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New Validated UV Spectrophotometric Method for the Determination of a New Pregabalin Derivative in Capsule Dossage Form

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Abstract: *Pregabalin an anti-epileptic drug has very low UV absorptivity and hence normally it is difficult to analyze this drug by UV Spectroscopy. Benzene sulfonyl chloride, a derivatizing agent, was used to introduce a chromogen for the purpose of detecting pregabalin in bulk and capsules. A wavelength of 205nm was used to find the pregabalin after derivatization by UV-spectroscopy. The spectrophotometric validation parameters such as linearity, precision, accuracy, robustness, and ruggedness were studied and verified using the ICH guidelines. With a correlation coefficient of 0.999, the linearity between 20µg/ml and 100µg/ml was observed. The intermediate and intraday precision's respective RSDs were found to be 1.27% and 1.40%. The accuracy concentration range was spiked at 50%, 100%, and 150%, and the %recovery values were found to be in the range of 95.7% to 99.4%. The method was found to be rugged and robust. Without any interference from typical excipients, the devised approach was effectively verified and applied to the detection of pregabalin in bulk and pharmaceutical formulation.*

The method was validated with Respect to accuracy, precision, assay, ruggedness, robustness, limit of detection and limit of Quantitation. This is found to be simple, specific, precise, accurate, reproducible and low-cost UV-Spectrophotometric method. The method can be useful for the day-to-day routine analysis in the quality Control departments of bulk and pharmaceutical formulations industries.

The present study focuses on the development and validation of a simple, precise, accurate, And cost-effective UV spectrophotometric method for the quantitative determination of a novel Pregabalin derivative in capsule dosage form. Pregabalin, a structural analogue of gamma-Aminobutyric acid (GABA), is widely used in the treatment of neuropathic pain, epilepsy, and Generalized anxiety disorders. The newly synthesized derivative requires a reliable analytical Method for routine quality control and formulation analysis.

The method was developd using a suitable solvent system, and the maximum absorbance (λmax) of the pregabalin derivative was determined using a UV-visible spectrophotometer. The Analysis was carried out at the selected wavelength, where the drug showed significant Absorbance with minimal interference from excipients present in the capsule formulation.The developd UV spectrophotometric method was successfully applied for the estimation of The pregabalin derivative in capsule dosage form, with no interference from common Excipients. The assay results were found to be within acceptable limits, confirming the Suitability of the method for routine analysis..

Keywords: *Pregabalin*

I. INTRODUCTION

Pregabalin is chemically known as (S)-3(aminomethyl)-5-methyl hexanoic acid, commonly used to control seizures & convulsions. Although pregabalin is a derivative of GABA (γ-aminobutyric acid), it has no impact on GABA receptors.

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The two primary manifestations of neuropathic pain, allodynia, and hyperalgesia are lessened by pregabalin. Additionally, it acts as an analgesic, anxiolytic, and in the management of opioid withdrawal.

Pregabalin is a saturated carboxylic acid that lacks π electron density. It has very low UV absorptivity and hence it is difficult to accurately estimate it by UV spectroscopy. Chemical derivatization of this molecule increases its UV absorptivity. Earlier workers have analyzed pregabalin by UV-Visible spectrometry after carrying out its derivatization with reagents like xanthone, ninhydrin, ascorbic acid etc.[2,3] For UV-spectroscopic studies of pregabalin, mostly methanol was used as solvent.[4,5] Apart from UV-spectrophotometry were used to estimate pregabalin. All of the strategies that have been described so far involve intricacy in derivatization and evaluation. Hence the present work was aimed to prepare a simple, stable, economic derivative of pregabalin using a very basic reagent, benzene sulfonyl chloride (Hinsberg reagent) in distilled water at basic pH and to estimate it easily, quickly, and accurately by UVspectrophotometry.

Pregabalin is a structural analogue of Gamma-aminobutyric acid (GABA) and is Commonly used in the treatment of Neuropathic pain, epilepsy, fibromyalgia, And generalized anxiety disorder. It works By binding to the α2-δ subunit of voltage-Gated calcium channels in the central Nervous system, thereby reducing the release Of excitatory neurotransmitters. Due to its Therapeutic importance, pregabalin and its Derivatives are extensively studied for Improved pharmacological activity, Bioavailability, and reduced side effects.

