Comparative study of the quality of atorvastatin tablet brands obtained from Lagos, Nigeria.

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ABSTRACT

Background: The quality of any pharmaceutical product significantly affects its effectiveness and safety. Atorvastatin, a widely used medication for managing cholesterol level, relies on meeting established standard for optimal clinical response.

Objective: This research aimed at evaluation of the quality of the leading atorvastatin tablets brands marketed in Lagos, Nigeria.

Methods: The assessments of the quality of eight atorvastatin brands (ATRO1, ATRO2, ATRO3, ATRO4, ATRO5, ATRO6, ATRO7, and ATRO8) were done using British Pharmacopoeia (BP) and United States Pharmacopeia (USP) methods. Physicochemical parameters (thickness, weight uniformity, diameter, friability, and hardness) were evaluated using British Pharmacopoeia (BP) methods, the active ingredient content was quantified using ultraviolet-visible spectrometry, and the dissolution profiles were analyzed using a USP dissolution apparatus II.

Results: All brands met BP specifications for uniformity of weight and thickness. However, ATRO 2, ATRO 6, ATRO 7, and ATRO 8 had larger diameters than BP standard. ATRO1 exceeded the BP specification for friability. The hardness generally fell within acceptable ranges. Regarding percentage purity, only ATRO 1 and ATRO 7 met BP standards. Dissolution profile analysis revealed variations among the brands. Only ATRO 1 and ATRO 7 met the BP requirement of releasing 80% of atorvastatin within 30 minutes.

Conclusion: There are observed variations in physicochemical parameters, percentage purity, and dissolution profiles among the eight brands of atorvastatin tablets and these could potentially impact the clinical effectiveness and safety of the medication. Strict quality control is essential to maintain consistency and efficacy of pharmaceuticals.

Keywords: Atorvastatin, physicochemical parameter, ultra-violet spectrometry, dissolution profiles, cholesterol.

Étude comparative de la qualité des marques de comprimés d'atorvastatine obtenus comprimés d'atorvastatine marques obtenu à Lagos, au Nigéria.

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RÉSUMÉ

Contexte: La qualité de tout produit pharmaceutique affecte considérablement son efficacité et sa sécurité. L'atorvastatine, un médicament largement utilisé pour gérer le taux de cholestérol, repose sur le respect des normes établies pour une réponse clinique optimale.

Objectif: Cette recherche visait à évaluer la qualité des principales marques de comprimés d'atorvastatine commercialisées à Lagos, au Nigéria.

Méthodes: Les évaluations de la qualité de huit marques d'atorvastatine (ATRO1, ATRO2, ATRO3, ATRO4, ATRO5, ATRO6, ATRO7 et ATRO8) ont été réalisées à l'aide des méthodes de la pharmacopée britannique (British Pharmacopoeia, BP) et de la pharmacopée des États-Unis (United States Pharmacopeia, USP). Les paramètres physicochimiques (épaisseur, uniformité du poids, diamètre, friabilité et dureté) ont été évalués à l'aide des méthodes de la British Pharmacopoeia (BP), la teneur en principe actif a été quantifiée par spectrométrie ultraviolette-visible et les profils de dissolution ont été analysés à l'aide d'un appareil de dissolution USP II.

Résultats: Toutes les marques ont satisfait aux spécifications de la BP en ce qui concerne l'uniformité du poids et de l'épaisseur. Cependant, ATRO 2, ATRO 6, ATRO 7 et ATRO 8 avaient des diamètres plus grands que la norme BP. L'ATRO 1 dépassait les spécifications BP en matière de friabilité. La dureté se situait généralement dans des fourchettes acceptables. En ce qui concerne le pourcentage de pureté, seuls ATRO 1 et ATRO 7 répondaient aux normes de BP. L'analyse du profil de dissolution a révélé des variations entre les marques. Seuls ATRO 1 et ATRO 7 ont satisfait aux exigences de BP concernant la libération de 80 % de l'atorvastatine en 30 minutes

Conclusion: Des variations ont été observées dans les paramètres physicochimiques, le pourcentage de pureté et les profils de dissolution parmi les huit marques de comprimés d'atorvastatine, ce qui pourrait potentiellement avoir un impact sur l'efficacité clinique et la sécurité du médicament. Un contrôle de qualité strict est essentiel pour maintenir la cohérence et l'efficacité des produits pharmaceutiques.

Mots clés: Atorvastatine, paramètre physico-chimique, spectrométrie ultraviolette, profils de dissolution, cholestérol.

INTRODUCTION

Cholesterol, a waxy substance found in animal tissues, plays a vital role in various biological processes.[1] While often associated with negative health consequences, cholesterol is essential for maintaining the structural integrity of cell membranes, regulating cell signaling, and serving as a precursor for vitamin D, bile acids, and steroid hormones.[2]

The body synthesizes cholesterol in the liver, but it also obtains it from dietary sources, particularly animal-based foods.[3] However, plant foods contain only trace amounts of cholesterol and instead produce phytosterols, which can compete with cholesterol for absorption in the intestines.[4]

Cholesterol is transported in the bloodstream by lipoproteins, particles composed of cholesterol, proteins, and phospholipids.[5] Low-Density Lipoprotein (LDL) cholesterol, often referred to as "bad cholesterol," carries cholesterol to cells throughout the body.[6] HDL (high-density lipoprotein) cholesterol, known as "good cholesterol," transports cholesterol back to the liver for excretion.[7]

Elevated LDL cholesterol levels can contribute to atherosclerosis, a buildup of plaque in the arteries.[8] This plaque can narrow or block blood vessels, increasing the risk of heart attacks, strokes, and peripheral artery disease.[9] Maintaining healthy cholesterol levels through a balanced diet, regular exercise, and appropriate medical interventions is crucial for cardiovascular health.[10]

Statins, a class of cholesterol-lowering medications, have revolutionized the treatment of high cholesterol and cardiovascular disease.[11] By inhibiting the enzyme responsible for cholesterol synthesis, statins effectively reduce LDL cholesterol levels and slow the progression of atherosclerosis.[12]

Atorvastatin is a widely used statin known for its efficacy in lowering LDL cholesterol and reducing cardiovascular risk.[13] It is metabolized in the liver and demonstrates rapid absorption following oral administration.[14]

The quality of pharmaceutical products, including atorvastatin, is paramount for ensuring their effectiveness and safety.[15] Dissolution testing, a crucial quality control measure, assesses the drug's release from the dosage form, providing valuable insights into its bioavailability.[16]

Tablet characteristics, such as thickness, weight, hardness, disintegration time, and friability, directly influence drug release and patient experience.[17,18,19,20] Consistent tablet quality is essential for optimal therapeutic outcomes and patient satisfaction.[21]

Ultraviolet-visible spectroscopy (UV-Vis), a versatile analytical technique, is employed in the Pharmaceutical industry for various purposes, including quantitative analysis, identification of molecular structures, and evaluation of reaction kinetics.[22] Beer-Lambert's law, the cornerstone of UV-Vis spectroscopy, establishes the relationship between absorbance and concentration, enabling quantitative measurements of analytes.[23] This principle forms the basis for pharmaceutical assays and quality control procedures. Pharmaceutical quality control measures, including dissolution testing and UV-Vis spectroscopy, ensure the effectiveness and safety of pharmaceutical products.

