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# A COMPARATIVE QUALITATIVE STUDY OF COMMERCIALLY AVAILABLE BRANDS OF LOVASTATIN TABLETS IN MALAYSIA

**Lee Xin Huai, *Nabila Perveen and Naeem Hasan Khan**

Faculty of Pharmacy, AIMST University, Malaysia.

***Corresponding Author: Nabila Perveen**

Faculty of Pharmacy, AIMST University, Malaysia.

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## ABSTRACT

**Introduction:** Lovastatin (LVS) is a commonly prescribed group of statins used to lower cholesterol levels and reduce the risk of cardiovascular diseases (CVD). Despite its widespread use, variations in the quality of different commercial brands can affect their efficacy and patient outcomes. This study aims to evaluate and compare the quality of various LVS tablet brands available in Malaysia. **Objectives:** The primary objective was to assess the consistency and efficacy of different LVS brands by examining their physical characteristics, disintegration strength, and dissolution rates. Specifically, the study seeks to determine if there are significant variations in weight, diameter, thickness, and drug release profiles among the brands. **Method:** The study involved a series of evaluations on multiple brands of LVS tablets. Physical tests included measurements of weight, diameter, and thickness. Chemical characterization was conducted using Fourier Transform Infrared (FTIR) spectroscopy. Disintegration tests assessed the time taken for the tablets to break down, while dissolution tests measured the rate and extent of drug release using a USP Type 2 apparatus and UV-visible spectroscopy. **Result:** The findings revealed significant differences among the brands in terms of physical attributes and drug release profiles. Variations were observed in weight, diameter, and thickness, indicating slight inconsistencies in manufacturing processes. FTIR spectroscopy confirmed the chemical composition of the brands. Disintegration tests showed varying times, with some brands disintegrating faster than others. Dissolution studies highlighted that the drug release rates were not uniform, with some brands demonstrating faster and more complete dissolution compared to others. **Conclusion:** The study concludes that there are notable disparities in the quality of different LVS brands available in Malaysia. These variations can potentially impact the drug's efficacy and patient outcomes. Therefore, stricter regulatory oversight and quality control measures are recommended to ensure consistency and effectiveness of LVS tablets in the market.

**KEYWORDS:** Lovastatin, quality assessment, disintegration, dissolution, FTIR spectroscopy, pharmaceutical tablets, Malaysia.

## INTRODUCTION

Hyperlipidemia is a common ailment characterized by increased levels of lipids in the human body due to a combination of inherited and acquired problems. It is a common ailment that occurs worldwide, although it is more common in Western nations. Lipids comprise apolipoproteins, cholesterol levels, chylomicrons, high-density lipoproteins, low-density lipoproteins, lipoproteins and very low-density lipoproteins. (Hill & Bordoni, 2023) According to CPG 2023 ("CPG on Management of Dyslipidemia," 2023), dyslipidemia indicates that lipid levels exist on a continuous spectrum, without a distinct threshold separating "normal" from "abnormal" levels. The commonly employed threshold values for dyslipidemia, as adopted include:

- Total cholesterol > 5.2 mmol/L
- High-density lipoprotein cholesterol < 1.0 mmol/L for males and < 1.2 mmol/L for females
- Triglycerides > 1.7 mmol/L
- LDLC levels, rely on the cardiovascular risk of the patient.

In the NHMS VI, hypercholesterolemia was prevalent at 38.1%, showing similarity between rural and urban populations. (Institute for Public Health et al., 2019) (Noor Hassim et al., 2016) (Mohd Nor et al., 2022) Even among young adults aged 30-34 years, the prevalence reached 27.9%. (Institute for Public Health et al, 2019) According to MyHeARTs, approximately 20-25% of 13-year-old students in selected urban and rural public schools had total cholesterol levels exceeding 5.2 mmol/L. (Hazreen et al., 2014) The cardiovascular health of these adolescents has undergone adverse changeovers over time, with an increasing number of school

children displaying a higher prevalence of cardiovascular risk factors.

(Thangiah et al., 2020) Despite remaining elevated, it seemed to have stabilized and been on a downward trajectory. (Mohd Nor et al., 2022).

Statins function as inhibitors of Hydroxy-methyl-glutaryl-CoA reductase, the essential enzyme in hepatic cholesterol synthesis. This inhibition leads to a result in reduction of intracellular cholesterol, triggering an elevation in LDL receptor expression on hepatocyte surfaces. As a result, the bloodstream's clearance of LDL and other lipoproteins carrying Apo B including triglyceride-rich particles is enhanced. One of the most important components of lipid-lowering therapy for reducing the risk of CVD is the reduction of LDL-C with statin treatment. Statins are the preferred drugs for lowering LDL-C due to the consistent findings from numerous randomized primary and secondary prevention clinical trials. (Baigent et al., 2010) (Collins et al., 2016) (Silverman et al., 2016) (Taylor et al., 2013) (Cholesterol Treatment Trialists' (CTT) Collaborators et al., 2012) (Tonelli et al., 2011) (Naci et al., 2013) The degree of LDL-C therapy attained determines how well lipid-modifying drugs work to prevent or delay the development of coronary atherosclerotic plaques. A substantial slowdown in the advancement of atherosclerosis appears to occur when the LDL-C level is kept below 1.6 mmol/L while on treatment. (Nissen et al., 2004) (Nissen et al., 2006) (Tsujita et al., 2015) (Nicholls et al., 2016) (Nicholls et al., 2011) (Shin et al., 2017).

LVS has the molecular formula of $C_{24}H_{36}O_5$ and molecular weight of 404.5 g/mol. LVS is defined as having a composition of the compound not less than 97.0 percent and not more than the equivalent of 102.0 percent of the compound (1S,3R,7S,8S,8aR)-8-[2-[(2R,4R)-4-hydroxy-6-oxotetrahydro-2H- pyran-2-yl] ethyl]-3,7-dimethyl-1,2,3,7,8,8a-hexahydronaphthalen-1-yl (2S)-2-methylbutanoate. It is somewhat soluble in ethanol and shows solubility in acetone. (British Pharmacopoeia Commission, 2007) (United States Pharmacopeial Convention, 2008) LVS is a fatty acid ester that is derived from Mevastatin, with the addition of a methyl group on the carbocyclic skeleton. Functionally, it is connected to (S)-2- methylbutyric acid and mevastatin. It is naturally present in fungal species such as Aspergillus terreus and Pleurotus ostreatus (oyster mushroom). Figure 1 shows the chemical structure of Lovastatin. Dissolution testing holds a crucial role in evaluating the performance of oral solid dosage forms, as emphasized by its important significance in pharmaceutical development.

Dissolution testing has a variety of significant responsibilities to play during a drug's developmental process. Its main duties in the initial phases are to evaluate bioequivalence, characterize therapeutic efficacy, and ascertain the bioavailability of the API. Dissolution testing expands and adjusts as product development moves into later phases and product registration, including quality control needs. Charlotte Clay, leader of Quotient Sciences' Analytical Development in Pharmaceutical Analysis, claims that the nature of dissolution tests and the data they yield change as molecules progress through different stages of development. (Thomas, 2019).

