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STABILITY INDICATING METHOD DEVELOPMENT & VALIDATION OF LORCASERIN HYDROCHLORIDE BY RP-HPLC METHOD

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Abstract:

The current investigation aimed to develop and progressively validate a novel, simple, responsive, and stable RP-HPLC method for the Quantitative Determination of Lorcaserin Hydrochloride in active pharmaceutical ingredients and marketed pharmaceutical dosage forms. A simple, selective, validated and well-defined stability that shows isocratic RP-HPLC methodology for the quantitative determination of Lorcaserin Hydrochloride. The chromatographic strategy utilised a Symmetry ODS (C18) RP Column, 250 mm x 4.6 mm, 5µm, with isocratic elution using a mobile phase consisting of Phosphate Buffer (0.02 M) and Acetonitrile (pH 2.80) in a 60:40 v/v ratio. A flow rate of 1.0 ml/min and a detector wavelength of 225nm, utilising the UV detector, were given in the instrumental settings. Validation of the proposed method was carried out according to the International Conference on Harmonisation (ICH) guidelines. LOD and LOQ for the active ingredients were established with respect to test concentration. The calibration charts plotted were linear with a regression coefficient of R2>0.999, which means the linearity was within the limit. Recovery, specificity, linearity, accuracy, robustness, and ruggedness were determined as part of method validation, and the results were found to be within the acceptable range. The proposed method is to be fast, simple, feasible and affordable in assay condition. During stability tests, it can be used for routine analysis of the selected drugs.

Key Words:*Lorcaserin Hydrochloride, RP-HPLC, Method Development, Validation, Accuracy.*

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INTRODUCTION:

Lorcaserin was used as a weight management medication that demonstrated significant anti-diabetic benefits, including a reduced risk of developing type 2 diabetes and improved glycemic control in patients who already had it. However, the medication was withdrawn from the market in 2020 due to safety concerns regarding a possible increased risk of cancer. Lorcaserin Hydrochloride is a serotonin 2C receptor agonist used in conjunction with physical activity and calorie restriction for weight loss in obese patients with a body mass index (BMI) of 30 and above, and in overweight patients with weight-related comorbidities[1].Lorcaserin (previously APD-356), a highly selective 5-HT2C receptor agonist, is used for the treatment of obesity. It has been shown to reduce body weight and food intake in animal models of obesity, and it is thought that targeting the 5-HT2C receptor may alter body weight by regulating satiety. Lorcaserin is marketed as a salt form called Belviq, which is Lorcaserin hydrochloride[2]. In February 2020, the FDA issued a Drug Safety Communication requesting the manufacturer of Belviq (Lorcaserin hydrochloride tablets, 10 mg) and Belviq XR (Lorcaserin hydrochloride extended-release tablets, 20 mg) to voluntarily withdraw these products from the U.S. market, and the company has submitted a request to voluntarily withdraw the drug. This decision was based on the results of a clinical trial assessing the risk of heart-related problems that found that patients treated with Lorcaserin may have a higher risk of cancer[3]. For the treatment of obesity, as an adjunct to a reduced-calorie diet and increased physical activity. The IUPAC name of Lorcaserin hydrochloride is (1R)-8-chloro-1-methyl-2,3,4,5-tetrahydro-1H-3-benzazepine. The Chemical Structure of Lorcaserin hydrochloride is shown in the following figure-1.

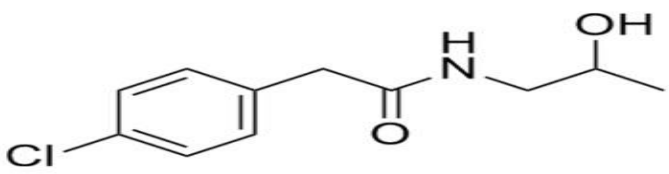

Fig-1: Chemical Structure of Lorcaserin Hydrochloride

MATERIALS AND METHODS

1. Instruments Used:

Table-1: List of Instrument Used

S. No.	Instruments/Equipments/Apparatus
1.	**Waters HPLC** with Empower2 Software with Isocratic with UV-Visible Detector.
2.	**ELICO SL-159** UV – Vis Spectrophotometer
3.	Electronic Balance **(SHIMADZU ATY224)**
4.	Ultra Sonicator**(Wensar wuc-2L)**
5.	Thermal Oven
6.	Symmetry RP C_{18}, 5µm, 250mmx4.6mm i.d.
7.	P^H Analyzer **(ELICO)**
8.	Vacuum Filtration Kit **(BOROSIL)**