Capsule dosage forms are one of the most commonly used oral delivery systems due to their Ease of administration, accurate dosing, and improved stability. The presence of excipients in Capsule formulations may interfere with drug estimation; therefore, it is important to develop A method that is specific and free from such interferences.

UV spectrophotometric methods are based on the measurement of absorbance of ultraviolet Light by the analyte at a specific wavelength. These methods are particularly useful for routine Quality control analysis because they require minimal sample preparation and instrumentation Compared to more advanced techniques such as HPLC or LC-MS. However, the method must Be properly developed and validated to ensure its reliability and reproducibility.

Pharmaceutical analysis plays a vital role in ensuring the quality, safety, and efficacy of drug Products. The development of reliable and validated analytical methods is essential for the Quantitative determination of drugs in bulk and pharmaceutical dosage forms. Among the Various analytical techniques available, UV spectrophotometry is widely used due to its Simplicity, cost-effectiveness, rapidity, and adequate sensitivity.

II. LITERATURE REVIEW

The analytical determination of pregabalin and its derivatives in pharmaceutical formulations Has been widely studied using various analytical techniques such as UV spectrophotometry, High-performance liquid chromatography (HPLC), and liquid chromatography–mass Spectrometry (LC-MS). Each method offers specific advantages depending on sensitivity,Accuracy, and application.

Several researchers have reported UV spectrophotometric methods for the estimation of Pregabalin in bulk and dosage forms. These methods are generally based on the direct Measurement of absorbance at a specific wavelength (λmax) or involve derivatization Techniques to enhance the chromophoric properties of pregabalin, which inherently lacks strong UV absorption. The reported methods are simple, economical, and suitable for routine analysis But may sometimes lack sensitivity and specificity compared to chromatographic techniques.

High-performance liquid chromatography (HPLC) methods have also been extensively Developed for the determination of pregabalin in pharmaceutical dosage forms and biological Samples. These methods provide high accuracy, precision, and sensitivity. Reverse-phase HPLC (RP-HPLC) methods using different stationary phases and mobile phase compositions Have been reported, offering reliable quantification even in the presence of impurities and Degradation products. However, HPLC methods require expensive instrumentation, skilled Personnel, and longer analysis time.

Liquid chromatography coupled with mass spectrometry (LC-MS/MS) has been employed for The determination of pregabalin in plasma and other biological matrices. These methods are Highly sensitive and selective, making them

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suitable for pharmacokinetic and bioequivalence Studies. Despite their advantages, LC-MS/MS methods are costly and not always feasible for Routine quality control in pharmaceutical industries.

III. AIM AND OBJECTIVE

Aim: New validated UV spectrophotometric method for the Determination of a new pregabalin derivative in capsule dosage form

Objective:

- To develop a suitable UV spectrophotometric method for the estimation of the Pregabalin derivative.
- To determine the maximum absorbance (λmax) of the drug in an appropriate solvent System.
- To prepare standard and sample solutions of the pregabalin derivative for analysis.
- To establish a calibration curve and evaluate the linearity over a suitable concentration Range
- To apply the validated method for the estimation of the pregabalin derivative in capsule Dosage form.
- To ensure that the developed method is simple, economical, and suitable for routine Quality control analysis.
- To determine the λmax (maximum wavelength) of the pregabalin derivative
- To validate the method as per ICH Guidelines
- To apply the method for analysis of capsule formulation

IV. PLAN FOR WORK

Method development and validation of Pregabalin in tablet dosage form by UV Visible Spectrophotometer methods.
Survey of literature review on selected drugs and the mode of analysis.

- Analytical method development
- Selection of Wave length
- Selection of Solvent

Analytical method validation for the estimation of compound.
The developed method is validated according to ICH guidelines for various parameters specified in ICHQ2B.

UV Spectrophotometry

UV spectrophotometry is one of the most widely used analytical techniques in pharmaceutical analysis for the quantitative estimation of drugs. It is based on the measurement of absorption of ultraviolet radiation by a substance in the wavelength range of 200–400 nm. When a beam of UV light passes through a solution, certain wavelengths are absorbed by the analyte, leading to electronic transitions in the molecules.

