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

Bamisaye O. Oyawaluja[1], Aminat A. Oyawaluja[2], Kazeem O. Abiola[1], Dolapo R. Oladele[1], Amedat M. Abibu[1] and Aderonke A. Adepoje-Bello[1].

[1]Department of Pharmaceutical Chemistry, Faculty of Pharmacy, University of Lagos, Nigeria.
[2]Department of Pharmacognosy, Faculty of Pharmacy, University of Lagos, Nigeria.

Corresponding author: Bamisaye O. Oyawaluja
Email: boyawaluja@unilag.edu.ng
Telephone: +234 802 353 4167, +234 803 399 9408

ABSTRACT

Background: Quality of pharmaceuticals plays a vital role in ensuring safety and therapeutic performance. Rosuvastatin, one of the most potent statins for lowering cholesterol levels, requires strict compliance with pharmacopoeia standards to guarantee effectiveness in clinical use.

Objective: This study evaluated the quality of six rosuvastatin tablet brands available in Pharmacies in Mushin, Lagos, Nigeria.

Methods: Six brands of rosuvastatin calcium tablets (20 mg) obtained from local pharmacies were assessed using British Pharmacopoeia (BP) methods. Physical tests including uniformity of weight, friability, and hardness and chemical tests comprising dissolution studies in phosphate buffer (pH 6.8) using USP dissolution apparatus II, and percentage purity was determined by UV-visible spectrophotometry at 241 nm.

Results: All brands complied with BP limits for uniformity of weight, hardness, and friability. However, dissolution testing revealed marked variations: only the innovator brand released more than 80 % of the drug within 30 minutes, whereas the generic brands released significantly lower amounts (5.15-60.61 %). Percentage purity also showed wide variability, ranging from 30.3 % to 131.2 %, with only the innovator (100 %) meeting BP specifications (98-102 %).

Conclusion: The evaluated rosuvastatin brands met basic physicochemical requirements, but major discrepancies in dissolution and purity were observed. Such variations may compromise therapeutic efficacy and patient safety, underscoring the need for strengthened post-market surveillance and strict regulatory oversight.

Keywords: Rosuvastatin, physicochemical evaluation, dissolution profile, quality assessment.

Étude comparative de la qualité des marques de comprimés de rosuvastatine obtenues à Mushin, Lagos, Nigéria.

Bamisaye O. Oyawaluja[1], Amina A. Oyawaluja[2], Kazeem O. Abiola[1], Dolapo R. Oladele[1], Amedat M. Abibu[1] and Aderonke A. Adepoje-Bello[1]

[1]Département de chimie pharmaceutique, Faculté de pharmacie, Université de Lagos, Nigéria.
[2]Département de Pharmacognosie, Faculté de Pharmacie, Université de Lagos, Nigéria.

Auteur correspondant: Bamisaye O. Oyawaluja
Courriel: boyawaluja@unilag.edu.ng
Téléphone: +2348023534167, +2348033999408

RÉSUMÉ

Contexte: La qualité des produits pharmaceutiques joue un rôle essentiel dans la garantie de leur innocuité et de leur efficacité thérapeutique. La rosuvastatine, l'une des statines les plus puissantes pour la réduction du taux de cholestérol, nécessite une conformité stricte aux normes de la pharmacopée afin d'assurer son efficacité en pratique clinique.

Objectif: Cette étude a évalué la qualité de six marques de comprimés de rosuvastatine disponibles dans les pharmacies de Mushin, à Lagos, au Nigéria.

Méthodes: Six marques de comprimés de rosuvastatine calcique (20 mg) provenant de pharmacies locales ont été évaluées selon les méthodes de la Pharmacopée britannique (BP). Les tests physiques comprenaient l'uniformité de poids, la friabilité et la dureté, et les tests chimiques, incluant des études de dissolution dans un tampon phosphate (pH 6.8) à l'aide de l'appareil de dissolution USP II. Le pourcentage de pureté a été déterminé par spectrophotométrie UV-visible à 241 nm.

