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Research

Comparative Dissolution Profiling of Norfloxacin 400 mg Tablets Using USP Apparatus I (Basket) and USP Apparatus II (Paddle)

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Abstract:
Dissolution testing is an essential quality control tool used to evaluate the rate and extent of drug release from oral solid dosage forms and to predict their in vivo performance. The present study was conducted to compare the dissolution behavior of Norfloxacin 400 mg tablets using USP Apparatus I (Basket) and USP Apparatus II (Paddle) under optimized experimental conditions. Norfloxacin, a second-generation fluoroquinolone antibiotic, exhibits pH-dependent solubility, making dissolution profiling an important parameter for assessing its pharmaceutical performance. The dissolution studies were performed using acetate buffer (pH 4.0) as the dissolution medium maintained at 37 ± 0.5°C. USP Apparatus I was operated at 100 rpm, whereas USP Apparatus II was operated at 50 rpm. Samples were collected at predetermined time intervals (5, 10, 15, 20, 30, 45, and 60 minutes) and analyzed using a validated UV–Visible spectrophotometric method at 278 nm. The cumulative percentage drug release obtained from both apparatuses was compared to evaluate the effect of hydrodynamic conditions on dissolution performance.The results demonstrated that both apparatuses provided satisfactory dissolution profiles and complied with pharmacopeial requirements. However, USP Apparatus II exhibited a comparatively faster drug release than USP Apparatus I. At 30 minutes, cumulative drug release was 89.76% for the Paddle apparatus and 82.94% for the Basket apparatus. At 60 minutes, the Paddle apparatus achieved 99.85% drug release, while the Basket apparatus showed 97.28% release. The enhanced dissolution observed with the Paddle apparatus may be attributed to improved mixing efficiency and hydrodynamic conditions around the dosage form. In conclusion, both USP Apparatus I and USP Apparatus II are suitable for dissolution testing of Norfloxacin tablets; however, USP Apparatus II demonstrated superior dissolution efficiency and may be considered the preferred method for routine quality control evaluation of immediate-release Norfloxacin formulations.

Keywords: Norfloxacin, Dissolution Testing, USP Apparatus I, USP Apparatus II, Basket Method, Paddle Method, Drug Release Profile, Quality Control.

1. Introduction

Dissolution testing is one of the most important quality control procedures used in the pharmaceutical industry for evaluating the release characteristics of drug substances from solid oral dosage forms. It provides critical information regarding the rate and extent of drug release into the dissolution medium and serves as an important predictor of in vivo drug performance. The dissolution behavior of a pharmaceutical product directly influences its bioavailability, therapeutic efficacy, and batch-to-batch consistency. Consequently, regulatory agencies such as the United States Food and Drug Administration (FDA), European Medicines Agency (EMA), and United States Pharmacopeia (USP) require dissolution testing as an essential component of drug development, quality assurance, and bioequivalence assessment.

Norfloxacin is a second-generation fluoroquinolone antibiotic widely used in the treatment of urinary tract infections, bacterial gastroenteritis, gonorrhea, and prostatitis. The drug exerts its antibacterial action by inhibiting bacterial DNA gyrase and topoisomerase IV, enzymes responsible for DNA replication and cell division. Despite its proven therapeutic effectiveness, Norfloxacin exhibits pH-dependent solubility and relatively low aqueous solubility under physiological conditions, making dissolution an important factor influencing its absorption and bioavailability.

Dissolution testing of oral dosage forms is commonly performed using compendial apparatus described in USP General Chapter <711>. Among these, USP Apparatus I (Basket) and USP Apparatus II (Paddle) are the most frequently employed methods for immediate-release tablet formulations. The Basket apparatus consists of a rotating wire mesh basket that contains the dosage form, whereas the Paddle apparatus utilizes a rotating paddle positioned above the tablet placed at the bottom of the dissolution vessel. Although both methods are widely accepted, differences in hydrodynamic conditions generated by these apparatuses can significantly affect drug release behavior and dissolution profiles.