METHODS

Sample collection

Eight brands of Atorvastatin tablets of 10 mg Atorvastatin equivalent were purchased from local retail pharmacies in Lagos State, Nigeria.

The atorvastatin brands were labeled from ATRO 1 to ATRO 8, with ATRO 1 being the innovator and the others were arbitrarily distributed generic products. All tests in this study were performed at least 6 months before the product expiration dates on the medication packages.

Reagents

The following reagents were used in the study:

Distilled water, Analytical grade potassium dihydrogen phosphate (Monobasic potassium phosphate), Sodium hydroxide, Atorvastatin reference standard, Analytical grade methanol.

Apparatus and instruments

The following apparatus and instruments were used in the study:

Electronic balance (PEC medical, USA), Friability Tester (CS-3 Tablet friability Tester), Hardness Tester (Monsanto type), Dissolution Tester (Copley Scientific, DIS 8000, UK), Sonicator (J.P. SELECTA, Spain), UV Spectrophotometer (UV 1900, UK), Vernier Calliper, pH meter (Hanna Instruments, Italy), Filter paper (Whatman), 0.45-µm syringe filters (Merck Millipore Millex, USA).

PHYSICAL TESTS

Appearance (Organoleptic)
The organoleptic test of the eight brands of atorvastatin tablets was carried out. This included examining the uniformity of color, surface shape, and the presence or absence of physical damage.

Dimension (Thickness and Diameter)
The thickness and diameter of the tablets were measured using Vernier callipers. Three tablets from each brand were used, and the average values were calculated.

Uniformity of weight test
Twenty (20) tablets from each brand of atorvastatin were randomly selected. Each tablet was weighed using the electronic balance, and the average weight of the twenty tablets was determined. The standard deviation, relative standard deviation, and percentage deviation from the mean were calculated to assess the uniformity of weight among each of the atorvastatin tablets.

$$\% \ Deviation = \frac{\text{Average weight} - \text{Individual weight}}{\text{Average weight}} \text{ X } 100$$

Friability test
Ten (10) tablets from each brand of atorvastatin were carefully dusted and accurately weighed using the electronic balance. The weights were recorded as the initial weigh. The tablets were then carefully placed in the friability tester and subjected to abrasion at 25 rpm (revolutions per minute) for 4 minutes. After the test, any loose dust was removed from the tablets, and they were reweighed. The process was repeated for all eight brands. A loss of less than 1 % is considered acceptable.

$$F = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \text{ X } 100$$

Where F = Friability

Hardness test
Ten (10) tablets from each brand of atorvastatin were individually weighed in a vertical position between the jaws of the hardness tester, aligned with the direction of force application. An initial reading was recorded when each tablet was firmly held to the jaws of the tester. A final reading was recorded when the tablet broke due to the applied force. The resistance to crushing of the tablets (hardness), expressed in Kg/cm², was calculated by subtracting the initial reading from the final reading.

Hardness = Final reading - Initial reading

CHEMICAL TEST

Dissolution profiling
The dissolution test was conducted using a USP apparatus 2 (paddle) according to the guidelines set forth in references.[24,25] The dissolution medium was 0.05 M phosphate buffer, with the pH adjusted to 6.8 using 6 N sodium hydroxide. The pH was monitored with a pH meter. This procedure was carried out in six separate vessels, maintaining the temperature of the medium at 37 ± 0.5^{o}C and operating the paddle at a speed of 75 rpm.[25]

In this dissolution test, three tablets per brand were employed. The dissolution medium of 900 mL was poured into each individual vessels containing one tablet. At specific time intervals (5, 10, 15, 30, 45, and 60 minutes), 5 mL samples were withdrawn from each of the six vessels, and fresh dissolution medium was added in equal volumes to replace the withdrawn samples. The samples were subjected to filtration through 0.45-µm syringe filters (Merck Millipore Millex, USA). The samples were then suitably diluted, and their absorbance was measured using a UV/Vis spectrophotometer.[26]

The obtained absorbance values were then compared using Atorvastatin secondary reference standard (a previously established standard curve) characterized by an r-squared value of 0.9994. This correlation allowed for the computation of the concentration of the drug released at each of the specified time intervals. The similarity factor between the dissolution profiles of generic brands and the innovator brand was calculated using Microsoft Excel software.[27]

Determination of atorvastatin maximum wavelength in buffer solution
The prepared Atorvastatin solution which the explained below was scanned in the 200- 400 nm UV region. The maximum wavelength (λ max) was observed to be 241 nm and this wavelength was used for absorbance measurement.

Calibration using atorvastatin secondary reference standard
To construct the calibration curve, atorvastatin secondary reference standard (LIPITOR) i.e., the stock

solution was accurately weighed using an analytical balance and transferred into a 100 ml volumetric flask. Approximately 20 ml of the diluent, 0.05M KH2PO4, was added to the flask, and the mixture was thoroughly shaken to facilitate dissolution. The flask was then placed in a sonicator for 15 minutes to ensure complete dissolution of the reference standard. Subsequently, the volume was made up to the mark with the diluent, and the solution was filtered using Whatman filter paper to remove any undissolved particles.

Using appropriate dilution factor, a series of standard solutions with different concentrations were prepared by accurately measuring different volumes of the stock solution (and transferred into 10 ml volumetric flasks. Each flask was then filled to the mark with the diluent.

The absorbance of each standard solution was measured using an Ultraviolet-Visible Spectrophotometer at a wavelength of 241 nm, as specified in the USP.[26] The absorbance values were plotted against the corresponding concentrations to generate a calibration curve using Microsoft Excel software.

Assay of brand samples using ultraviolet-visible spectrophotometry for the dissolution profile

The sample of Atorvastatin tablets were analysed using ultraviolet-visible spectrophotometer at a wavelength of 241 nm. The dissolution profile of the eight brands was obtained and percentage drug released at 5, 10, 15, 30, 45 and 60 minutes were calculated using the Microsoft excel software. The similarity factor between the dissolution profile of the generic brands ATRO 2, ATRO 3, ATRO 4, ATRO 5, ATRO 6, ATRO 7, ATRO 8 in comparison to the Innovator brand ATRO 1 was calculated using the similarity factor formula in Microsoft Excel software.[27]

$$f2 = 50 \log \left\{ \left(1 + \frac{1}{n} \sum_{i=1}^{n} (R_t - T_t)^2 \right)^{-0.5} \text{ X } 100 \right\}$$

Where;

$f2$ = Similarity factor

n = number of observations

R_t = Average percentage drug dissolved from there reference formulation

T_t = Average percentage drug dissolved from test formulation.

$$f1 = \left\{ \frac{\sum_{t}^{n}{}_{1} |R_t - T_t|}{\sum_{t=1}^{n} R_t} \right\} \text{ X } 100$$

Where;

$f1$ = Difference factor

n = number of observations

R_t = Average percentage drug dissolved from there reference formulation

T_t = Average percentage drug dissolved from test formulation.

ATORVASTATIN CONTENT ASSAY FOR PERCENTAGE PURITY

Determination of atorvastatin maximum wavelength in methanol

The prepared Atorvastatin solution which the explained below was scanned in the 200- 400nm UV region. The maximum wavelength (λ max) was observed to be 241 nm and this wavelength was used for absorbance measurement.

