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A Review on Analytical Method Development andValidation (With Case Study)

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ABSTRACT
Analytical technique development, validation, and transfer are critical components of any pharmaceutical development effort. Effective method development optimizes laboratory resources and ensures techniques meet drug development objectives at all stages.
High performance liquid chromatography is a reliable technology for analyzing medicinal products, both qualitatively and quantitatively. Developing and validating analytical methods is crucial for drug discovery, development, and manufacturing. It comprises determining the purity and toxicity of a pharmacological substance.
Method development for the interested component in finished product or in process tests and the sample preparation of drug product and to provide practical approaches for determining selectivity, specificity, limit of detection, limit of quantitation, linearity, range accuracy, precision, recovery solution stability, ruggedness, and robustness of liquid chromatographic methods to support the Routine, in process and stability analysis.
Keywords – Analytical Method Development. Method Validation, Accuracy, Precision, LOD,LOQ, System Suitability ,case Study on Climbazole and Montelukast

I. INTRODUCTION-

Any product or service needs analysis, but since drugs involve human life, they require it much more. The study of separation, measurement, and identification of chemical additives is known as analytical chemistry.[2]

Materials made of herbs and synthetics that contain one or more substances or ingredients. Two main classes make up analytical chemistry: qualitative evaluation, which identifies the chemical additives present in the sample, and quantitative evaluation, which calculates the quantity of positive detail or compound present in the substance, or sample.[3,]

Pharmaceutical analysis plays a very outstanding role in the examination of pharmaceutical formulations and bulk drugs regarding the quality control and assurance.[4,5]

The development of analytical tools has led to advances in scientific and practical analytical approaches. The time and cost of analysis have decreased and precision and accuracy have increased due to advancements in analytical technique development and analytical instrumentation.[6] An essential component of the requirements for regulatory organizations is the development and validation of analytical techniques for active pharmaceutical ingredients, excipients, related substances, drug products, degradation products, residual solvents, etc.[7]

Analytical method development finally results in official test method.[9]Consequently quality control laboratories used these methods to check the efficacy, identity, purity, safety as well as performance of products of the drug. The significance of analytical procedures in production is highly valued by regulatory bodies. Drug approval by regulatory authorities requires the applicant to prove control of the entire process of drug development by using validated analytical methods.[10]

DEFINITION ON VALIDATION-

The FDA (FOOD AND DRUG ADMINISTRATION) defines validation as a production and process control procedure that ensures the identity, strength, quality, and purity of drug products. FDA guidelines from May 1987 state that the validation package needs to include all the data and test procedures needed to demonstrate that the system and process satisfy the standards.[8,29]

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ANALYTICAL METHOD DEVELOPMENT-

For the analysis of novel products, new methods are being developed when authoritative methods are not accessible. Novel techniques are created to examine the current pharmacopoeialor non-pharmacopoeial products and save costs while improving robustness and precision.

These methods are optimized and validated through trial runs. With all available benefits and drawbacks, alternative approaches are suggested and implemented to replace the current strategy in the comparative laboratory data.[11-14]

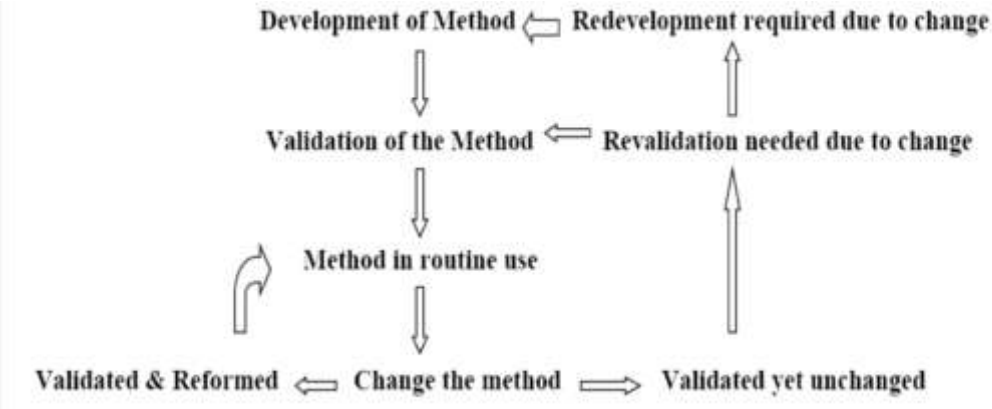

Fig. 1: Life cycle of the analytical method[15]

