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A REVIEW ON GREEN HPLC METHOD DEVELOPMENT FOR DISSOLUTION PROFILING OF PHARMACEUTICAL DRUGS

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ABSTRACT

The development of Green High-Performance Liquid Chromatography (Green HPLC) offers the prospect of an environmentally sustainable method of pharmaceutical analysis. Traditional HPLC techniques have been associated with the use of harmful organic solvents and production of large amounts of chemical waste, which have caused many environmental and health hazards. Green HPLC, on the other hand, involves minimal usage of solvents, use of environment-friendly solvents, low energy consumption, and efficient analytical technique. Dissolution profiling serves as an important quality assurance test which assesses the release characteristics of pharmaceutical formulations and there in vivo behavior. The use of green HPLC in dissolution studies facilitates the development of pharmaceuticals sustainably without compromising on accuracy, precision, and compliance to regulations.

INTRODUCTION

Analytical chemistry has progressed with improvements in instrumentation and application methods. However, there has been increased concern over the ecological footprint left behind by laboratory centres.[1] The traditional analytical methods produce waste, use a lot of organic solvents, and require a lot of energy.[2] Even though they are effective, over the years, tests have been carried out in laboratories, quality control processes have been developed, and methods developed by pharmaceutical industries have led to the production of millions of litters of waste.[3]

The problem of taking care of the earth is a deal. This is because of new rules and people being more aware of what we can do to help the earth.[4] This has led to the creation of Green Analytical Chemistry as a way of doing things in this field.

Green Analytical Chemistry is based on the idea that we should be kind to the earth when we do chemistry.[5] This idea was first talked about by Anastas and Warner in 1998. They came up with twelve rules for doing chemistry.[6]

People who do chemistry started to think about how they could apply these rules to their work. This happened in the 2000s. They realized that even though they do not use much chemistry as some other people they still use a lot and make a lot of waste.

The International Union of Pure and Applied Chemistry is a group that is helping to spread the word about Green Analytical Chemistry. They are doing this by having meetings publishing papers and starting projects.[7] They want to make sure that we can do chemistry in a way that's good for the earth without making it harder to get the answers we need.[8]

The International Union of Pure and Applied Chemistry is working hard to make sure that people know about the importance of being kind, to the earth when we do chemistry.[9,10]

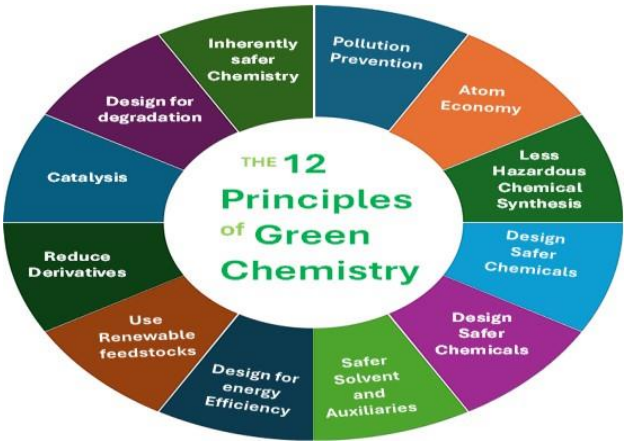

Figure 1: Twelve principals of green chemistry.

HPLC (High Performance Liquid Chromatography)

High Performance Liquid Chromatography is now one of the most powerful tools in analytical chemistry. It has the ability to separate, identify, and quantify the compounds that are present in any sample that can be dissolved in a liquid.

