

Method Development and Evaluation of Furosemide Tablets Formulation with Validated Analytical Method

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ABSTRACT

Furosemide is a potent loop diuretic widely used in the treatment of edema associated with congestive heart failure, liver cirrhosis, and renal disease. The present study focuses on the formulation and evaluation of Furosemide tablets along with the development and validation of an analytical method for quantitative estimation of the drug. Tablets were prepared by direct compression method using suitable excipients. Pre-compression and post-compression parameters were evaluated to ensure acceptable tablet quality. A UV-visible spectrophotometric analytical method was developed for the estimation of Furosemide and validated according to ICH guidelines. The developed method showed good linearity, precision, accuracy, specificity, and robustness within the selected concentration range. The formulated tablets exhibited acceptable hardness, friability, weight variation, disintegration time, and drug content. Dissolution studies indicated satisfactory drug release. The study concludes that the developed formulation and analytical method are suitable for routine quality control analysis of Furosemide tablets.

Keywords: Furosemide, Tablet formulation, UV spectrophotometry, Method validation, Dissolution study, ICH guidelines.

I. Introduction:

Furosemide is a potent loop diuretic widely prescribed for the management of edema associated with congestive heart failure, liver cirrhosis, renal disorders, and hypertension. It acts primarily by inhibiting the sodium-potassium-chloride co-transporter in the ascending loop of Henle, thereby promoting rapid diuresis and enhanced excretion of

electrolytes. Due to its fast onset of action and significant therapeutic importance, furosemide has become one of the most commonly used diuretic agents in pharmaceutical therapy. Despite its extensive clinical use, the formulation of furosemide tablets presents several pharmaceutical challenges. Furosemide exhibits poor aqueous solubility and variable bioavailability, which can influence drug dissolution, absorption, and therapeutic efficacy. Therefore, the development of a stable and effective tablet formulation requires careful selection of excipients, optimization of manufacturing parameters, and evaluation of critical quality attributes such as hardness, friability, disintegration time, weight variation, and dissolution profile. The formulation process must ensure uniform drug distribution, adequate mechanical strength, and consistent release characteristics to achieve the desired therapeutic response.

In pharmaceutical industries, method development and validation play a crucial role in ensuring the quality, safety, and efficacy of dosage forms. Analytical method validation is an essential regulatory requirement recommended by the International Council for Harmonisation and other pharmacopeial authorities. A validated analytical method ensures that the developed method is reliable, accurate, precise, specific, and reproducible for routine quality control analysis. Among various analytical techniques, UV-visible spectrophotometry and high-performance liquid chromatography (HPLC) are commonly employed for the estimation of furosemide in bulk drugs and pharmaceutical formulations due to their simplicity, sensitivity, and cost-effectiveness. The present study focuses on the formulation development and evaluation of furosemide tablets along with the development and validation of an analytical method for quantitative

estimation of the drug. The prepared tablet formulations are evaluated using standard pharmacopoeial tests to assess their physicochemical properties and performance characteristics. Simultaneously, the analytical method is validated according to ICH guidelines with respect to parameters such as accuracy, precision, linearity, specificity, robustness, limit of detection (LOD), and limit of quantification (LOQ). The study aims to establish a stable tablet formulation and a reliable analytical procedure suitable for routine quality control and pharmaceutical analysis.

Furosemide is a potent loop diuretic extensively used in the treatment of edema associated with congestive heart failure, nephrotic syndrome, hepatic cirrhosis, and hypertension. It belongs to the sulfonamide class of drugs and acts by inhibiting the $\text{Na}^+\text{-K}^+\text{-2Cl}^-$ co-transporter in the thick ascending limb of the loop of Henle, resulting in increased excretion of sodium, chloride, potassium, and water. Due to its rapid onset and strong diuretic effect, furosemide remains an important therapeutic agent in emergency and chronic cardiovascular management.

Although furosemide is widely utilized clinically, its formulation into a stable and effective oral tablet dosage form is challenging because of its poor aqueous solubility and variable gastrointestinal absorption. Furosemide is classified under the Biopharmaceutical Classification System (BCS) as a Class IV drug, exhibiting both low solubility and low permeability, which may lead to inconsistent bioavailability. Therefore, optimization of formulation parameters is necessary to improve dissolution characteristics and ensure uniform therapeutic action. The selection of suitable excipients such as binders, diluents, lubricants, disintegrants, and glidants significantly influences tablet performance and stability.