PURPOSE OF ANALYTICAL METHOD DEVELOPMENT-

The identification, characterization, and determination of pharmaceuticals in mixtures, such as dosage forms and biological fluids, are revealed by drug analysis. The primary goal of analytical methods in the manufacturing process and drug development is to provide information about potency (which can be directly related to the need for a known dose), impurity (related to the drug's safety profile), bioavailability (which includes important drug characteristics like crystal form, drug uniformity, and drug release), stability (which indicates the products of degradation), and the impact of manufacturing parameters to guarantee consistent drug product production.[2,16]

The goal of quality control is to evaluate and identify a true and correct product through a set of procedures meant to prevent and eliminate mistakes at various production stages. A product's release or disposal decision is based on one or more types of control actions. Ensuring a straightforward and analytical procedure for diverse complex formulations is an extremely significant topic. The need for new analytical techniques in the pharmaceutical industry has quickly increased due to the industries' rapid growth and continuous drug production across the globe. As a result, developing analytical methods has become the fundamental analysis task in a quality control laboratory.[6]

NEED OF ANALYTICAL METHOD DEVELOPMENT VALIDATION-

- Available method can be too costly, time ingesting or power extensive, or that won't be without problems computerized.
- Present approach can be too much errors, infection susceptible or they may be unreliable.
- Present approach may not offer adequate sensitivity.
- For requirements related to regulations, it's necessary.
- The main criteria for choosing drugs while developing a new analytical method.
- The drug or drug combination might not be dependable according to any pharmacopoeias.
- Because of the interference caused by the excipients in the formula, analytical procedures may not be available for the drug in the form of a formula.
- There won't be an analytical method available for quantifying the medication in biological fluids.

  There won't be analytical methods accessible for a medicine when combined with other drugs.[18-20]

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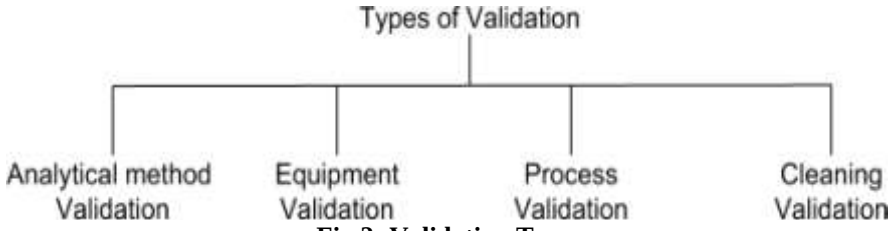

Fig 2: Validation Type

ANALYTICAL METHOD VALIDATION-[1, 22-23]

Method validation, as defined by ICH Q2 (R1), involves establishing written proof that a process consistently produces desired results within predetermined parameters and quality characteristics.

Analytical processes must be appropriate for their intended application and support the identity, quality, purity, and potency of pharmacological substances and products. Method validation is necessary for both new and established methods utilized across several laboratories and analysts.

The performance characteristics required to validate various methods by using various guidelines such as USP, ICH, FDA, European guidelines etc.

1. According to USP

The analytical parameters can be validated are accuracy, precision, specificity, detection of limit, quantitation limit, linearity, range, ruggedness and robustness.

2. According to ICH

The analytical parameters can be validated are accuracy, precision, specificity, detection of limit, quantitation limit, linearity, range, system suitability and robustness.

3. According to FDA

The analytical parameters can be validated are accuracy, precision, specificity/selectivity, detection of limit, quantitation limit, linearity, range, system suitability, reproducibility, sample solution stability and robustness.

