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EVALUATION AND DRUG STABILITY STUDIES SOME ATORVASTATIN TABLETS BRANDS AVAILABLE IN SANA'A MARKET YEMEN

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ABSTRACT

This study evaluated the quality of five commercially available of Atorvastatin Calcium tablets products marketed in Sana'a Yemen, with a view to determine their interchangeability in clinical practice. Survey of the assessed Atorvastatin brands was carried out in Sana'a city, Yemen. Drug products' quality assessment included visual examination for their organoleptic properties; tests for weight variation, friability, hardness, disintegration time, dissolution profile and assay for Atorvastatin Content. Five marketed brands of Atorvastatin 20 mg tablets were collected from different pharmacies in Sana'a city. Quality parameters such as weight variation, hardness, thickness and friability were determined according to established protocols. In-vitro dissolution test, potency, disintegration time were also carried out. Dissolution and assay were determined by UV spectrophotometer at 241 nm. All the brands comply the requirements of Pharmacopoeia as they offer acceptable weight variation range hardness of all brands were within range "4-10 kg/cm" except Atorlip and no significant differences in disintegration times as they disintegrated within 5 minutes. In case of dissolution profile, all brands released more than 90% of drug in 60 minutes. We can conclude that there are all brands tablets it complies to **(USP)** and **(BP)** specifications in evaluation parameters. While in assay test all brands does not comply with the pharmacopoeia specifications, except Lipitor.

KEYWORDS: Atorvastatin**,** Drug Stability, Evaluation, Sana'a market Yemen.

INTRODUCTION

Atorvastatin (AVS) is lipid-lowering agent, which is selective, competitive inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme. A reductase which catalyzes the conversion of HMG-CoA to mevalonate, which is a rate limiting step in cholesterol biosynthesis. AVS decreases the levels of low-density lipoprotein (bad cholesterol) and triglycerides in the blood, while enhancing the levels of high-density lipoprotein (good cholesterol).[1] The empirical formula of AVS calcium is $(C_{33}H_{34}FN_2O_5)2Ca_2{+}{\cdot}3H_2O$ with a molecular weight of 1209.42. AVS is widely used to treat high cholesterol, to lower the risk of heart attack, myocardial infarction, angina, stroke, and other heart complications in people with type II diabetes and coronary heart disease. The dosage range of AVS is 10-80mg once a daily as a single dose with or without food at any time of the day. [2]

Atorvastatin calcium tablets, description, FDA drug information; the starting recommended dose of AVS is 10-20mg once daily. Rapidly absorbed after oral administration. The half-life is approximately 12h, extensively metabolized to ortho and para-hydroxylated derivatives and various beta-oxidation products (cytochrome P450 3A4) in the liver (hepatic metabolism) and a small amount of the drug metabolites from urine, elimination is mainly through bile.[3,4]

Oral dosage forms are safest and commonest route of when its quality is reliable. Systems usually depend on their formulation and manufacturing techniques; therefore, the quality of dosage system may vary. [5-7]

The therapeutic efficacy of a drug in clinical practice depends on the rate and extent of its availability in the systemic circulation. The dissolution rate of poorly water-soluble drugs is often a rate-limiting step in their absorption from the GI tract. Such drugs suffer limited oral bioavailability and are often associated with high intra subject and inter subject variability.[8]

Spectrophotometric methods. Generally, spectrophotometry is the most widely used method in drug analysis as a result of its simplicity, the cost of analysis and wide acceptability in most quality control laboratories.[9] The therapeutic efficacy of a drug depends on rate and extent of drug absorption from the site of administration to the systemic circulation. The dissolution rate of poorly water-soluble drugs is often a rate-limiting step in their absorption from the GI tract.[10] Recently it is used as calcium salt for the treatment of hypercholesterolemia.[8]

According to the biopharmaceutical classification system, it is a low soluble and highly permeable drug. [11]

It is slightly soluble in water and its intestinal permeability is high but the absolute bioavailability of Atorvastatin is only 12% after a 40 mg oral dose.[12]

The reduced bioavailability of the drug might be due to low dissolution, degradation in gastrointestinal tract and hepatic first-pass metabolism.[13]

The drug stability studies are important in all stages of pharmaceutical manufacturing, marketing, or post-marketing follow up because the drug stability is the basis for the effectiveness and safety of drug and to ensure that its bioavailability reach the site of action. Studying the factors that affect the validity of drug stability is part of the drug development stage and pharmaceutical innovations in manufacturing. Good medicine and advanced drug delivery systems. Drug stability is required preformulation, formulation, evaluation studies, in the marketing and clinical use stage. Formulation scientist from his experience and knowledge have to significantly in the stability study stage and is an important factor in the ADDS (Advanced Drug Delivery Systems) product development process and bioavailability.[14-49]

OBJECTIVES

The objective of the present study was to evaluate the different brands of Atorvastatin tablets available in Sana'a, Yemen market.