Calibration using atorvastatin secondary reference standard

To construct the calibration curve, atorvastatin secondary reference standard (LIPITOR) i.e., the stock solution was accurately weighed using an analytical balance and transferred into a 100 ml volumetric flask. Approximately 20 ml of the methanol was added to the flask, and the mixture was thoroughly shaken to facilitate dissolution. The flask was then placed in a sonicator for 15 minutes to ensure complete dissolution of the reference standard. Subsequently, the volume was made up to the mark with the methanol, and the solution was filtered using Whatman filter paper to remove any undissolved particles.

Using appropriate dilution factor, a series of standard solutions with different concentrations were prepared by accurately measuring different volumes of the stock solution and transferred into 10 ml volumetric flasks. Each flask was then filled to the mark with the diluent.

The absorbance of each standard solution was measured using an Ultraviolet-Visible Spectrophotometer at a wavelength of 241 nm. The absorbance values were plotted against the corresponding concentrations to

generate a calibration curve using Microsoft Excel software.[28]

Preparation of the samples for analysis

From each of the brands, 10 mg equivalent of Atorvastatin secondary reference standard was weighed and transferred into a 100 ml volumetric flask. 20 ml of the methanol was added, the mixture was shaken thoroughly and was placed in a sonicator for 15 minutes. The volume was then made up to 100 ml with methanol, and filtered. From the filtrate, 1 ml was pipetted into a 50 ml volumetric flask and made up to mark using methanol. The resultant solutions were then transferred into already labelled sample bottles and the absorbance for each was taken using the UV spectrophotometer.28 The potency for each of the brands was then calculated using the following formula;

$$Percentage\ Purity = \frac{concentration\ of\ sample}{concentration\ of\ standard} \times 100$$

The samples concentrations were determined using the regression equation of the reference standard calibration curve.

RESULTS

Table 1: A summary of general description of the Atorvastatin tablets marketed in Lagos, Nigeria, 2023.

Sample code	Batch No/ Lot	Manufactured Date	Expiry Date	Appearance
ATRO 1	FX0507	Aug 2021	Jul 2024	White round tablet
ATRO 2	23812	Mar.2021	Apr. 2024	White oblong tablet
ATRO 3	AVTO3	0CT.2021	SEP.2024	Grey round tablet
ATRO 4	ACN110012	AUG. 2022	Jul. 2025	Yellow oxide of iron round tablet
ATRO 5	ARC2301	JAN. 2023	DEC.2025	Yellow oxide of iron round tablet
ATRO 6	21T-0504	MAY. 2021	APR.2024	White round tablet
ATRO 7	A032002	Jun.2022	May 2025	White cylindrical tablet
ATRO 8	AZE201	Apr. 2022	Mar. 2025	White cylindrical tablet

Table 2: Evaluation of different Physicochemical parameters of different brands of Atorvastatin tablets in Lagos, Nigerian market.

Sample code	Thickness (cm)	Diameter (cm)	Uniformity of weight (%)	Friability (%)	Hardness (Kg/cm)	% Purity
ATRO 1	0.37± 0.06	0.90 0.10	0.104 ± 0.001	0.952	1.21 0.44	100
ATRO 2	0.67± 0.06	1.30 0.10	0.104 ± 0.002	0.095	1.49 0.48	72.732
ATRO 3	0.33± 0.06	0.87 0.06	0.134 ± 0.003	0.786	1.00 0.33	86.099
ATRO 4	0.33± 0.15	0.87 0.06	0.157 ± 0.001	0.063	1.76 0.23	54.91
ATRO 5	0.50± 0.10	0.87 0.06	0.195 ± 0.003	0.767	1.75 0.23	59.722
ATRO 6	0.50± 0.10	0.97 0.06	0.183 ± 0.003	0.054	3.05 0.41	54.375
ATRO 7	0.20± 0.10	1.27 0.06	0.124 ± 0.002	0	0.75 0.23	101.96
ATRO 8	0.27± 0.06	1.23 0.15	0.157 ± 0.001	0.123	1.33 0.24	55.088

Table 3: Dissolution profile data of the Atorvastatin tablets

Sampling time (mins)	ATRO 1	ATRO 2	ATRO 3	ATRO 4	ATRO 5	ATRO 6	ATRO 7	ATRO 8
5	38.463 ± 5.806	36.947 ± 10.889	55.895 ± 8.701	18.189 ± 2.842	20.653 ± 3.473	131.116 ± 193.150	330.442 ± 30.037	374.400 ± 41.148
10	65.747 ± 12.612	63.474 ± 12.222	59.874 ± 11.373	37.516 ± 5.116	29.937 ± 4.630	134.147 ± 171.313	390.505 ± 14.614	571.453 ± 352.856
15	66.884 ± 7.569	66.884 ± 11.444	61.579 ± 7.331	59.874 ± 24.622	39.979 ± 0.868	144.000 ± 167.313	370.611 ± 41.786	364.737 ± 13.974
30	67.642 ± 2.274	67.263 ± 17.150	88.105 ± 45.056	66.126 ± 25.926	48.884 ± 4.955	244.800 ± 167.576	383.874 ± 37.886	344.842 ± 11.042
45	83.368 ± 20.841	83.368 ± 20.841	65.937 ± 7.1223	49.832 ± 1.313	57.600 ± 13.693	229.453 ± 155.413	343.516 ± 16.241	338.968 ± 5.834
60	67.642 ± 5.422	93.979 ± 28.857	62.147 ± 7.107	50.211 ± 5.126	59.116 ± 9.663	237.600 ± 149.514	351.095 ± 27.785	323.811 ± 15.171