4. According to European guidelines

The analytical parameters can be validated are accuracy, precision, specificity, detection of limit, quantitation limit, linearity and range

Analytical methods need to be validated, verified, or revalidated in the following instances (24)

- Before initial use in routine testing
- When transferred to another laboratory
- Whenever the conditions or method parameters for which the method has been validated change (for example, an instrument with different characteristics or samples with different matrix).

Types of analytical procedures to be validated[25]

The following types analytical procedures to be validated.

- Identification tests
- Quantitative tests for impurities content
- Limit tests for the control of impurities
- Quantitative tests of the active moiety in samples of drug substance or drug product.

1. Identification Test –

Identification tests are used to ensure the identity of an analyte in a sample. This is normally achieved by comparison of a property of the sample to that of a reference standard

2.Quantitative tests and Limit tests for impurity control

Testing of impurities can be performed by using a quantitative test or a limit test for the impurity in a sample. Different validation parameters are required for a quantitative test than for a limit test

3.Quantitative tests of the active moiety in samples of drug substance or drug product

In this type, assay procedures are used to measure the analyte present in a given sample. The assay represents a quantitative measurement of the major component(s) in the drug substance.

OBJECTIVES OF METHOD VALIDATION-[26]

- To obtain consistent, reliable and true data.
- To demonstrate that it is suitable for its intended purpose.
- To form a base for written procedure for production and process control which are designed to assure that the drug products have the identity, strength, quality and purity.
- To hold the quality, safety and efficacy in final product.

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- To control each step of manufacturing process.
- To produce the best analytical results possible.
- It decreases risk of regulatory noncompliance
- Critical parameters of the process can be fully understood due to analytical method.
- Minimization of interference on accuracy and precision

ADVANTAGESOF METHOD VALIDATION- [26-27]

- It builds a degree of confidence, not only for the developer but also to the user.
- Produces quality products.
- Reduce the product cost by increasing efficacy, few reject and longer equipment life.
- Helps in optimization of process or method.
- Helps in process improvement, technology transfer related products validation and increased employee awareness.
- It eliminates testing repetitions and leads to better time management in the end.

PARAMETERS OF ANALYTICAL METHOD VALIDATION-

The main aim of method validation is to produce proof that the method will what it is supposed to do, accurately, reliable and consistent.Analytical method have been validated in accordance with ICH requirements of Q2 (R1). The validation parameters are

- Accuracy
- Precision
- Repeatability
- Intermediate precision
- Reproducibility
- Specificity/Selectivity
- Limit of Detection (LOD)
- Limit of Quantitation (LOQ)
- Linearity
- Range
- Robustness
- Ruggedness
- System suitability testing.

1.Accuracy-

Accuracy refers to the degree of agreement between found values and existing data. It can alternatively be described as the closeness of the true value to the observed value. It is sometimes known as trueness.

Accuracy is defined as the ability to get at least 9 judgments from a minimum of three concentration levels within the prescribed range.[28]

Determination methods [29]

1.Application of analytical method to an analyte of known concentration–

To verify accuracy, apply the analytical method to a known pure analyte (e.g., reference standard) and compare the findings to verified alternate procedures.

2.Spiked – placebo recovery method -

This procedure involves adding a known amount of pure active elements to a formulation blank, which contains all other ingredients but the active. The resulting mixture is then assayed and compared to predicted results.

3.Standard addition method -

This method involves first assaying a sample and then adding a known amount of an active element to it. Following that, the sample is tested again. The differences between the two assays are compared to expected findings.

4.Recommended Data –

ICH document recommend that accuracy should be measured using a minimum of nine determinations per 3 concentration level.

Acceptance criteria –

The mean value should be within 15% of the expected value, except at the limit of quantification (LLOQ), when it should not exceed 20%. The deviation of the mean from the nominal value acts as an accuracy metric.

2.Precision -

For the homogeneous sample, sampling should be done for the multiple time. Precision are performed in predetermined condition.