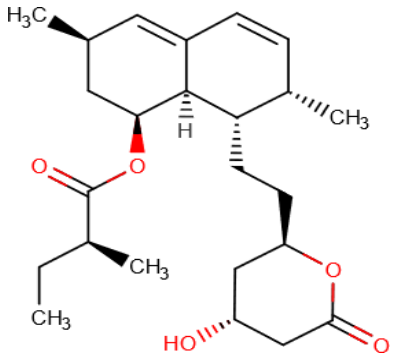



**Figure 1: Chemical structure of lovastatin.**

## METHODOLOGY

### Evaluation of Various Brands of LVS Tablets and Weight, Diameter & Thickness Tests for Each Brand of Tablets

Three brands of LVS tablets—Brand A, Brand B, and Brand C—were collected. Each strip and tablet were observed.

For each brand, 20 LVS tablets were individually weighed, and the average weight was calculated. The individual tablet weights were compared to the average weight. According to the U.S.P. test, the tablets pass if no more than two tablets deviate from the percentage limit and if no tablet deviates by more than twice the percentage limit. ("EVALUATION of TABLETS – Pharma State Academy," n.d.)

The diameter and thickness of the tablets were measured. The deviation should not exceed ± 5% for tablets with a diameter of less than 12.5 mm and ± 3% for tablets with a diameter of 12.5 mm or more. (Chan, 2015). 20 tablets from each brand were crushed using mortar and pestle and stored in labeled zipper bags such as A, B, and C. Table 1shows the variations tolerance for uncoated tablets.

**Table 1: Weight Variation Tolerances for Uncoated Tablets.**

| S. No | Average Weight of Tablets (mg) | Max. % Difference Allowed |
|---|---|---|
| 1 | 130 or less | ± 10 |
| 2 | 130-324 | ± 7.5 |
| 3 | More than 324 | ± 5 |

Table adapted from ("EVALUATION of TABLETS – Pharma State Academy," n.d.)

**Characterization of LVS by (Fourier Transform Infrared spectroscopy (FTIR) Spectroscopy Method**
**Materials**
Powder form of brands of LVS tablets

**Procedure**
To obtain sample discs, the powder form of Brands A, B and C were placed on the sample compartment using spatula under 15,000 lbs using the hydraulic pressure system in the die press. Die press was clean before inserting the sample material. The diffuse reflectance mode FT-infrared spectra were obtained. With an accumulation of 16 spectral scans, the spectra were captured at a spectral resolution of 4 $cm^{-1}$ and in the range of 4000–450 $cm^{-1}$. To create a single spectrum for every sample, two spectra were interpreted. (Abdel Hakiem et al., 2021)

**Disintegration Study of LVS**
**Procedure**
("EVALUATION of TABLETS – Pharma State Academy," n.d.)
For the disintegration test, 900 mL of distilled water was used as the disintegration medium. The U.S.P. device employed for this test consists of six glass tubes, each 3 inches long, open at the top, with a 10-mesh screen at the bottom. Four LVS tablets of Brands A, B and C were placed in each tube, and the basket rack was positioned in a 1-liter beaker of distilled water maintained at 37 ± 2°C. The tablets were set to remain 2.5 cm below the liquid surface at their highest point and not closer than 2.5 cm from the beaker's bottom at their lowest point.

The basket containing the tablets moved up and down through a distance of 5-6 cm at a frequency of 28 to 32 cycles per minute. To prevent the tablets from floating, perforated plastic discs were placed on each tablet. According to the test criteria, the tablets must disintegrate, with all particles passing through the 10-mesh screen within the specified time. Any residue left must form a soft mass. Disintegration time for uncoated tablet is 15 minutes.

Dissolution Study of LVS by USP Type 2 Apparatus and UV-Visible Spectroscopy Method Preparation of Standard LVS Solutions:
To prepare a dissolution medium (phosphate buffer), 1.38g of $NaH_2PO_4$ and 20g of SDS were dissolved in 900ml of distilled water. NaOH was used to adjust the pH to 7.0. The pH value was measured with a digital pH meter. Next, the resulting solution was diluted to 1000ml with distilled water.

5mg of LVS was dissolved in 10ml of buffer solution and transferred into 50ml volumetric flask. The volume was made up with distilled water. Then, 1ml, 2ml, 3ml, 4ml and 5ml were pipetted out into 10ml volumetric flasks to prepare five different standard solutions with the concentrations of 10 µg/ml, 20 µg/ml, 30 µg/ml, 40 µg/ml and 50 µg/ml. The volumes were made up with distilled water.

**Preparation of Blank for Baseline Correction for Standard Solutions**
Distilled water was used as blank.

**Dissolution Test**
The dissolution study was done by using USP Type 2 Apparatus (paddle apparatus), one of the most widely used tools for dissolution testing of oral dosage forms, such as tablets and capsules, at 37 ± 0.5 °C and 50 rpm. Six LVS tablets of Brands A, B and C were inserted in each chamber filled with 900 ml of pH 7.0 phosphate buffer. 10ml of the dissolution media were withdrawn from the chambers and 10ml of buffer were replaced into the chambers at the same time every 30, 60, 90 and 120 minutes. After withdrawing, samples are filtered using syringe filter and placed in 50ml volumetric flasks.

**Preparation of Sample Solutions**
The volumes in six of the 50ml of volumetric flasks were made up with distilled water.

**Preparation of Blank for Baseline Correction for Sample Solutions**
10ml of buffer solution was placed into 50ml volumetric flask and the volume was made up with distilled water.

**Absorbance Measurement**
UV-Visible Spectrophotometer was switched on and allowed to stabilize for 15 minutes. Baseline corrections of both standard and sample solutions were performed using the blank prepared. The absorbances of the respective dilutions were measured at λ max of 240 nm and triplicate readings were recorded. The standard calibration curve of LVS was used to calculate concentration of LVS sample solutions. Lastly, the percentage of drug released can be calculated with the formula:

Amount of drug released = Concentration x Volume of dissolution medium / 1000

% of drug release = Amount of drug released x Dilution factor / Drug dose Measuring absorbances of standard and sample solutions with UV-Visible Spectrophotometer.

## RESULTS

**Observation of Various Brands of LVS Tablets and Data Tabulation of Weight, Diameter & Thickness Tests of Each Brand of Tablets showed in Table 2.**

**Table 2: Evaluation of LVS Tablets.**

| Brands of LVS Tablets | Descriptions |
|---|---|
| **A**  | • 1 strip contains 10 tablets<br>• Tablet was light blue in colour<br>• Tablet had a flat octagon shape with beveled- edge<br>• Tablet was engraved "APO" on one side, scored and engraved "LOVA" over "20" on the other side |
| **B**  | • 1 strip contains 10 tablets<br>• Tablet was light blue in colour<br>• Tablet had an octagon shape<br>• Tablet was one side impressed with the mark "YUNG SHIN" |
| **C**  | • 1 strip contains 10 tablets<br>• Tablet was blue in colour<br>• Tablet had a flat round shape<br>• Tablet was scored on one side |

Tables 3-5 shows the weight variations of different brands of lovastatin while tables 6-8 Shows the Diameter and Thickness Variations of A-C brands.

