantitative and on nature of matter.

- **Qualitative analysis**(3-4)is the identification of elements, species and compoundspresent in a sample.
- **Quantitative analysis** is the determination of the absolute or relative amounts ofelements, species or compounds present in a sample.
- An element, species or compound which is the subject for analysis is known as an**analyte.**

Generally analytical methods can be categorized into:

I. Chemical analysis

II. Instrumental method

1.1.1 Analytical Method Development:

the variety of drugs added into the market is increasing each yr. those capsules may be either new entities or partial structural amendment of the prevailing one. very frequently there is a time lag from the date of introduction of a drug into the marketplace to the date of its inclusion in pharmacopeias. this occurs the viable uncertainties in the continuous and wider usage of these drugs, reports of recent toxicities (ensuing of their withdrawal from the marketplace), development of affected person resistance and advent of higher tablets by competition, underneath those situations, standards and analytical methods for those tablets may not be to be had within the pharmacopeia, it becomes necessary, consequently to broaden newer analytical strategies for such pills.

1.1.2 Steps involved in method development:

Documentation starts at the very starting of the development manner. a device for complete documentation of improvement studies must be set up. All information referring to those studies ought to be recorded in laboratory pocket book or an electronic database.

(a) Analyte preferred characterization:

- All regarded statistics about the analyte and its structure is gathered i.e., bodily and chemical residences.
- The same old analyte (a hundred % purity) is received. Important arrangement is made for the proper garage (refrigerator, desiccators and freezer).
- When multiple components are to be analyzed inside the pattern matrix, the number of components is referred to, information is assembled and the supply of standards for everyone is decided. Most effective those methods (spectroscopic, MS, GC, HPLC and so on.,) which can be like minded with sample balance are considered.

(b) Technique necessities:

The desires or requirements of the analytical approach that want to be evolved are considered and the analytical figures of advantage are described. The required detection limits, selectivity, linearity, range, accuracy and precision are defined.

(c) Literature search and previous technique:

The literature for all varieties of data associated with the analyte is surveyed. for synthesis, physical and chemical properties, solubility and relevant analytical strategies, books, periodicals, chemical manufacturers and regulatory company compendia which include USP / NF, are reviewed. Chemical Abstracts Provider (CAS) automated computerized literature searches are convenient.

(d) Selecting a technique:

- The use of the records in the literatures and prints, method is adapted. The techniques are modified anyplace necessary. every so often it is necessary to gather extra instrumentation to reproduce, adjust, improve or validate existing techniques for in-house analyte and samples.
- If there are not any earlier techniques for the analyte in the literature, from analogy, the compounds which can be similar in structure and chemical properties are investigated and are labored out.
- There's typically one compound for which analytical approach exist already that is similar to the analyte of hobby.

(e) Instrumental setup and preliminary studies:

The required instrumentation is setup. set up, operational and overall performance qualification of instrumentation using laboratory widespread operating procedures (sop’s) are verified. Always new consumables (e.g. solvents, filters and gases) are used. For instance, approach development is by no means started on a GC column that has been used earlier. The analyte preferred in a suitable injection / creation answer and in regarded concentrations and solvents are organized. It's miles vital first of all an real, recognized general in preference to with a complex pattern matrix. If the pattern is extremely close to the standard (e.g., bulk drug), then it's miles possible to start paintings with the real pattern.

(f) Optimization:

For the duration of optimization one parameter is modified at a time and set of situations are remoted, as opposed to using a trial and error technique. Paintings has been completed from a prepared methodical plan, and every step is documented (in a lab notebook) in case of lifeless ends.

(g) Documentation of analytical figures of advantage:

The at the beginning determined analytical figures of merit are restriction of quantification (LOQ), limit of detection (LOD), linearity, time per analysis, value, pattern guidance and many others., are documented.

(h).Assessment of method development with real samples:

The sample solution have to lead to unequivocal, absolute identity of the analyze height of hobby other than all other matrix additives.

