ISSN: 2278-2648

International Journal of Research in Pharmacology & Pharmacotherapeutics (IJRPP)

IJRPP |Vol.15 | Issue 2 | Apr - Jun -2026

www.ijrpp.com

DOI : https://doi.org/10.61096/ijrpp.v15.iss2.2026.755-759

Stability Study of Syrup Vs Tablet Formulation of an Anti-Viral Drug Using UV Spectrophotometer

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Published by: 22.04.2026

Abstract: Stability testing is a fundamental requirement within pharmaceutical development ensure indicating that drug products maintain their safety, efficacy, and quality throughout their shelf life (9).

The evaluation of stability involves monitoring physical, chemical, and microbiological characteristics as per controlled environmental conditions since as temperature, humidity, light-induced exposure (9)

UV-visible spectrophotometry is generally employed in stability studies caused by its simplicity, expedited analysis, cost-effectives, suitability for routine quality control applications (7, 18).

Tablet and syrup dosage forms differ significantly in their composition, physical nature, and degradation behavior, so that influences analytical approaches used for stability assessment (15, 16).Solid dosage is the forms like tablets generally exhibit greater stability compared to liquid formulations due to they lack free water which promotes hydrolysis (15).Syrup formulation, being aqueous system, occur more susceptible to hydrolytic degradation, oxidation, microbial contamination (14, 15).

Numerous validated UV spectrophotometric methods have been developed for stability evaluation of both solid and liquid drug formulation forms within accordance with ICH guidelines (1, 8).

This review acutely compares stability studies of syrup and tablet formulations with the help of UV-visible spectrophotometry, highlighting analytical challenges, forced degradation strategies, validation requirements, and regulatory considerations (8, 9).

Keywords: Stability study, UV-Visible spectrophotometry; Syrup formulation, Tablet formulation, forced degradation, ICH guideline

1. INTRODUCTION

Stability studies are performed to determine how the quality of a drug substance or drug product shows variation along with time under environmental factors such as temperature, humidity, and light (9).

These studies help in the course of establishing storage requirements, retest periods, and expiry dates for pharmaceutical products (9).

According to ICH Q1A (R2), stability testing must evaluate physical, chemical, and microbiological properties belonging to dosage form (9).

Analytical methods used for stability testing should be validated for accuracy, precision, specificity, and durability as per ICH Q2 (R1) guidelines (8).

UV-visible spectrophotometry is one of the most frequently used analytical techniques in pharmaceutical quality control laboratories (7). The principle of UV spectroscopy is depending on the absorption of ultraviolet radiation by molecules containing chromophores, resultant in electronic transitions (18).

Because various drugs absorb in the UV region between 200–400 nm, UV spectroscopy is widely applicable for assay and degradation studies (7).

Stability studies are essential in pharmaceutical development to ensure the quality, safety, and efficacy of drug products throughout their shelf life. UV spectrophotometry is one of the most commonly used analytical techniques for this purpose due to its simplicity, sensitivity, and cost-effectiveness (20, 23). Antiviral drugs such as Acyclovir and Oseltamivir are available in multiple dosage forms, including syrups and tablets, to accommodate diverse patient needs. However, the stability of these formulations differs considerably depending on their physical and chemical characteristics. Liquid dosage forms are generally more susceptible to degradation caused by hydrolysis, oxidation, and microbial growth, whereas solid forms tend to exhibit greater stability under similar environmental conditions (21, 22). Hence, comparative evaluation using UV spectrophotometric methods is important for understanding stability profiles and ensuring consistent drug performance.

1.1. UV-Visible Spectrophotometry in stability studies

UV spectrophotometric methods involve selection of an appropriate wavelength corresponding toward the maximum absorbance (λmax) part of the drug (1). Method development involves preparation of calibration curves to establish linearity during a specified concentration range (1, 3).

Validation parameters including as accuracy, precision, limit of detection, and limit of quantification need to be determined before application in stability testing (8). Forced degradation studies under acidic, alkaline, oxidative, photo-induced and thermal environment help in identifying stability-indicating properties of the method (5, 19).

UV methods had been reported as stability-indicating for several tablet formulations including antihypertensive and antibiotic drugs (1, 3, 4). Derivative spectrophotometry may improve selectivity when overlapping spectra are recorded (3).

The simplicity and rapidity of UV methods create them particularly useful for comparative stability assessment between dosage forms (7).

1.2. Stability Studies of Tablets Dosage Forms by Using UV-Visible spectrophotometry

Tablets are solid dosage forms composed of active pharmaceutical ingredients and various excipients especially as binders, Fragmentation lubricants, and fillers (15).

The solid state of tablets generally supplies greater chemical stability owing to limited molecular mobility (15). However, tablets could go through degradation due to moisture absorption, oxidation, photolytic degradation, or thermal stress (16).