**Table 3: Weight Variation of Brand A.**

| Tablet | Weight (mg) | Percentage of Deviation |
|---|---|---|
| 1 | 189.9 | -0.45 |
| 2 | 192.7 | 1.01 |
| 3 | 189.1 | -0.87 |
| 4 | 190.1 | -0.35 |
| 5 | 187.1 | -1.92 |
| 6 | 192.7 | 1.01 |
| 7 | 190.5 | -0.14 |
| 8 | 192.3 | 0.80 |
| 9 | 192.5 | 0.91 |
| 10 | 188.0 | -1.45 |
| 11 | 190.8 | 0.02 |
| 12 | 188.8 | -1.03 |
| 13 | 192.2 | 0.75 |
| 14 | 189.8 | -0.51 |
| 15 | 190.7 | -0.03 |
| 16 | 191.7 | 0.49 |
| 17 | 193.2 | 1.28 |
| 18 | 191.7 | 0.49 |
| 18 | 190.1 | -0.35 |
| 20 | 191.4 | 0.33 |
| Average | 190.765 | 0.00 |

**Table 4: Weight Variation of Brand B.**

| Tablet | Weight (mg) | Percentage of Deviation |
|---|---|---|
| 1 | 204.4 | 0.94 |
| 2 | 203.4 | 0.44 |
| 3 | 206.1 | 1.78 |
| 4 | 205.9 | 1.68 |
| 5 | 201.2 | -0.64 |
| 6 | 200.2 | -1.14 |
| 7 | 204.3 | 0.89 |
| 8 | 195.8 | -3.31 |
| 9 | 199.1 | -1.68 |
| 10 | 199.4 | -1.53 |
| 11 | 203.7 | 0.59 |
| 12 | 207.9 | 2.67 |
| 13 | 201.2 | -0.64 |
| 14 | 203.2 | 0.35 |
| 15 | 205.0 | 1.23 |
| 16 | 204.2 | 0.84 |
| 17 | 199.1 | -1.68 |
| 18 | 207.1 | 2.27 |
| 18 | 197.8 | -2.32 |
| 20 | 200.9 | -0.79 |
| Average | 202.5 | 0.00 |

**Table 5: Weight Variation of Brand C.**

| Tablet | Weight (mg) | Percentage of Deviation |
|---|---|---|
| 1 | 207.7 | 0.39 |
| 2 | 206.1 | -0.39 |
| 3 | 204.5 | -1.16 |
| 4 | 207.7 | 0.39 |
| 5 | 208.5 | 0.77 |
| 6 | 205.5 | -0.68 |
| 7 | 207.2 | 0.14 |
| 8 | 204.6 | -1.11 |
| 9 | 210.4 | 1.69 |
| 10 | 206.1 | -0.39 |
| 11 | 205.3 | -0.77 |
| 12 | 207.7 | 0.39 |
| 13 | 207.6 | 0.34 |
| 14 | 209.1 | 1.06 |
| 15 | 204.8 | -1.01 |
| 16 | 205.6 | -0.63 |
| 17 | 208.0 | 0.53 |
| 18 | 204.5 | -1.16 |
| 19 | 208.0 | 0.53 |
| 20 | 208.4 | 0.72 |
| Average | 206.9 | -0.02 |

**Table 6: Diameter and Thickness Variations of Brand A**

| Tablet | Diameter (mm) | Percentage of Deviation | Thickness (mm) |
|---|---|---|---|
| 1 | 5.70 | 0.11 | 0.51 |
| 2 | 5.69 | -0.07 | 0.54 |
| 3 | 5.67 | -0.42 | 0.47 |
| 4 | 5.67 | -0.42 | 0.44 |
| 5 | 5.70 | 0.11 | 0.47 |
| 6 | 5.70 | 0.11 | 0.51 |
| 7 | 5.68 | -0.25 | 0.55 |
| 8 | 5.68 | -0.25 | 0.57 |

| | | | |
|---|---|---|---|
| 9 | 5.67 | -0.42 | 0.47 |
| 10 | 5.71 | 0.28 | 0.47 |
| 11 | 5.70 | 0.11 | 0.49 |
| 12 | 5.70 | 0.11 | 0.45 |
| 13 | 5.68 | -0.25 | 0.59 |
| 14 | 5.68 | -0.25 | 0.49 |
| 15 | 5.72 | 0.46 | 0.56 |
| 16 | 5.67 | -0.42 | 0.57 |
| 17 | 5.67 | -0.42 | 0.57 |
| 18 | 5.73 | 0.63 | 0.48 |
| 18 | 5.73 | 0.63 | 0.43 |
| 20 | 5.73 | 0.63 | 0.51 |
| Average | 5.694 | 0.00 | 0.507 |

**Table 7: Diameter and Thickness Variations of Brand B.**

| Tablet | Diameter (mm) | Percentage of Deviation | Thickness (mm) |
|---|---|---|---|
| **1** | 7.99 | -0.29 | 3.02 |
| **2** | 8.01 | -0.04 | 3.03 |
| **3** | 8.00 | -0.16 | 3.09 |
| **4** | 8.00 | -0.16 | 3.08 |
| **5** | 8.02 | 0.09 | 3.08 |
| **6** | 7.98 | -0.41 | 3.01 |
| **7** | 8.05 | 0.46 | 3.14 |
| **8** | 8.05 | 0.46 | 3.01 |
| **9** | 8.01 | -0.04 | 3.02 |
| **10** | 8.03 | 0.21 | 3.02 |
| **11** | 8.00 | -0.16 | 3.03 |
| **12** | 8.01 | -0.04 | 3.06 |
| **13** | 8.05 | 0.46 | 3.00 |
| **14** | 8.07 | 0.71 | 3.03 |
| **15** | 7.97 | -0.54 | 3.04 |
| **16** | 8.05 | 0.46 | 3.00 |
| **17** | 7.96 | -0.66 | 3.03 |
| **18** | 8.00 | -0.16 | 3.06 |
| **18** | 7.99 | -0.29 | 3.03 |
| **20** | 8.01 | -0.04 | 3.02 |
| **Average** | **8.013** | **-0.01** | **3.04** |

**Table 8: Diameter and Thickness Variations of Brand C.**

| Tablet | Diameter (mm) | Percentage of Deviation | Thickness (mm) |
|---|---|---|---|
| **1** | 8.08 | -0.05 | 3.10 |
| **2** | 8.12 | 0.45 | 3.24 |
| **3** | 8.09 | 0.07 | 3.18 |
| **4** | 8.08 | -0.05 | 3.10 |
| **5** | 8.07 | -0.17 | 3.10 |
| **6** | 8.07 | -0.17 | 3.25 |
| **7** | 8.06 | -0.30 | 3.11 |
| **8** | 8.09 | 0.07 | 3.16 |
| **9** | 8.11 | 0.32 | 3.18 |
| **10** | 8.12 | 0.45 | 3.10 |
| **11** | 8.08 | -0.05 | 3.18 |
| **12** | 8.07 | -0.17 | 3.24 |
| **13** | 8.07 | -0.17 | 3.23 |
| **14** | 8.11 | 0.32 | 3.11 |
| **15** | 8.10 | 0.20 | 3.04 |
| **16** | 8.06 | -0.30 | 3.22 |
| **17** | 8.08 | -0.05 | 3.24 |

| | | | |
|---|---|---|---|
| **18** | 8.07 | -0.17 | 3.16 |
| **18** | 8.08 | -0.05 | 3.30 |
| **20** | 8.07 | -0.17 | 3.12 |
| **Average** | **8.084** | **0.00** | **3.168** |

Spectra of LVS by FTIR Spectroscopy is shown in Figures 2-4 while the characteristics of IR Absorptions are given in Tables 9-11. The disintegration time of various brands is given in Tables 12A-12C. The Data Tabulation of Dissolution Study of LVS is shown in Table 13.