1.2 ULTRAVIOLET-VISIBLE SPECTROPHOTOMETRY

The approach of ultraviolet-visible spectrophotometry is one of the most regularly employed in pharmaceutical analysis. It entails the measurement of quantity of ultraviolet (one hundred ninety-380nm) or seen (380-800nm) radiation absorbed by using a substance in answer. Units which measure the ratio, or characteristic of the ratio, or the depth of two beams of mild within the ultraviolet-visible vicinity are known as ultraviolet-seen spectrophotometers. Absorption of light in both the ultraviolet and visible areas of the electromagnetic spectrum happens while the strength of the light suits that required to induce within the molecule an electronic transition and its associated vibration and rotational transitions.

1.2. beer-lambert regulation

Whilst a beam of light is surpassed thru a obvious mobile containing a solution of an soaking up substance, reduction of the depth of the mild may additionally occur.

That is because of:

(a) Reflections on the internal and outer surfaces of the cellular.

(b) Scatter with the aid of debris within the answer.

(c) Absorption of mild by using molecules in the solution.

The reflections on the cell surfaces may be compensated by a reference cellular containing the solvent only, and scatter may be eliminated via filtration of the answer. The depth of mild absorbed is then given by

$$I \text{ absorbed} = io - it$$

In which i o is the authentic intensity incident at the mobile and it's far the reduced depth transmitted from the cell.

The transmittance (t) is the ratio it/ io and the % transmittance (%t) is given by way of,

$$\%t = 100it / i\ o$$

In 1760, lambert investigated the connection among io and that i t for various thickness of substance and discovered that the price of decrease inside the depth of mild with the thickness, b, of the medium is proportional to the intensity of incident light.

Expressed mathematically

$$-dI/db\ \alpha I \text{ or } -dI/db = k' I$$

Where k' is a proportionally constant. Therefore,

$$-db/dI = 1/k' I$$

Integrating

$$-b = 1/k' \ln IT + C$$

Where *I*T is the intensity transmitted at thickness b.

When b = 0,

$$C = -1/k' \ln Io$$

therefore, -b = 1/k' In *I*T – 1/k' In *I*o

Therefore, In *I*o/*I*T = k' b

On conversion to a common logarithm, the expression becomes

$$\log Io/It = k'b/2.303$$

The quantity log*I*o/log*I*t is called **absorbance** (A) and is equal to the reciprocal of the common logarithm of transmittance.

$$A = \log 10 Io/IT = \log 10\ (1/T) = -\log T = 2 - \log (\%T)$$

Lambert's regulation is described as follows: The intensity of a beam of parallel monochromatic radiation decreases exponentially because it passes through a medium of homogenous thickness. Greater in reality it's far stated that the absorbance is proportional to the thickness of the answer. Beer showed in 1852 that a comparable dating exists among the absorbance and the attention.

$$\log Io/IT = k''c/2.303$$

Where k" is a proportionally regular and c is the concentration

Beer's law is defined as follows: the intensity of a beam of parallel monochromatic radiation decreases exponentially with the number of soaking up molecule. extra genuinely it's miles said that the absorbance is proportional to the awareness.

a combination of the two legal guidelines yields the beer-lambert law:

a = log io/it = abc

wherein the proportionality constants okay'/2.303 and okay"/2.303 are combined as a single

constant known as the absorptivity (a).

MATERIALS AND REAGENTS

PURE DRUG SAMPLE: Loratadine pure drug sample was obtained from Yarrochem. products Mumbai.

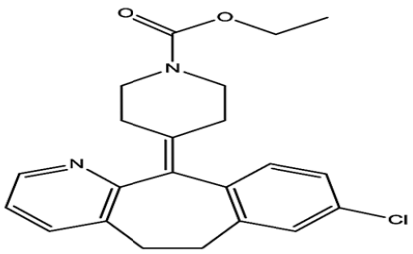
MARKETED FORMULATION: Lorfast 10mg.

DRUG PROFILE

NAME OF THE DRUG: Loratadine (USP, BP EP)

PROPRIETARY NAMES: Alavert , Children Claritin, Claritin- D.