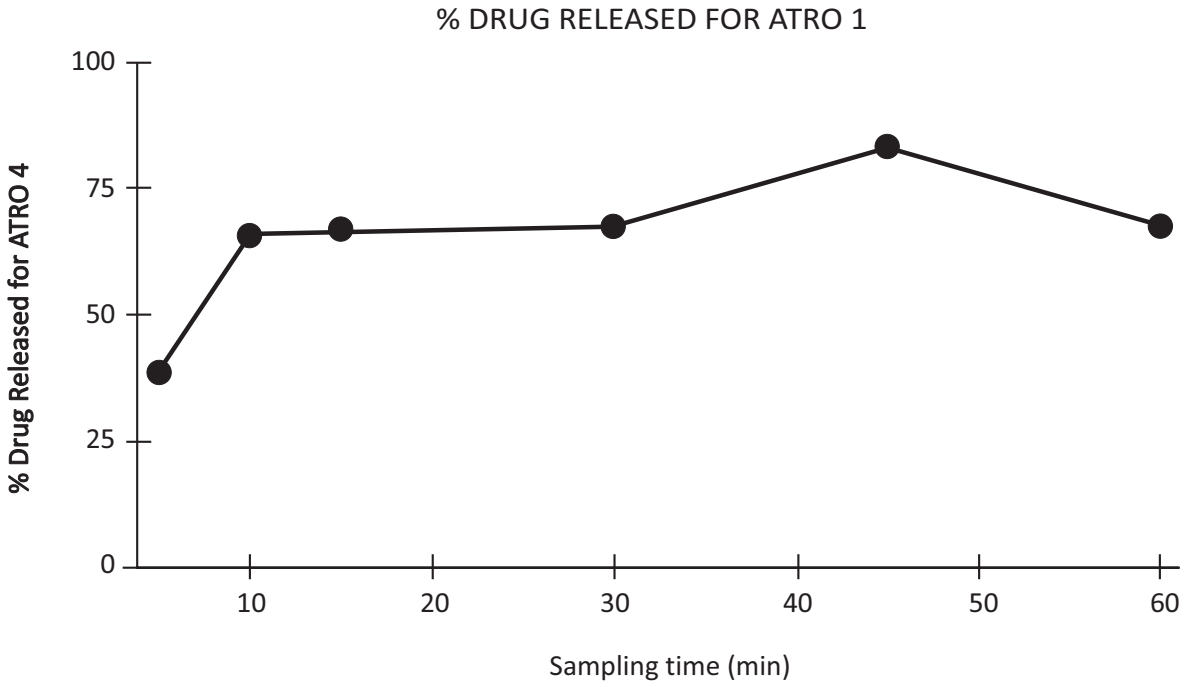

FIGURE 1: DISSOLUTION PROFILE OF ATRO 1

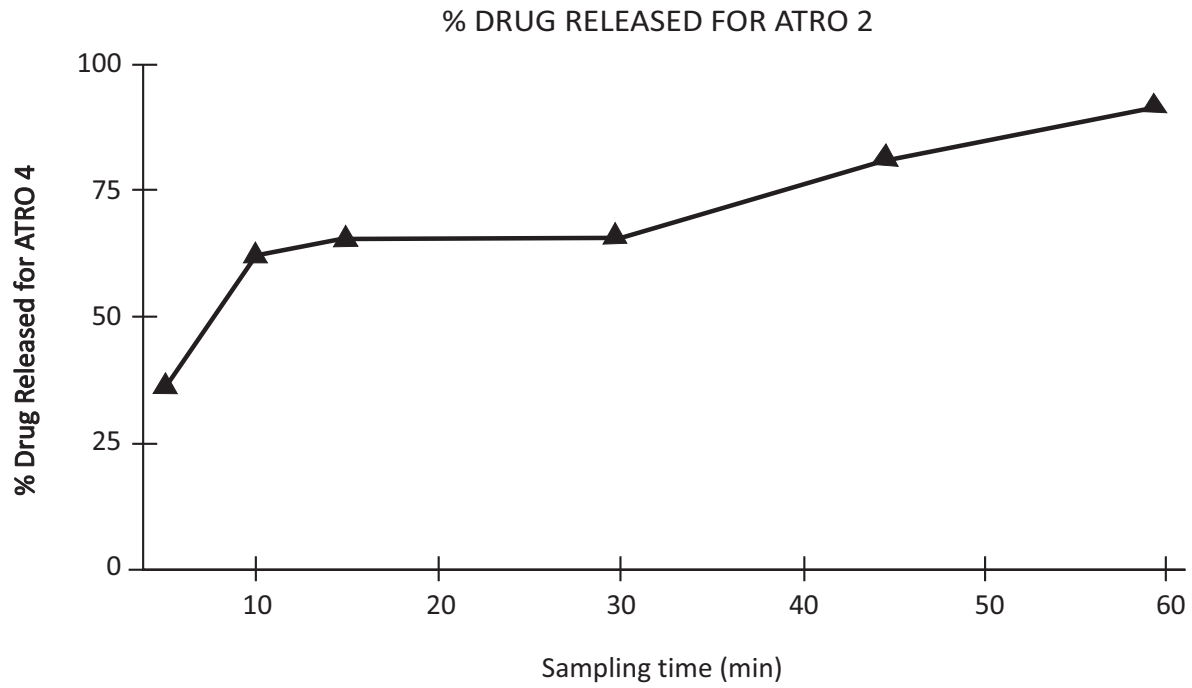

FIGURE 2: DISSOLUTION PROFILE OF ATRO 2

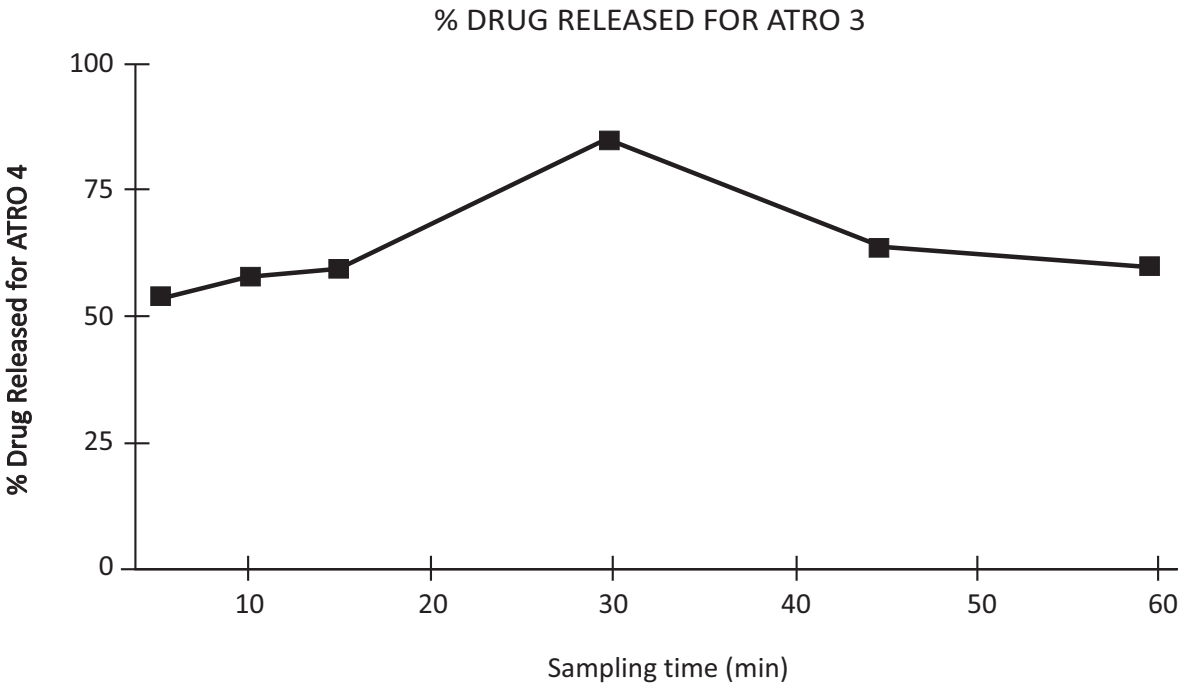

FIGURE 3: DISSOLUTION PROFILE OF ATRO 3

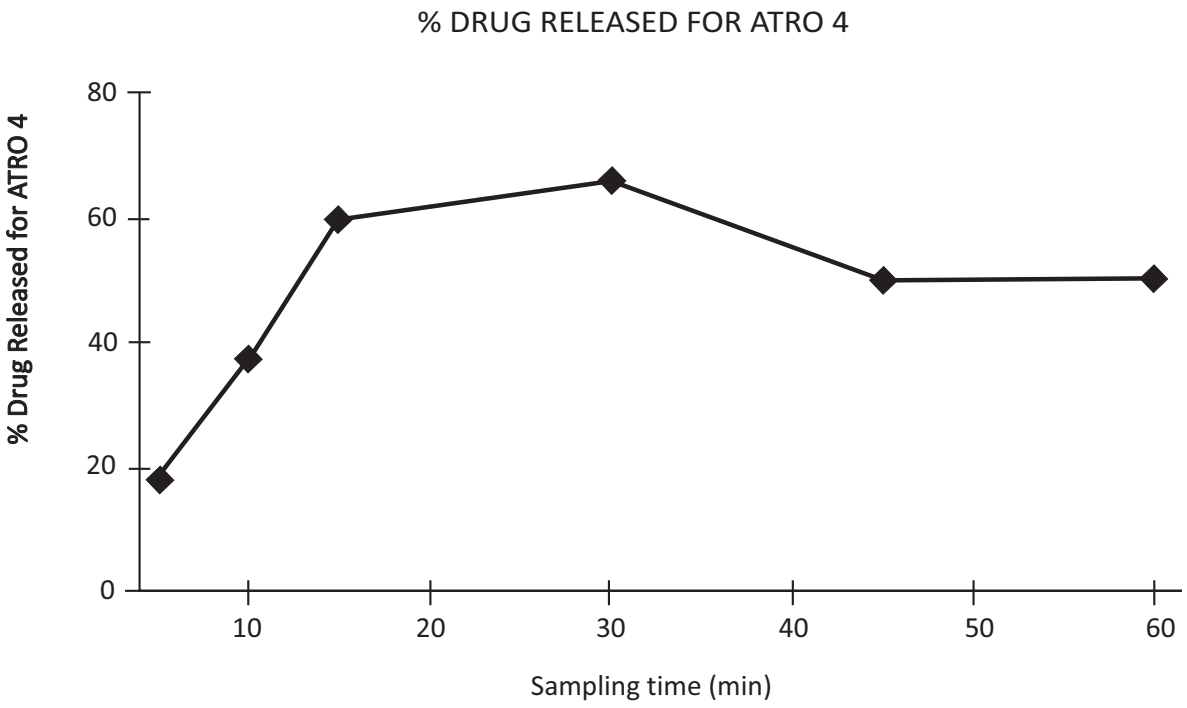

FIGURE 4: DISSOLUTION PROFILE OF ATRO 4

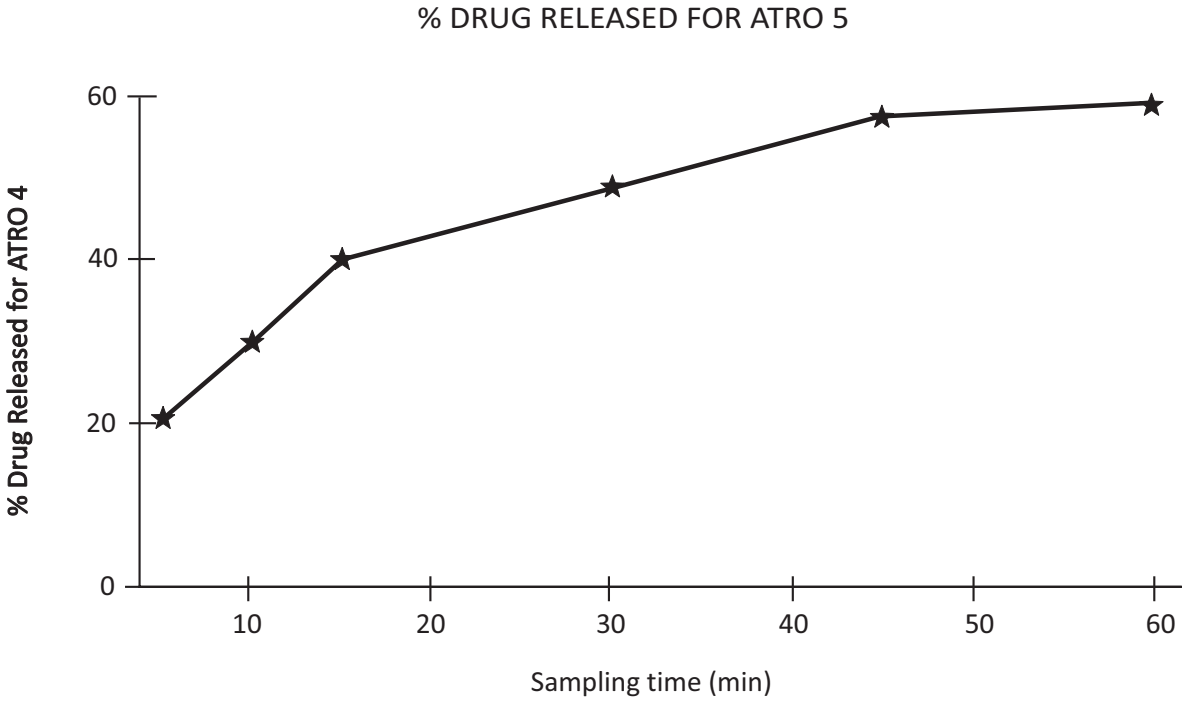

FIGURE 5: DISSOLUTION PROFILE OF ATRO 5

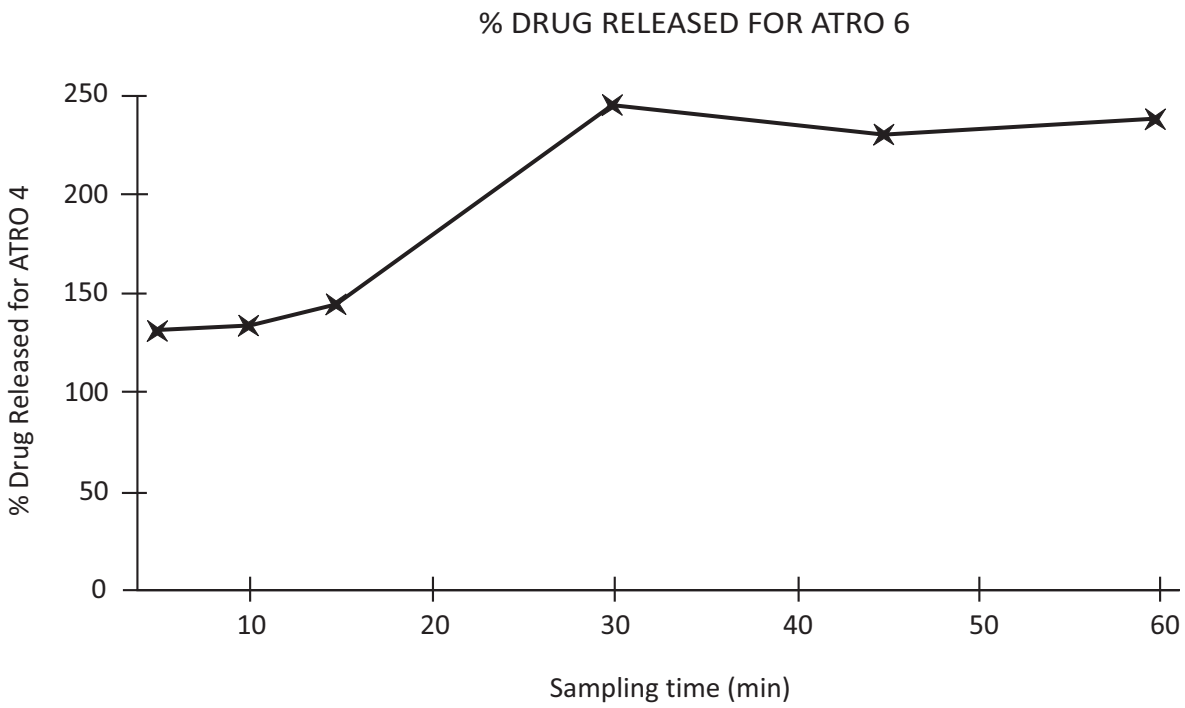

FIGURE 6: DISSOLUTION PROFILE OF ATRO 6

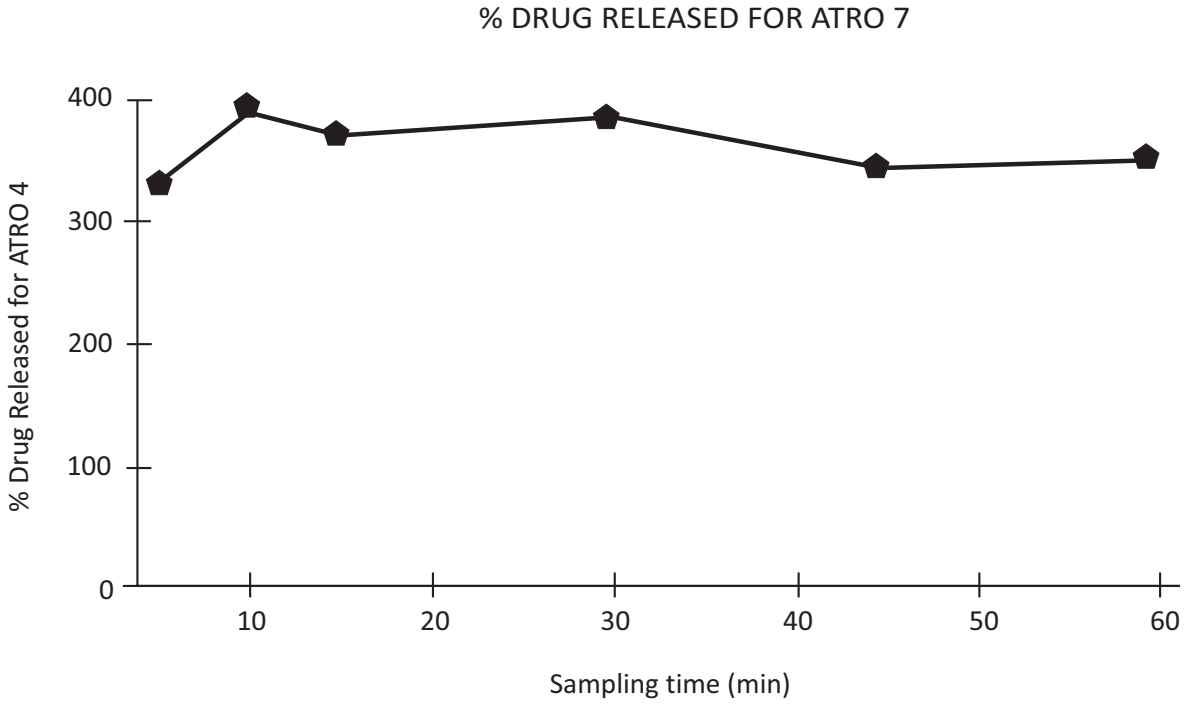

FIGURE 7: DISSOLUTION PROFILE OF ATRO 7

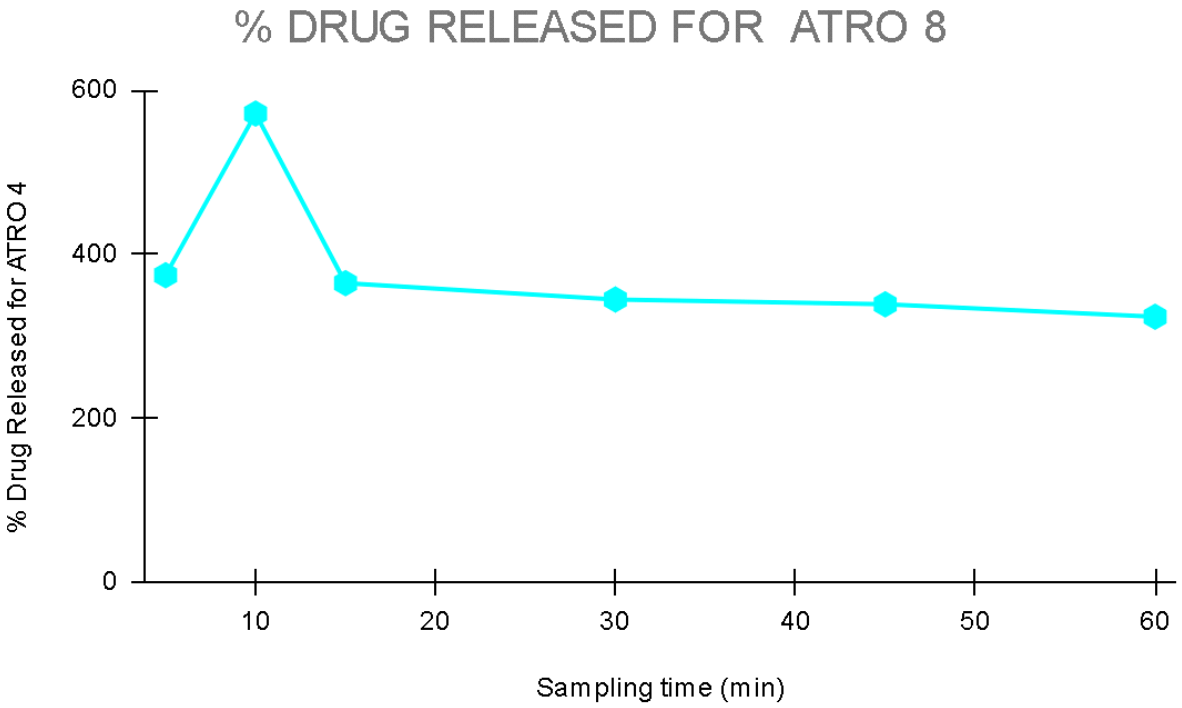

FIGURE 8: DISSOLUTION PROFILE OF ATRO 8

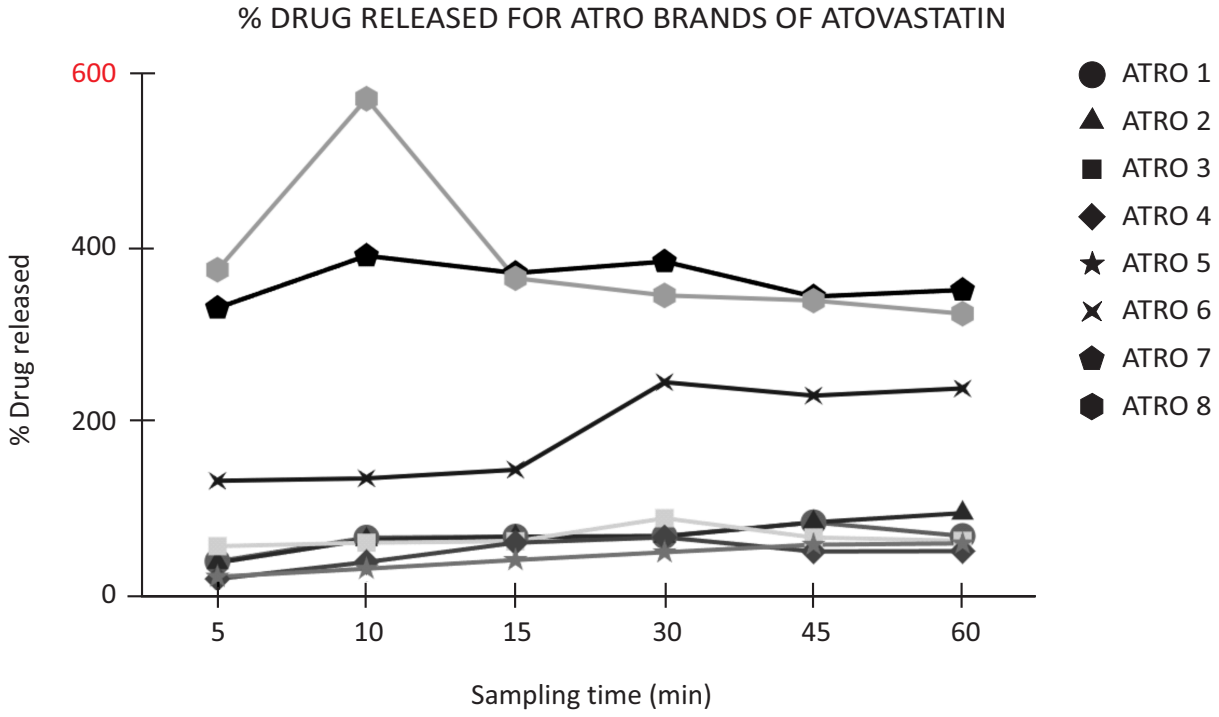

FIGURE 9: DISSOLUTION PROFILE OF ALL THE BRANDS OF ATROVASTATIN

Table 4: Similarity Factor and Difference Factor Between Dissolution Profiles of The Generic Brands and Innovator Brand.

Brand code	Similarity factor	Difference factor
ATRO 2	80.5	12.4
ATRO 3	90.3	6.3
ATRO 4	59.7	17.8
ATRO 5	66.1	15.9
ATRO 6	54.2	21.3
ATRO 7	93.7	3.5
ATRO 8	61.9	11.7

Innovator brand - ATRO 1

DICUSSION

The quality of a drug product is essential to its effectiveness. Drug products are made up of active ingredients and inactive ingredients called excipients. Both the active ingredients and excipients must meet the standards set forth in the official monograph for physical, chemical, and microbiological properties in order to provide the desired clinical response with maximal efficacy and minimal side effects. Therefore, it is essential to adequately verify that these properties comply with the official monograph.

Drug product conformity to the official monograph on a particular characteristic can be carried out using the simple and robust analytical method outlined in the official monograph. The validation of these methods is essential for the acceptability of the results obtained.