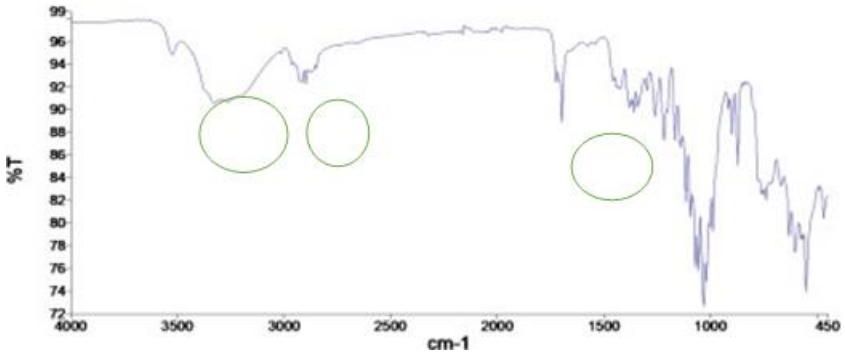



**Figure 2: Spectrum of Brand A.**

**Table 9: Characteristics IR Absorptions of Brand A.**

| Frequency ($cm^{-1}$) | Intensity | Peak | Bond | Functional Group | Notes |
|---|---|---|---|---|---|
| 3330 | Strong | Broad | O-H Stretch | Alcohol | Intermolecular bonding |
| 2900 | Medium | - | C-H Stretch | Alkane | - |
| 1750 | Strong | - | C=O Stretch | Ester | 6-membered lactone |

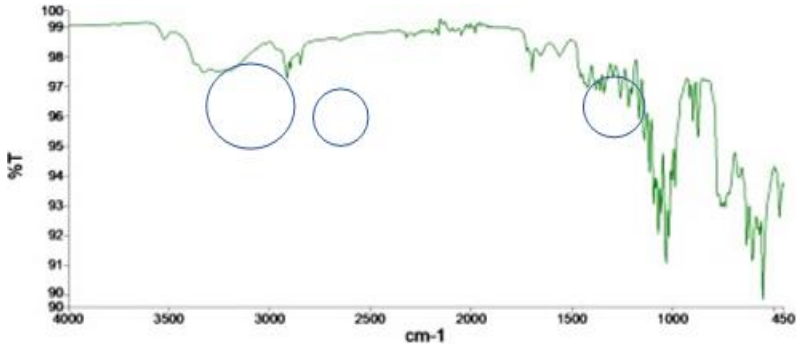



**Figure 3: Spectrum of Brand B.**

**Table 10: Characteristics IR Absorptions of Brand B.**

| Frequency ($cm^{-1}$) | Intensity | Peak | Bond | Functional Group | Notes |
|---|---|---|---|---|---|
| 3330 | Strong | Broad | O-H Stretch | Alcohol | Intermolecular bonding |
| 2900 | Medium | - | C-H Stretch | Alkane | - |
| 1750 | Strong | - | C=O Stretch | Ester | 6-membered lactone |

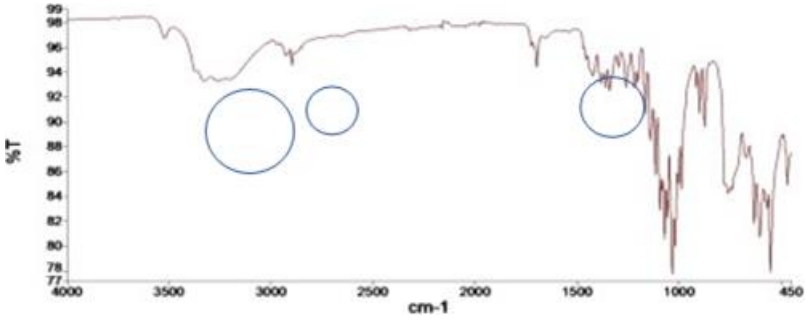



**Figure 4: Spectrum of Brand C.**

**Table 11: Characteristics IR Absorptions of Brand C.**

| Frequency ($cm^{-1}$) | Intensity | Peak | Bond | Functional Group | Notes |
|---|---|---|---|---|---|
| 3330 | Strong | Broad | O-H Stretch | Alcohol | Intermolecular bonding |
| 2900 | Medium | - | C-H Stretch | Alkane | - |
| 1750 | Strong | - | C=O Stretch | Ester | 6-membered lactone |

**Disintegration Time Taken by LVS**

**Table12A: Disintegration Time Taken by Brand A.**

| Tablet | Time Taken (min) |
|---|---|
| 1 | 5.67 |
| 2 | 4.78 |
| 3 | 6.12 |
| 4 | 5.37 |
| **Average** | **5.485** |

**Table12B: Disintegration Time Taken by Brand B.**

| Tablet | Time Taken (min) |
|---|---|
| 1 | 7.16 |
| 2 | 5.89 |
| 3 | 6.33 |
| 4 | 9.55 |
| **Average** | **7.23** |

**Table 12C: Disintegration Time Taken by Brand C.**

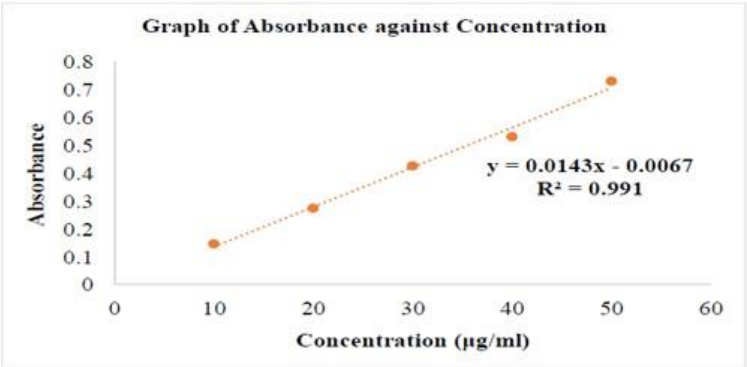
| Tablet | Time Taken (min) |
|---|---|
| 1 | 12.22 |
| 2 | 10.56 |
| 3 | 10.81 |
| 4 | 11.22 |
| **Average** | **11.20** |

**Data Tabulation of Dissolution Study of LVS**

**Table 13: Absorbance of Standard LVS Solutions.**

| Concentration (µg/ml) | Absorbance | | | |
|---|---|---|---|---|
| | First trial | Second Trial | Third Trial | Average |
| **10** | 0.134 | 0.152 | 0.152 | **0.146** |
| **20** | 0.276 | 0.271 | 0.271 | **0.273** |
| **30** | 0.426 | 0.424 | 0.426 | **0.425** |
| **40** | 0.524 | 0.533 | 0.533 | **0.530** |
| **50** | 0.736 | 0.727 | 0.726 | **0.730** |

Standard Calibration Curve against concentration of LVS is shown in Graph 1. Graph of Accumulated Percentage of Drug Released against Time shown in Graph 2.