STRUCTURE: Figure No: 01



IUPAC NAME: Ethyl 4-(8-chloro-5,6-dihydro-11*H*-benzo[5,6]- cyclohepta[1,2 b]pyridine-11-ylidine)-1-piperidinecarboxylate

MOLECULAR FORMULA: $C_{22}H_{23}ClN_2O_2$

MOLECULAR WEIGHT: 382.88 g/mole

NATURE: Solid

SOLUBILITY: Water Solubility: 0.000011 mg/ml

It is soluble in DMSO [Dimethyl sulfoxide] an aprotic solvent (50 mg/ml) and Ethanol (77 mg/ml at 25º C)

ASSAY: 95.44%

MELTING POINT: 134-136º C

CATEGORY: Antihistamine agent

❖ PHARMACOKINETIC PROPERTIES:

BIOAVAILABILITY: 40%

HALF - LIFE: 8.0-8.4 Hrs.

METABOLISM:first-pass hepatic metabolism; it's miles metabolized by means of isoenzymes of the cytochrome p450 system, which includes cyp3a4, cyp2d6.

EXCRETION: urinary excretion is primary route of excretion of loratadine metabolites. approximately 40% is excreted as conjugated metabolites into the urine. strains of unmetabolised loratadine may be observed in the urine.

- **Scientific pharmacology / mechanism of movement :**

Loratadine is a tricyclic antihistamine, which acts as a selective inverse agonist of peripheral histamine h1-receptors.

Loratadine competes with loose histamine and exhibits specific, selective peripheral h1 opposed activity. This blocks the movement of endogenous histamine, which sooner or later lead to temporary alleviation of the poor signs and symptoms (eg. nasal congestion, watery eyes) brought on by using histamine. Loratadine has low affinity for cholinergic receptors and does not exhibit any considerable alpha-adrenergic blocking activity in-vitro. loratadine additionally appears to suppress the release of histamine and leukotriene's from animal mast cells, and the discharge of leukotriene's from human lung fragments treatment of allergic rhinitis (hay fever) and urticaria (hives).

Aspect results:

Sleepiness, anti-muscarinic results together with urinary retention, dry mouth, blurred imaginative and prescient, headache and gastrointestinal troubles. critical side outcomes are rare and encompass allergic reactions, seizures, and liver troubles.

Over dosage

- Speedy or pounding heartbeat
- Drowsiness
- Headache
- Unusual frame actions

Contraindications

Patients with severe hepatic (liver) problems might also want first of all a lower dose. no dose version is important for aged or renally(kidney) impaired patients.

Antihistamines ought to be discontinued about 48 hrs previous to skin allergic reaction tests, given that those pills might also prevent or diminish in any other case-high quality reactions to dermal hobby indicators.

Toxicity

Somnolence (drowsiness), tachycardia, and headache ld50=mg/kg (orally in rat).

Table no: 01 Materials and reagents

S.NO	EQUIPMENT AND CHEMICALS	COMPANY
1	U.V-Visible Spectrophotometer	Analytical 2060 plus Model
2	Methanol, Hydrochloric acid	S.D Fine Chemical Limited, Mumbai
3	Electronic Precision Balance	Contech-Citizen Sales Private Limited.
4	Magnetic Stirrer	Remi.

METHODOLOGY- EXPERIMENTAL WORK

Instrument used was Analytical UV- Visible Spectrophotometer and ContechElectronic precision balance. Loratadine was purchased from Yarrow Chem Pvt. Ltd.Dombivali, India. All chemicals and reagents used were of analytical grade.

GENERAL ASSAY PROCEDURE:

PREPARATION OF STANDARD STOCK SOLUTION:

Standard drug solution of Loratadine was prepared by dissolving 10mgLoratadine in 20mL of 0.1N MethanolicHCl and was transferred to 100mL volumetricflask and volume was made upto mark with 0.1N MethanolicHCl to obtain stocksolution of 100µg/mL concentration.