MATERIALS AND METHODS

MATERIALS: Different brands of Atorvastatin were used in the study and were purchased from the local market. The brands analyzed were, Lipitor (Pfizer, USA), Clostat (Shaphaco, Yemen), Atorva (Modern Pharma, Yemen), Atorlip (Cipla, India) and Ateroz (Bilim, Turkey). Various pharmaceutical parameters were employed as in (USP) and (BP), as weight variation thickness, diameter, friability, hardness, disintegration, dissolution and Assay to test the different brands of Atorvastatin tablets available in Sana'a, Yemen market. As shown in Table 1.

Table 1: General Table of Different Brands of Atorvastatin Collected from Sana'a Market Yemen.

Trade Name	Batch. No	Company	Country	MFD Date	EXP Date	Cost /Tab YR
Lipitor	DP8603	Pfizer	U. S. A	01/2020	12/2022	600
Atorlip	BA11331	Cipla	India	05/2021	04/2024	120
Clostat	60821	Shaphaco	Yemen	07/2021	07/2024	100
Atorva	21020	Modern Pharma	Yemen	01/2021	01/2024	120
Ateroz	21198006A	Bilim	Turkey	01/2021	01/2024	133

Equipment's: Analytical balance, (electronic balance type bl-220h, Shimadzu corporation Japan), weight variation, (electronic balance type bl-220h, Shimadzu corporation Japan), thickness & diameter tester (G.T. tools micrometer Japan), friability test (Veego, India and Aoe, instruments), hardness tester, (Erweka GmbH, Germany), disintegration test apparatus, (digital table disintegration test apparatus) and dissolution spectrophotometer tester, (Veego, India and Aoe, instruments).

METHODOLOGY

Weight Variation Test:[50] The test used to ensure the proper amount of the drug in the tablet by weight of 20 tablets is routinely evaluated. An analytical balance and the average weights were then determined **(**electronic balance type bl-220h, Shimadzu Corporation Japan**)** as shown in Table 3 as mean ± S.D. of each brand tested of Atorvastatin.

Thickness Test:[50] The test used for measurement of 20 tablets is routinely evaluated to ensure the proper size of the drug in the tablet. An analytical balance (G.T. Tools micrometer Japan) were used to determine the thickness of 20 tablets. Table 3 shows mean ± S.D. of each brand tested of Atorvastatin.

Diameter Test:[50] The measurement of 20 tablets is routinely evaluated to ensure the proper size of the drug in the tablet. An analytical balance (G.T. Tools micrometer Japan) was used to determine the diameter of 20 tablets. Table 3 shows mean ± S.D. of each brand tested.

Friability Test:[50] In friability test 20 tablets were taken randomly and placed on a sieve. Loose dust was removed with the aid of a soft brush. Tablet samples were weighed accurately and placed in the fabricator (Veego, India). After 100 rotations/4 min., loose dust was removed from the tablets as before. Finally, the tablets were weighed. The loss in weight indicates the ability of the tablets to withstand this type of wear and the results were shown in Table 3.

Hardness Test:[50] Hardness of the tablet is controlled by the degree of the pressure applied during the compression stage. It is an important criterion since it can affect disintegration and dissolution. A hardness tester (Erweka GmbH, Germany) was used for 10 tablets which were taken randomly, Results are shown in Table 3 of each brand tested.

Disintegration Test:[51] The apparatus consists of a basket made of transparent plastic or polyvinyl material, which has six tubes set with equal diameter and a wire mesh of stainless steel with uniform size. Small metal discs were used to enable immersion of the dosage form completely. The entire basket-rack assembly is connected to a motor, which is immersed in a vessel containing the dissolution medium (0.1N -HCL) in which the disintegration test is to be carried out. The vessel is provided with a thermostat to regulate the temperature of the dissolution medium at 37 ± 0.5ºC. One tablet was placed in each of the tube in the basket, the time required for complete disintegration of the tablet in each tube was determined.