**Graph 1: Absorbance against concentration.**

The absorption of sample solutions is shown in Tables 14-16 while Percentage of Drug Release is given in Tables 17-19. The Average Percentage of Drug Released of Brands A, B and C are given in Table 20.

Area Under curve ($AUC_{0-2}$) of different brands is shown in Tables 21-23.

**Table 14: Absorbance of Sample Solutions of Brand A.**

| Tablet | Trials | Time (min) | | | |
|---|---|---|---|---|---|
| | | 30 | 60 | 90 | 120 |
| First | First Trial | 0.193 | 0.252 | 0.262 | 0.292 |
| | Second Trial | 0.200 | 0.257 | 0.258 | 0.273 |
| | Third Trial | 0.199 | 0.251 | 0.258 | 0.271 |
| | **Average** | **0.197** | **0.253** | **0.259** | **0.279** |
| Second | First Trial | 0.221 | 0.247 | 0.253 | 0.268 |
| | Second Trial | 0.207 | 0.248 | 0.248 | 0.262 |
| | Third Trial | 0.209 | 0.246 | 0.248 | 0.262 |
| | **Average** | **0.212** | **0.247** | **0.250** | **0.264** |
| Third | First Trial | 0.238 | 0.324 | 0.272 | 0.269 |
| | Second Trial | 0.204 | 0.282 | 0.271 | 0.268 |
| | Third Trial | 0.196 | 0.278 | 0.270 | 0.267 |
| | **Average** | **0.213** | **0.295** | **0.271** | **0.268** |
| Fourth | First Trial | 0.210 | 0.304 | 0.268 | 0.263 |
| | Second Trial | 0.203 | 0.272 | 0.274 | 0.258 |
| | Third Trial | 0.207 | 0.263 | 0.264 | 0.247 |
| | **Average** | **0.207** | **0.280** | **0.269** | **0.256** |
| Fifth | First Trial | 0.228 | 0.233 | 0.255 | 0.253 |
| | Second Trial | 0.211 | 0.231 | 0.257 | 0.256 |
| | Third Trial | 0.199 | 0.228 | 0.254 | 0.249 |
| | **Average** | **0.213** | **0.231** | **0.255** | **0.253** |
| Sixth | First Trial | 0.191 | 0.249 | 0.275 | 0.257 |
| | Second Trial | 0.173 | 0.245 | 0.269 | 0.257 |
| | Third Trial | 0.169 | 0.247 | 0.267 | 0.257 |
| | **Average** | **0.178** | **0.247** | **0.270** | **0.257** |

**Table 15: Absorbance of Sample Solutions of Brand B.**

| Tablet | Trials | Time (min) | | | |
|---|---|---|---|---|---|
| | | 30 | 60 | 90 | 120 |
| First | First Trial | 0.268 | 0.267 | 0.251 | 0.238 |
| | Second Trial | 0.270 | 0.267 | 0.254 | 0.239 |
| | Third Trial | 0.267 | 0.271 | 0.252 | 0.237 |
| | **Average** | **0.268** | **0.268** | **0.252** | **0.238** |
| Second | First Trial | 0.257 | 0.265 | 0.262 | 0.245 |
| | Second Trial | 0.265 | 0.265 | 0.264 | 0.247 |
| | Third Trial | 0.264 | 0.266 | 0.262 | 0.247 |
| | **Average** | **0.262** | **0.265** | **0.263** | **0.246** |
| Third | First Trial | 0.251 | 0.257 | 0.254 | 0.250 |
| | Second Trial | 0.249 | 0.259 | 0.257 | 0.250 |
| | Third Trial | 0.248 | 0.253 | 0.257 | 0.250 |
| | **Average** | **0.249** | **0.256** | **0.256** | **0.250** |
| Fourth | First Trial | 0.247 | 0.254 | 0.247 | 0.245 |
| | Second Trial | 0.240 | 0.252 | 0.247 | 0.245 |
| | Third Trial | 0.247 | 0.253 | 0.249 | 0.245 |
| | **Average** | **0.245** | **0.253** | **0.248** | **0.245** |
| Fifth | First Trial | 0.268 | 0.255 | 0.251 | 0.201 |
| | Second Trial | 0.260 | 0.254 | 0.250 | 0.200 |
| | Third Trial | 0.260 | 0.254 | 0.250 | 0.200 |
| | **Average** | **0.263** | **0.254** | **0.250** | **0.200** |
| Sixth | First Trial | 0.279 | 0.271 | 0.264 | 0.245 |
| | Second Trial | 0.278 | 0.271 | 0.265 | 0.244 |

| | | | | | |
|---|---|---|---|---|---|
| | Third Trial | 0.278 | 0.271 | 0.264 | 0.244 |
| | **Average** | **0.278** | **0.271** | **0.264** | **0.244** |

**Table 16: Absorbance of Sample Solutions of Brand C.**

| Tablet | Trials | Time (min) | | | |
|---|---|---|---|---|---|
| | | 30 | 60 | 90 | 120 |
| **First** | First Trial | 0.250 | 0.259 | 0.279 | 0.273 |
| | Second Trial | 0.250 | 0.260 | 0.280 | 0.275 |
| | Third Trial | 0.236 | 0.260 | 0.280 | 0.278 |
| | **Average** | **0.245** | **0.260** | **0.280** | **0.275** |
| **Second** | First Trial | 0.263 | 0.273 | 0.279 | 0.277 |
| | Second Trial | 0.264 | 0.275 | 0.281 | 0.278 |
| | Third Trial | 0.258 | 0.274 | 0.277 | 0.278 |
| | **Average** | **0.262** | **0.274** | **0.279** | **0.278** |
| **Third** | First Trial | 0.259 | 0.267 | 0.293 | 0.263 |
| | Second Trial | 0.259 | 0.266 | 0.283 | 0.263 |
| | Third Trial | 0.249 | 0.267 | 0.279 | 0.264 |
| | **Average** | **0.256** | **0.267** | **0.285** | **0.263** |
| **Fourth** | First Trial | 0.256 | 0.265 | 0.277 | 0.265 |
| | Second Trial | 0.258 | 0.268 | 0.278 | 0.266 |
| | Third Trial | 0.254 | 0.265 | 0.278 | 0.265 |
| | **Average** | **0.256** | **0.266** | **0.278** | **0.265** |
| **Fifth** | First Trial | 0.261 | 0.268 | 0.281 | 0.274 |
| | Second Trial | 0.261 | 0.269 | 0.280 | 0.274 |
| | Third Trial | 0.261 | 0.271 | 0.280 | 0.274 |
| | **Average** | **0.261** | **0.269** | **0.280** | **0.274** |
| **Sixth** | First Trial | 0.258 | 0.290 | 0.281 | 0.277 |
| | Second Trial | 0.258 | 0.286 | 0.282 | 0.278 |
| | Third Trial | 0.258 | 0.286 | 0.282 | 0.279 |
| | **Average** | **0.258** | **0.287** | **0.282** | **0.278** |