The fundamental principle governing UV spectrophotometry is the Beer-Lambert Law, which states that the absorbance of a solution is directly proportional to the concentration of the absorbing species and the path length of the cell. This relationship allows accurate determination of drug concentration in pharmaceutical formulations.

In pharmaceutical industries and research laboratories, UV spectrophotometry plays a vital role in drug analysis due to its simplicity, rapidness, cost-effectiveness, and reliability. It is commonly used for routine quality control, dissolution studies, stability testing, and assay of bulk drugs and dosage forms.

Method development and validation of UV spectrophotometric techniques are carried out according to guidelines provided by the International Council for Harmonisation, ensuring the accuracy, precision, specificity, and reproducibility of the analytical method.

In this project, a UV spectrophotometric method is developed and validated for the estimation of a pharmaceutical compound in its dosage form. The developed method aims to provide a simple, accurate, and precise approach suitable for routine analysis in quality control laboratories.

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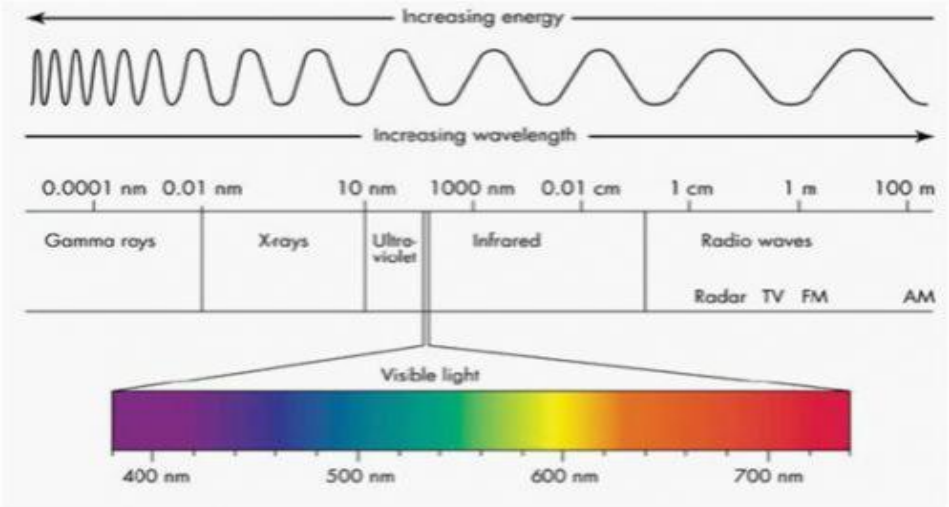
Principle of UV Spectrophotometry :-

UV spectrophotometry is based on the absorption of ultraviolet (UV) radiation by molecules. When UV light in the range of 200–400 nm passes through a solution, the molecules of the analyte absorb specific wavelengths of light. This absorption causes electronic transitions, mainly from lower energy levels (ground state) to higher energy levels (excited state), such as $\pi \rightarrow \pi^*$ and $n \rightarrow \pi^*$ transitions.

The quantitative estimation of a substance is governed by the Beer-Lambert Law, which states: Absorbance is directly proportional to the concentration of the solution when the path length and wavelength are constant.



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Instrumentation of UV Spectrophotometer:-

A UV spectrophotometer is an analytical instrument used to measure the absorbance of UV light by a sample. It consists of several key components that work together to analyze the sample accurately.

1. Light Source

Provides continuous radiation in the UV region (200–400 nm)
Common sources:
Deuterium lamp (for UV region)
Tungsten lamp (for visible region)
The light source must be stable and intense for accurate results.

2. Monochromator

Separates polychromatic light into monochromatic (single wavelength) light
Components include:
Prism or diffraction grating
Entrance and exit slits
Helps in selecting the desired wavelength (λmax).

3. Sample Holder (Cuvette)

Holds the sample solution
Made of quartz (required for UV analysis)
Standard path length = 1 cm
Glass cuvettes are not used in UV because they absorb UV light.