2. Chemicals / Reagents Used:

Table-2: List of Chemicals Used

S.No.	Name	Specifications		Manufacturer/Supplier
		Purity	Grade	
1.	Doubled distilled water	99.9%	HPLC	Sd fine-Chem ltd; Mumbai
2.	Methanol	99.9%	HPLC	Loba Chem; Mumbai.
3.	Dipotassiumhydrogen orthophosphate	96%	L.R.	Sd fine-Chem ltd; Mumbai
4.	Acetonitrile	99.9%	HPLC	Loba Chem; Mumbai.
5.	Potassium dihydrogen orthophosphate	99.9%	L.R.	Sd fine-Chem ltd; Mumbai
6.	Sodium hydroxide	99.9%	L.R.	Sd fine-Chem ltd; Mumbai
7.	Hydrochloric acid	96%	A.R.	Sd fine-Chem ltd; Mumbai
8.	3% Hydrogen Peroxide	96%	A.R.	Sd fine-Chem ltd; Mumbai

Method Development:

Selection of Wavelength:

The general & pattern inventory options had been organized one by one by means of dissolving widespread & pattern in a solvent two in cell section diluting with the equal solvent.(After optimization of all conditions) for UV two analysis. It scanned in the UV spectrum in the vary of 200 to 400nm[4]. This has been carried out to understand the maxima of Lorcaserin hydrochloride, so that the identical wave wide variety can be utilized in HPLC UV detector for estimating the Lorcaserin hydrochloride.

Sample & Standard Preparation for the Analysis:

10mg of Lorcaserin hydrochloride standard was transferred into 10 ml volumetric flask, dissolved & make up to volume with mobile phase.Further dilution was done by transferring 1 ml of the above solution into a 10 ml volumetric flask and make up to volume with mobile phase[5].

Optimization of Chromatographic Conditions:

The chromatographic conditions were optimized by different means. (Using different column, different mobile phase, different flow rate, different detection wavelength & different diluents for sample preparation etc[6].

Table-3:Summary of Process Optimization

Column Used	Mobile Phase	Flow Rate	Wave length	Observation	Result
Symmetry ODS (C_{18}) RP Column, 250 mm x 4.6 mm, 5µm	Methanol : Water = 50 : 50	1.0ml/min	225nm	Very Low response	Method rejected
Symmetry ODS (C_{18}) RP Column, 250 mm x 4.6 mm, 5µm	Acetonitrile : Water = 60 : 40	1.0ml/min	225nm	Low response	Method rejected
Symmetry ODS (C_{18}) RP Column, 250 mm x 4.6 mm, 5µm	Acetonitrile: Water= 70 : 30	1.0ml/min	225nm	Tailing peaks	Method rejected
Symmetry ODS (C_{18}) RP Column, 250 mm x 4.6 mm, 5µm	Phosphate Buffer : Methanol = 20:80 (pH-4.0)	1.0ml/min	225nm	Resolution was not good	Method rejected
Symmetry ODS (C_{18}) RP Column, 250 mm x 4.6 mm, 5µm	Phosphate Buffer : Acetonitrile = 30:70 (pH-3.8)	1.0ml/min	225nm	Tailing peak	Method rejected
Symmetry ODS (C_{18}) RP Column, 250 mm x 4.6 mm, 5µm	Phosphate Buffer :Acetonitrile = 60:40 (pH-2.8)	1.0ml/min	225nm	Nice peak	Method accepted

Preparation of 0.02M Potassium Dihydrogen Orthophosphate Solution:
About 2.72172grams of Potassium dihydrogen orthophosphate was weighed and transferred into a 1000ml beaker, dissolved and diluted to 1000ml with HPLC Grade water. The pH was adjusted to 2.80 with diluted orthophosphoric acid Solution.

