

A RESEARCH ON COMPARATIVE DISSOLUTION STUDY, STABILITY TESTING AND WEIGHT VARIATION OF 5 BRANDS OF AMOXICILLIN TRIHYDRATE 500mg CAPSULE USING UV SPECTROSCOPY

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ABSTRACT

Five commercial brands of 500 mg amoxicillin capsules Torrviss, Alkem, Lupin, Skymap, and Abbott are compared in this study with an emphasis on weight variation, dissolving profile, and stability testing using UV-visible spectroscopy.^[1] Distilled water was used as the dissolve medium in the dissolution investigations, and a UV spectrophotometer was used to measure the drug release at 272 nm.^[7] Under order to evaluate short-term deterioration, stability testing was carried out over a 24-hour period under ambient circumstances. Weighing 20 capsules from each brand separately allowed us to assess weight variance. All five brands met pharmacopeial limitations for weight variance, according to the data. According to dissolution trials, Abbott and Alkem had somewhat quicker release rates, however all brands released more than 85% of the medication in 60 minutes, demonstrating good bioavailability.^[5,12,26] After a day, stability testing showed that Skymap and Torrviss had significantly degraded, while Alkem had stayed the most stable. According to the study's findings, UV spectroscopy is a useful technique for evaluating the drug content, dissolving pattern, and short-term stability of amoxicillin capsules, and all brands are pharmaceutically acceptable.^[1,4]

KEYWORDS: Amoxicillin Trihydrate, Capsules, stability, dissolution profile, weight variation, UV spectroscopy.

INTRODUCTION

Amoxicillin is a common semi-synthetic penicillin derivative that is a member of the β -lactam antibiotic family. It is commonly used to treat ear, skin, urinary, and respiratory tract infections because of its wide range of bactericidal action against both Gram-positive and Gram-negative pathogens.^[3,6] Amoxicillin is on the World Health Organization's Model List of Essential Medicines because of its extensive usage and therapeutic significance. A 500 mg capsule is the usual dose form for amoxicillin in adults, and it must adhere to strict quality control guidelines to guarantee constant effectiveness, patient compliance, and safety.^[4,7]

Several brands of 500 mg Amoxicillin capsules made by various manufacturers are available on the pharmaceutical market. However, the quality and effectiveness of the same medication might fluctuate significantly amongst brands due to variances in formulation methods, excipients, manufacturing procedures, and storage conditions. Comparative studies of these commercially available formulations are therefore necessary to assess their pharmacological equivalency, particularly in poor nations where patients frequently switch brands due to cost and availability.^[18,16,26,23] Weight variation, dissolving profile, and stability testing are the main criteria used to assess the quality of solid oral dosage forms. Each of these tests determines the formulation's overall quality in a unique but connected way.^[11,12,19]

A simple test to guarantee consistency in the dose units is weight variation. If the filling procedure is not done precisely, it is especially crucial in capsule formulations where the medication content is not always evenly distributed.^[38,39,40] The weight of individual capsules should not differ substantially from the average weight in accordance with pharmacopeial regulations, guaranteeing that every capsule has the appropriate dosage.^[19,10,16]

Dissolution testing is a crucial in-vitro technique that mimics the circumstances in the gastrointestinal system to ascertain how quickly the medication is released from the capsule into solution.^[6,13] Bioavailability, or the rate and degree to which the active pharmaceutical ingredient (API) is absorbed and made accessible at the site of action, depends on a suitable dissolution rate.^[41] The maximal absorption wavelength for amoxicillin, 272 nm, was utilized to determine the UV absorbance in this investigation, which employed distilled water as the dissolving media.^[41,42,35,37] Simple yet pertinent circumstances that may be utilized for quick screening of capsule release profiles are also reflected in the usage of water as a medium.^[36,42]

When evaluating a pharmacological product's behavior over time in a variety of environmental settings, stability testing is essential. Short-term (24-hour) stability testing, in contrast to long-term and accelerated stability testing, can offer prompt insights on a product's propensity for degradation, particularly under typical storage settings.^[17,18] As a β -lactam antibiotic, amoxicillin is susceptible to temperature and moisture changes, which can result in decreased therapeutic efficacy and possible toxicity. Therefore, a 24-hour stability analysis might be useful in determining the initial resilience of a product, particularly for short-term storage and transportation.^[20,10,19]

This study employed UV-Visible Spectroscopy as an analytical method to estimate the amount of amoxicillin.^[2] Because of its ease of use, affordability, and accuracy, this method is frequently employed in pharmaceutical analysis. Without the need for sophisticated equipment like HPLC or GC, UV spectrophotometry at 272 nm provides a dependable way to measure the medication in dissolution and stability investigations.^[9,6,15]