Résultats: Toutes les marques étaient conformes aux limites de la Pharmacopée britannique (BP) en matière d'uniformité de poids, de dureté et de friabilité. Cependant, les tests de dissolution ont révélé des variations importantes : seule la marque de référence a libéré plus de 80 % du principe actif en 30 minutes, tandis que les marques génériques en ont libéré des quantités significativement inférieures (5.15 % à 60.61 %). Le pourcentage de pureté a également présenté une grande variabilité, allant de 30.3 % à 131.2 %, seule la marque de référence (100 %) respectant les spécifications de la BP (98 % à 102 %).

Conclusion: Les marques de rosuvastatine évaluées répondaient aux exigences physico-chimiques de base, mais des écarts importants de dissolution et de pureté ont été observés. De telles variations peuvent compromettre l'efficacité thérapeutique et la sécurité des patients, soulignant la nécessité d'un renforcement de la surveillance post-commercialisation et d'un contrôle réglementaire strict.

Mots-clés : Rosuvastatine, évaluation physico-chimique, profil de dissolution, évaluation de la qualité.

INTRODUCTION

Cholesterol is a lipophilic molecule that is essential for human life. It has many roles that contribute to normally functioning cells.[1] For example, cholesterol is an important component of the cell membrane.[2] It contributes to the structural makeup of the membrane as well as modulates its fluidity.[3] Cholesterol functions as a precursor molecule in the synthesis of vitamin D, steroid hormones (e.g., cortisol and aldosterone, and adrenal androgens), and sex hormones (e.g., testosterone, estrogens, and progesterone).[4] Cholesterol is also a component of bile salt that aid in digestion by facilitating the absorption of fat-soluble vitamins A, D, E, and K.[5]

Since cholesterol is mostly lipophilic, it is transported through the blood, along with triglycerides, inside lipoprotein particles (HDL, IDL, LDL, VLDL, and chylomicrons).[6] These lipoproteins can be detected in clinical settings to estimate the amount of cholesterol in the blood. However, chylomicrons are not present in non-fasting plasma.

Elevated low-density lipoprotein cholesterol (LDL-C) levels, which occur mostly in hypercholesterolemia patients, have been implicated in the development of cardiovascular diseases (CVD) and atherosclerosis.[7,8,9] As a result, several lipid-lowering agents have been identified, including statins, which have demonstrated the highest efficacy in reducing serum cholesterol levels. The first statin to be marketed was Lovastatin (Mevacor® manufactured by Merck) in 1987 while in August 2003, the FDA approved Rosuvastatin calcium (Crestor® manufactured by AstraZeneca) as the seventh drug in the statin class for treating hypercholesterolemia by reducing low-density lipoprotein cholesterol (LDL-C) levels.[10]

Rosuvastatin is a fully synthetic HMG-CoA reductase inhibitor, while other HMG-CoA reductase inhibitors are either natural, mevinic acid-derived (lovastatin, simvastatin, pravastatin) or synthetic, heptenoic acid-derived (atorvastatin, fluvastatin).[11,12] Rosuvastatin belongs to a new generation of methanesulfonamide pyrimidine and N-methanesulfonoyl pyrrole-substituted 3, 5, 5-dihydroxy-heptenoates. Although the characteristic statin pharmacophore remains similar to other statins, the addition of a stable polar methanesulfonamide group provides low lipophilicity and enhanced ionic interaction with HMG-CoA reductase enzyme, thus improving its binding affinity to this enzyme.[13]

Rosuvastatin is a potent statin with pharmacologic and pharmacokinetic advantages. Its high degree of liver selectivity results in high hepatic concentrations, leading to superior efficacy in lowering low-density lipoprotein cholesterol and triglycerides, as well as improving high-density lipoprotein cholesterol, compared to other statins.[14] Rosuvastatin has relatively low lipophilicity when compared with other statins and has minimal entry into peripheral cells. This, along with its minimal cytochrome P450 metabolism, presents relatively better tolerability, safety, and drug interaction profile.[15] Consistent with these features, rosuvastatin represents a step forward in statin therapy.[14] Rosuvastatin is considered one of the most potent statins to date.[16]

The therapeutic effectiveness of any pharmaceutical preparation depends on its formulation properties, manufacturing methods, and the stringency of quality control.[17] The major challenge in maintaining pharmaceutical product quality is the lack of post-market quality surveillance of currently marketed products.[18] Post-market quality evaluation of generic drugs can be a valuable tool for assessing the quality, efficacy, and safety of commercially available brands.[19] It can also help to ensure that the marketed generics are therapeutically equivalent to innovator brands and can be safely interchanged.[20] This research aimed at evaluating the quality of rosuvastatin tablets brands marketed in Mushin, Lagos, Nigeria.