High performance liquid chromatography (HPLC) is the most accurate analytical methods widely used for the quantitative as well as qualitative analysis of drug product.[11] The principle is that a solution of the sample is injected into a column of a porous material (stationary phase) and a liquid (mobile phase) is pumped at high pressure through the column. The separation of sample is based on the differences in the rates of migration through the column arising from different partition of the sample between the stationary and mobile phase. Depending upon the partition behaviour of different components, elution at different time takes place.[12]

The sample compound with the greater affinity to the stationary layer will travel slower and for a shorter distance in comparison to compounds with less affinity which travel faster and for a longer distance.[13] The High-Performance Liquid Chromatography is more versatile than gas chromatography since (a) it is not limited to volatile and thermally stable samples, and (b) the choice of mobile and stationary phases is wider.[14]

HPLC has numerous advantages like

- Simultaneous Analysis
- High Resolution
- High Sensitivity
- Good repeatability
- Small sample size
- Moderate analysis condition.
- Easy to fractionate the sample and purify.[15]

Classification of HPLC can be done as

- preparative HPLC and analytical HPLC (based on scale of operation)
- affinity chromatography, adsorption chromatography, size exclusion chromatography, ion exchange chromatography, chiral phase chromatography (based on principle of separation)
- gradient separation and isocratic separation, (based on elution technique)
- normal phase chromatography and reverse phase chromatography (based on modes of operation).[16]

A. Normal Phase Chromatography

In normal phase chromatography, mobile phase is non-polar and stationary phase is polar. Hence, the station phase retains the polar analyte. An increase in polarity of solute molecules increases the adsorption capacity leading to an increased elution time. Chemically modified silica (cyanopropyl, aminopropyl and diol) is used as a stationary phase in this chromatography.[17] For example. A typical column has an internal diameter of around 4.6 mm, and a length in the range of 150 to 250 mm. Polar compounds in the mixture that are passed through the column will stick longer to the polar silica than the non-polar compounds. Therefore, the non-polar ones will pass more quickly through the column.[18]

B. RP-HPLC (Reversed phase HPLC)

RP-HPLC has a non-polar stationary phase and polar or moderately polar mobile phase. RP-HPLC is based on the principle of hydrophobic interaction.[19] In a mixture of components those analytes which are relatively less polar will be retained by the non-polar stationary phase longer than those which are relatively more polar. Therefore, the most polar component will elute first.[20]

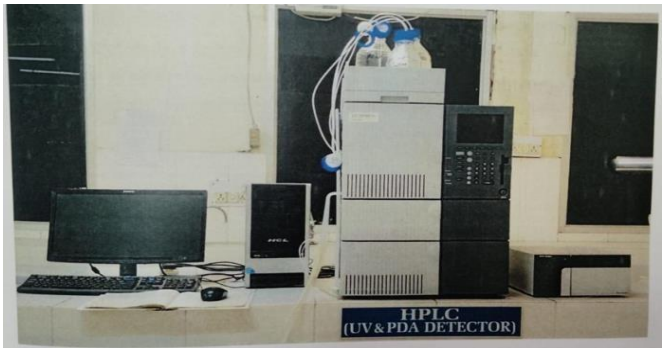

Figure 2: HPLC (UV and PDA Detector).

METHOD DEVELOPMENT ON HPLC

A step involved in method development of HPLC is as follows:

1 Understanding the Physicochemical properties of drug molecule.
2 Selection of chromatographic conditions.
3 Developing the approach of analysis.
4 Sample preparations
5 Method optimization
6 Method validation