4. Beam Splitter (in Double Beam Instrument)

Divides light into two beams:
Sample beam
Reference (blank) beam
Improves accuracy by reducing errors due to fluctuations.

5. Detector

Converts transmitted light into an electrical signal
Common detectors:
Photodiode
Photomultiplier tube
Signal intensity is proportional to transmitted light.

6. Amplifier

Amplifies the electrical signal received from the detector
Ensures better sensitivity and readability.

7. Readout / Display System

Displays the absorbance or transmittance values

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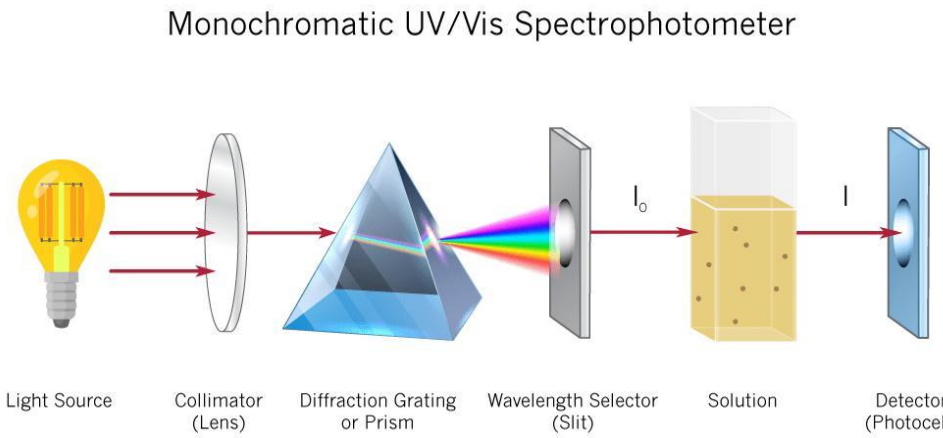

Method Validation Parameters

Method validation is the process of proving that an analytical method is suitable for its intended purpose. In UV spectrophotometry, validation is performed according to guidelines given by the International Council for Harmonisation (ICH Q2(R1)).

- Linearity
- Accuracy
- Precision
- Specificity
- Limit of Detection (LOD)
- Limit of Quantification (LOQ)
- Ruggedness
- Robustness

V. MATERIALS AND METHODS

Materials: Pregabalin API was a gift sample from Dr Reddy's laboratories. Pregabalin-75mg capsules were purchased from Shree Medicals to conduct derivatization and recovery studies. Methanol, ethanol, n-hexane, ethyl acetate, benzene sulfonyl chloride, chloroform, sodium carbonate and dimethyl sulfoxide (DMSO) were used for this study.
Instruments:
Lab India-T60 and SHIMADZU-1800 Double Beam UVVisible Spectrophotometer with pair of 10mm matched quartz cells, BRUKER ALPHA- FTIR Spectrophotometer and. BRUKER AVANCE III 700 MHz NMR spectrometer (CSIR-IICT, Hyderabad) were used for the study.

Methods:

Chemical derivatization of pregabalin:

In a beaker, Pregabalin (2.02g, 12.7 mmol) was Dissolved in 15-20ml of distilled water. Drop By drop, 3% sodium carbonate solution was added until the Pregabalin completely dissolved And the pH was Between 8-9. Then, benzene sulfonyl chloride (1.904ml) in an equimolar ratio Was added to the mixture (Scheme 1). At room temperature, it was agitated Using a magnetic Stirrer. The reaction mixture's pH Was maintained at 8 to 9 by periodically adding a few Drops Of Na2CO3 solution.Stirring continued till the Completion of reaction. At this point, the solutions pH ceased to Decrease and remained constant. Then, precipitate was filtered, washed with distilled water, Dried and recrystallized from aqueous alcohol.