The precision of an analytical method refers to the degree of agreement between successive measurements taken from the same homogeneous material under similar conditions.
The three types of precision which are repeatability, intermediate precision and reproducibility can be considered.[2]

Expressed as SD/ RSD[29]
% RSD = Standard Deviation/ Mean x 100

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3.Repeatability-[29-30]

Repeatability refers to the precision achieved under the same operating condition over a short period of timei.e analysis of replicates by the analyst using the same equipment and method. Repeatability is also known as intra-assay precision. It must be completed in small interval of time.

Evaluation of this test is done from nine conclusions. It should cover the specific range while preparing the sample.

4.Intermediate precision-[33]

This type of precision can be performed by variation in laboratory condition test can be done in alternate days, by another person, by other machine, etc.

The need for intermediate precision varies based on which procedure isintended to be used.

5.Reproducibility-[29]

This term refers to the precision of two-way studies used to standardize methods for adding procedures to pharmacopoeias

Reproducibility is assessed by means of an inter-laboratory trial.

Acceptance Criteria –

Precision at each concentration level should not exceed 15% of the coefficient of variation (CV), with the exception of the LLOQ, which should not exceed 20%.

6.Specificity-[29]

ICH defines assay specificity as the ability to reliably measure an analyte in the presence of other components in the sample medium. Specific methods give responses for only one analyte.

ICH document divides specifically in to three categories.

Identification tests –

To ensure the identity of an analyte.

Purity tests –

To ensure that all analytical procedures performed allow an accurate statement of the content of impurities of an analyte, i.e. related substances test, heavy metals etc

Assay –

To provide an exact result which allows an accurate statement on the content or potency of an analyte in a sample?

7.Selectivity-[29]

The method's selectivity for detecting the analyte in the presence of predicted sample matrix components. Simply put, it refers to a separative method's ability to resolve various molecules. It measures the relative placement of two peaks. This approach responds to many chemical entities, which may or may not be segregated. The determination is made by comparing test results for an analyte with and without addition of potentially interfering material

8.Limit of Detection (LOD)-[29,32]

The detection limit of an individual analytical procedure is the lowest amount of analyte in a sample which can be detected but not necessarily quantitated as an exact value

The LOD will not only depend on the procedure of analysis but also on type of instrument

Measurement is based on

- Visual evaluation.
- Signal to noise ratio.
- The standard deviation of the response and the slope

Visual evaluation –

LOD is determined by the analysis of samples with known concentration of analyte and by establish the minimum level at which the analyte can be detected. It can be used for instrumental and non-instrumental procedure

Signal to noise ratio –

This approach can only be applied to analytical procedure which shows baseline noise. It is performed by comparing measured signals from samples with known low concentration of analyte with those of blank samples and establishes the minimum concentration at which the analyte can be detected. Signal to noise ratio 2:1 or 3:1 is generally accepted.

The standard deviation of the response and the slope –

$LOD = 3.3\sigma/S$

σ = Standard deviation of the response.

S = Slope of the calibration curve of the analyte from regression line.

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9.Limit of Quantification-[29,17]

The minimum amount of analyte in a sample that can be quantitatively quantified with sufficient precision and accuracy. The quantitation limit is a parameter used in quantitative assays to determine low amounts of chemicals in sample matrices, including contaminants and degradation products. There are different ways for establishing the quantitation limit based on whether the procedure is non-instrumental or instrumental. Alternative approaches to those stated below may be acceptable.

- Based on Visual Evaluation
- Based on Signal-to-Noise Approach
- Based on the Standard Deviation of the Response and the Slope

Visual Evaluation –

LOD is determined by the analysis of samples with known concentration of analyte and by establish the minimum level at which the analyte can be detected. It can be used for instrumental and non-instrumental procedure

Signal-to-Noise Approach -

This approach can only be applied to analytical procedure which shows baseline noise. It is performed by comparing measured signals from samples with known low concentration of analyte with those of blank samples and establishes the minimum concentration at which the analyte can be detectedSignal to noise ratio 10:1 is generally accepted.

The standard deviation of the response and the slope –

LOD = 10 σ/**S**

σ = Standard deviation of the response.