Tablet dosage forms are among the most preferred pharmaceutical preparations due to their convenience, accurate dosing, ease of administration, cost-effectiveness, and patient compliance. The development of furosemide tablets requires careful consideration of pre-formulation studies including drug-excipient compatibility, flow properties, compressibility, and stability characteristics. Various formulation techniques such as direct compression and wet granulation can be employed depending on the physicochemical properties of the drug and excipients. Among these, wet granulation is commonly used to improve

flowability and compressibility of poorly flowing drugs.

Evaluation of tablet formulations is a critical step in pharmaceutical development to ensure product quality and compliance with pharmacopoeial standards. The prepared tablets are generally evaluated for parameters including thickness, hardness, friability, weight variation, disintegration time, drug content uniformity, and in vitro dissolution studies. These tests help determine the mechanical integrity, uniformity, and drug release behavior of the dosage form. Dissolution studies are particularly important for furosemide tablets because the rate and extent of drug release directly influence bioavailability and therapeutic efficacy.

Analytical method development and validation are equally important components in pharmaceutical research and quality control. Reliable analytical methods are required for the estimation of furosemide in bulk drug substances and finished pharmaceutical formulations. Analytical techniques such as UV-visible spectrophotometry and High-Performance Liquid Chromatography (HPLC) are frequently used because of their sensitivity, specificity, simplicity, and reproducibility. The developed analytical method must be capable of accurately quantifying the drug without interference from excipients, impurities, or degradation products. According to the guidelines established by the International Council for Harmonisation, analytical method validation is essential to demonstrate that the method is suitable for its intended purpose. Validation parameters typically include linearity, accuracy, precision, specificity, robustness, ruggedness, limit of detection (LOD), and limit of quantification (LOQ). A validated analytical method ensures consistency in quality control testing and regulatory acceptance of pharmaceutical products.

In recent years, there has been growing emphasis on the development of cost-effective and reproducible pharmaceutical formulations with enhanced therapeutic performance. Research on furosemide tablets focuses not only on improving dissolution and stability but also on developing analytical methods that are rapid, precise, and economical for routine industrial application. Such studies contribute significantly to pharmaceutical quality assurance and support the production of safe and effective medications. The present research work is aimed at the development and evaluation of furosemide tablet formulations along with the validation of an analytical method for quantitative

estimation of the drug. The study involves formulation optimization, physicochemical evaluation, dissolution assessment, and analytical method validation as per ICH guidelines. The developed formulation and validated method are expected to provide a reliable approach for routine quality control and pharmaceutical manufacturing of furosemide tablets. The increasing demand for high-quality pharmaceutical products has created the need for robust formulation strategies and validated analytical techniques. Research involving formulation development and analytical method validation contributes significantly to improving product quality, therapeutic effectiveness, patient safety, and industrial productivity. In the case of furosemide tablets, optimization of formulation variables along with the establishment of a reliable analytical method is essential for maintaining batch-to-batch consistency and ensuring compliance with

pharmacopeial standards. The present study is therefore focused on the development and evaluation of furosemide tablet formulations using suitable pharmaceutical excipients and manufacturing techniques. The study also includes the development and validation of an analytical method for quantitative estimation of furosemide in tablet dosage forms according to ICH guidelines. The formulated tablets are evaluated for various physicochemical parameters and dissolution characteristics, while the analytical method is validated for accuracy, precision, linearity, specificity, robustness, LOD, and LOQ. The findings of this research are expected to provide a stable, effective, and quality-assured formulation along with a reliable analytical procedure suitable for routine pharmaceutical quality control and industrial applications.