Preparation of Mobile Phase:
600mL (45%) of above Phosphate buffer solution and 400mL of HPLC Grade Acetonitrile (55%) were mixed well and degassed in ultrasonic water bath for 15 minutes. The resulting solution was filtered through 0.45 µm filter under vacuum filtration[7].

RESULTS AND DISCUSSION

Analytical Method Development:

Selection of Wavelength:
While scanning the Lorcaserin hydrochloride answer we found the maxima at 225 nm[8]. The UV spectrum has been recorded on ELICO SL-159 make UV – Vis spectrophotometer mannequin UV-2450. The scanned UV spectrum is connected in the following page,

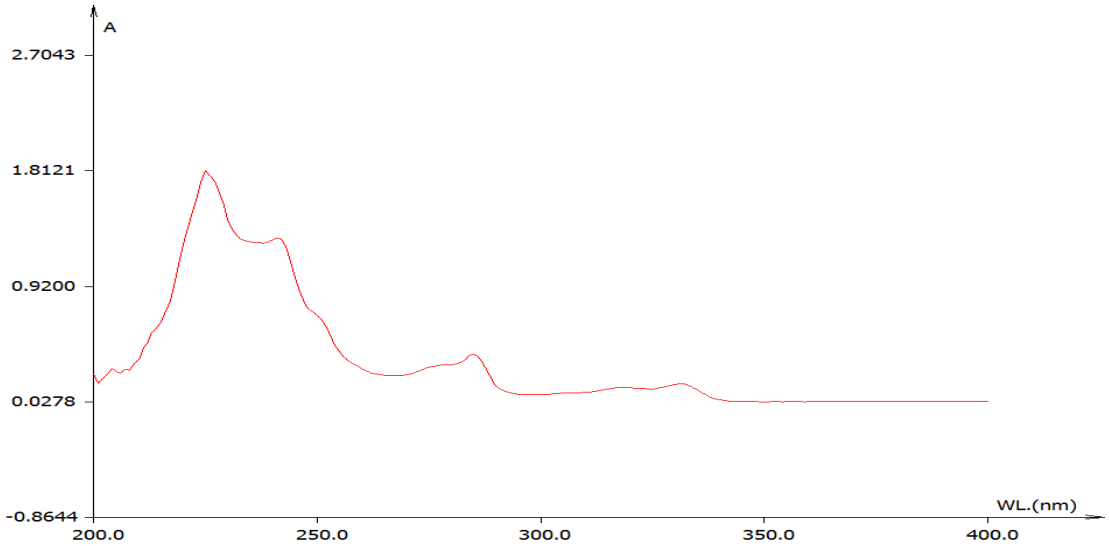

Fig-2: UV Spectrum for Lorcaserin hydrochloride

Summary of Optimized Chromatographic Conditions:
The Optimum conditions obtained from experiments can be summarized as below:

Table-4:Summary of Optimised Chromatographic Conditions

Mobile phase	Phosphate Buffer (0.02M): Acetonitrile = 60:40 (pH-2.80)
Column	Symmetry ODS (C_{18}) RP Column, 250 mm x 4.6 mm, 5µm
Column Temperature	Ambient
Detection Wavelength	225 nm
Flow rate	1.0 ml/ min.
Run time	08 min.
Temperature of Auto sampler	Ambient
Diluent	Mobile Phase
Injection Volume	20µl
Mode of Elution	Isocratic
Retention time	3.867 minutes