PREPARATION OF SAMPLE SOLUTION:

Ten tablets were weighed and powdered. The amount of tablet powder equivalentto 10mg of Loratadine was weighed accurately and transferred to 20mL 0.1N MethanolicHCl and kept for 15 mins with frequent shaking and volume was made upto 100mL markwith 0.1N MethanolicHCl. The solution was then filtered through Whatmann filter paper#41. The absorbance was measured against blank. The drug content of the preparationwas calculated using standard calibration curve.

DETECTION METHOD

PREPARATION OF CALIBRATION CURVE:

Calibration curve was prepared in 0.1N MethanolicHCl at λmax 275nm (figure 3)using UV- Visible Spectrophotometer for stock solution of 100mg/ml. serial dilutions of1,3,5,7,9µg/mL were prepared and absorbance was scanned in the range of 200-400 nmagainst blank. The calibration curve was plotted. The optical characteristics aresummarized in Table-02.

VALIDATION OF THE PROPOSED METHOD

The proposed method was validated for the following parameters.

1. **LINEARITY**

PREPARATION OF STANDARD STOCK SOLUTION:

Standard drug solution of Loratadine was prepared by dissolving 10mg Loratadine in20mL of 0.1N MethanolicHCl and was transferred to 100mL volumetric flask andvolume was made upto mark with 0.1N MethanolicHCl to obtain stock solution of 100µg/mL concentration.

Preparation of linearity solution (10%)

0.1ml of stock solution was taken in 10ml of volumetric flask, dilute upto themark with diluent. The solution was mixed well and used for spectrophotometricestimation.

Preparation of linearity solution (30%)

0.3ml of stock solution was taken in 10ml of volumetric flask, dilute upto themark with diluent. The solution was mixed well and used for spectrophotometricestimation.

Preparation of linearity solution (50%)

0.5ml of stock solution was taken in 10ml of volumetric flask, dilute upto themark with diluent. The solution was mixed well and used for spectrophotometricestimation.

Preparation of linearity solution (70%)

0.7ml of stock solution was taken in 10ml of volumetric flask, dilute upto themark with diluent. The solution was mixed well and used for spectrophotometricestimation.

Preparation of linearity solution (90%)

0.9ml of stock solution was taken in 10ml of volumetric flask, dilute upto themark with diluent. The solution was mixed well and used for spectrophotometricestimation.

PROCEDURE:

The absorbance of appropriate dilutions of standard stock solutions was measuredas per the developed method to confirm the linearity. A graph was plotted and correlationcoefficient (r2) was calculated.

2. ACCURACY

Accuracy is the percentage of analyte recovered by assay from known addedamount. Analysis was performed at 50%, 100% & 150% levels.

PREPARATION OF STOCK SOLUTION:

Standard drug solution of Loratadine was prepared by dissolving 10mgLoratadine in 20mL of 0.1N MethanolicHCl and was transferred to 100mL volumetricflask and volume was made upto mark with 0.1N MethanolicHCl to obtain stocksolution of 100µg/mL concentration.

PREPARATION OF SAMPLE SOLUTION:

50% Sample Preparation

Weigh accurately5 mg Loratadine working reference standard is taken in to100ml volumetric flask and then it was dissolved and diluted to volume with mobilephase upto the mark. After that 50ml of the above solution was taken into 100ml standardflask and made up with mobile phase (Stock solution).

100% Sample Preparation

Weigh accurately 10 mg Loratadine working reference standard is taken in to100ml volumetric flask and then it was dissolved and diluted to volume with mobilephase upto the mark. After that 50ml of the above solution was taken into 100ml standardflask and made up with mobile phase (Stock solution).

150% Sample Preparation

Weigh accurately 15 mg Loratadine working reference standard is taken in to100ml volumetric flask and then it was dissolved and diluted to volume with mobilephase upto the mark. After that 50ml of the above solution was taken into 100ml standardflask and made up with mobile phase (Stock solution).

PROCEDURE:

The standard solution was injected in triplicate for Accuracy-80%, 100% and 120%solutions.

Calculate the amount found and amount added for Loratadine and calculate the

individual recovery and mean recovery values.

$$\% \text{ Recovery} = \frac{\text{Sample peak area} * \text{weight of standard}}{\text{Standard peak area} * \text{weight of sample}} * 100$$

3. PRECISION

Precision was determined by studying the repeatability and intermediateprecision. The standard deviation, coefficient of variance and standard error werecalculated for the drug.