S = Slope of the calibration curve of the analyte from regression line.

10.Linearity-[33]

Linearity is typically represented by the calibration curve indicates that the measurement or data from testing the material is directly proportional to the quantity of the testing chemical in sample. Such capacity is known as linearity.

It should be done withinrange.Thevalue of R2 is examined in the linearity. It must be within the rangei.eClose to one. Samples are prepared by diluting a typical stock solution or Weighing different quantities of samples according to protocol. Prepare solutions at various concentrations. At least five concentrations should be prepared for analysis. (ICH Harmonized Tripartite Guideline, 2005).

11.Range -

The range of an analytical procedure is the interval between the upper and lower concentration (amounts) of analyte in the sample (including these concentrations) for which it has been demonstrated that the analytical procedure has a suitable level of precision, accuracy and linearity.[29]

The following minimum specified ranges should be considered:[30]

- Assay of a drug substance or a finished (drug) product: 80 to 120 % of the test concentration.
- Content uniformity: 70 to 130 % of the test concentration.
- Dissolution testing: +/-20 % over the specified range;
- Impurities - reporting level – 120% of impurity specification limit

12.Robustness-[2]

Robustness is defined by the measure of the capability of an analytical method to stay unchanged by small deliberate changes in method parameters.

The variable method parameters in HPLC technique may involves flow rate, column temperature, sample temperature, pH and mobile phase composition.

13.Ruggedness-[30]

Ruggedness refers to the reproducibility of test results among laboratories and analysts, taking into account suggested variations in environment. The robustness of an analytical method refers to the reproducibility of test findings derived from the same samples under various settings, including different laboratories, analysts, instruments, reagents, temperature, and time.

14.System Suitability Testing-[30,33]

After validating a method or system, system suitability testing ensures that it performs within the validated limits. The tests consider the equipment, electronics, analytical operations, and samples to be analyzed as an integrated system that can be evaluated as such.

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Case Study 1 –

U. C. Galgatte perform research on Analytical Method Development and Validation of UV - Visible Spectrophotometer for the estimation of Climbazole

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ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF UV-VISIBLE SPECTROPHOTOMETRIC METHOD FOR THE ESTIMATION OF CLIMBAZOLE

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Keywords:
Climbazole, UV-spectrophotometry, Ethanol, Method Development, Validation, ICH Q2 (R1)

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ABSTRACT: Climbazole is a topical antifungal agent commonly used to treat human fungal skin infections such as dandruff and eczema. The goal of research work was to develop and validate a simple, precise, quick, and highly efficient UV spectrophotometric approach for quantifying Climbazole in bulk and shampoo dosage form. The quantification was completed using a twin beam UV spectrophotometer at 222 nm and ethanol (99.9%) as the solvent for the estimate. The Climbazole calibration curve exhibit strong correlation coefficient (R^2=0.9938) and high linearity in the range of 5–25 µg/ml concentrations. The accuracy was found to be between 98.21%- 99.83%. The accuracy of the approach was proved by the percent relative standard deviation being less than 2.0%. It was observed that the intraday and interday precision found within acceptable ranges. The method's sensitivity was assessed using the detection limit and quantification limit, which were discovered to be 2.37 µg/ml and 7.20 µg/ml, respectively. In this paper, we introduce a UV-spectrophotometric technique for investigating Climbazole using ethanol as solvent. The suggested method demonstrated excellent selectivity, specificity, and linearity in accordance with ICH Q2 (R1) requirements. Also, marketed pharmaceutical formulations were used to show the developed approach's efficiency and a high recovery rate. It is obvious that the suggested method will serve as a normative approach for the regular testing of Climbazole in pharmaceutical formulations and bulk dosage forms.

Climbazole has been Estimated by using UV Spectrophotometric Techniques with a Ethanol: Water (50:50) solvent solution

Climbazole's maximum absorbance wavelength was discovered to be 222 nm

II. RESULT AND DISCUSSION –

The newly established analytical technique was developed, optimized approved and used for the quantitative evaluation of Climbazole as a pure drug.