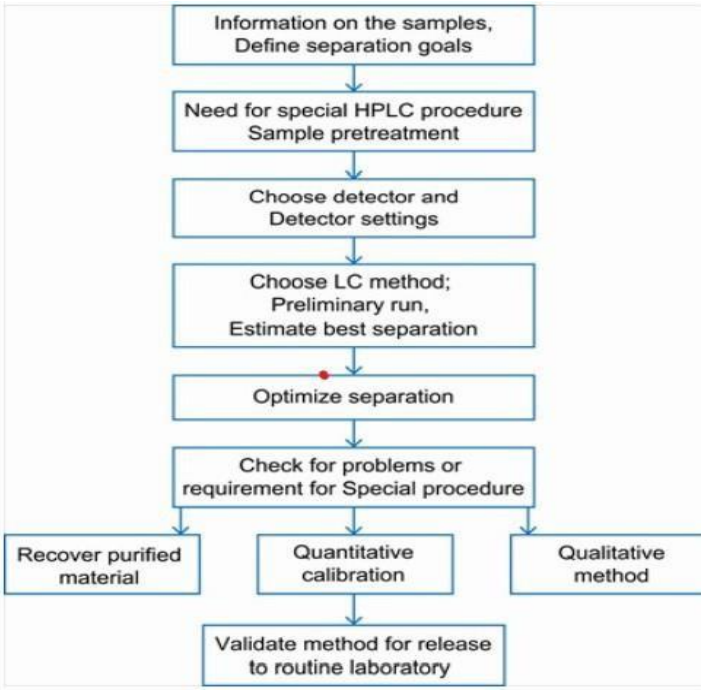

Figure 3: METHOD DEVELOPMENT ON HPLC.

Dissolution Profiling

Dissolution is an official test. These used by pharmacopeias for evaluating drug release of solid and semisolid dosages forms. The application of the dissolution testing ensures consistent product quality and to predict in vivo drug bioavailability. The dissolution test, in its simplest form, placing the formulation in a dissolution apparatus containing suitable dissolution medium, allowing it to dissolved specified period of time and then using appropriate rational method to determine the amount of drug. Dissolution test is probative and analysis like drug degradation profile, shelf-life studies, stability, physical and mechanical testing of dosage forms. The present review outlines findings on various dissolution apparatus, various methods and their modification.[21] Dissolution testing the of various dosage form like Delayed release dosage form, Immediate release dosage form, Extended-release dosage form, Powders, Chewable tablets, Transdermal delivery system, Buccal tablets, soft gelatin capsule, Chewing gums, Suppositories, Aerosols and others semisolids.

The purpose of dissolution testing

For a commercial product, this test is routinely used for quality-control and quality-assurance purposes, to ensure consistency between production batches, or to justify scale-up and post-approval changes made to the manufacturing process.[22] In early phase drug development, dissolution testing aids formulation design and drug delivery optimization; it is primarily carried out to assess product stability, monitor formulation changes over time, and establish *in-vitro–in-vivo* correlations.[23] In cases where *in vitro–in vivo* correlations have been demonstrated; dissolution can be used as a surrogate test

to predict the *in-vivo* performance of drug products. From a regulatory perspective, dissolution testing plays a major role in the decision-making process, particularly in the development and approval of generic dosage forms, where unnecessary human studies can be avoided without compromising the quality of the generic drug products.[24]

Factors affecting dissolution

A dissolution test measures the amount of drug that goes into solution over a period of time under standardized conditions. Factors that affect the dissolution of a drug product include the intrinsic properties of the API (e.g., solubility, wettability, particle size, surface area, morphology, polymorphs), the formulation composition and characteristics (e.g., excipients, hardness, manufacturing process), and the dissolution method used for its assessment (e.g., apparatus, medium, test conditions, sampling, and sample analysis).

Dissolution apparatus

The *United States Pharmacopeia* and *European Pharmacopoeia* describe four different dissolution apparatuses that can be used to develop an appropriate dissolution method for oral solid-dosage forms based on the drug product characteristics.[24]

Apparatus 1 (basket) and Apparatus 2 (paddle) are most commonly used methods in dissolution testing. Apparatus 3 (reciprocating cylinder), Apparatus 4 (flow-through cell)