Hydrolysis can take place in tablets when submitted to high humidity conditions (15).

Excipient-drug interactions may also lead to instability in solid dosage preparation (16).

Tablet analysis typically involves powdering, weighing accurately, dissolving in a appropriate solvent, and prior filtration to spectrophotometric measurement (1). Stability-indicating UV methods have become successfully established for candesartan cilexetil tablets under forced degradation conditions (1).

Derivative UV methods have been approved for benazepril hydrochloride tablets with appropriate precision and accuracy (3). Marbofloxacin tablets have been evaluated using eco-friendly

UV methods demonstrating good linearity and durability (4). Accelerated stability testing at 40°C and 75% RH is commonly administered to tablets to predict long- duration stability (9).

UV methods have established high degree of correlation coefficients ($R^2 > 0.999$) in tablet stability studies (1, 4).

The simplicity of UV analysis makes it suitable for routine monitoring during product life analysis of solid dosage forms (7).

1.3. Stability studies of syrups dosage forms

Syrups are concentrated aqueous solutions containing high sugar level or alternative sweetening substance (14).

The presence of water increases sensitivity to hydrolysis compared to solid pharmaceutical dosage forms (15).

Liquid formulations are also prone to oxidative degradation attributable to dissolved oxygen (17).

Microbial growth is a significant concern in syrups, making necessary use of preservatives (9).

Flavoring agents, colorants, and viscosity enhancers may impact with UV absorbance measurements (16). Syrup analysis normally requires dilution with a suitable solvent prior to UV measurement (14).

Blank correction is fundamental to eliminate interference from excipients (14).

Forced degradation studies of antihistamine syrups have been undertaken using UV spectrophotometry in acidic and oxidative conditions (12).

Accelerated stability testing of liquid formulations consists storing samples at enhanced temperatures and periodically measuring absorbance changes (17).

Matrix effects in syrups can lead to spectral overlap, which can be minimized through derivative techniques (16).

Despite challenges, UV spectroscopy is maintained rapid and economical method for monitoring stability in syrup preparation (7).

1.4. Forced Degradation Studies

Forced degradation studies intentionally expose drug products to stress conditions to evaluate degradation pathways (19).

Acidic and alkaline hydrolysis are commonly observed degradation mechanisms in aqueous preparation (15).

Oxidative degradation may arise in the appearance of hydrogen peroxide or atmospheric oxygen (17).

Thermal degradation studies contain exposing samples to raised temperatures (9).

Photo stability studies analyze the impact of UV and visible light exposure on drug formulation (9).

UV spectroscopy enables monitoring of degradation through assessment decrease in absorbance of the intact drug (1).

1.5. Comparative Evaluation of syrups and tablets

Tablet formulations usually show superior chemical stability compared to syrups due to the unavailability of free water (15).

Syrups are more susceptible to hydrolysis and oxidation because of their water- based nature (15, 17).

Tablets may experience moisture-mediated degradation under high –moisture environment (16).

Sample processing for tablets is more resource-intensive than for syrups (1).

Syrups require careful blank correction due to excipient -related interference (14).

UV spectroscopy is suitable for comparative stability analysis due to its repeatability and quick data gathering (7, 18).

1.6. Regulatory Considerations

ICH Q1A (R2) outlines specification for stability testing conditions and data evaluation (9).

ICH Q2 (R1) provides guidelines for validation of analytical techniques (8).

Regulatory authorities insist on stability-testing methods capable of distinguishing API from degradation products (8).

Proper documentation and statistical evaluation of stability data are compulsory for regulatory submissions (9).

1.7. Limitation of UV –Spectrophotometry

UV spectroscopy offers effortlessness, minimal operating cost, and rapid analysis time (7).

The technique requires resource- efficient sampling preparation compared to chromatographic methods (18).

However, UV spectroscopy unable to separate complex mixtures of degraded compounds (6).

Matrix interference is a limitation especially in pharmaceutical syrup (16). Even with limitations, UV spectroscopy remains an essential tool for preliminary and routine stability studies (7).

2. CONCLUSION

Stability studies are essential for ensuring pharmaceutical formulation safety and efficacy throughout their shelf life (9). Tablet dosage forms usually demonstrate greater chemical stability compared to syrups due to reduced hydrolytic exposure (15).

Syrup formulations require careful analytical method refinement because of sample matrix complexity and vulnerability to degradation (14, 16).

UV-visible spectrophotometry is a dependable, affordable, and widely established technique for stability testing of both solid and liquid dosage

When validated according to ICH guidelines, UV methods can adequately perform as stability-indicating tools for comparative assessment of tablets and syrups (8, 9).

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