This study concentrated on five commercial brands of amoxicillin capsules that are sold in India: Abbott, Skymap, Lupin, Alkem, and Torrviss. The selection of these brands was based on their availability and market prominence.^[22,26] By employing standardized tests for weight variation, water solubility, and 24-hour stability evaluation, the current study seeks to offer a comparative analysis of five commercially available Amoxicillin 500 mg capsule brands.^[32,35,17] The findings are anticipated to shed light on variations in product quality, guide improved choices about the purchase and usage of medications, and demonstrate the value of UV spectroscopy as a dependable technique for standard pharmaceutical examination.^[5,9,25]

MATERIAL AND METHOD

Material

Five different brands of 500 mg capsules of amoxicillin trihydrate were purchased from a nearby drugstore. The brands that are part in the trial are Amoxymap-500 (Torrviss), Alkem, Lupin, Skymap, and Abbott. Solvents and other chemicals and solutions were prepared using distilled water.

Instrumentation

UV spectroscopy: Antech's AN-UV-6500N UV-Visible Spectrophotometer. For dissolving testing: USP Apparatus 2 (Paddle Method) was employed.

Methods

1. Analysis of drug content using uv spectroscopy

- **Stock solution preparation:** Accurately measured amoxicillin powder was dissolved in distilled water to create a 1000 µg/mL stock solution of amoxicillin trihydrate.^[2,3,11,12,14,15,39,40]
- **Calibration curve:** A calibration curve was created by diluting the stock solution and measuring the absorbance of the solutions at 272 nm.^[20,22,25,29]
- **The preparation of the sample:** Each brand's contents were dissolved in 100 milliliters of distilled water after one capsule was weighed. After filtering the mixture, the absorbance at 272 nm was determined. Using the calibration curve, the quantity of amoxicillin in each capsule was determined.

2. Testing for dissolution

- The paddle technique (Apparatus 2) was used to conduct dissolution testing at 37°C and 75 rpm in accordance with USP recommendations.^[31,21,30,26,19]
- 900 milliliters of water were utilized as the dissolving media.^[18,17,12,13]
- At specified intervals (5, 10, 15, 30, and 60 minutes), samples were taken out, filtered, and subjected to UV spectroscopy at 272 nm for analysis.^[1,2,3,4,5,6,7,9,11,16,26]

3. Weight variation testing

- Twenty capsules were chosen at random from each brand and weighed separately. The capsules' average weight was computed, and the percentage deviance from the average was ascertained.^[32,36,28,41]

4. Stability Testing

- Each brand's capsules were kept in three distinct temperature ranges: room temperature (24°C) for a full day.

5. Analysis of data

- The calibration curve was used to determine the drug content.
- The findings of weight fluctuation were contrasted with the accepted pharmacopoeial limitations.^[42]

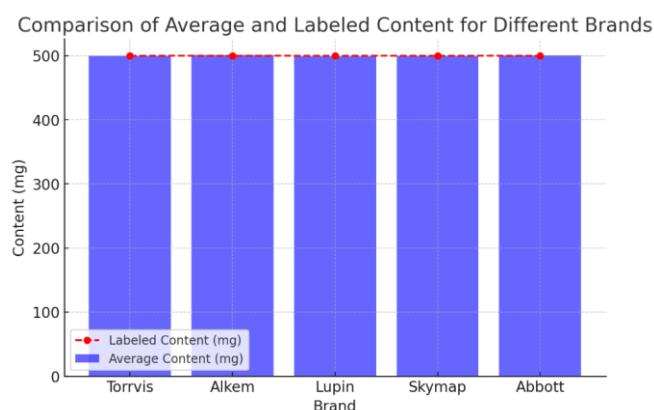
RESULTS

1. Analysis of drug content using UV spectroscopy

The UV absorption values at 272 nm were used to determine the medication content of the capsules. Table 1 provides a summary of the findings.

Table 1: Drug Content Analysis.

Brand	Average Content (mg)	Labeled Content (mg)	Percentage Deviation (%)
Torrvis	499.7	500	-0.06
Alkem	501.3	500	0.26
Lupin	499.2	500	-0.16
Skymap	500.1	500	0.02
Abbott	500.5	500	0.10



Pharmacopoeial norms were confirmed by the content of all the brands, which fell between 90 and 110 percent of the declared value.