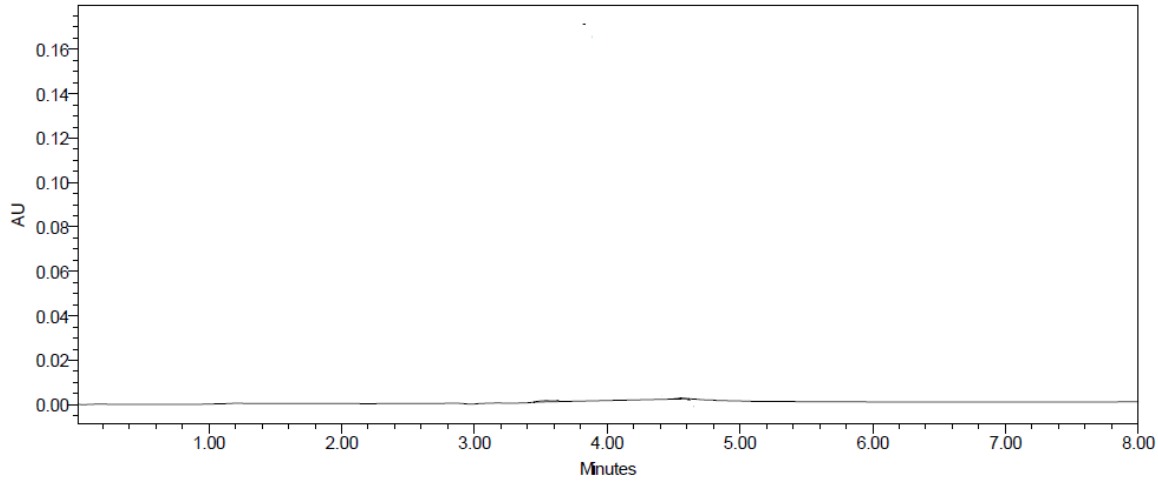

Fig-3: HPLC Spectrum of Lorcaserin hydrochloride (Blank Solution)

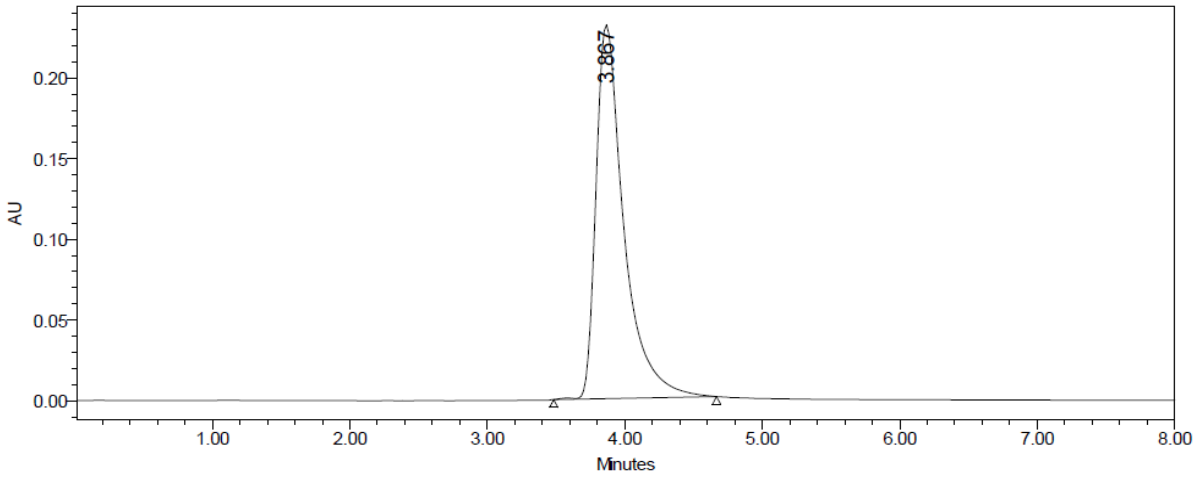

Fig-4: Chromatogram of Lorcaserin hydrochloride in Optimized Chromatographic Condition

Method Validation:

Validation of the optimized HPLC method was carried out with the following parameters[9-15].