Linearity-[36]

Displays Climbazole's UV spectra and calibration curve into the ethanol at 222 nm. Climbazole's linearity was observed between 5-30 µg/ml, having a correlation coefficient of 0.9938.

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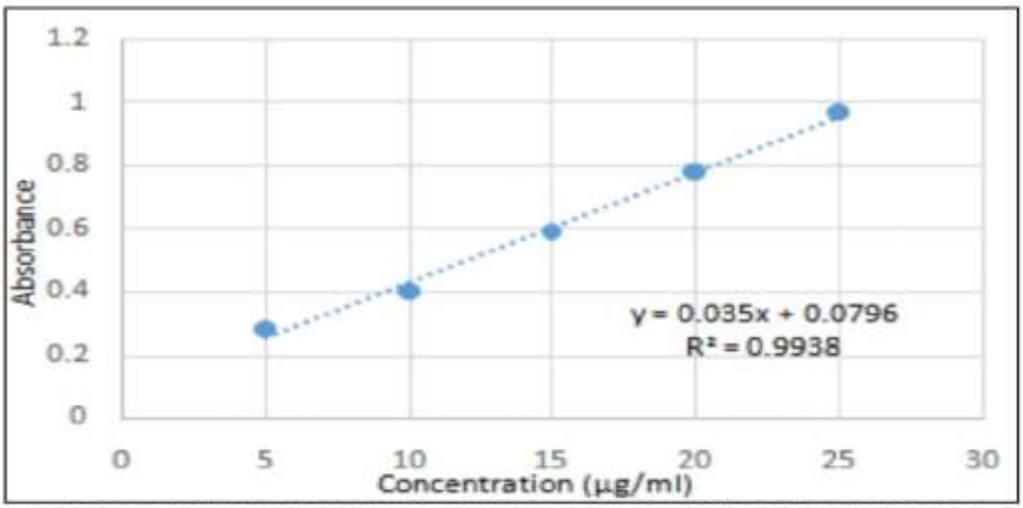

FIG. 3: CALIBRATION CURVE OF CLIMBAZOLE

Table 1: LINEARITY OFCLIMBAZOLE

Concentration(µg/ml)	Absorbance value
5	0.282
10	0.401
15	0.591
20	0.779
25	0.967
Regression equation	Y=0.035x +0.0796
R^2	0.9938

Range: The linearity has been observed in the 5-30 µg/ml range.

Accuracy:

Recovery studies were conducted to evaluate the accuracy of the UV Climbazole technique. The mean recovery rates for Climbazole were 98.21% at 80% standard addition, 99.83% at 100% standard addition, and 98.93% at 120% standard addition. According to the Climbazole recovery study, the percentage relative standard deviation (% RSD) was found to be less than 2, as shown in Table 2. These accuracy study results indicate that the UV method is highly effective, with a percent recovery range between 98.21% and 99.83% and an RSD well below 2%[37].

TABLE 2: ESTIMATION OF ACCURACY BY % RECOVERY METHOD

Sr.no	Concentration(%)	Sample conc. (µg/ml)	Amount added (µg/ml)	% Recovery	Statistical analysis
1	80	5	4	98.08	
2	80	5	4	98.40	
3	80	5	4	98.15	%RSD= 99.89
4	100	5	5	99.50	
5	100	5	5	101.04	
6	100	5	5	98.60	%RSD= 1.66
7	120	5	6	99	
8	120	5	6	99.80	
9	120	5	6	98.01	%RSD= 1.05

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Conc.: Concentration, RSD: Relative standard deviation.