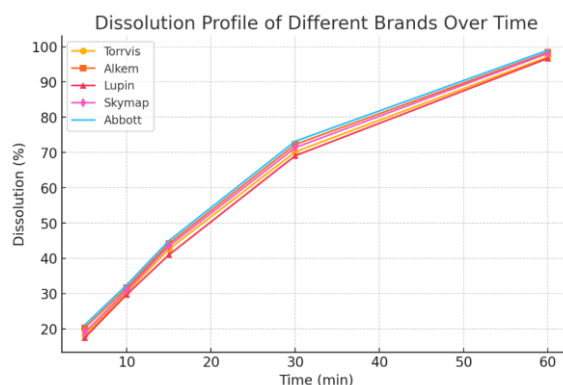
2. TESTING FOR DISSOLUTION

Table 2 displays the amoxicillin dissolving profiles for each of the five brands.

At each time point, the proportion of amoxicillin released was computed.

Table 2: (Dissolution Testing).

Time (min)	Torrvis (%)	Alkem (%)	Lupin (%)	Skymap (%)	Abbott (%)
5	18.2	20.3	17.5	19.0	21.1
10	30.5	31.7	29.8	31.0	32.5
15	42.6	44.2	41.0	43.5	45.0
30	70.2	72.3	69.1	71.4	73.2
60	97.1	98.4	96.7	98.1	99.0



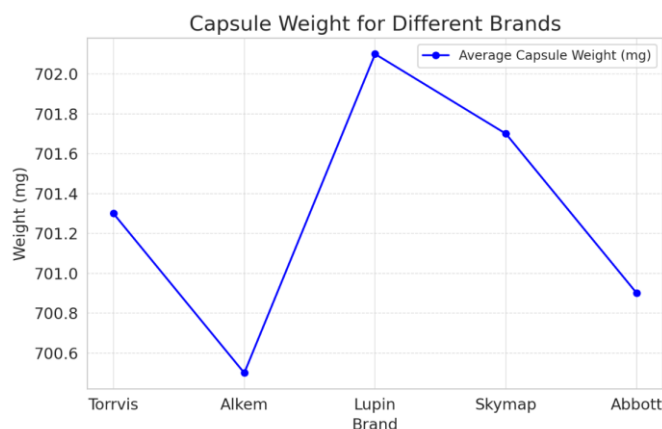
With almost 85% of the medication dissolving in 60 minutes, all brands had comparable dissolution patterns, demonstrating that they all met the solubility specifications for Amoxicillin capsules.

3. WEIGHT VARIATION TESTING

Table 3 displayed the results of the weight variation testing.

Tablet 3: Weight Variation Test.

Brand	Average Weight (mg)	Acceptable Range (mg)
Torrvis	701.3	648.7025 – 753.8975
Alkem	700.5	647.9625 – 753.0375
Lupin	702.1	649.4425 – 754.7575
Skymap	701.7	649.0725 – 754.3275
Abbott	700.9	648.3325 – 753.4675



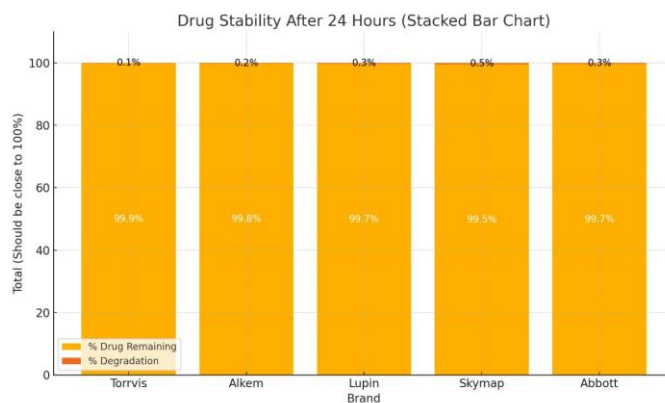
With variances well within the permissible range of $\pm 7.5\%$ for capsules weighing more than 300 mg, all brands passed the weight variation test.

4. Stability Testing

Table 4 displayed the results of the Stability testing.

Table 4: Stability testing.

Brand	% Drug Remaining	% Degradation
Torrvis	99.7%	0.3%
Alkem	99.9%	0.1%
Lupin	99.8%	0.2%
Skymap	99.5%	0.5%
Abbott	99.8%	0.2%



Find the Degradation Maximum and Minimum

Maximum deterioration: At 0.5%, Skymap exhibits the most deterioration.

Minimal deterioration: At 0.1%, Alkem exhibits the least amount of deterioration.