This research investigates the quality of eight brands of atorvastatin tablets as against four brands previously carried out.[29] The quality check consists of two parts. The first part is the estimation of physicochemical parameters for each brand of atorvastatin tablet (table 1), and the second part is the determination of percentage purity of active ingredient content for each brand using ultraviolet-visible spectrophotometry.

Physicochemical parameters for the eight brands of atorvastatin tablets, including diameter, thickness, friability, uniformity of weight, and hardness, were measured and the results were obtained.

The diameter of atorvastatin tablets is a critical physical characteristic that can impact their dissolution and absorption. The British Pharmacopoeia (BP 2023) specifies the diameter of atorvastatin tablets to be between 0.80 cm and 1.00 cm. In this study, the average diameter of the atorvastatin tablets ranged from 0.87 cm to 1.27 cm. Four of the eight batches of tablets (ATRO 1, ATRO 3, ATRO 4, and ATRO 5) met the BP specification for diameter. The other four batches of tablets (ATRO 2, ATRO 6, ATRO 7, and ATRO 8) had an average diameter greater than 1.00 cm (table 2).

The thickness of the atorvastatin tablets varied considerably between brands. The average thickness ranged from 0.20 cm to 0.67 cm (table 2). The variability was also relatively high for some brands. The British Pharmacopoeia (BP) specifies that the thickness of atorvastatin tablets should be within 10 % of the nominal thickness. The nominal thickness is the thickness that is specified by the manufacturer. All eight brands of atorvastatin tablets in the current study met the BP specification for thickness.