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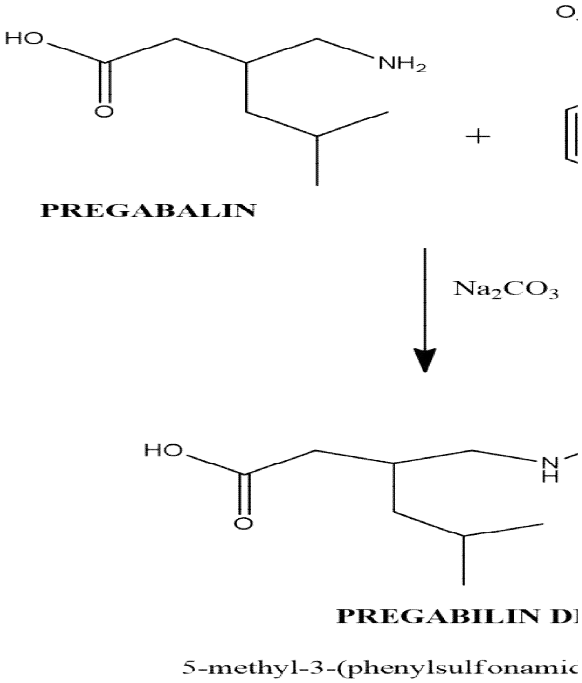

Analytical method development:

Preparation of Stock Solution: Accurately weighed 100 mg of Pregabalin derivative and dissolved in 10 ml of methanol in a 100 ml volumetric flask and diluted up to the mark with methanol to obtain the stock solution having a final concentration of 1000µg/ml. Standard solutions of different concentrations were prepared by diluting this Stock solution.

Preparation of Primary Standard Solution: The primary standard solution was prepared by diluting 1 ml of stock solution with 9 ml of methanol in a 10 ml volumetric flask to produce 100µg/ml.

Preparation of Secondary Standard Solution: Pipetted out 0.1 ml, 0.2 ml, 0.4 ml, 0.6 ml, 0.8 ml and 1 ml from the primary standard solution and diluted with methanol to obtain 1µg/ml, 2µg/ml, 4µg/ml. 6µg/ml, 8µg/ml and 10µg/ml respectively.

Determination of λmax:

A 10µg/ml solution of pregabalin derivative in methanol was scanned in the 190–300nm region to obtain the absorption maxima (λmax).

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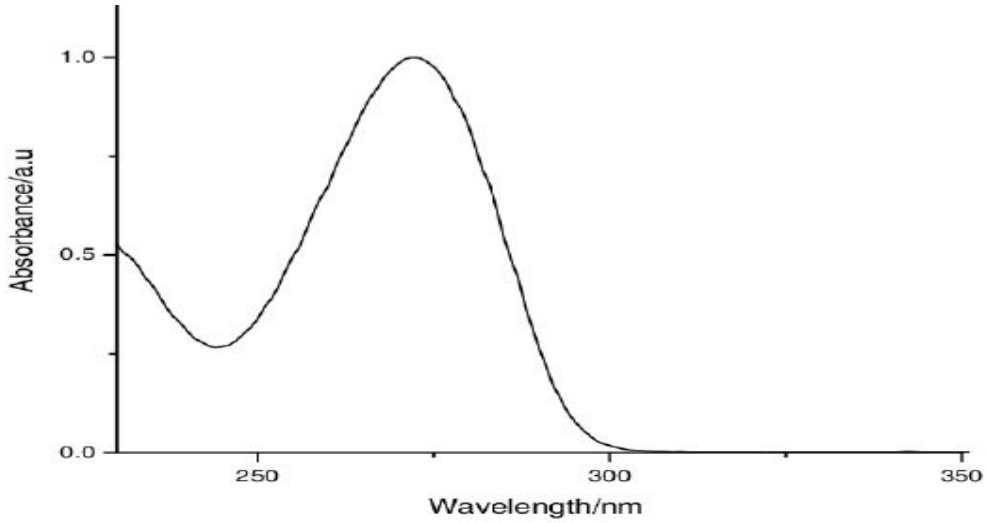

Assay:

Twenty capsules of Pregabalin were taken and the contents were carefully collected. The capsules powder equivalent to 200 mg of Pregabalin was accurately weighed and transferred into 250ml beaker. It was mixed with 0.19 ml of benzene sulphonyl chloride in 10-15 ml of distilled water and proceeded as described in the derivatization procedure. The entire product obtained was dissolved in methanol and then further diluted to obtain concentration equivalent to 10 µg/ml. The absorbance of this sample solution was measured at 205 nm.