Accuracy:

Recovery Study:

To determine the accuracy of the proposed method, recovery studies were carried out by adding different amounts (80%, 100%, and 120%) of pure drug of Lorcaserin hydrochloride were taken and added to the pre-analyzed formulation of concentration 30µg/ml. From that percentage recovery values were calculated[16-18]. The results were shown in table-5.

Table-5: Accuracy Readings for Lorcaserin hydrochloride

Sample ID	Concentration (µg/ml)			%Recovery of Pure drug	Statistical Analysis
	Conc. Found	Conc. Recovered	Peak Area		
S_1 : 80 %	12	12.13253	239853	101.1044	Mean= 101.005% S.D. = 0.99684 % R.S.D.= 0.986921
S_2 : 80 %	12	12.23316	241842	101.943	
S_3 : 80 %	12	11.99486	237132	99.9572	
S_4 : 100 %	15	15.07956	298101	100.5304	Mean= 100.139% S.D. = 0.49021 R.S.D.= 0.489529
S_5 : 100 %	15	15.0447	297412	100.298	
S_6 : 100 %	15	14.9384	295311	99.58933	
S_7 : 120 %	18	17.97928	355414	99.88489	Mean= 100.8044% S.D. = 0.835526 % R.S.D. = 0.82885
S_8 : 120 %	18	18.18201	359421	101.0112	
S_9 : 120 %	18	18.27308	361221	101.5171	

Precision:

Repeatability

The precision of each method was ascertained separately from the peak areas & retention times obtained by actual determination of six replicates of a fixed amount of drug Lorcaserin hydrochloride (API)[19-22]. The percent relative standard deviation was calculated for Lorcaserin hydrochloride are presented in the table.

Table-6: Repeatability Readings

HPLC Injection Replicates of Lorcaserin hydrochloride	Retention Time (Minutes)	Peak Area
Replicate – 1	3.873	598647
Replicate – 2	3.867	586484
Replicate – 3	3.866	594624
Replicate – 4	3.865	588642
Replicate – 5	3.865	584213
Replicate – 6	3.867	589874
Average		**590414**
Standard Deviation		**5344.816**
% RSD		**0.905266**

Intermediate Precision:

Intra-Assay & Inter-Assay:

The intra & inter day variation of the method was carried out & the high values of mean assay & low values of standard deviation & % RSD (% RSD < 2%) within a day & day to day variations for Lorcaserin hydrochloride revealed that the proposed method is precise[23].

Table-7: Results of Intra-Assay & Inter-Assay

Conc. of Lorcaserin hydrochloride(API) (µg/ml)	Observed Conc. of Lorcaserin hydrochloride (µg/ml) by the Proposed Method			
	Intra-Day		Inter-Day	
	Mean (n=6)	% RSD	Mean (n=6)	% RSD
24	23.86	0.95	24.79	0.86
30	30.09	0.64	29.89	0.43
36	36.07	0.87	36.12	0.91

Linearity & Range:

The calibration Curve showed good linearity in the range of 0 – 50 µg/ml, for Lorcaserin hydrochloride (API) with correlation coefficient (r2) of 0.999 (Fig-5). A typical calibration curve has the regression equation of y =19765 x + 5352 for Lorcaserin hydrochloride[24].