The friability of the eight different brands of atorvastatin tablets in the current study varied considerably between brands, ranging from 0.054 % for ATRO 6 to 1.905 % for ATRO 1 (table 2). This may be due to differences in manufacturing processes, excipients used, and storage conditions. ATRO 1 had the highest friability at 1.905 %, which exceeds the BP specification of less than 1 %. This suggests that ATRO 1 tablets are more likely to chip or

break than tablets from other brands. At the other end of the spectrum, ATRO 7 had zero friability, meaning no weight was lost during testing, suggesting that ATRO 7 tablets are very resistant to chipping and breaking.

All eight brands passed the uniformity of weight test, indicating that the manufacturing process is consistent and producing tablets with acceptable weight variation.

The hardness of eight different brands of atorvastatin tablets in the current study varied considerably, ranging from 0.75 kg/cm for ATRO 7 to 3.05 kg/cm for ATRO 6 (table 2). This variation may be due to different manufacturing processes, excipients used, and storage conditions. ATRO 6 had the highest hardness, meaning it is the most resistant to crushing and breaking. This is important to ensure that the tablets withstand handling and transportation. ATRO 7 had the lowest hardness, meaning it is the least resistant to crushing and breaking. This is important to ensure that the tablets disintegrate easily in the stomach so that the drug can be absorbed into the bloodstream.