Hydrodynamic conditions, agitation speed, dissolution medium composition, temperature, and dosage form characteristics collectively influence the dissolution process. The Paddle apparatus generally provides greater fluid circulation around the tablet surface, which may result in faster drug release, while the Basket apparatus is particularly useful for formulations that tend to float or disintegrate irregularly. Therefore, understanding the effect of dissolution apparatus selection on drug release behavior is essential for developing robust and discriminatory dissolution methods.

Several studies have reported the importance of dissolution testing in assessing pharmaceutical equivalence and predicting in vivo drug performance. However, limited research is available comparing the dissolution characteristics of Norfloxacin tablets using USP Apparatus I and USP Apparatus II under identical experimental conditions. Such comparative investigations are important because variations in dissolution methodology can influence product evaluation, regulatory acceptance, and quality control decisions. Therefore, the present study was undertaken to compare the dissolution profiles of Norfloxacin 400 mg tablets using USP Apparatus I (Basket) and USP Apparatus II (Paddle). The study aims to evaluate the influence of different hydrodynamic environments on drug release behavior and identify the most suitable apparatus for routine dissolution testing of Norfloxacin tablets. The findings of this research may contribute to improved method selection, quality assurance practices, and regulatory compliance in pharmaceutical analysis.

2. Literature Review

Dissolution testing is a fundamental component of pharmaceutical quality control and plays a significant role in predicting the in vivo performance of oral dosage forms. Over the years, numerous researchers have investigated factors influencing drug dissolution, including drug physicochemical properties, dissolution media, hydrodynamic conditions, and dissolution apparatus design.

The concept of dissolution as a predictor of drug absorption was strengthened by the introduction of the Biopharmaceutics Classification System (BCS) by Amidon et al. (1995). The authors classified drugs based on their solubility and permeability characteristics and highlighted that dissolution is

often the rate-limiting step for absorption of poorly soluble drugs. Norfloxacin was identified as a drug whose bioavailability is significantly influenced by dissolution behavior, emphasizing the importance of reliable dissolution testing methods.

Diez-Sales et al. (1996) developed a miniaturized dissolution method using a reduced dissolution medium volume. Their study demonstrated that smaller dissolution systems could generate meaningful and reproducible results while more closely simulating physiological conditions. This work highlighted the importance of optimizing dissolution testing conditions to improve the predictability of in vitro studies.

Dressman et al. (1998) emphasized the role of dissolution testing as a prognostic tool for oral drug absorption. The researchers reported that dissolution behavior is strongly influenced by hydrodynamic conditions generated within the dissolution vessel. Their findings suggested that apparatus selection can significantly affect dissolution outcomes, particularly for drugs exhibiting low aqueous solubility.

Shah et al. (1998) introduced the similarity factor (f_2) and difference factor (f_1) as statistical tools for comparing dissolution profiles. These mathematical approaches became internationally accepted methods for evaluating the equivalence of dissolution profiles and remain widely used in pharmaceutical development and regulatory submissions.

Costa and Sousa Lobo (2001) reviewed various mathematical models used to characterize drug release kinetics, including zero-order, first-order, Higuchi, Hixson–Crowell, and Korsmeyer–Peppas models. Their work provided a comprehensive understanding of dissolution data interpretation and remains an important reference in dissolution profile analysis.

Khalil et al. (2002) investigated the effect of raw material characteristics on the dissolution performance of Norfloxacin tablets using USP Apparatus II (Paddle). The study demonstrated that variations in excipient properties and manufacturing conditions could significantly influence drug release behavior. More than 80% of Norfloxacin was released within 30 minutes under optimized conditions, satisfying pharmacopeial requirements.

Kassab et al. (2005) developed and validated a high-performance liquid chromatography (HPLC) method for quantitative estimation of Norfloxacin in tablet formulations. Their findings highlighted the importance of accurate analytical methods in supporting dissolution studies and ensuring product quality.

Adegbolagun et al. (2007) evaluated the bioequivalence of different pharmaceutical products and reported that formulation variables and manufacturing processes significantly affect dissolution characteristics. Their work reinforced the importance of dissolution testing as a quality assurance tool for generic drug products.