Dissolution Test:[51] The drug release study is a measure of the amount of the drug released into the dissolution medium over time. This study gives an idea of amount of drug available for absorption after oral administration to having suitable dissolution characteristics is important for a satisfactory tablet. The dissolution test measures the amount of time required for a certain percentage of the drug substance in a tablet to go into solution under a specified set of conditions. It describes a step towards physiological availability of the drug substance, but it is not designed to measure the safety or efficacy of the tablet being tested. It provides an in vitro control procedure to eliminate variation among production batches.

Medium: 0.1N HCL buffer (Buffer Solutions under Reagents, Indicators) and H_2O 900 Ml. Apparatus: II, paddle type. Time: at (15, 30, 45 and 60) minutes. Temperature: 37±0.5°C.

Dissolution studies were conducted using a USP the standard preparation, about 20 mg of the drug was placed in a 50 ml volumetric flask and dissolved with 0.1N hydrochloric acid and then the volume was made up to 50 ml with 0.1N hydrochloric acid. 1 ml of this solution was transferred to another 50 ml volumetric flask and diluted to 50 ml with the same solvent for the sample, about 900 ml of 0.1N HCL was placed in the dissolution bowl with one tablet and the apparatus was started. The sample was drawn at time intervals of 15, 30, 45, and 60 minutes for each formulation procedure determine the amount of Atorvastatin calcium dissolved by employing UV absorbance at a wavelength of about 241 nm on littered portions of the solution under test in comparison with the standard solution. Tolerances Not less than 80% of the labeled amount of Atorvastatin calcium is dissolved in 60 minutes. Drug concentrations were measured spectrophotometrically, and the results are shown in Table 3 and Figure1.

Assay Test:[51] Atorvastatin calcium contains NLT 98.0% and NMT 102.0 % of Atorvastatin calcium calculated. Assay preparation Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 20 mg of Atorvastatin calcium to a 100-mL volumetric and add 50 mL of 0.1 N HCL. Sonicate for 5 minutes and stir for 30 minutes. Dilute with 0.1 N HCL to volume, and mix. Transfer 5.0 mL of this solution to the ask, dilute with 0.1 N HCL to 50.0 mL, and mix. Pass a portion of this solution through a filter having a finer porosity and use the filtrate after discarding the first 5-mL. The content was mixed well, and the absorbance was measured at 246 nm against a reagent blank. Calculate the percentage of Atorvastatin and any other individual impurity in the portion of the sample taken:

Result = $(r_u/r_s) \times (C_s/C_u) \times 100$

RESULTS AND DISCUSSION

RESULTS: As illustrated in Table 2, the organoleptic appearance of different Brands of Atorvastatin calcium tablets**.** As shown in Table 3, the weight variation, thickness and diameter of Atorvastatin brands coated tablets. Revealed that all brand tablets were passing according to the (BP), except Atorlip for hardness and for friability (BP) and disintegration (USP) of all Atorvastatin tablets coated brands pass the pharmacopeial limit. As illustrated in Table 3 and Figure 1, the dissolution profile of Atorvastatin calcium brands tablets and at the end 60 minutes of the in-vitro release test, the percentage drug released for Lipitor, Clostat, Ateroz, Atorlip and Atorva brands was found to be 95.43%, 94.46%, 95.14%, 93.15%, and 93.61% respectively. The results obtained from the study revealed that all brands' tablets released the drug in more than (90%). As illustrated in Table 3, the assay of Atorvastatin calcium branded tablets as percentage drug potency for brands Lipitor, Clostat, Ateroz, Atorlip and Atorva were as found to be 100.00, 90.00, 95.25, 84.00, and 91.25 (%) respectively. These results obtained revealed that, all brands were rejected, except Lipitor brand according to the USP.

Table 2: Organoleptic Appearance of Different Brands of Atorvastatin Collected from Sana'a Market Yemen.

Trade Name	Type of Tablets	Color	Shape	Odor	Trade Name	Generic Name
Lipitor	Film Coated	White	Caplet	Odorless	Lipitor	Atorvastatin
Atorlip	Film Coated	White	Caplet	Odorless	Atorlip	Atorvastatin
Clostat	Film Coated	White	Caplet	Odorless	Clostat	Atorvastatin
Atorva	Film Coated	White	Round	Odorless	Atorva	Atorvastatin
Ateroz	Film Coated	White	Caplet	Odorless	Atroz	Atorvastatin