Analytical method validation:

Linearity:

According to the defined range, linearity is the capacity to get findings that are directly proportional to the analyte concentration in the sample. The linearity was measured by preparing solutions of 20µg/ml, 40µg/ml, 60µg/ml, 80µg/ml and 100µg/ml via serial dilution process. The linearity was determined at a wavelength of 205nm. Linearity

Precision:

When the method is used repeatedly to do multiple sampling of a homogenous sample, the precision of an analytical method is measured by the degree of agreement among individual test findings.

Intermediate precision:

Intermediate precision was done for three consecutive days. The triplicate absorbance values of solutions ranging from 20µg/ml to 60µg/ml were noted at a wavelength of 205nm and the %RSD was calculated.

Intraday precision:

Intraday precision was done by recording the absorbances of sample solutions ranging from 20 µg/ml to 60µg/ml at three different timings in same day. The %RSD was calculated for the noted absorbances.

Accuracy:

The degree to which test findings acquired using an analytical procedure are accurate in relation to the true value. The solutions ranging from 20µg/ml to 60µg/ml are spiked by adding a known concentration of analyte to the sample to 50%, 100% and 150%. The % recovery was calculated for the noted absorbances.

Robustness:

Robustness is the measurement of an analytical Method's ability to produce results that are accurate Even under slightly different circumstances. The Absorbances of solutions ranging from 20µg/ml –60µg/ml were recorded at various temperatures and Wavelengths.

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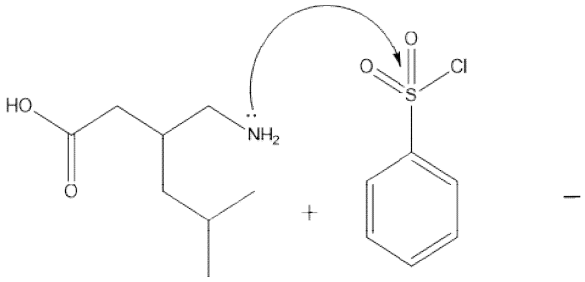
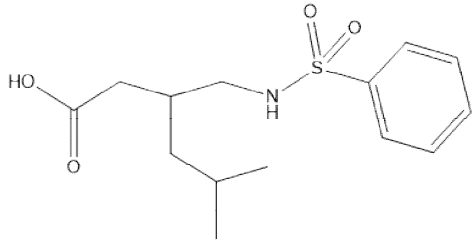
Ruggedness:

Reproducibility of test results under the range of Conditions often anticipated between laboratories And analysts is measured by ruggedness. The Absorbances for sample solutions 20 µg/ml –60µg/ml are recorded when performed in different Instruments i.e., SHIMADZU-1800 Double Beam UV-Visible Spectrophotometer with a pair of 10mm Matched quartz cells and LAB INDIA UV-Visible Spectrophotometer and performed by different Analysts.



PREGABALIN BENZENE SULPHONYL CHLO

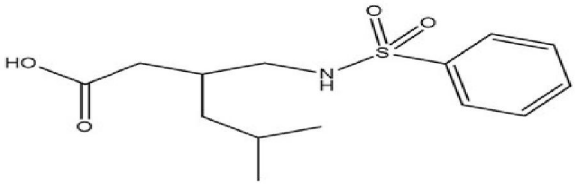


PREGABALIN DERIVATIVE

5-METHYL-3-(PHENYLSULFONAMIDOMETHYL)l

Mechanism of reaction for the new Pregabalin derivative

Physical data of Pregabalin derivative:



PREGABILIN DERIVATIVE

5-methyl-3-(phenylsulfonamidomethyl)hexanoic acid

Chemical structure of Pregabalin Derivative

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IUPAC Name: 5-methyl-3-(phenyl ssulfonamid Methyl) hexanoic acid
Molecular Formula : C14H21NO4S
Molecular Weight : 299.39
Description: White solid
Melting Point: 118-122ºC
Solubility: Methanol
Rf value: 0.6 (n-hexene: ethyl acetate-1:0.5)
% Yield: 88

Analytical method development:

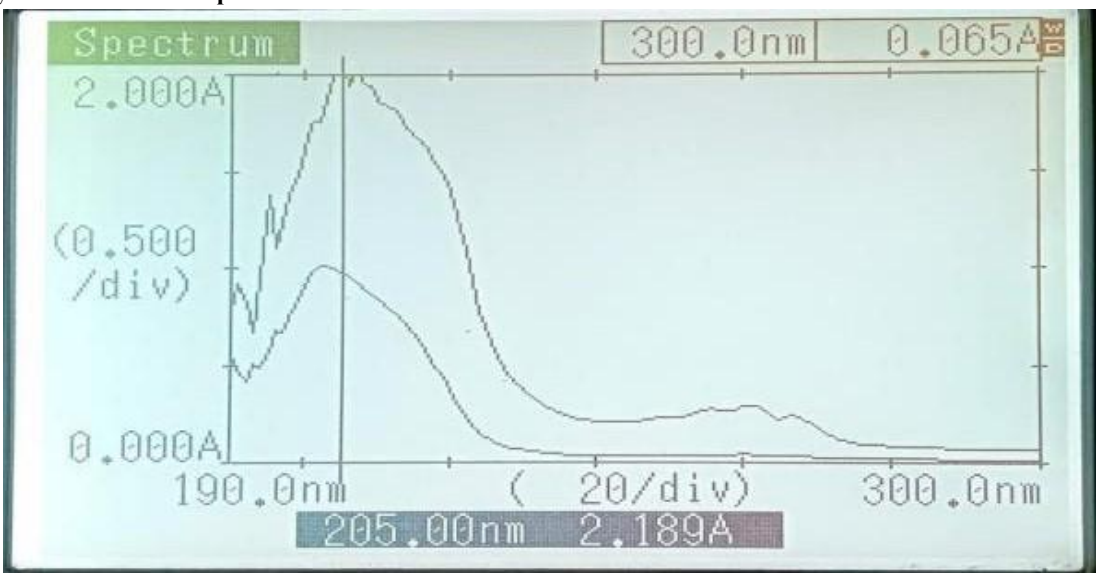

Fig. : Determination of λmax of pregabalin derivative

Linearity:The linearity was observed in the concentration Range of 20µg/ml-100µg/ml (Table) with the Correlation coefficient $r^2 = 0.999$

Concentration (µg/ml)	Absorbance at 205nm
20	0.254
40	0.428
60	0.605
80	0.789
100	0.948

Table : Linearity of Pregabalin derivative

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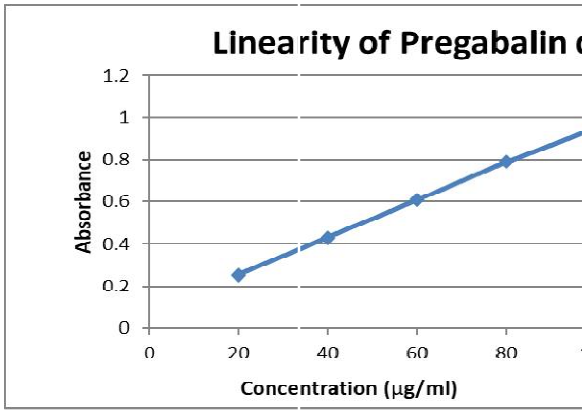

Fig .Calibration curve of Pregabalin derivative at 205nm

Precision: The precision of the analytical method was studied by analysis of multiple sampling of Homogeneous sample. The precision results were expressed as standard deviation or relative standard Deviation

Sr. No.	Concentration	Absorbance
1	20	0.2442
2	40	0.2543
3	60	0.2518
4	80	0.2483
5	100	0.2330
	STDEV	0.00436
	AVG	0.2441666
	%RSD	1.78

Table: intraday precision results for pregabalin

Fig. : Spectrum showing overlay of Pregabalin derivative at different concentrations.

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Accuracy: The accuracy results of Pregabalin derivative are Presented in Table . The % recovery was Calculated using the following equation:% Recovery = (ASpiked-ATest/AStandard) x 100 The mean % recovery was found to be in the Range of 95.7 to 99.4. The % RSD values at all the Three spike levels were found to be less than 2.