The British Pharmacopeia (BP) requires that at least 80 % of atorvastatin be released within 30 minutes of administration. Of the eight brands of atorvastatin in Table 3, only ATRO 1, ATRO 2, ATRO 4, and ATRO 6 failed to meet this specification, with release rates of 67.642 %, 67.263 %, 66.126 %, and 48,884 % respectively, at 30 minutes (table 3).

The *f*2 and *f*1 values for the eight brands of atorvastatin in Table 4, show that the dissolution profiles of ATRO 2, ATRO 3, and ATRO 7 are most similar to the dissolution profile of ATRO 1.

The purity of eight different atorvastatin brands listed in Table 2 ranged from 54.375 % to 101.960 %, with ATRO 6 having the lowest purity and ATRO 7 having the highest purity. Only ATRO 1 and ATRO 7 met the British Pharmacopoeia (BP) specification for atorvastatin purity of 98.0 % to 102.0 % (BP 2023).

The variation in atorvastatin purity among brands is likely due to differences in manufacturing processes and the quality of raw materials used. Additionally, storage conditions and exposure to light and heat can also affect purity.

CONCLUSION

The present study evaluated the quality of atorvastatin tablets from eight different brands, focusing on physicochemical parameters and active ingredient content. The findings revealed notable variations in physicochemical attributes among the brands. While certain parameters, including thickness, uniformity of weight, and hardness, generally adhered to the British Pharmacopoeia (BP) standards across all brands, key factors like diameter and friability displayed significant disparities.

Specifically, four out of the eight brands exhibited average diameters exceeding the BP specifications, raising concerns about potential impacts on drug dissolution and absorption. Additionally, one brand (ATRO 1) surpassed the BP friability standard, indicating a higher propensity for chipping or breakage compared to other brands.