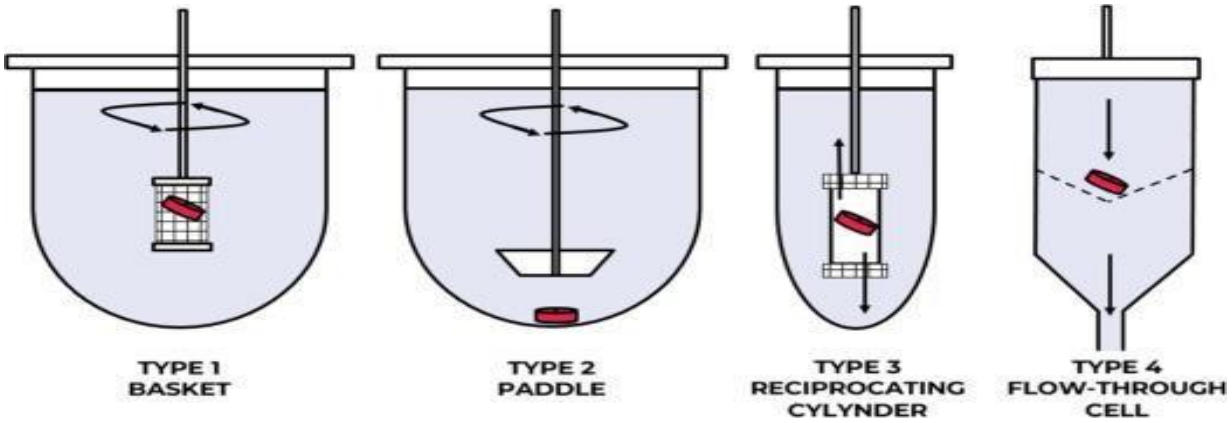

Figure 4: Types of Dissolution Apparatus. Method development.

In dissolution testing, the aim is to develop a discriminatory method that is sensitive to variables that affect the dissolution rate, and consequently, the *in-vivo* performance of the drug product. The method must be able to distinguish between drug products manufactured under target conditions and formulations with meaningful variations for the most relevant critical manufacturing variables, such as drug substance particle size, compression force, and tablet hardness, for example.[25] The dissolution method should also be sufficiently rugged and reproducible for daily operations as well as transferable between laboratories.

Physical and Chemical Properties of the Drug Substance[26]

The properties of the active pharmaceutical ingredient (API) significantly influence the design of a dissolution test. Key factors include solubility, ionization constants, particle size, and polymorphic forms of the API. These factors dictate the selection of the dissolution medium, apparatus, and testing parameters.

1. Solubility and pH Dependency

The solubility of the drug in various media is one of the first considerations in method development. APIs that have poor solubility in aqueous media may require the use of surfactants or organic solvents to facilitate dissolution. Moreover, the solubility often varies with pH, making it necessary to test in multiple media with pH ranges that mimic physiological conditions (e.g., pH 1.2 for gastric conditions and pH 6.8 for intestinal conditions).

2. Ionization Constant (pKa)

Knowing the pKa of the API is crucial, as it affects the ionization of the drug in different pH environments. This in turn influences its solubility and dissolution rate. For example, weakly acidic drugs may dissolve more readily in basic media, while weakly basic drugs may require acidic media to achieve optimal dissolution.

3. Particle Size and Surface Area

The size of drug particles impacts the dissolution rate, with smaller particles generally dissolving more quickly due to increased surface area. Particle size distribution should be controlled during manufacturing, as variability can lead to differences in dissolution behavior.

4. Crystal Form and Polymorphism

APIs can exist in different polymorphic forms, each with unique solubility and dissolution properties. Developing a dissolution method requires understanding these variations, as some forms may dissolve more readily than others, affecting the drug's bioavailability.

Selection of Dissolution Medium[25]

The dissolution medium serves as the solvent in which the drug is released, and its composition can impact the test results significantly. When selecting a dissolution medium, developers consider factors such as pH, the presence of surfactants, and the physiological relevance of the medium.

pH Range and Buffers: For oral formulations, the dissolution medium is often selected to replicate the pH conditions of the gastrointestinal tract. The physiological pH ranges from approximately 1.2 in the stomach to 6.8 in the intestines. Buffered solutions help maintain these pH levels throughout the test, which is particularly important for weakly acidic or basic drugs.

Surfactants and Solubility Enhancers: Surfactants such as sodium lauryl sulfate or polysorbate 80 may be added to the medium to improve the solubility of poorly soluble drugs. However, it is essential to balance surfactant concentration to prevent artificial enhancement of the dissolution rate beyond what is observed in physiological conditions.