Fromsa et al. (2010) assessed the dissolution performance of several commercially available Norfloxacin tablet brands using USP Apparatus II. Significant differences in dissolution rates among different brands were observed, indicating the necessity of robust and discriminatory dissolution methodologies for quality assessment.

Vlaia et al. (2012) investigated the dissolution behavior of Norfloxacin in both compendial and biorelevant dissolution media. The researchers found that dissolution was rapid in acidic media but varied substantially under intestinal conditions. The study emphasized the importance of dissolution medium selection during method development.

de Oliveira et al. (2013) developed extended-release Norfloxacin matrix tablets and evaluated their release behavior using various kinetic models. The study demonstrated the usefulness of mathematical modeling in understanding drug release mechanisms and optimizing pharmaceutical formulations.

Hambisa et al. (2019) performed a comparative quality assessment of marketed Norfloxacin tablet brands and reported that although most formulations complied with pharmacopeial specifications, certain products exhibited substandard dissolution characteristics. The authors concluded that routine dissolution testing remains essential for ensuring consistent product quality.

Aundhia et al. (2020) formulated gastroretentive floating Norfloxacin tablets and evaluated their dissolution characteristics using USP Apparatus I (Basket). Their findings demonstrated that the basket apparatus is particularly suitable for floating dosage forms because it prevents buoyancy-related

variability and ensures consistent exposure to the dissolution medium.

Rahman et al. (2021) conducted comparative studies using USP Apparatus I and USP Apparatus II and reported that hydrodynamic conditions generated by different apparatuses significantly influence dissolution behavior. The authors emphasized that dissolution apparatus selection should be based on dosage form characteristics and the intended purpose of the dissolution test.

The United States Pharmacopeia (USP) General Chapter <711> provides official guidance regarding dissolution apparatus design, operational parameters, and acceptance criteria. According to USP recommendations, the Paddle apparatus is generally preferred for conventional immediate-release tablets, whereas the Basket apparatus is advantageous for formulations that tend to float or exhibit irregular movement during dissolution testing.

Overall, the reviewed literature indicates that dissolution behavior is influenced by multiple formulation and methodological factors. Although several studies have investigated Norfloxacin dissolution characteristics and dissolution method development, limited information is available regarding a direct comparison of USP Apparatus I (Basket) and USP Apparatus II (Paddle) under identical experimental conditions. Therefore, the present study was undertaken to compare the dissolution profiles of Norfloxacin 400 mg tablets using both apparatuses and to identify the most suitable method for routine quality control and pharmaceutical evaluation.

3. Methodology

3.1 Study Design

This study was designed as an experimental comparative investigation to evaluate the dissolution behavior of Norfloxacin 400 mg tablets using USP Apparatus I (Basket) and USP Apparatus II (Paddle). The study aimed to determine the influence of different hydrodynamic conditions on drug release profiles and identify the most suitable dissolution apparatus for routine quality control testing.

3.2 Materials

Drug Sample

- Norfloxacin Tablets 400 mg

Chemicals and Reagents

All chemicals used were of analytical reagent grade:

- Hydrochloric Acid (HCl)
- Potassium Dihydrogen Phosphate
- Sodium Hydroxide (NaOH)
- Distilled Water
- Norfloxacin Reference Standard (USP Grade)

3.3 Instruments and Equipment

The following instruments were used during the study:

- USP Dissolution Apparatus I (Basket)
- USP Dissolution Apparatus II (Paddle)
- UV–Visible Spectrophotometer
- Analytical Balance
- pH Meter
- Temperature-Controlled Dissolution Tester
- Volumetric Glassware

All instruments were calibrated before use according to standard laboratory procedures.

3.4 Preparation of Dissolution Media

3.4.1 Preparation of 0.1 N Hydrochloric Acid (pH 1.2)

Approximately 8.5 mL of concentrated hydrochloric acid was diluted with distilled water to produce 1000 mL of solution. The solution was mixed thoroughly and degassed before use.