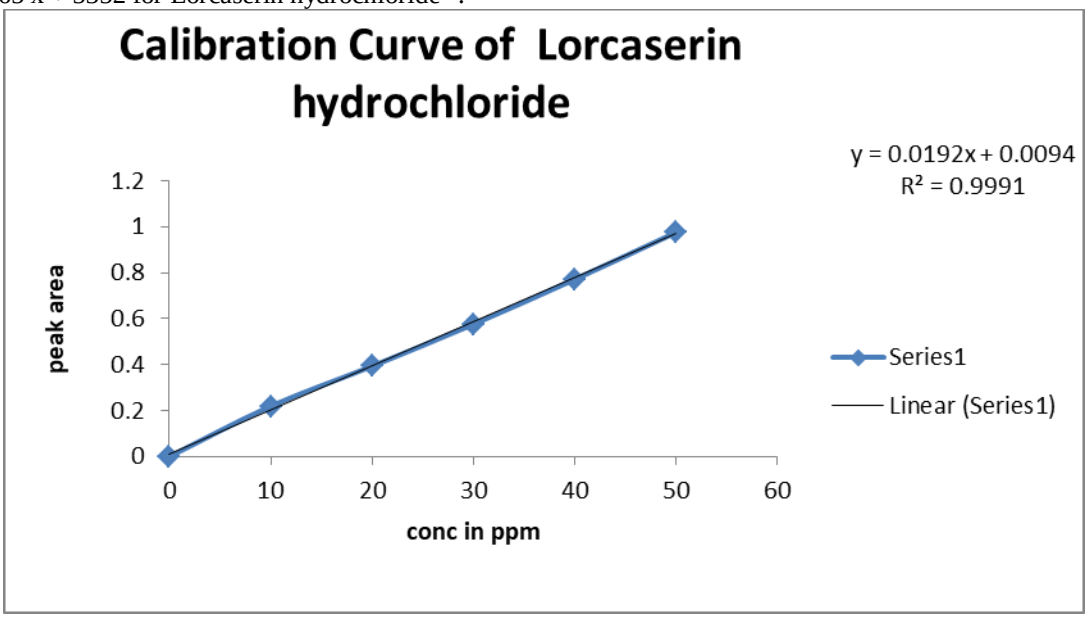

Fig-5: Calibration Curve of Lorcaserin hydrochloride

Table-8: Linearity Results

CONC.(µg/ml)	MEAN AUC (n=6)
0	0
10	221404
20	386157
30	592106
40	805041
50	992196

Method Robustness:

Influence of small changes in chromatographic stipulations such as change in waft cost (± 0.1ml/min), Temperature (±2^{0}C), Wavelength of detection (±2nm) & Acetonitrile content material fabric in cell area (±2%) studied to figure out the robustness of the approach are moreover in favour of (Table-9, percentage RSD < 2%) two the developed RP-HPLC method for the contrast of two Lorcaserin hydrochloride (API)[25].

Table-9: Result of Method Robustness Test

Change in Parameter	% RSD
Flow (1.1 ml/min)	0.78
Flow (0.9 ml/min)	0.69
Temperature (27^{0}C)	0.87
Temperature (23^{0}C)	0.92
Wavelength of Detection (226 nm)	0.76
Wavelength of detection (230 nm)	0.92

LOD & LOQ: The Minimum concentration level at which the analyte can be reliable detected (LOD) & quantified (LOQ) were found to be 0.07 & 0.21µg/ml respectively[26-27].

System Suitability Parameter: System suitability checking out is a crucial phase of many analytical procedures. The exams are based totally on the notion that the equipment, electronics, analytical operations and samples to be analyzed represent a critical machine that can be evaluated as such. Following machine suitability check parameters have been established[28].

The data are shown in Table-10.

Table-10: Data of System Suitability Parameter

S.No.	Parameter	Limit	Result
1	Resolution	Rs > 2	8.54
2	Asymmetry	T ≤ 2	Lorcaserin hydrochloride =0.98
3	Theoretical plate	N > 2000	Lorcaserin hydrochloride =4782
4	Tailing Factor	T<2	Lorcaserin hydrochloride =1.49

Estimation of Lorcaserin hydrochloride in Pharmaceutical Dosage Form:

Each Tablet Contains: 20 mg

Twenty pharmaceutical dosage types have been taken and the I.P. approach used to be followed to decide the common weight. Above weighed pills had been subsequently powdered and triturated well. A volume of powder equal to 25 mg of capsules have been transferred to 25 ml volumetric flask, make two and answer used to be sonicated for 15 minutes, there after quantity was once made up to 25 ml with identical solvent. Then 10 ml of the above answer used to be diluted to one hundred ml with cell phase. The answer was once filtered via a membrane filter (0.45 µm) and sonicated to degas. The answer organized was once injected in 5 replicates into the HPLC device and the observations have been recorded[29].