**Table 17: Percentage of Drug Released of Brand A.**

| Tablet | Time (min) | Absorbance | | Concentration (µg/ml) | Amount of Drug Released | % of Drug Released |
|---|---|---|---|---|---|---|
| **First** | 30 | 0.197 | | 14.24 | 12.82 | 32.05 |
| | 60 | 0.253 | | 18.16 | 16.34 | 40.86 |
| | 90 | 0.259 | | 18.58 | 16.72 | 41.81 |
| | 120 | 0.279 | | 19.98 | 17.98 | **44.95** |
| **Second** | 30 | 0.212 | | 15.29 | 13.76 | 34.41 |
| | 60 | 0.247 | | 17.74 | 15.97 | 39.92 |
| | 90 | 0.250 | | 17.95 | 16.16 | 40.39 |
| | 120 | 0.264 | | 18.93 | 17.04 | **42.59** |
| **Third** | 30 | 0.213 | | 15.36 | 13.83 | 34.57 |
| | 60 | 0.295 | | 21.10 | 18.99 | 47.47 |
| | 90 | 0.271 | | 19.42 | 17.48 | 43.69 |
| | 120 | 0.268 | | 19.21 | 17.29 | **43.22** |
| **Fourth** | 30 | 0.207 | | 14.94 | 13.45 | 33.62 |
| | 60 | 0.280 | | 20.05 | 18.04 | 45.11 |
| | 90 | 0.269 | | 19.28 | 17.35 | 43.38 |
| | 120 | 0.256 | | 18.37 | 16.53 | **41.33** |
| **Fifth** | 30 | 0.213 | | 15.36 | 13.83 | 34.57 |
| | 60 | 0.231 | | 16.62 | 14.96 | 37.40 |
| | 90 | 0.255 | | 18.30 | 16.47 | 41.18 |
| | 120 | 0.253 | | 18.16 | 16.34 | **40.86** |
| **Sixth** | 30 | 0.178 | | 12.92 | 11.62 | 29.06 |
| | 60 | 0.247 | | 17.74 | 15.97 | 39.92 |
| | 90 | 0.270 | | 19.35 | 17.41 | 43.54 |
| | 120 | 0.257 | | 18.44 | 16.60 | **41.49** |

**Table 18: Percentage of Drug Released of Brand B.**

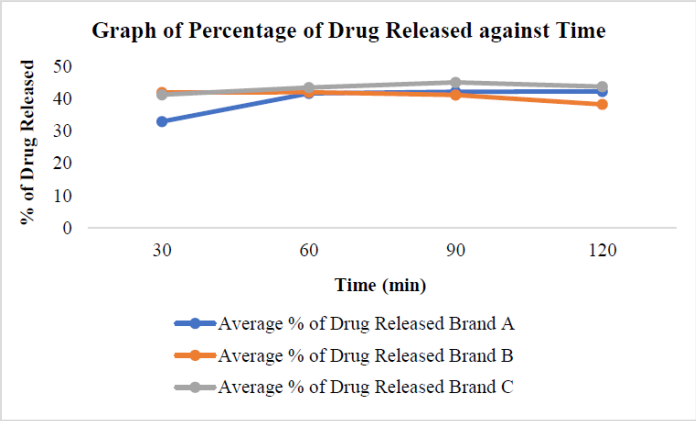
| Tablet | Time (min) | Absorbance | Concentration (µg/ml) | Amount of Drug Released | % of Drug Released |
|---|---|---|---|---|---|
| **First** | 30 | 0.268 | 19.21 | 17.29 | 43.22 |
| | 60 | 0.268 | 19.21 | 17.29 | 43.22 |
| | 90 | 0.252 | 18.09 | 16.28 | 40.70 |
| | 120 | 0.238 | 17.11 | 15.40 | **38.50** |
| **Second** | 30 | 0.262 | 18.79 | 16.91 | 42.28 |
| | 60 | 0.265 | 19.00 | 17.10 | 42.75 |
| | 90 | 0.263 | 18.86 | 16.97 | 42.44 |
| | 120 | 0.246 | 17.67 | 15.90 | **39.76** |
| **Third** | 30 | 0.249 | 17.88 | 16.09 | 40.23 |
| | 60 | 0.256 | 18.37 | 16.53 | 41.33 |
| | 90 | 0.256 | 18.37 | 16.53 | 41.33 |
| | 120 | 0.250 | 17.95 | 16.16 | **40.39** |
| **Fourth** | 30 | 0.245 | 17.60 | 15.84 | 39.60 |
| | 60 | 0.253 | 18.16 | 16.34 | 40.86 |
| | 90 | 0.248 | 17.81 | 16.03 | 40.08 |
| | 120 | 0.245 | 17.60 | 15.84 | **39.60** |
| **Fifth** | 30 | 0.263 | 18.86 | 16.97 | 42.44 |
| | 60 | 0.254 | 18.23 | 16.41 | 41.02 |
| | 90 | 0.250 | 17.95 | 16.16 | 40.39 |
| | 120 | 0.200 | 14.45 | 13.01 | **32.52** |
| **Sixth** | 30 | 0.278 | 19.91 | 17.92 | 44.80 |
| | 60 | 0.271 | 19.42 | 17.48 | 43.69 |
| | 90 | 0.264 | 18.93 | 17.04 | 42.59 |
| | 120 | 0.244 | 17.53 | 15.78 | **39.45** |

**Table 19: Percentage of Drug Released of Brand C.**

| Tablet | Time (min) | Absorbance | Concentration (µg/ml) | Amount of Drug Released | % of Drug Released |
|---|---|---|---|---|---|
| **First** | 30 | 0.245 | 17.60 | 15.84 | 39.60 |
| | 60 | 0.260 | 18.65 | 16.79 | 41.96 |
| | 90 | 0.280 | 20.05 | 18.04 | 45.11 |
| | 120 | 0.275 | 19.70 | 17.73 | **44.32** |
| **Second** | 30 | 0.262 | 18.79 | 16.91 | 42.28 |
| | 60 | 0.274 | 19.63 | 17.67 | 44.17 |
| | 90 | 0.279 | 19.98 | 17.98 | 44.95 |
| | 120 | 0.278 | 19.91 | 17.92 | **44.80** |
| **Third** | 30 | 0.256 | 18.37 | 16.53 | 41.33 |
| | 60 | 0.267 | 19.14 | 17.23 | 43.06 |
| | 90 | 0.285 | 20.40 | 18.36 | 45.90 |
| | 120 | 0.263 | 18.86 | 16.97 | **42.44** |
| **Fourth** | 30 | 0.256 | 18.37 | 16.53 | 41.33 |
| | 60 | 0.266 | 19.07 | 17.16 | 42.91 |
| | 90 | 0.278 | 19.91 | 17.92 | 44.80 |
| | 120 | 0.265 | 19.00 | 17.10 | **42.75** |
| **Fifth** | 30 | 0.261 | 18.72 | 16.85 | 42.12 |
| | 60 | 0.269 | 19.28 | 17.35 | 43.38 |
| | 90 | 0.280 | 20.05 | 18.04 | 45.11 |
| | 120 | 0.274 | 19.63 | 17.67 | **44.17** |
| **Sixth** | 30 | 0.258 | 18.51 | 16.66 | 41.65 |
| | 60 | 0.287 | 20.54 | 18.48 | 46.21 |
| | 90 | 0.282 | 20.19 | 18.17 | 45.42 |
| | 120 | 0.278 | 19.91 | 17.92 | **44.80** |