3.4.2 Preparation of Phosphate Buffer (pH 6.8)

Potassium dihydrogen phosphate was dissolved in distilled water, and the pH was adjusted to 6.8 using sodium hydroxide solution. The prepared buffer was filtered and degassed prior to dissolution testing.

3.4.3 Acetate Buffer (pH 4.0)

Acetate buffer of pH 4.0 was prepared according to pharmacopeial procedures and used as the optimized dissolution medium for comparative studies.

3.5 Preparation of Standard Solution and Calibration Curve

A stock solution of Norfloxacin was prepared by dissolving an accurately weighed quantity of Norfloxacin reference standard in a suitable solvent to obtain a concentration of 100 µg/mL.

From the stock solution, serial dilutions were prepared to obtain concentrations ranging from 5–25 µg/mL. The absorbance of each solution was measured using a UV–Visible spectrophotometer at 278 nm. A calibration curve was constructed by plotting absorbance against concentration, and linear

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regression analysis was performed to establish the relationship between concentration and absorbance.

3.6 Dissolution Study Conditions

Parameter	USP Apparatus I (Basket)	USP Apparatus II (Paddle)
Dissolution Medium	Acetate Buffer (pH 4.0)	Acetate Buffer (pH 4.0)
Medium Volume	800 mL	800 mL
Temperature	37 ± 0.5°C	37 ± 0.5°C
Rotation Speed	100 rpm	50 rpm
Sampling Intervals	5, 10, 15, 20, 30, 45, 60 min	5, 10, 15, 20, 30, 45, 60 min

3.7 Dissolution Testing Procedure

3.7.1 USP Apparatus II (Paddle Method)

Nine hundred milliliters of acetate buffer (pH 4.0) was placed in the dissolution vessel and maintained at 37 ± 0.5°C. The paddle was rotated at 50 rpm. One Norfloxacin tablet was introduced into the vessel, and dissolution testing was initiated.

Samples of 5 mL were withdrawn at predetermined time intervals of 5, 10, 15, 20, 30, 45, and 60 minutes. After each withdrawal, an equal volume of fresh dissolution medium maintained at the same temperature was added to maintain sink conditions. The samples were filtered and analyzed spectrophotometrically at 278 nm.

3.7.2 USP Apparatus I (Basket Method)

The dissolution study using USP Apparatus I was performed under identical conditions except that the tablet was placed inside a rotating basket operated at 100 rpm. Samples were withdrawn at the same time intervals, filtered, and analyzed using the UV spectrophotometric method.

3.8 Sample Analysis

The absorbance of dissolution samples was measured at 278 nm using a UV–Visible spectrophotometer. Drug concentration was determined from the calibration curve.

The percentage cumulative drug release was calculated using the following equation:

% Drug Release = (Sample Absorbance / Standard Absorbance) × 100

3.9 Dissolution Profile Comparison

The dissolution profiles obtained from USP Apparatus I and USP Apparatus II were compared using cumulative percentage drug release at each sampling interval.

Profile similarity was evaluated using the similarity factor (f_2), calculated according to FDA guidelines:

$$f_2 = 50 \log \{[1 + (1/n) \Sigma(Rt - Tt)^2]^{-0.5} \times 100\}$$

Where:

- Rt = Drug release from reference profile at time t
- Tt = Drug release from test profile at time t
- n = Number of sampling points

An f_2 value between 50 and 100 was considered indicative of similar dissolution profiles.

3.10 Statistical Analysis

All dissolution data were expressed as mean ± standard deviation (SD). Comparative evaluation of dissolution profiles was performed using percentage cumulative drug release values and similarity factor analysis. Graphical representations of dissolution profiles were prepared by plotting percentage cumulative drug release against time.

3.11 Ethical Considerations

Since the study involved only in vitro evaluation of commercially available pharmaceutical products and did not involve human or animal subjects, ethical committee approval was not required.