Precision :

The proposed approach was demonstrated to be accurate as the average %RSD values for the intraday and interday precision studies were found to be 0.50% and 0.88%, respectively Table 3 and Table 4 [38]

TABLE 3: INTRADAY PRECISION STUDIES OF CLIMBAZOLE

Sample no	Concentration (µg/ml)	Absorbance			%RSD	Average %RSD
		Morning	Afternoon	Evening		
1	10	0.470	0.470	0.472	0.24%	
2	10	0.475	0.478	0.482	0.73%	0.050%
3	10	0.480	0.482	0.485	1.35%	

TABLE 4: INTERDAY PRECISION STUDIES OF CLIMBAZOLE

Sample no	Concentration (µg/ml)	Absorbance			%RSD	Average %RSD
		Day1	Day2	Day3		
1	10	0.431	0.435	0.440	1.03%	
2	10	0.452	0.455	0.460	0.88%	0.88%
3	10	0.482	0.484	0.489	0.74%	

Limit of Detection and Limit of Quantitation:

According to Table 5, the LOD and LOQ of the established UV technique were determined to be 2.37 and 7.20 µg/ml, respectively.

TABLE 5: EVALUATION DATA OF LOD AND LOQ

Drug	LOD(µg/ml)	LOQ (µg/ml)
Climbazole	2.37	7.20

LOD: Limit of detection, LOQ: Limit of quantitation.

Robustness –

The examination of the Climbazole solution in ethanol across different wavelengths (±2 nm) shows the reliability of the proposed method, indicating that variations in absorption levels have a minimal impact. Table 6 presents the robustness results from this study.[39,40]

Sample no	Concentration (µg/ml)	Wavelength			%RSD	Average %RSD
		220nm	222nm	224nm		
1	10	0.429	0.430	0.439	1.27%	
2	10	0.427	0.430	0.467	0.48%	1.05%
3	10	0.467	0.476	0.472	1.40%	

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Ruggedness :
Table 7 demonstrates that changing analysts did not significantly alter the outcome, confirming the robustness of the presented study.

Analysis	Sample no	Concentration (µg/ml)	Absorbance	Statistical analysis
Analyst 1	1	10	0.421	Mean ± SD = 0.4215±0.0007 % RSD = 0.167
	2	10	0.422	
		10	0.452	Mean ± SD = 0.4535±0.0021 % RSD = 0.467

Assay:
The assay of the commercially available product was observed to be 98% Table 8.

TABLE 8: ANALYSIS OF MARKETED FORMULATION

Sr .no	Sample	Absorbance	%Assay
1	Standard Solution	0.254	98%
2	Marketed Solution	0.249	

Case Study 2-[41]
Analytical method development and validation of Montelukast by UV:
Montelukast has been Estimated by using UV Spectrophotometric Techniques with alcohol and montelukast sodium Montelukast maximum absorbance wavelength was discovered to be 345nm

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ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR DETERMINATION OF MONTELUKAST BY UV-SPECTROSCOPY IN API& IN PHARMACEUTICAL DOSAGE FORMS

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ABSTRACT

An accurate, precise, and specific method developed for estimation of Montelukast in bulk. The API is used for the method development by UV spectroscopy with alcohol. The calibration curve method showed wavelength maxima for Montelukast at 345 nm with alcohol. This method obeys Beer's law in the concentration range of 5-30µg/ml with correlation coefficient 0.999 for Montelukast. The precision results are not more than 2%. The percentage assay of Montelukast in API and in pharmaceutical dosage form was 100.50% and 99.08% respectively. The results of analysis have been validated in order to verify linearity, precision, and accuracy for the goal intended and further implementation for the quantification analysis in the pharmaceutical dosage form. The newly developed spectroscopic method is used for the routine analysis for Montelukast in pharmaceutical dosage forms.