Label Value (mg)	Amount Found (mg)	n	Recovery (%)	%RSD
75	73.5	10	98	1.58

Concentration (µg/ml)	Standard Absorbance	Test Absorbance	Spiked Absorbance	%Recovery	%RSD
20	0.228	0.254	0.479	98.0	1.04
40	0.302	0.401	0.693	96.6	0.52
60	0.345	0.424	0.765	98.8	1.94

Table : Accuracy results of Pregabalin derivative

Ruggedness: Ruggedness is a measure of the reproducibility of a test result under normal, expected operating Condition from instrument to instrument and from analyst to.

Sr. No.	Analyst-1		Analyst-2	
	Concentration (µg/ml)	Absorbance	Concentration (µg/ml)	Absorbance
1	20	0.2485	20	0.2450
2	20	0.2237	20	0.2440
3	20	0.2424	20	0.2379
4	20	0.2491	20	0.2474
5	20	0.2426	20	0.2424
	STDEV	0.004324	**STDEV**	0.00382187
	AVG	0.2407	**AVG**	0.24246667
	%RSD	1.79	**%RSD**	1.57

Table: ruggedness studies of pregabalin by uv- visible spectroscopic method

Robustness: The robustness of an analytical procedure is a measure of its capacity to remain unaffected by small, but Deliberate variations in method parameters and provides an indication of its reliability during normal usage.

Sr. No.	Condition	Modification	Mean Absorbance ± STDEV	% RSD (for Absorbance
1.	**Wavelength (nm)**	223	0.2189 ±0.003712	1.69
		227	0.21125±0.004027	1.90

Table : robustness summary for wavelength

Assay: The method was used to estimate Pregabalin in Pharmaceutical formulation (capsule) and the results Obtained are presented in Table, which reveal that Pregabalin can be recovered well by this method.

Table : Assay results of Pregabalin in Capsules

Sensitivity: Limit of detection (LOD) and limit of quantitation (LOQ) were determined from standard deviation And slope method as per ICH guideline, for Pregabalin. LOD was found to be and LOQ was Found to be 0.9282 and 2.8192.

Sr. No.	Slope	STDEV of precision	LOD
1.	0.0155	0.00436	0.9282

Table: observation of limit of detection

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Sr. No.	Slope	STDEV	LOQ
1.	0.0155	0.00436	2.8129

Table: observation of limit of quantifitation

VI. RESULTS AND DISCUSSION

Chemical derivatization of Pregabalin derivative: Chemical derivatization of Pregabalin with benzene Sulphonyl chloride (Hinsberg reagent) via addition-Elimination reaction produced the new, Stable, colorless sulphonamide derivative of Pregabalin, 5-methyl-3-(phenylsulfonamidomethyl) Hexanoic acid. It was purified and characterized by Physical and spectral data.

Parameters	UV
Calibration range (µg / ml)	2-12µg/ml
Wavelength(nm)	225
Slope	0.0155
LOD (µg / ml)	0.9282
LOQ (µg / ml)	2.8129

VII. CONCLUSION

A new, simple UV-spectrophotometric method was Developed for the determination of Pregabalin in Capsules. It was validated for linearity, accuracy, Precision, robustness, and ruggedness. According to ICH criteria, all parameter values were found to be Within the acceptable ranges. It can be concluded That this new spectrophotometric method was found To be accurate, precise, robust, rugged, reliable and Cost-effective. Hence, it can be employed for the Routine quantitative analysis of Pregabalin in bulk And capsules using a UV spectrophotometer.

In the present investigation of, UV method for the quantitative estimation of Pregabalin in Pharmaceutical dosage form has been developed and validated. The proposed UV method is more sensitive, accurate and precise and is suggested for routine Analysis.

A simple, accurate, and precise UV spectrophotometric method was successfully developed for The estimation of the new pregabalin derivative in capsule dosage form.

The method follows Beer-Lambert's law within the selected concentration range and shows Excellent linearity.

Validation parameters such as accuracy, precision, LOD, LOQ, and robustness were found to Be within acceptable limits as per ICH guidelines.

The developed method is cost-effective, rapid, and suitable for routine quality control analysis.Therefore, the method can be reliably used for the quantitative determination of the drug in Pharmaceutical formulations.

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