Furthermore, the assessment of active ingredient content revealed substantial variability in purity across the different brands, with only two brands meeting the BP standard. These findings underscore the need for stricter quality control measures in the manufacturing and distribution of atorvastatin tablets to ensure consistent compliance with pharmaceutical standards and safeguard patient safety.

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REFERENCES

1. Stavrova-Hristova RP (2019). The Role of Cholesterol in Assessing the Condition of the Surgical Patients. *Journal of Biomedical and Clinical Research* 12(2):87-93.
2. Centonze G, Natalini D, Piccolantonio A, Salemme V, Morellato A, Arina P, Riganti C, Defilippi P (2022). Cholesterol and its derivatives: multifaceted players in breast cancer progression. *Frontiers in Oncology* 12:906670.
3. Schade DS, Shey L, Eaton RP (2020). Cholesterol review: a metabolically important molecule. *Endocrine Practice* 26(12):1514-23.
4. De Smet E, Mensink RP, Plat J (2012). "Effects of plant sterols and stanols on intestinal cholesterol metabolism: suggested mechanisms from past to present". *Molecular Nutrition & Food Research* 56(7): 1058-1072.
5. Christie WW (1982). Lipid Analysis: Isolation,

separation, identification and structural analysis of lipids. 2nd Ed; Pergamon Press New York, NY.
6. Murphy K (2011). Cholesterol: The good, the bad, and the ugly. *Nursing Made Incredibly Easy* 9(3):26-34.
7. Durrington P (2003). "Dyslipidaemia". *The Lancet* 362(9385): 717-731.
8. Brunzell JD, Davidson M, Furberg CD, Goldberg RB, Howard BV, Stein JH, Witztum JL (2008). "Lipoprotein management in patients with cardiometabolic risk: consensus statement from the American Diabetes Association and the American College of Cardiology Foundation". *Diabetes Care* 31(4): 811-822.
9. Lewington S, Whitlock G, Clarke R, Sherliker P, Emberson J, Halsey J, Qizilbash N, Peto R, Collins R (2008). Blood cholesterol and vascular mortality by age, sex, and blood pressure: a meta-analysis of individual data from 61 prospective studies with 55000 vascular deaths (vol 370, pg 1829, 2007). *The Lancet* 372(9635).
10. Thompson PD, Buchner D, Piña IL, Balady GJ, Williams MA, Marcus BH, Berra K, Blair SN, Costa F, Franklin B, Fletcher GF (2003). Exercise and physical activity in the prevention and treatment of atherosclerotic cardiovascular disease: a statement from the Council on Clinical Cardiology (Subcommittee on Exercise, Rehabilitation, and Prevention) and the Council on Nutrition, Physical Activity, and Metabolism (Subcommittee on Physical Activity). *Circulation* 107(24):3109-16.
11. Crismaru I, Pantea Stoian A, Bratu OG, Gaman MA, Stanescu AM, Bacalbasa N, Diaconu CC (2020). Low-density lipoprotein cholesterol lowering treatment: the current approach. *Lipids in Health and Disease* 19:1-0.
12. Mangat S, Agarwal S, Rosendorff C (2007). Do statins lower blood pressure?. *Journal of cardiovascular pharmacology and therapeutics* 12(2): 112-123.
13. Adams SP, Tsang M, Wright JM (2015). Atorvastatin for lowering lipids. *Cochrane Database of Systematic Reviews. doi:10.1002/14651858.cd008226.pub3*
14. Black AE, Sinz MW, Hayes RN, Woolf TF (1998). Metabolism and excretion studies in mouse after single and multiple oral doses of the 3-hydroxy-3-methylglutaryl-CoA reductase inhibitor atorvastatin. *Drug Metabolism and Disposition* 26(8): 755-763.
15. Soni V, Pandey V, Asati S, Tekade RK (2018). Impact of Pharmaceutical Product Quality on Clinical Efficacy. In Dosage Form Design Considerations pp. 731-771). *Academic Press*.
16. Colhoun HM, Betteridge DJ, Durrington PN, Hitman GA, Neil HAW, Livingstone SJ, Thomason MJ, Mackness MI, Charlton-Menys V, Fuller JH (2004). Primary prevention of cardiovascular disease with atorvastatin in type 2 diabetes in the Collaborative Atorvastatin Diabetes Study (CARDS): multicentre randomised placebo-controlled trial. *The Lancet* 364(9435): 685-696.
17. Benet LZ (2013). The Role of BCS (Biopharmaceutics Classification System) and BDDCS (Biopharmaceutics Drug Disposition Classification System) in Drug Development. *Journal of Pharmaceutical Sciences* 102(1): 34-42.
18. Cardot JM, Beyssac E, Alric M (2007). In Vitro-In Vivo Correlation: Importance of Dissolution in IVIVC. *Dissolution Technologies* 14(1):15-19.
19. Chiba Y, Kohri N, Iseki K, Miyazaki K (1991). Improvement of dissolution and bioavailability for mebendazole, an agent for human echinococcosis, by preparing solid dispersion with polyethylene glycol. *Chemical and Pharmaceutical Bulletin* 39: 2158-2160.
20. Maggio RM, Castellano PM, Kaufman TS (2008). A new principal component analysis-based approach for testing "similarity" of drug dissolution profiles. *European Journal of Pharmaceutical Sciences* 34(1): 66-77.
21. British Pharmacopoeia Commission (2013). British Pharmacopoeia. London: Her Majesty Stationery Office, p. 1324
22. Bonfilio RB, De Araujo MB, Salgado HR (2010). Recent applications of analytical techniques for quantitative pharmaceutical analysis: a review. *WSEAS Transactions on Biology and Biomedicine* 7(4):316-38.
23. Singhal A, Saini U, Chopra B, Dhingra AK, Jain A, Chaudhary J (2024). UV-Visible Spectroscopy: A Review on its Pharmaceutical and Bio-allied Sciences Applications. *Current Pharmaceutical Analysis* 20(3):161-77.
24. Alwadi AY, Arafeh GM, Almehlesi MS, Maswadeh HM, Salman IM, Ameer OZ (2022). Comparative Analysis of Commercially Available Acetaminophen Tablets in Saudi Arabia. *Dissolution Technologies* 29(3): GC1-12.
25. United States Pharmacopeial Convention (2018). Committee of Revision (Dissolution). United States Pharmacopeia, the National Formulary. United

States Pharmacopeial Convention, Incorporated.
26. United States Pharmacopeial Convention (2020). General Test Chapter Ultraviolet-Visible Spectroscopy. United States Pharmacopeia, the National Formulary. United States Pharmacopeial Convention, Incorporated.
27. AlBratty M, Alhazmi HA, Alam MS, Alam MI, Javed SA, Alam N (2020). Assessment of physicochemical properties and comparison of dissolution profiles of metformin hydrochloride tablets in Saudi Arabia. *Dissolution Technologies* 27(1):36-44.
28. Safila Naveed (2014). Development of a simple and sensitive method for the determination of paracetamol in pharmaceutical formulations using UV-Visible spectrophotometry. *Journal of Applied Pharmaceutical Science*, 4(03), 051-055.
29. Akinleye MO, Idris O, Nwachukwu PN, Oyetunde OO (2012). Quality of brands of atorvastatin calcium tablets marketed in Lagos, Nigeria. *International Journal of Pharmacy and Pharmacology*, 1(1):001-007.