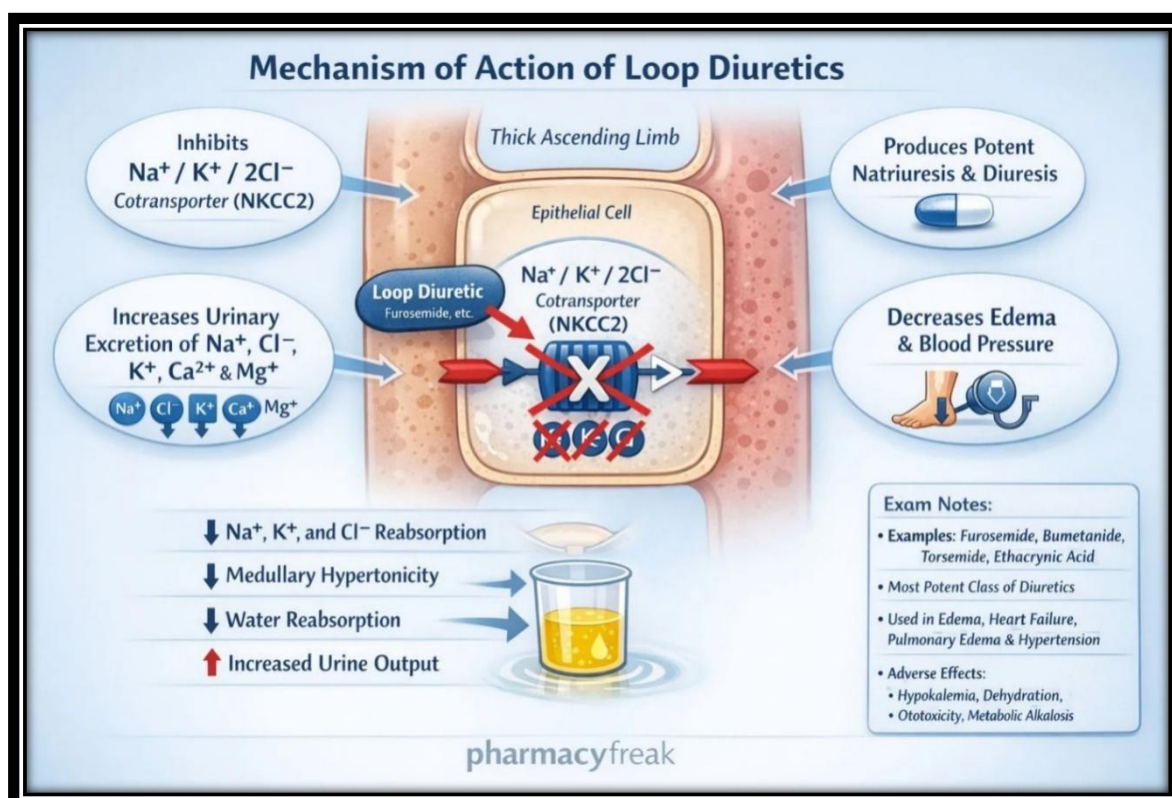



Fig: Mechanism of Action of Furosemide

Objective of study:

1. To develop a suitable tablet formulation of Furosemide using appropriate pharmaceutical excipients.
2. To evaluate the pre-formulation parameters of the drug and excipients.
3. To prepare furosemide tablets by suitable manufacturing technique such as wet granulation or direct compression.
4. To evaluate the prepared tablets for physicochemical parameters including hardness, friability, thickness, weight

- variation, disintegration time, and drug content.
5. To perform in vitro dissolution studies of the formulated tablets.
 6. To develop a simple, accurate, and precise analytical method for estimation of furosemide.
 7. To validate the developed analytical method according to International Council for Harmonisation guidelines.
 8. To determine validation parameters such as accuracy, precision, linearity, robustness, specificity, limit of detection (LOD), and limit of quantification (LOQ).
 9. To compare the evaluation results of formulated tablets with official pharmacopeial standards.
 10. To establish a stable and effective furosemide tablet formulation suitable for routine pharmaceutical use

Drug Profile:

Parameter	Information
Drug Name	Furosemide
Brand Name	Lasix
Structure	
Weight	330.745g/mol
Chemical formula	C ₁₂ H ₁₁ ClN ₂ O ₅
IUPAC Name	4-chloro-2-(furan-2-ylmethylamino) -5-sulfamoylbenzoic acid
BCS Class	Class IV
Half life	2 Hours
Pka 1	3.8
Pka2	3.9
Log P	2.3
Particle size	120nm to 360nm
Hygroscopicity	Solid Dispersion

Polymorphic form	Form 1 and 2
Solid state Stability	Stable for room Temperature
Melting Point	between 205°C and 220°C
T max	(T max, 2.4 +/- 2.5 hours)

II. Literature Review:

- (Patel et al., 2022):** Studies on Furosemide API have demonstrated its effectiveness as a potent loop diuretic used in the management of edema associated with congestive heart failure, liver cirrhosis, and renal disease. The drug acts by inhibiting sodium and chloride reabsorption in the thick ascending limb of the loop of Henle, leading to increased urine output. However, its poor aqueous solubility significantly affects its bioavailability.
- (Kumar et al., 2021):** Research on oral tablet formulations of Furosemide highlights challenges related to its low solubility and variable gastrointestinal absorption. The drug shows pH-dependent solubility, being more soluble in alkaline conditions. Various formulation strategies such as solid dispersions and use of surfactants have been explored to enhance dissolution rate and improve therapeutic efficacy.
- (Sharma et al., 2020):** The physicochemical characterization of Furosemide API indicates that it is a BCS Class IV drug, possessing low solubility and low permeability. Techniques such as micronization, complexation, and use of hydrophilic polymers have been investigated to improve its dissolution profile and bioavailability.
- (Singh et al., 2020):** Analytical methods including UV spectroscopy and HPLC have been widely used for the quantitative estimation of Furosemide in pharmaceutical dosage forms. These methods provide high accuracy, precision, and reproducibility for routine quality control analysis.