STANDARD PREPARATION:

Standard drug solution of Loratadine was prepared by dissolving 10mgLoratadine in 20mL of 0.1N MethanolicHCl and was transferred to 100mL volumetricflask and volume was made upto mark with 0.1N MethanolicHCl to obtain stocksolution of 100µg/mL concentration.

SAMPLE PREPARATION:

Amount 0.375mg of the tablet powder was taken in to 100ml standard flask. Avolume of 20ml of mobile phase was added and sonicated for 30min. Then the solutionwas cooled and diluted to volume with mobile phase and filtered through 0.45µmmembrane filter.

4. LIMIT OF DETECTION (LOD)

LOD can be calculated based on the standard deviation of the response (SD) andthe slope of the calibration curve (S) at levels approximately the LOD according to theformula. The standard deviation of the response can be determined based on the standarddeviation of y-intercepts of regression lines.

LOQ= 3*σ/S

Where, σ- Standard deviation (SD)

S – Slope

5. LIMIT OF QUANTIFICATION (LOQ)

LOQ can be calculated based on the standard deviation of the response (SD) andthe slope of the calibration curve (S) at levels approximately the LOD according to theformula. The standard deviation of the response can be determined based on the standarddeviation of y-intercepts of regression lines.

LOQ= 10*σ/S

6. RECOVERY STUDIES

So as to check the accuracy and reproducibility of the proposed method, recuperation research had been conducted. Healing research are carried out spiking approach on this approach the check sample having the concentration of 4µg/ml. To this the standard drug is spiked by using including into the test answer. A concentration of 2, four and sixµg/ml are added to the pattern solutions and the absorbance's of the 3 spiked concentrations had been taken. From this absorbance we will decide the quantity of drug that can be recovered via the proposed technique.

RESULTS

1. Spectrophotometric result:

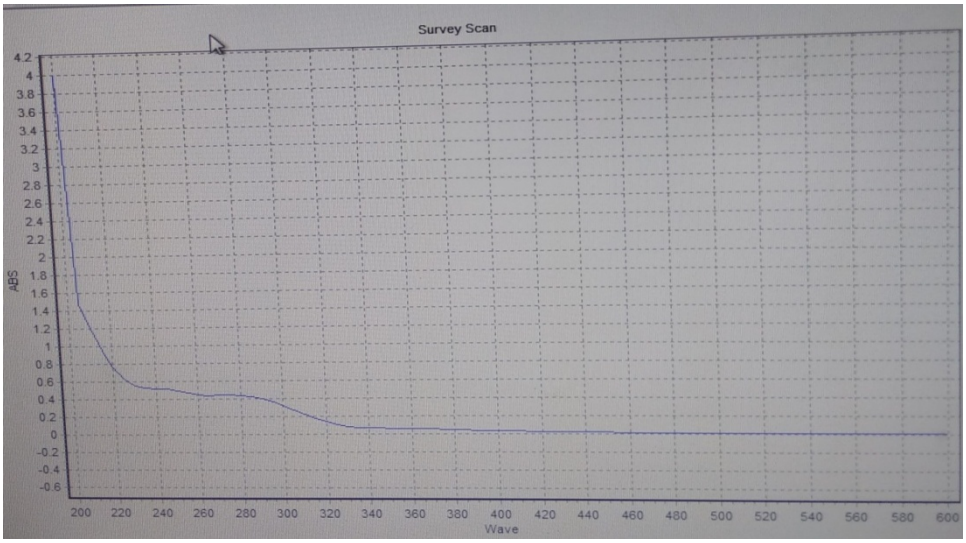


Fig.01, LAMBDA(λ) MAX OF LORATADINE (275nm)