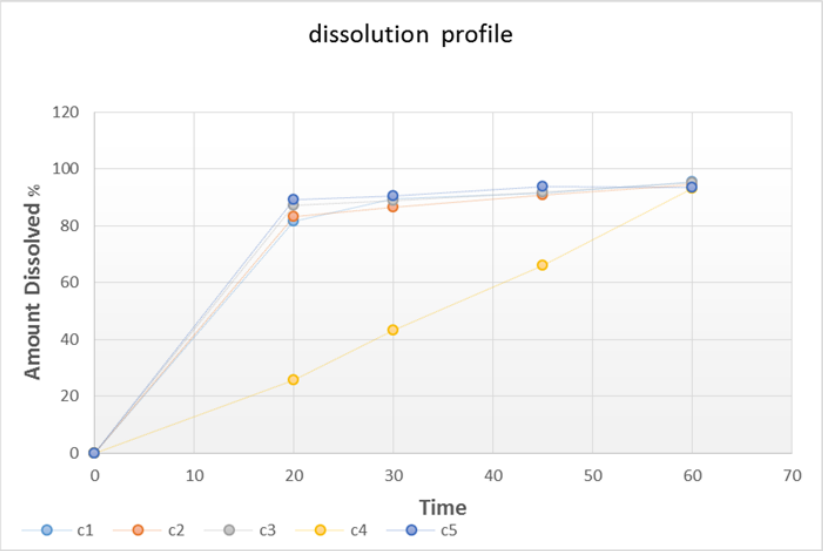

Figure 1: Dissolution Profile for Different Brands of Atorvastatin Collected from Sana'a Market Yemen.

Table 3: Assessment of Physicochemical Parameters of Various Atorvastatin Tablets Brands Present in Sana'a Market Yemen.

Formulation	W.V (Mg) ± S.D	Hardness (kg) ± S.D	Thickness (mm) ± S.D	Diameter (mm) ± S.D	Friability (%)	Disintegration Test min ± S.D	Dissolution Test (%) ± S.D	Assay Test (%) ± S.D
Lipitor	310±15.5	9.7±0.63	5±0.25	12±0.6	0.96%	2:20±0.149	95.43±0.29	100±0.070
Atorlip	299.5±14.97	12.7±0.54	2.5±0.12	11±0.55	0.12%	2:95±0.766	94.46±0.12	90±0.63
Clostat	308±15.4	9.25±0.63	4±0.2	11±0.55	0.91%	2:39±0.721	95.14±0.17	95.25±0.091
Atorva	190±14.25	6.1±0.87	2±0.1	8±0.4	0.61%	3:78±0.72	93.15±0.12	84±0.63
Ateroz	309±14.25	4.85±0.47	3±0.15	11±0.55	0.47%	2:02±0.672	93.61±0.41	91.25±0.098

DISCUSSION

All the tested brands of Atorvastatin calcium tablets complied with the official quality specifications. By comparing the quality results, In this study, five different brands of Atorvastatin calcium, i.e. Lipitor, Atorlip, Clostat, Atorva, and Ateroz mast were analyzed. The results of the Atorvastatin calcium brands show that differences are present during the manufacture of these products, i.e., excipients, speed of machine, etc. The weight variation has a direct impact on the assay of the tablets. the results shown that weight variation test of the tablets is within specified limits. As shown in Table 3. We can conclude that best result as followed, Ateroz > Atorva > Atorlip > Clostat > Lipitor.

For the thickness we can conclude that best result as follow, Atorva > Atorlip > Ateroz > Clostat > Lipitor. For diameter test Atorva > Ateroz > Clostat > Atorlip > Lipitor, for hardness test best result show in, Atorlip > Lipitor > Clostat > Atorva > Ateroz and for disintegration all tablets disintegrated in less than 10 minutes, Ateroz > Lipitor > Clostat > Atorlip > Atorva.

The dissolution rate was higher with Lipitor which consider to be the product having the best priorities according (USP) follow by Clostat > Atorlip > Ateroz > Atorva. For assay test, the results revealed that Lipitor showed the highest drug content show the best result and considered to be reference brand with best priorities, whereas Atorva gave the lowest results. The assay results of Lipitor, and Clostat brand show within limit according USP. The final assay results of Atorvastatin as follow, Lipitor > Clostat > Ateroz > Atorlip > Atorva.

CONCLUSION

Quality control of Atorvastatin tablets is essential to determine the quality of brands. The drugs have been arranged according to the USP and BP quality control from the best to the lowest, as the following: Lipitor > Clostat > Ateroz > Atorlip > Atorva. We can conclude that there are all brands tablets it complies to **(USP)** and **(BP)** specifications in evaluation parameters. While in assay test all brands does not comply with the pharmacopoeia specifications, except Lipitor.

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