- (Brijesh et al., 2019):** Studies on tablet evaluation parameters of Furosemide formulations reveal that hardness, friability, disintegration time, and dissolution rate are critical factors influencing drug release. Optimization of excipients plays a key role in achieving desired release characteristics.
- (Anderson et al., 2009):** Stability studies of Furosemide API indicate that the drug is sensitive to light and moisture, which may lead to degradation. Proper packaging and storage conditions are essential to maintain its stability and therapeutic effectiveness over time.

III. Materials and Methods:

The active pharmaceutical ingredient used in the present study was Furosemide. Various pharmaceutical excipients were selected for the preparation of tablet formulations based on their functional properties and compatibility with the drug. Lactose was used as a diluent to increase tablet bulk and improve compressibility. Starch was used as a disintegrating agent to facilitate rapid tablet breakdown after administration. Polyvinyl pyrrolidone (PVP K-30) was used as a binder to provide mechanical strength to granules and tablets. Magnesium stearate was employed as a lubricant to reduce friction during compression, while talc was used as a glidant to improve flow properties of granules. All chemicals and reagents used in the analytical studies were of analytical grade. Methanol, distilled water, phosphate buffer, and other solvents used during analytical method development were procured from standard laboratory suppliers. The materials used throughout the study complied with pharmacopeial standards.

Instruments and Equipment:

The instruments used during formulation development and analytical studies included a digital weighing balance, mortar and pestle, sieve shaker, hot air oven, tablet compression machine, Monsanto hardness tester, Roche friabilator, disintegration test apparatus, dissolution test apparatus, UV-visible spectrophotometer, pH meter, and glassware required for laboratory analysis. All instruments were calibrated before use to ensure accuracy and reliability of experimental results.

IV. Methodology:

Preformulation Studies

Preformulation studies were carried out to determine the physicochemical properties of furosemide and to evaluate its suitability for tablet formulation. The drug was examined for

organoleptic properties such as color, odor, and appearance. Solubility studies were performed in different solvents including distilled water, methanol, and phosphate buffer to determine the solubility characteristics of the drug. The melting point of furosemide was determined using the capillary method to assess drug purity.

Flow properties of the drug powder were evaluated by determining bulk density, tapped density, angle of repose, Carr's index, and Hausner ratio. These studies helped in assessing the flowability and compressibility of the powder blend. Drug-excipient compatibility studies were also performed to identify any possible interaction between the drug and excipients during formulation development.

Sr.No	Parameter	Inference
1	Nature	Crystalline powder
2	Color	White
3	Melting point	209 °C
4	Odor	Odorless
5	Taste	Slightly bitter
6	ph	4-6 (Slightly soluble)
7	Appearance	Crystalline powder

Preparation of Calibration Curve

A standard stock solution of furosemide was prepared by dissolving an accurately weighed quantity of the drug in a suitable solvent such as methanol or phosphate buffer. From the stock solution, a series of dilutions were prepared to obtain different concentrations. The absorbance of each solution was measured using a UV-visible spectrophotometer at the selected wavelength of

maximum absorption (λ_{max}). A calibration curve was constructed by plotting concentration versus absorbance, and the linearity of the method was evaluated.

Formulation of Furosemide Tablets

The tablets were prepared by the wet granulation method. Accurately weighed quantities of furosemide and excipients were passed through a suitable sieve to obtain uniform particle size. The

drug and diluent were mixed thoroughly in a mortar to ensure uniform distribution. Binder solution containing PVP K-30 was prepared separately and added slowly to the powder mixture to form a coherent wet mass. The wet mass was passed through a sieve to prepare granules and dried in a hot air oven at controlled temperature until adequate moisture removal was achieved. The dried granules were again passed through a sieve to break aggregates and obtain uniform granule size. Magnesium stearate and talc were added to the dried granules and mixed properly to improve lubrication and flow properties. The lubricated granules were

compressed into tablets using a tablet compression machine with suitable punches and dies. The prepared tablets were stored in airtight containers for further evaluation studies.

Evaluation of Granules

Before compression, the prepared granules were evaluated for pre-compression parameters such as bulk density, tapped density, angle of repose, Carr's index, and Hausner ratio. These parameters were studied to determine the flowability and compressibility characteristics of the granules.