KEY WORDS
Method development, Montelukast, Validation, UV spectroscopy

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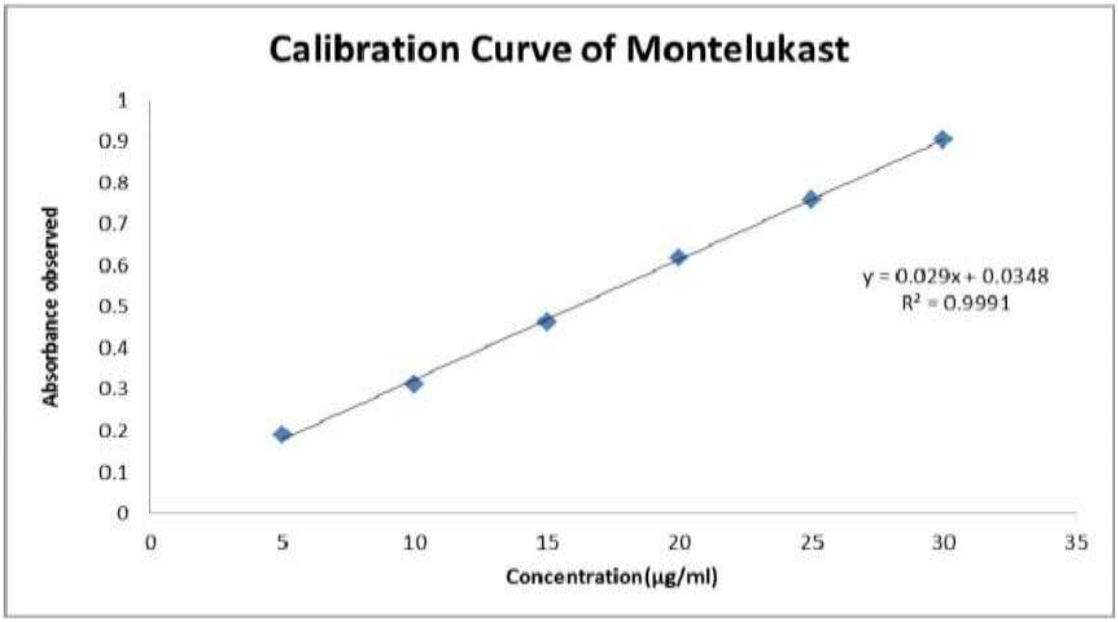
III. RESULT :

Validation of the development method performed according to ICH guidelines



Linearity and Range:

Sr.no	Concentration(µg/ml)	Absorbance
1	5	0.1908
2	10	0.312
3	15	0.4639
4	20	0.6199
5	25	0.7601
6	30	0.905

Precision :

Repeatability:

Nominal Conc.(µg/ml)	Absorbance	Observed Conc.(µg/ml)	Mean Conc.(µg/ml	S.D	%RSD
	0.1220	9.60			
	0.1128	9.98			
	0.1226	9.44	9.671	0.07	0.58
10	0.1129	10.01			
	0.1231	9.44			
	0.1127	9.56			

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	Nominal Conc.(µg/ml)	%RSD
Intra-day Precision	3	1.691
	8	0.366
	16	0.238 Mean: 0.765 %
Inter-day Precision	3	1.07
	8	0.30
	16	0.51 Mean :1.88 %

Accuracy:

Level %	%RSD
10	0.28
20	0.80
30	0.69 Mean:0.59

Assay :

Result of assay (API) :

Absorbance	%Assay
0.3250	101.65
0.3190	99.78
0.3200	100.09 Mean:100.50

Result of assay (Montecip):

Absorbance	%Assay
0.3146	98.40
0.3200	100.0
0.3160	98.84 Mean :99.08%

IV. CONCLUSION –

This review article gives idea that what is validation, its type, their purpose and why it is necessary and gives information about all validation parameter such as linearity, accuracy, precision, Range, LOD, LOQ, specificity etc.

Validation is necessary technique in the pharma department and it is used to assure that the quality is worked into the procedure supporting the development of drug and production.

The main objective of this review article is to improve the quality of analytical method development and validation.

The determination of Climbazole using UV spectroscopic analysis has been established and validated ,as stated in section Q2 (R1) of the ICH guidelines.

The %RSD in the validation parameters of both approaches was not more than 2%.

The accuracy of existing procedures was checked by performing accuracy parameters that revealed results within the range. Using intraday and interday precision tests, the precision of current procedures was verified. Test findings show that UV spectroscopy is one of the best methods for quantifying Climbazole.The newly developed method of Montelukast is simple, precise, and validate in terms of linearity, precision, accuracy, reproducibility. Therefore, the developed spectroscopic method used for routine estimation of Montelukast in tablet dosage form.

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