2. Linearity:

Table No: 02 Calibration values of Loratadine

S.NO	CONCENTRATION (µg/ml)	ABSORBANCE
1	1	0.171
2	3	0.374
3	5	0.594
4	7	0.788
5	9	0.954

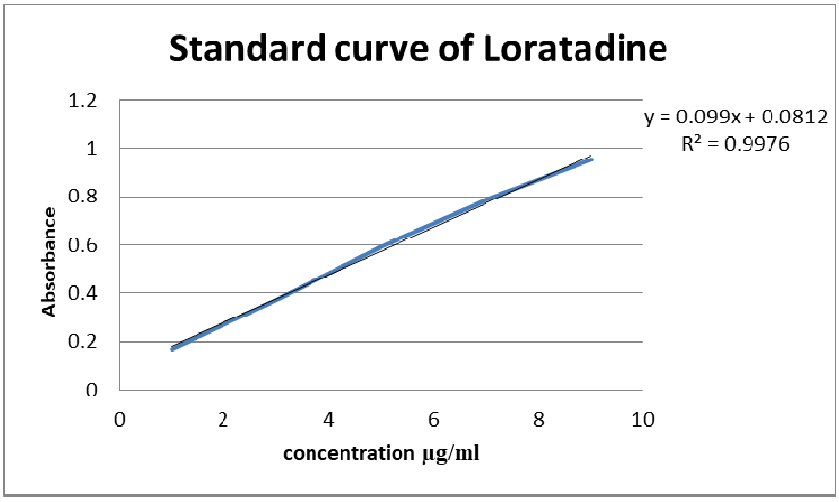


Figure 02 Calibration curve of Loratadine

3. Method Validation Results:

Table no: 03 Method validation parameters

PARAMETERS	RESULTS
1. Lambda max	275 nm
2. Beers law limit	2-10µg/ml
3. Regression equation(y=mx+c)	Y=0.099x+0.0812
4. Slope	0.099
5. Intercept	0.812
6. Correlation coefficient	0.997606
7. LOD value	0.009
8. LOQ value	0.027

Table no: 04 Precision Studies

Sample (µg/ml)	Intraday precision		Inter day precision	
	Absorbance	RSD	Absorbance	RSD
2	0.288 0.283 0.289	0.915582	0.287 0.285 0.289	0.568987
4	0.468 0.463 0.465	0.441577	0.466 0.467 0.466	0.101087
6	0.680 0.678 0.680	0.138784	0.681 0.678 0.681	0.207973

Table no: 05 Recovery Studies

Test µg/ml	Amount of standard drug added µg/ml	% Recovery of Loratadine	Standard deviation	%RSD
4	2	99.02%	0.090185	0.091
	4	101.95%	0.045092	0.0441
	6	99.50%	0.21362	0.2148

Table no: 06 Analysis of Tablet Formulation of LORATADINE

Drug	Label claim(mg)	Amount found (mg)	% Purity
Loratadine	10 mg	9.54 mg	95.54

DISCUSSION:

The recovery research confirmed proposed technique is correct and reproducible. The outcomes of recovery take a look at revealed that any small alternate in the drug awareness in the solution can be appropriately decided with the aid of the proposed technique. Accuracy, reproducibility and precision of the proposed techniques had been in addition confirmed with the aid of percent recuperation values, which had been near a hundred with low values of popular deviation. Repeatability results indicated the precision under the identical running situations over a brief c program languageperiod time and inter assay precision. Intermediate precision look at expresses within laboratory version in special days. In both intra and inter-dayPrecision study for the approach RSD had been no longer extra than 1.0% indicates correct intermediate precision. The low values of LOD and LOQ, 0.006 and 0.027 for Loratadine imply right sensitivity of proposed method. (Table no 03).

CONCLUSION:

- The effects of the prevailing have a look at indicated that the evolved approach is straightforward, precise and cost effective for the UV Spectrophotometric technique for estimation of Loratadine for routine quality manage analysis of it both in bulk and pharmaceutical method.
- The advanced and verified technique outlined could be very apparent, low priced, dynamic, low price, rapid and smooth to perform with small pattern volume and appropriate repeatability. It can be followed for the recurring best manipulate evaluation of UV Spectrophotometric method for estimation of Loratadine.

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