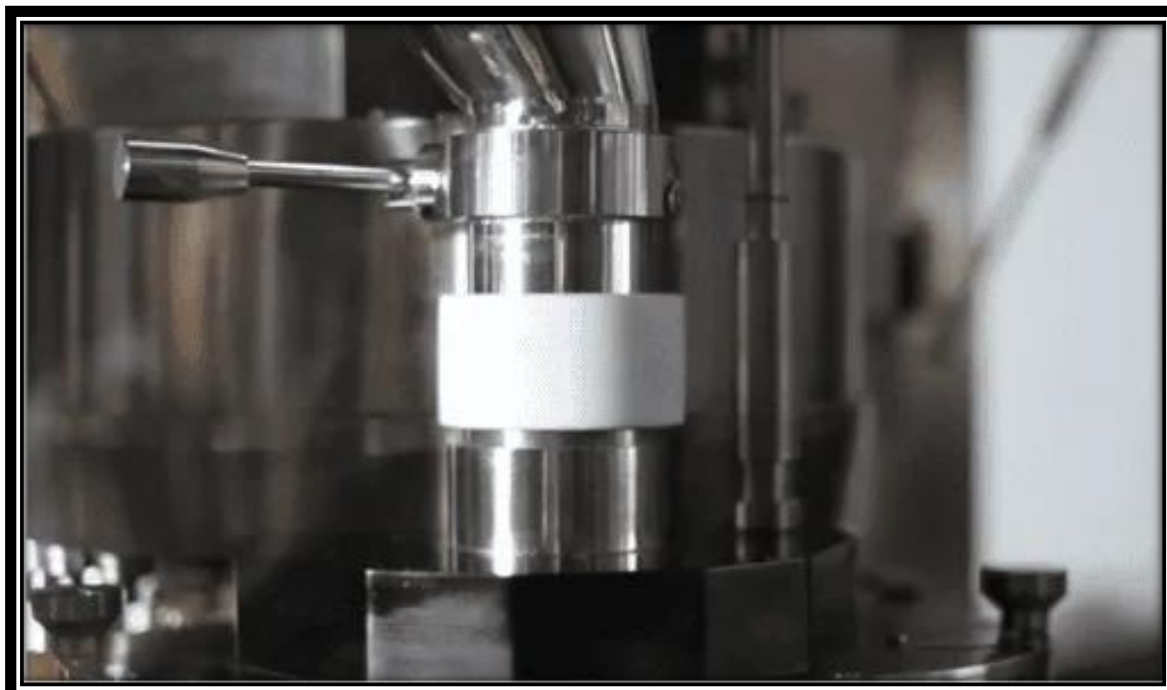


Fig: Tablet Punching Machine

Evaluation of Tablets

The prepared tablets were evaluated for various post-compression parameters according to pharmacopeial standards.

Weight Variation Test

Twenty tablets were selected randomly and weighed individually using a digital balance. The average weight was calculated and compared with individual tablet weights to determine weight uniformity.

Thickness Test

The thickness of tablets was measured using a vernier caliper to ensure uniformity in tablet size.

Hardness Test

Tablet hardness was determined using a Monsanto hardness tester to evaluate the mechanical strength of the tablets.

Friability Test

Friability testing was carried out using a Roche friabilator. Tablets were rotated at a specified speed, and percentage weight loss was calculated to determine resistance to abrasion.

Disintegration Test

The disintegration time of tablets was determined using a disintegration test apparatus in distilled water maintained at $37 \pm 0.5^\circ\text{C}$. The time required for complete tablet disintegration was recorded.

Drug Content Uniformity

An accurately weighed quantity of powdered tablets equivalent to a specific amount of furosemide was

dissolved in suitable solvent and analyzed spectrophotometrically. The percentage drug content was calculated.

Analytical Method Development

An analytical method for estimation of furosemide was developed using UV-visible spectrophotometry. Different solvents and wavelengths were evaluated to obtain maximum sensitivity and accuracy. The wavelength showing maximum absorbance was selected for quantitative analysis. Standard and sample solutions were prepared under optimized conditions and analyzed for absorbance.

Method Validation

The developed analytical method was validated according to International Council for Harmonisation guidelines.

Linearity

Linearity was evaluated by analyzing different concentrations of furosemide and plotting a calibration curve between concentration and absorbance.

Accuracy

Accuracy was determined by recovery studies using standard addition method at different concentration levels.

Precision

Precision of the method was evaluated in terms of repeatability and intermediate precision by analyzing multiple samples under the same experimental conditions.

Specificity

Specificity was assessed by evaluating the ability of the method to measure the drug accurately in the presence of formulation excipients.