Volume and Sink Conditions: A common guideline is to use a volume of medium that is at least three times the amount required to dissolve the maximum dose of the drug, referred to as "sink conditions." Sink conditions ensure that the medium does not become saturated with the drug, which could skew the dissolution rate data.

Selection of Dissolution Apparatus[26]

The choice of dissolution apparatus depends on the dosage form and the characteristics of the API. The USP defines seven types of apparatuses for dissolution testing, each suited to different formulations.

Basket Apparatus (USP Apparatus 1)

The basket method is ideal for solid oral dosage forms such as tablets and capsules, particularly those prone to disintegration. The basket rotation speed, usually set between 50-100 rpm, can be adjusted based on the physical characteristics of the dosage form.

Paddle Apparatus (USP Apparatus 2)

This apparatus is widely used for immediate-release tablets and capsules. It involves a paddle that stirs the dissolution medium at a specified speed, typically 50-75 rpm. The paddle method is particularly suitable for dosage forms that sink to the bottom of the vessel and require uniform agitation.

Flow-Through Cell (USP Apparatus 4)

For modified-release and low-solubility APIs, the flow-through cell provides a controlled environment where dissolution medium is pumped through the cell, maintaining sink conditions. This apparatus is especially useful for sustained-release formulations, implants, and poorly soluble drugs.

Paddle Over Disk and Cylinder Apparatus (USP Apparatuses 5 and 6)

These are used for transdermal patches, where the drug must dissolve in media at skin-like conditions. Each apparatus requires careful calibration and qualification to ensure it provides consistent and accurate data. In some cases, modifications such as using sinkers to prevent floating or adjusting the agitation rate are necessary to improve test reliability.

Study Design and Testing Parameters[27]

The design of a dissolution study includes defining the testing parameters, such as time points, sampling methods, and analysis techniques. For immediate-release products, dissolution is usually measured over a short period, with samples taken at several time points to capture the release profile. Extended-release formulations require longer testing durations, with multiple sampling points to understand the release mechanism.

Time Points and Sampling Intervals: For immediate-release dosage forms, testing intervals are short, often within 30-60 minutes, while extended-release products may require sampling over several hours.

Analytical Techniques: Dissolution samples are commonly analyzed using UV spectrophotometry or high-performance liquid chromatography (HPLC). Spectrophotometry is generally used for single-component formulations, while HPLC is preferable for complex formulations with potential interference from excipients.

Dissolution procedure validation[28]

Validation of dissolution procedures is crucial to ensure that the test provides accurate, consistent, and reliable data across various product batches and manufacturing sites. Validated methods are a requirement for regulatory approval and routine quality control, establishing that a dissolution test can accurately assess the quality and performance of a pharmaceutical product. According to guidelines from the FDA, USP, and ICH, dissolution methods must be validated for a series of parameters, each designed to confirm specific aspects of the method's reliability and applicability.

Validation Parameters

Each parameter addresses a unique aspect of the dissolution process, ensuring the method's suitability across different formulations and production batches.[29]

Specificity

Specificity is the ability of a dissolution method to accurately identify and quantify the API without interference from other components in the formulation, such as excipients, degradants, or other active ingredients.

Achieving specificity is essential to ensure that results reflect the dissolution of the target compound alone. For

xample, in complex formulations, excipients might have overlapped absorbance at the API's analytical wavelength if UV spectrophotometry is used. In such cases, high-performance liquid chromatography (HPLC) is often the preferred technique, providing separation of the API from other formulation components, which helps avoid interference.

Specificity can be tested by analyzing the placebo mixture (all excipients without the API) in the dissolution medium. If the placebo exhibits less than 2% interference, the method is considered specific. For products with multiple active ingredients, the method must be validated for each API individually, ensuring that all actives are accurately identified.