A replica injection of the popular answer used to be additionally injected into the HPLC device and the top areas have been recorded.The data are shown in Table-11.

ASSAY:-

Assay % =

$$\frac{AT}{AS} \times \frac{WS}{DS} \times \frac{DT}{WT} \times \frac{P}{100} \times \text{Avg. Wt} = \text{mg/tab}$$

Where:

AT = Peak Area of drug obtained with test preparation
AS = Peak Area of drug obtained with standard preparation
WS = Weight of working standard taken in mg
WT = Weight of sample taken in mg
DS = Dilution of Standard solution
DT = Dilution of sample solution
P = Percentage purity of working standard

Table-11: Recovery Data for Estimation Lorcaserinhydrochloride Tablet

Brand Name of Lorcaserin hydrochloride	Labelled Amount of Drug (mg)	Mean (± SD) amount (mg) Found by the Proposed Method (n=6)	Assay % (± SD)
BELVIQTablet (20mg)	20mg	19.98 (± 0.682)	99.9 (±0.364)

STABILITYSTUDIES

Results of Degradation Studies:-

The effects of the stress research indicated the specificity of the approach that has been developed. Lorcaserin hydrochloride used to be secure in photolytic and peroxide stress conditions[30-31]. The end result of compelled degradation research are given in the following table-12.

Table-12:Results of Forced Degradation Studies of Lorcaserin hydrochloride API

Stress Condition	Time	Assay of Active Substance	Assay of Degraded Products	Mass Balance (%)
Acid Hydrolysis (0.1 M HCl)	24Hrs.	73.616	26.384	100.0
Basic Hydrolysis (0.1 M NaOH)	24Hrs.	95.475	4.525	100.0
Thermal Degradation (50 ^{0}C)	24Hrs.	91.106	8.894	100.0
UV (254nm)	24Hrs.	97.124	2.876	100.0
3 % Hydrogen Peroxide	24Hrs.	96.343	3.657	100.0

SUMMARY AND CONCLUSION:

- To boost a precise, linear, unique & appropriate balance indicating RP-HPLC approach for evaluation of Lorcaserin hydrochloride, one-of-a-kind chromatographic stipulations have been utilized & the consequences located are introduced in preceding chapters.
- Isocratic elution is simple, requires solely one pump & flat baseline separation for convenient and reproducible results. So, it was once favored for the modern-day find out about over gradient elution.
- In case of RP-HPLC a number of columns are available, however right here Symmetry ODS (C18) RP Column, 250 mm x 4.6 mm, 5µm was once desired due to the fact the use of this column top shape, decision and absorbance have been good.
- Mobile segment & diluent for instruction of more than a few samples have been finalized after reading the solubility of API in one-of-a-kind solvents of our disposal (methanol, Acetonitrile, dichloromethane, water, 0.1N NaOH, 0.1NHCl).
- The drug used to be located to be soluble in natural solvents such as ethanol, DMSO, and dimethyl formamide, which ought to be purged with an inert gas. The solubility of Lorcaserin hydrochloride in these solvents is about 30 mg/ml. Lorcaserin hydrochloride is sparingly soluble in aqueous buffers. Using these solvents with suitable composition more modern techniques can be developed and validated.
- Detection wavelength used to be chosen after scanning the preferred answer of drug over 200 to 400nm. From the U.V spectrum of Lorcaserin hydrochloride it is evident that most of the HPLC work can be carried out in the wavelength vary of 210-300 nm conveniently. Further, a glide price of 1 ml/min & an injection quantity of 20µl had been determined to be the quality analysis.
- The end result indicates the developed technique is but any other appropriate approach for assay and balance associated impurity research which can assist in the evaluation of Lorcaserin hydrochloride in exceptional formulations.

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