Robustness

Robustness was determined by introducing small deliberate variations in analytical conditions and observing their effect on results.

Limit of Detection and Limit of Quantification

LOD and LOQ were calculated using standard deviation and slope of calibration curve to determine the sensitivity of the method.

The validated analytical method was found suitable for routine quantitative analysis of furosemide in pharmaceutical tablet formulations.



Fig: Furosemide Tablet

**Evaluation Parameter:
Solubility of API (Furosemide):**



Fig:Solubility of API

UV of Test & Standard Sample:

Key Data Analysis

X-Axis (Wavelength): 200.000 nm to 400.000 nm.

Y-Axis (Absorbance): Scales from -0.72 to 4.62.

The Plateau: Your black curve is "flat-topping" or "clipping" around an absorbance of 3.5 to 4.0. In spectroscopy, this usually means the sample concentration is too high for the detector (saturation).

The Red Curve: This represents a much lower concentration or a different baseline, showing a clearer peak around 330–340nm

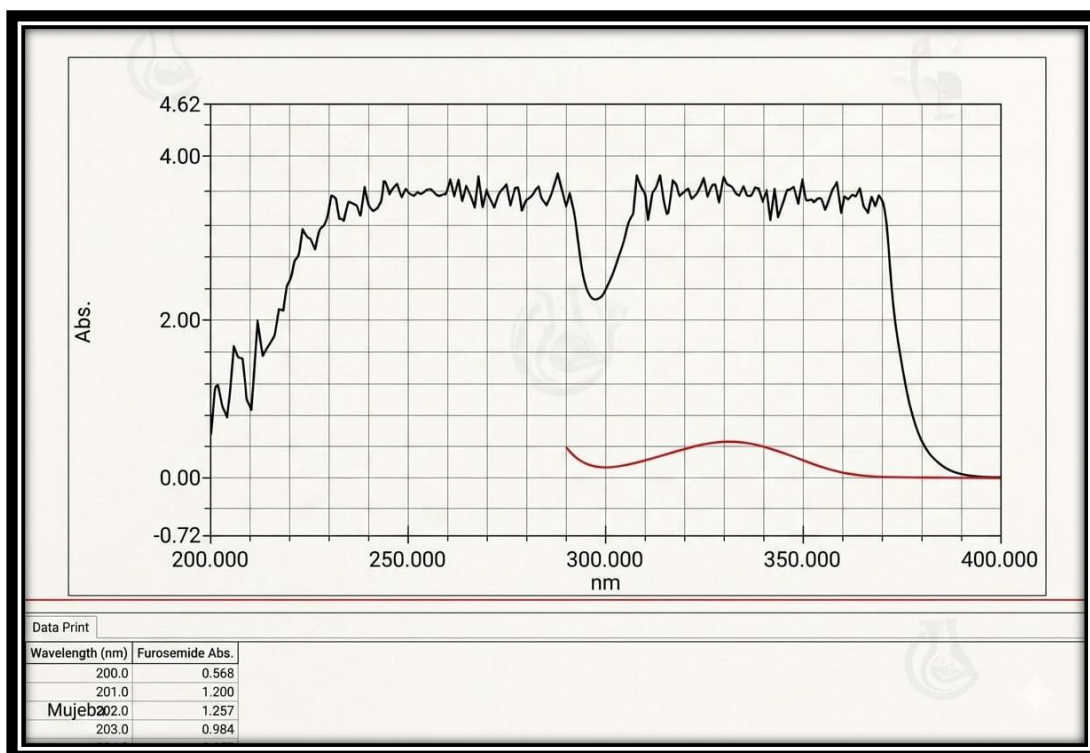


Fig: UV of Standard Tablet

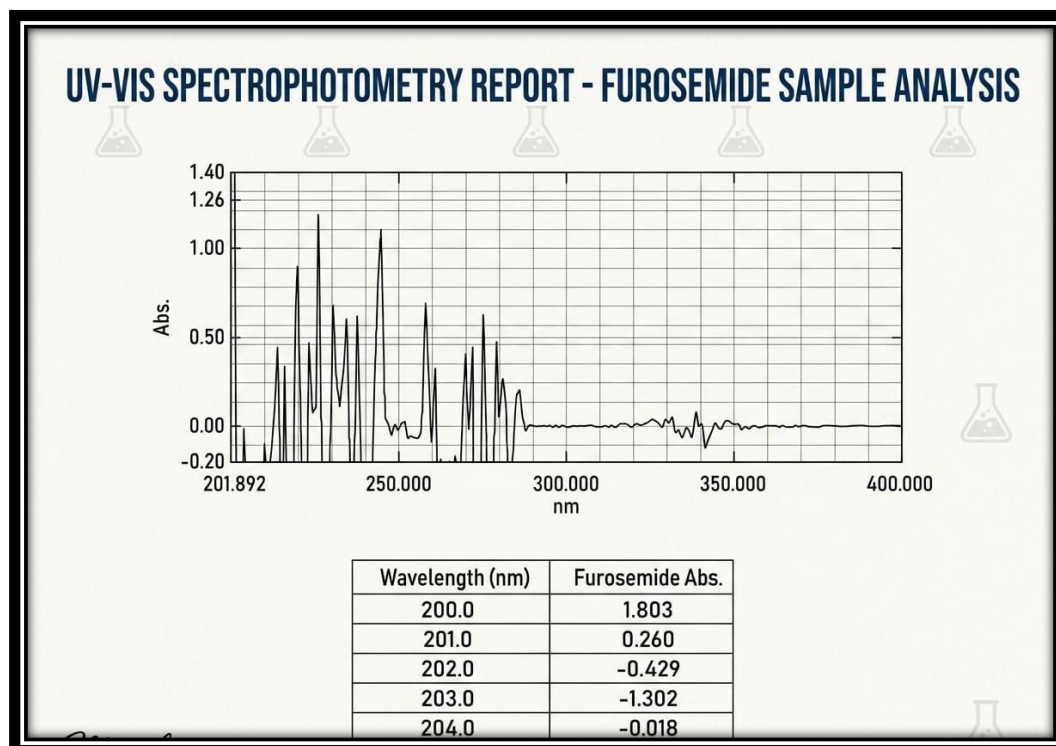


Fig: UV of Sample Tablet

TLC of Test & Sample:

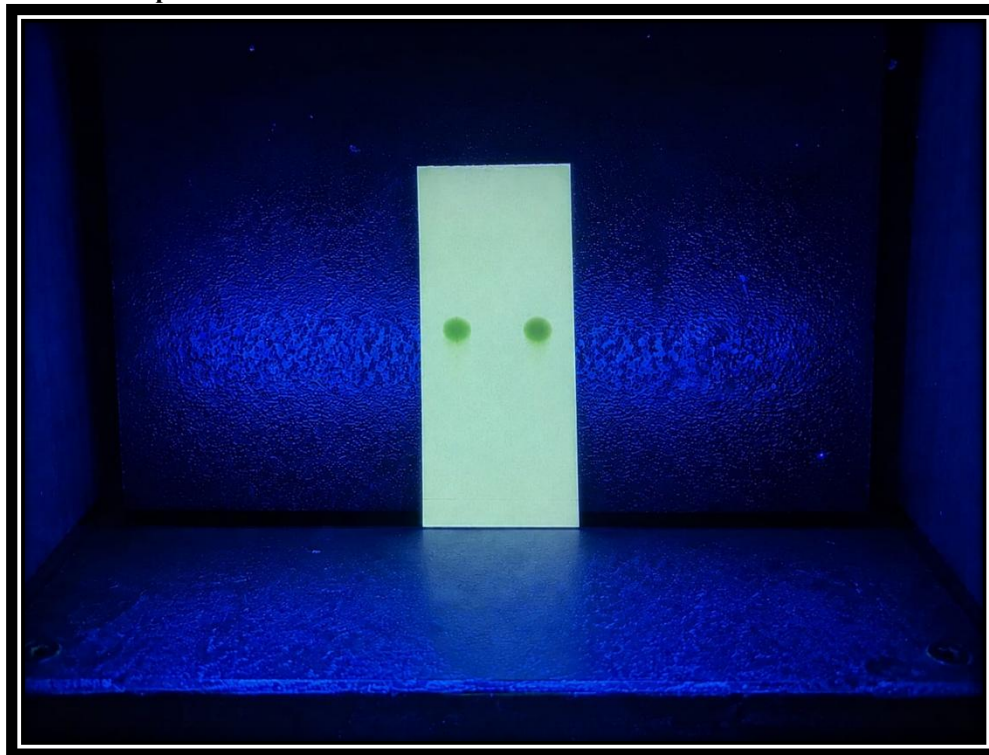


Fig: TLC of Test and Sample

V. Result:

The present research work was successfully carried out for the formulation and evaluation of Furosemide tablets along with the development and validation of a UV-visible spectrophotometric analytical method. The tablets were prepared using the wet granulation method with suitable pharmaceutical excipients including lactose, starch, PVP K-30, magnesium stearate, and talc. The prepared granules exhibited satisfactory flow properties, indicating good compressibility and suitability for tablet compression.