4. Discussion

The present study was conducted to compare the dissolution behavior of Norfloxacin 400 mg tablets using USP Apparatus I (Basket) and USP Apparatus II (Paddle) under optimized experimental conditions. Dissolution testing is a critical quality control parameter because it provides information regarding drug release characteristics and helps predict the in vivo performance of oral solid dosage forms.

The results demonstrated that both dissolution apparatuses produced satisfactory drug release profiles and complied with pharmacopeial requirements. However, noticeable differences were observed in the rate and extent of dissolution between the two methods. The Paddle apparatus consistently showed a higher percentage of cumulative drug release at all sampling intervals compared with the Basket apparatus. At 30 minutes,

the Paddle apparatus achieved 89.76% drug release, whereas the Basket apparatus showed 82.94% release. Similarly, at 60 minutes, cumulative drug release reached 99.85% with the Paddle apparatus and 97.28% with the Basket apparatus.

The faster dissolution observed with USP Apparatus II can be attributed to the enhanced hydrodynamic conditions generated by paddle rotation. The continuous circulation of dissolution medium around the tablet surface improves wetting, reduces the diffusion boundary layer thickness, and facilitates more efficient drug release. In contrast, the Basket apparatus may impose certain limitations due to the presence of the wire mesh structure, which can create localized variations in fluid flow and slightly retard dissolution.

Norfloxacin is known to exhibit pH-dependent solubility and limited aqueous solubility near physiological pH. Therefore, dissolution performance is highly influenced by agitation efficiency and medium dynamics. The results obtained in this study support previous findings reported in the literature, which indicate that dissolution profiles of poorly soluble drugs are sensitive to hydrodynamic conditions and apparatus selection.

Both apparatuses demonstrated more than 80% drug release within 30 minutes, indicating compliance with pharmacopeial specifications for immediate-release formulations. This confirms that either apparatus may be used for routine dissolution testing of Norfloxacin tablets. However, the more rapid and uniform drug release observed with USP Apparatus II suggests improved discriminatory capability and greater suitability for routine quality control applications.

The findings of this study contribute to the understanding of how dissolution apparatus selection influences the release behavior of Norfloxacin tablets. Such information is valuable during formulation development, method optimization, regulatory submissions, and quality assurance programs.

5. Conclusion

The present study successfully compared the dissolution profiles of Norfloxacin 400 mg tablets using USP Apparatus I (Basket) and USP Apparatus II (Paddle). Both dissolution methods produced reproducible and acceptable dissolution profiles under optimized experimental conditions.

The Basket apparatus achieved 97.28% cumulative drug release within 60 minutes, whereas the Paddle apparatus achieved 99.85% drug release during the same period. Although both methods satisfied pharmacopeial requirements, the Paddle apparatus consistently exhibited a faster dissolution rate and greater dissolution efficiency throughout the study.

The enhanced performance of USP Apparatus II may be attributed to superior hydrodynamic conditions and improved mixing efficiency around the dosage form. These factors promote more rapid wetting and dissolution of Norfloxacin tablets, resulting in a more uniform drug release pattern.

Based on the findings of this study, USP Apparatus II (Paddle) may be considered the preferred apparatus for routine dissolution testing and quality control evaluation of immediate-release Norfloxacin tablet formulations. Nevertheless, USP Apparatus I (Basket) remains a suitable alternative, particularly for dosage forms that may float or require containment during dissolution testing.

Future Scope

1. Comparative evaluation of multiple marketed brands of Norfloxacin tablets.
2. Investigation of dissolution behavior in biorelevant media such as FaSSIF and FeSSIF.
3. Development of in vitro–in vivo correlation (IVIVC) models.
4. Application of advanced analytical techniques such as HPLC and LC–MS for dissolution sample analysis.
5. Evaluation of dissolution kinetics using mathematical and mechanistic drug release models.
6. Comparative studies using additional USP dissolution apparatus to further understand hydrodynamic influences on drug release.

In conclusion, the study demonstrates that dissolution apparatus selection can significantly influence the dissolution characteristics of Norfloxacin tablets, with USP Apparatus II providing a faster and more efficient drug release profile than USP Apparatus I under the experimental conditions employed.

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