Linearity and Range: Linearity refers to the method's ability to produce results that are directly proportional to the concentration of the drug within a specified range. This linear relationship is essential, as it ensures that the dissolution method can accurately quantify the amount of drug released at different stages of the dissolution process. To assess linearity, a series of solutions with increasing concentrations of the API are prepared and measured. Statistical methods, such as linear regression analysis, are used to calculate the correlation coefficient(r), slope, and y-intercept of the regression line. A high correlation coefficient (close to 1.0) indicates a strong linear relationship, verifying the method's suitability within the defined range. For dissolution testing, linearity is typically validated over a range that spans from 20% to 120% of the drug's expected concentration in the medium.[30]

Accuracy and Recovery

Accuracy measures how close the results obtained by the dissolution test are to the true value or reference standard. Accurate methods ensure that the dissolution results reflect the actual amount of API released into the dissolution medium, providing reliable data for quality control and regulatory evaluation. The accuracy of a dissolution method is commonly assessed through recovery studies, where known amounts of the API are added to the dissolution medium and then tested using the dissolution method. The recovery rate should fall within an acceptable range, typically between 95% and 105% of the true value, for the method to be deemed accurate. For complex formulations or those with poor solubility, it may be necessary to dissolve the API in a small amount of organic solvent before adding it to the medium.[31]

Precision

Precision indicates the reproducibility of dissolution test results and measures variation in repeated analysis of the same sample. It includes

- **Repeatability:** Consistency under identical conditions in the same laboratory.
- **Intermediate Precision:** Consistency across different days, analysts, or instruments within the same laboratory.
- **Reproducibility:** Consistency of results between different laboratories. Precision is acceptable when %RSD remains within specified limits.

Detection Limit (DL) and Quantitation Limit (QL)

- **DL:** Lowest amount of drug that can be detected but not accurately measured.
- **QL:** Lowest amount that can be quantified accurately and precisely. These are important for low-dose formulations and dissolution studies.

Robustness

Robustness is the ability of the dissolution method to remain reliable despite small changes in parameters such as pH, agitation speed, temperature, and sampling time. Consistent results indicate a robust method.

System Suitability Test

System suitability ensures the dissolution system performs correctly before analysis. Key parameters include **theoretical plates, tailing factor, resolution, and %RSD** to confirm reliable and reproducible results.

Validation Guidelines

According to **FDA, USP, and ICH guidelines**, dissolution methods must be validated for **accuracy, precision, specificity, and linearity**. Full validation is required during advanced development and regulatory submission stages.

Automation in Dissolution Testing

Automation improves efficiency, reduces human error, and supports regulatory compliance by automating sampling, media replacement, and data analysis.

Types of Automated Systems

- **Semi-automated:** Some steps automated; others performed manually.
- **Fully automated:** Entire testing process performed automatically.

Advantages

- Better reproducibility
- Higher throughput
- Improved compliance and data integrity

Challenges

- High installation and maintenance cost
- Complex setup and validation

CONCLUSION

Green HPLC method development for dissolution profiling of pharmaceutical drugs has emerged as an important approach in modern pharmaceutical analysis by combining analytical performance with environmental sustainability. Conventional HPLC methods often involve large volumes of hazardous organic solvents, leading to increased environmental burden, operational costs, and safety concerns. Green HPLC addresses these

limitations through the use of eco-friendly solvents, reduced solvent consumption, shorter analysis time, and energy-efficient analytical practices.

Dissolution profiling plays a vital role in evaluating drug release behaviour, ensuring product quality, and supporting formulation development. The integration of green analytical principles into dissolution studies enables accurate, precise, robust, and reliable assessment of pharmaceutical products while minimizing environmental impact. Recent advancements such as automated systems, Quality by Design (QbD), and environmentally conscious method optimization further strengthen the applicability of Green HPLC.

Overall, Green HPLC represents a sustainable and efficient alternative for dissolution profiling and aligns with current regulatory expectations and green chemistry principles. Future developments are expected to focus on advanced green technologies, automation, and intelligent analytical platforms to improve method efficiency and sustainability in pharmaceutical research and quality control.

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