The formulated tablets were evaluated for various post-compression parameters such as weight variation, thickness, hardness, friability, disintegration time, and drug content uniformity. All evaluated parameters were found to be within acceptable pharmacopeial limits. The tablets showed adequate mechanical strength with acceptable hardness and friability values below 1%, indicating good resistance to abrasion during handling and transportation.

The disintegration test demonstrated that the tablets disintegrated within the prescribed pharmacopeial time limit, ensuring rapid drug release after administration. Drug content analysis

confirmed uniform distribution of Furosemide in the tablet formulations. Dissolution

studies indicated satisfactory drug release profiles, suggesting effective availability of the drug for absorption.

The UV-visible spectrophotometric analytical method developed for estimation of Furosemide showed maximum absorbance at the selected wavelength and obeyed Beer-Lambert's law within the selected concentration range. The calibration curve exhibited excellent linearity with a high correlation coefficient. Method validation studies performed according to ICH guidelines confirmed that the developed analytical method was accurate, precise, specific, robust, and reproducible. Recovery studies demonstrated good accuracy, while repeatability and intermediate precision studies indicated low percentage relative standard deviation values. The method was also found to be sensitive with suitable values of LOD and LOQ.

The TLC analysis of test and standard samples showed comparable retention characteristics, confirming the identity and purity of the drug. UV spectral analysis indicated proper absorption characteristics of Furosemide, although high absorbance plateau regions suggested that

dilution optimization was necessary for highly concentrated samples.

VI. Discussion:

Furosemide is a BCS Class IV drug characterized by poor aqueous solubility and low permeability, which presents significant formulation challenges. In the present study, the wet granulation method was selected because it improves the flowability and compressibility of poorly flowing drug powders. The granules produced showed satisfactory bulk density, tapped density, angle of repose, Carr's index, and Hausner ratio, indicating good flow properties suitable for compression.

The selection of excipients played an important role in achieving acceptable tablet characteristics. Lactose improved tablet bulk and compressibility, starch enhanced disintegration, and PVP K-30 provided sufficient binding strength to the granules. Magnesium stearate and talc improved lubrication and flow during compression. The optimized formulation produced tablets with uniform appearance, adequate hardness, and low friability, demonstrating proper mechanical integrity.

The dissolution profile of the formulated tablets indicated satisfactory drug release behavior. Since Furosemide possesses poor aqueous solubility, achieving an acceptable dissolution profile is essential for improving bioavailability and therapeutic efficacy. The use of wet granulation and suitable excipients contributed positively to dissolution enhancement.

The UV spectrophotometric method developed during the study proved to be simple, economical, rapid, and suitable for routine analysis of Furosemide tablets. The method demonstrated good linearity across the selected concentration range, confirming adherence to Beer-Lambert's law. Precision studies showed minimal variation in absorbance values, indicating high reproducibility of the analytical procedure.

Accuracy studies performed using the recovery method demonstrated that the developed analytical method could accurately estimate Furosemide in the presence of tablet excipients without interference. Robustness studies further confirmed that minor deliberate changes in analytical conditions did not significantly affect the results, highlighting the reliability of the method for routine quality control applications.

The TLC study confirmed the purity and identity of the drug sample by showing similar migration patterns for standard and test samples. UV spectral observations revealed a plateau effect at higher

concentrations, which may be attributed to detector saturation due to excessive absorbance values. This indicates the importance of appropriate dilution during spectrophotometric analysis to maintain absorbance within the optimal analytical range.

Overall, the findings of the present study demonstrate that the developed tablet formulation possesses acceptable pharmaceutical quality characteristics and that the validated UV spectrophotometric method is reliable for quantitative estimation of Furosemide in tablet dosage forms.

VII. Conclusion:

The present study successfully achieved the formulation and evaluation of Furosemide tablets along with the development and validation of a UV-visible spectrophotometric analytical method. The wet granulation technique was found to be suitable for preparing tablets with satisfactory physicochemical properties and acceptable mechanical strength.

The prepared tablets complied with pharmacopeial specifications for weight variation, hardness, friability, disintegration time, and drug content uniformity. Dissolution studies demonstrated satisfactory drug release, indicating the effectiveness of the developed formulation.

The analytical method developed for estimation of Furosemide was validated according to ICH guidelines and was found to be linear, accurate, precise, specific, robust, and reproducible. The method was suitable for routine quantitative analysis and quality control of Furosemide tablet formulations.

The overall study concludes that the developed formulation and validated analytical procedure provide a reliable, stable, and cost-effective approach for pharmaceutical manufacturing and routine quality control analysis of Furosemide tablets.

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