**Table 20: Average Percentage of Drug Released of Brands A, B and C.**

| Time (min) | Average % of Drug Released | | |
|---|---|---|---|
| | Brand A | Brand B | Brand C |
| **30** | 33.05 | 42.10 | 41.39 |
| **60** | 41.78 | 42.15 | 43.62 |
| **90** | 42.33 | 41.26 | 45.22 |
| **120** | 42.41 | 38.37 | 43.88 |




**Graph 2: Accumulated Percentage of Drug Released against Time.**

**Table 21: $AUC_{0-2}$ of Brand A.**

| Time (h) | Average Concentration (µg/ml) | (Cn-1 + Cn) / 2 | tn - tn-1 | AUC |
|---|---|---|---|---|
| **0.5** | 14.69 | 7.35 | 0.5 | 3.68 |
| **1** | 18.57 | 16.63 | 0.5 | 8.32 |
| **1.5** | 18.81 | 18.69 | 0.5 | 9.35 |
| **2** | 18.85 | 18.83 | 0.5 | 9.42 |
| **AUC0-2** | | | | **30.77** |

**Table 22: $AUC_{0-2}$ of Brand B.**

| Time (h) | Average Concentration (µg/ml) | (Cn-1 + Cn) / 2 | tn - tn-1 | AUC |
|---|---|---|---|---|
| **0.5** | 18.71 | 9.36 | 0.5 | 4.68 |
| **1** | 18.73 | 18.72 | 0.5 | 9.36 |
| **1.5** | 18.34 | 18.54 | 0.5 | 9.27 |
| **2** | 17.05 | 17.70 | 0.5 | 8.85 |
| **AUC0-2** | | | | **32.16** |

**Table 23: $AUC_{0-2}$ of Brand C.**

| Time (h) | Average Concentration (µg/ml) | (Cn-1 + Cn) / 2 | tn - tn-1 | AUC |
|---|---|---|---|---|
| **0.5** | 18.39 | 9.20 | 0.5 | 4.60 |
| **1** | 19.39 | 18.89 | 0.5 | 9.45 |
| **1.5** | 20.10 | 19.75 | 0.5 | 9.88 |
| **2** | 19.50 | 19.80 | 0.5 | 9.90 |
| **AUC0-2** | | | | **33.83** |

## DISCUSSION

Crushing tablets into powder is crucial for various pharmaceutical analyses and quality control measures. This process ensures uniformity and consistency across analytical procedures and is also vital for obtaining accurate results in methods like FTIR, which require the drug to be scanned. Additionally, crushing the tablets allows for homogeneous sampling, aids in stability studies, and ensures even distribution of the active ingredient, helping to detect any manufacturing defects. This process ultimately helps maintain the efficacy, quality, and shelf-life of drug.

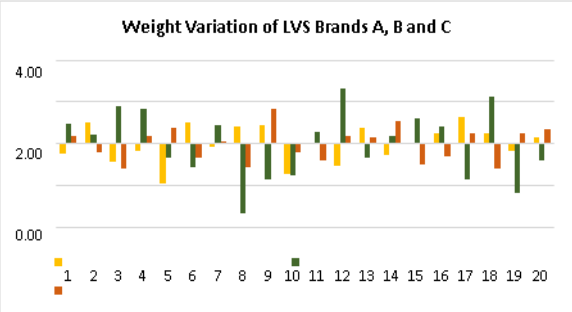
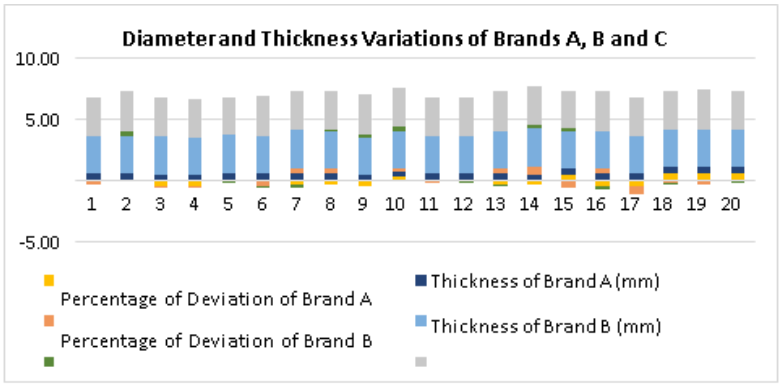



**Figure 5: Weight Variations of Brands A, B and C.**

In the weight variation test, the average weight of 20 tablets for Brand A was 190.765 mg, with percentage deviations ranging from -1.92% to 1.28%. For Brand B, the average weight was 202.5 mg, with deviations ranging from -3.31% to 2.67%. Brand C had an average weight of 206.9 mg, with deviations ranging from -1.16% to 1.69%. According to Table 4.11, Brands A, B, and C passed the test, as no more than two tablets deviated from the percentage limit, and no tablet deviated by more than twice the limit of ± 7.5%. Among the three brands, Brand C exhibited the smallest percentage deviation between tablets, while Brand B showed the largest. ("EVALUATION of TABLETS - PharmaState Academy," n.d.), as shown in Figure 5.




**Diameter and Thickness Variations of Brands A, B and C.**

In the diameter variation test, the average diameter of Brand A was 5.694 mm, with percentage deviations ranging from -0.42% to 0.63%. Brand B had an average diameter of 8.013 mm, with deviations ranging from -0.66% to 0.71%. For Brand C, the average diameter was 8.084 mm, with deviations ranging from -0.30% to 0.45%. All brands passed the test, as their percentage deviations did not exceed the ± 3% limit. Brand C showed the smallest percentage deviation between tablets, whereas Brand B had the largest deviation. (Chan, 2015), is shown in Figure 6.

Brand A tablets had an average thickness of 0.507 mm, with individual tablet thickness ranging from 0.43 mm to 0.59 mm. Brand B averaged 3.04 mm in thickness, with tablets ranging from 3.00 mm to 3.14 mm. Brand C averaged 3.168 mm in thickness, with tablets varying from 3.04 mm to 3.30 mm. These results indicate consistent tablet thickness across all brands.

When conducting weight, diameter, and thickness variation tests for tablets, several important factors must be carefully considered to ensure accurate and reliable results. Ultimately, these considerations not only ensure compliance with regulatory requirements but also contribute to continuous improvement in manufacturing processes to deliver safe and effective tablet products to consumers.

**Spectra of Each Brand of LVS, Spectra of all brands is laid down in Figure 7.**

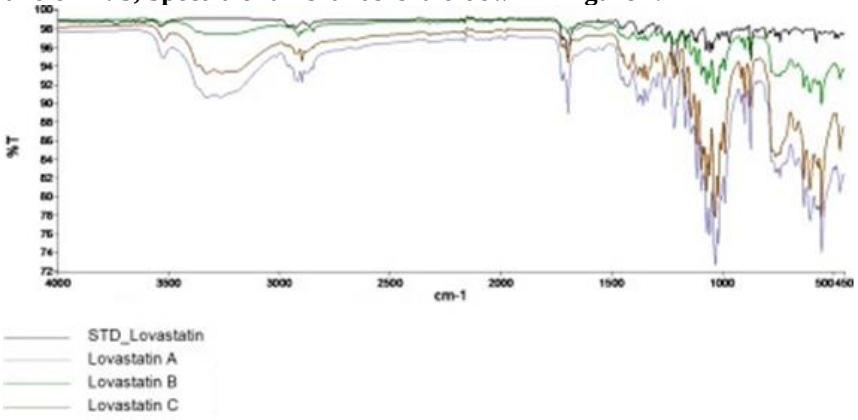



**Figure 7: Spectra of all brands.**

**Spectra of each brand of LVS comparing with standard LVS**

Comparing with standard LVS, Brands A, B, and C exhibited similar peaks at specific IR frequencies: 3330 $cm^{-1}$, 2900 $cm^{-1}$ and 1750 $cm^{-1}$. These peaks corresponded to alcohol, alkane, and 6-membered lactone functional groups, respectively, indicating consistency in chemical composition across the brands when analyzed by IR spectroscopy. Brand A displayed the sharpest peaks among the three brands, indicating a well-defined spectral pattern. In contrast, Brand B showed blurry peaks, suggesting less distinct or possibly broader absorption bands in its IR spectrum. (Libre Texts, 2014).