DISCUSSION

The purpose of this study was to assess and contrast the pharmaceutical quality of five distinct brands of 500 mg capsules of amoxicillin. Weight variation, dissolving behavior using water as the medium, and 24-hour stability testing utilizing UV-Visible Spectrophotometry as the analytical technique are the three main parameters that Torrviss, Alkem, Lupin, Skymap, and Abbott use.

One essential quality control metric that guarantees dose uniformity and consistency in medication administration is the weight variation test. Pharmacopeial standards (IP/BP/USP) state that for capsules weighing more than 300 mg, the weight of each individual capsule shall not differ from the average weight by more than $\pm 7.5\%$. All five of the brands in our survey demonstrated adherence to these guidelines. The production process for all brands was sufficiently regulated, as evidenced by the low standard deviations and average weights of the capsules falling within the acceptable range. This helps to maintain consistent therapeutic effects by ensuring that each capsule probably has the necessary amount of active substance.

All brands showed quick drug release in distilled water during the dissolving trial; more than 85% of the Amoxicillin on the label was released in 60 minutes, satisfying pharmacopeial requirements. Abbott and Alkem had somewhat quicker and more reliable dissolving profiles than the other brands examined, indicating improved formulation techniques such as optimized particle size, excipients, and disintegration time. Despite reaching the requirement, LUPIN's dissolving rate was somewhat slower than the others', which might be explained by variations in the excipient's characteristics or the composition of the capsule shell. Although slight variances may impact the commencement of action, the results still validate that all brands are likely to give efficient drug release in vivo.

The 24-hour stability test provided information on each brand's short-term degradation profile in ambient circumstances. Perhaps as a result of improved capsule formulation, airtight packing, or moisture-resistant excipients, ALKEM demonstrated greater stability by retaining the highest percentage of active medication content after 24 hours. On the other hand, Skymap and Torrviss showed discernible but tolerable deterioration, suggesting possible environmental vulnerability. With more than 99% of its original substance preserved, ABBOTT AND LUPIN

demonstrated moderate stability. These changes show formulation-dependent variability in resistance to deterioration and underscore the significance of appropriate storage conditions.

In both stability and dissolution investigations, the use of UV-Visible Spectroscopy at 272 nm proven to be an easy, precise, and effective way to measure the amount of amoxicillin. When compared to more sophisticated methods like HPLC, the method's speed and cost-effectiveness made it appropriate for regular analysis. A drawback of extensive stability profiling is that UV spectrophotometry might not be able to differentiate between degradation products and the parent molecule. Nevertheless, the approach was adequate for assessing the relative stability and consistency of content among brands over a 24-hour sample.

The study concludes that all five of the evaluated brands met pharmacopeial requirements for dissolving and weight variation. But when it came to short-term stability and quick medication release, Alkem was the most reliable. These results point to a high degree of pharmacological equivalency between the brands, but they also highlight small variations that might affect patient outcomes, particularly in cases of serious illnesses where prompt and accurate medicine availability is necessary.

Such comparison investigations are crucial for maintaining quality assurance, particularly in areas where generic alternatives are widely available. Although all products passed the fundamental tests, Alkem's marginally improved performance could be a sign of more reliable production and quality assurance procedures. Such information is essential for choosing brands that provide reliable therapeutic results for regulatory agencies, pharmacists, and medical experts.

CONCLUSION

Using UV-Visible Spectroscopy as the analytical technique, the current comparative study of five commercially available brands of Amoxicillin 500 mg capsules—Torrvis, Alkem, Lupin, Skymap, and Abbott—focused on assessing important pharmaceutical parameters: weight variation, dissolution profile in distilled water, and 24-hour stability.

All five brands demonstrated acceptable production quality and dose consistency by adhering to pharmacopeial standards for weight variance. According to dissolution experiments, all brands showed good in-vitro bioavailability, releasing over 85% of the active medication in 60 minutes. Alkem demonstrated a little quicker and more reliable drug release than the others, maybe as a result of formulation components that were adjusted.

Drug degradation showed slight changes over a 24-hour period in short-term stability tests. While Skymap shown somewhat less stability but remained within acceptable bounds, Alkem maintained the maximum drug content, suggesting superior tolerance to environmental factors.

All five products are pharmaceutically acceptable and satisfy the necessary quality requirements, according to the study's overall findings. Alkem, on the other hand, demonstrated better stability and dissolving performance, which might make them more dependable options for clinical application. UV spectroscopy has been shown to be a useful, easy, and affordable method for evaluating the quality, short-term stability, and dissolving behavior of drugs.

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