The variation in peak sharpness observed in the spectra of Brands A, B, and C can be attributed to multiple factors relating to the purity, formulation, and crystalline structure of LVS within each brand. Firstly, the purity of LVS directly influences the clarity and intensity of its IR absorption peaks; higher purity levels typically yield sharper and more defined peaks by minimizing the presence of impurities that could broaden spectral bands. Secondly, differences in the formulation of LVS across brands affect how the drug interacts with IR radiation during spectroscopic analysis. Variations in excipients or additives used in formulations may contribute to broader or less distinct absorption bands. Additionally, the crystalline form of LVS significantly impacts its IR spectrum, as different crystalline structures or polymorphs can exhibit unique spectral features, affecting peak shapes and widths. Moreover, the method of sample preparation for IR spectroscopy plays a critical role in peak sharpness, with factors such as sample homogeneity, particle size, and deposition method on the IR window influencing peak resolution. Lastly, variations in the IR spectrometer's resolution, sensitivity, and operational conditions including temperature and humidity can also influence spectral peak appearance. (*4 Factors Affecting Spectral Reflectance Measurements*, n.d.).

The average disintegration time for Brand A was the fastest, meaning it took the least amount of time to break down and dissolve compared to Brands B and C. It is due to its special excipient sodium croscarmellose which acts as a super disintegrant. Conversely, Brand C had the slowest disintegration time, taking the longest to dissolve. Despite these differences, all three brands met the required standard, as their disintegration times were within the acceptable limit of 15 minutes. This indicates that, although there is variation in how quickly each brand disintegrates, they all comply with the regulatory requirements for disintegration time, ensuring they will perform adequately in terms of dissolving in the body for absorption.

Temperature control is important, with the disintegration medium typically maintained at 37 ± 2°C to simulate physiological conditions. The correct volume (usually 900 ml) and composition of the disintegration medium, such as distilled water or simulated gastric fluid, must be used according to the specified protocol. Proper setup of the disintegration apparatus is crucial by ensuring the basket rack assembly moves at the specified rate and distance. Based upon results, it is observed that the LVS from Brands A, B, and C released similarly at 30, 60, 90, and 120 minutes, indicating that the drugs are sustained-release formulations. In Brand A, the excipients include lactose monohydrate, microcrystalline cellulose, magnesium stearate, sodium croscarmellose, Blue #2, and Brilliant Blue. Brand B's excipients are not specified. In Brand C, the excipients consist of lactose monohydrate, pregelatinized maize starch, microcrystalline cellulose, butylated hydroxyanisole, magnesium stearate, aluminum lake, and indigotin blue. The binders that help achieve sustained release in vitro for these brands are microcrystalline cellulose and pregelatinized maize starch. Brand C showed the most consistent and the highest percentage of drug released, likely due to the presence of two binders.

The sustained-release profile observed in all three brands indicates that the formulations are designed to maintain a steady release of LVS over an extended period. This is beneficial for patients as it ensures a more consistent therapeutic effect and potentially reduces the frequency of dosing. Brand C's similar and highest percentage of drug released over the tested intervals can be attributed to the dual binder system, which provides a more stable and controlled release mechanism compared to the other brands. This highlights the importance of excipient selection and formulation strategy in developing effective sustained-release pharmaceutical products.

The $AUC_{0-2}$ (Area under the curve from 0 to 2 hours) for Brand C was 33.83 mg.hr/l and for Brand B, it was 32.16 mg.hr/l. These values are the highest among the brands tested, indicating that these formulations release a significant amount of drug into systemic circulation within the first two hours after administration. This aligns with the high bioavailability rates observed for Brands C and B. But the high $AUC_{0-2}$ values confirm that Brand B exhibits immediate drug release characteristics during the study period. This immediate release profile correlates well with their high bioavailability rates, indicating efficient absorption and quick availability of the drug in the bloodstream. The statement suggests that other brands may show extended drug release profiles if the duration of the study were extended. This implies that while Brand B showed immediate release characteristics, other brands might exhibit slower and more sustained release profiles over a longer period of time.

The dissolution medium's composition and pH should closely mimic physiological conditions, ensuring reliable dissolution behaviour. Consistent volume across tests, typically 900 mL, as specified, is crucial for comparative analysis. Regular calibration of equipment, including dissolution apparatus, ensures accurate performance, with thorough cleaning before each use to prevent cross-

contamination. Tablet placement within the vessel should be consistent, ensuring proper submersion to avoid floating tablets. Sampling at specified intervals using precise methods which is the syringes minimizes errors and disturbance of the dissolution medium. Degassing the medium before testing removes dissolved air that could affect results, while ongoing equipment inspection identifies and eliminates air bubbles.

## CONCLUSION

The comparative qualitative study of commercially available brands of LVS tablets in Malaysia provides valuable insights into the quality and efficacy of different LVS brands. This thoroughly evaluated the physical and chemical properties of LVS tablets, including weight, diameter, thickness, disintegration time, and dissolution profile.

Although there were some variations in weight, diameter, and thickness among all brands of LVS tablets, these variations were within acceptable limits according to pharmacopeial standards. FTIR spectroscopy results confirmed the presence of characteristic functional groups of LVS in all brands, indicating that the API in each brand meets the required chemical specifications. Disintegration times and dissolution profiles varied among the brands, with some showing faster disintegration and higher dissolution rates. These differences could impact the bioavailability and therapeutic efficacy of the tablets. Despite variations in disintegration and dissolution profiles, all brands demonstrated sufficient bioequivalence in terms of API release, ensuring their effectiveness in lowering LDL-C levels in patients.

As mentioned, Brands A and C initially showed immediate drug release patterns. However, there is a suggestion that they might exhibit delayed drug release if the dissolution study were extended by a few more hours. This indicates that their release profiles may change over time. Brands A and C showed the signs of potential immediate drug release. Although Brand B showed a relatively low percentage of drug release initially, its Area Under the Curve (AUC) confirmed that it has the most immediate drug release formulation, particularly within one hour of the study. This suggests that Brand B releases the drug quickly despite the initial low percentage as compared to Brand C. Brand B is identified as having the most immediate drug release. Brand A showed prolonged drug release profiles during the study. If more time were allowed for dissolution (beyond the current study duration), their percentage drug release and AUC would likely continue to increase, indicating a slower and more sustained release over time.

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