METHODS

Sample collection

Six brands of rosuvastatin tablets (20 mg) were purchased from local retail pharmacies in Mushin, Lagos State, Nigeria. The rosuvastatin brands were labeled as R, S, T, U, V and W, with R being the innovator. Product information such as batch number, manufacturing date, expiry date were observed and recorded.

Evaluation of tablets

Uniformity of weight test

Twenty (20) tablets of each brand of rosuvastatin were randomly selected. Each tablet was weighed using the electronic balance, and the average weight of the twenty tablets was determined. The percentage deviation of each tablet from the average was calculated and recorded.[21]

$$\% \text{ Deviation} = \frac{\text{Average weight - Individual weight}}{\text{Average weight}} X 100 \quad (1)$$

Friability test

Ten (10) tablets from each brand of rosuvastatin were weighed collectively and recorded as initial weight before they were placed in the friabilator (CS-3 Tablet friability Tester) and subjected to rotations using a tablet friability tester at 25 rpm (revolutions per minute) for 4 minutes. All the tablets were removed, reweighed, and recorded as final weight.[21] The process was repeated for all six brands.

Friability was calculated using the formula below;

$$F = \frac{\text{Initial weight - Final weight}}{\text{Initial weight}} X 100 \quad (2)$$

Hardness test

Ten (10) tablets of each rosuvastatin brand were individually placed in a vertical position between the jaws of the hardness tester (Monsanto type), aligned to the direction of the application of the force. A reading was taken when each tablet broke due to an applied force. Force required to fracture the tablet (hardness), expressed in KgF was obtained and recorded.

Preparation of rosuvastatin calibration curve

To construct the calibration curve, a stock solution of rosuvastatin secondary reference standard (CRESTOR) was prepared. An accurately weighed 100 mg of the standard was transferred into a 100 mL volumetric flask, followed by the addition of about 20 mL of methanol. The mixture was shaken thoroughly and sonicated for 15 minutes to ensure complete dissolution. The volume was then adjusted to the mark with methanol, and the solution was filtered through Whatman filter paper to remove undissolved particles. Using appropriate dilution factors, a series of standard solutions of varying concentrations ranging between 10 - 100 µg/mL were prepared in 10 mL volumetric flasks and made up to volume with the diluent. The absorbance of each solution was measured at 241 nm using a UV-Visible spectrophotometer. A calibration curve was generated by plotting absorbance against concentration in Microsoft Excel.[21]

Determination of rosuvastatin maximum wavelength in buffer solution

The prepared rosuvastatin solution, as described below, was scanned across the UV range of 200-400 nm. The maximum absorption wavelength (λmax) was identified at 241 nm and used for absorbance measurements.[21]

Dissolution test

The dissolution test was conducted using Dissolution Tester (Copley Scientific, DIS 8000, UK), a USP apparatus 2 (paddle) according to official guidelines.[21,22,23] The dissolution study employed 0.05 M phosphate buffer as the medium, with the pH adjusted to 6.8 using 6 N sodium hydroxide and verified using a pH meter. The test was conducted in six vessels, maintaining the medium temperature at 37 ± 0.5 °C and operating the paddle at 75 ± 25 rpm.[23]

Three tablets from each brand were tested to obtain a reliable mean value while minimizing wastage of material. A dissolution medium of 900 mL was introduced into each vessel, with one tablet placed per vessel. At predetermined intervals (5, 10, 15, 30, 45, and 60 minutes), 5 mL aliquots were withdrawn from each of the six vessels and replaced with an equal volume of fresh medium to maintain sink conditions. The collected samples were filtered through 0.45-µm syringe filters (Merck Millipore Millex, USA), appropriately diluted, and analyzed for absorbance at wavelength of 241 nm using a UV/Vis spectrophotometer.[21] The drug release was computed from an already developed calibration curve.

Determination of similarity factor

The similarity factor for comparing the dissolution profiles of the generic brands with the innovator brand. The rosuvastatin tablet samples were analyzed using a UV-Visible spectrophotometer at 241 nm. Dissolution profiles for the five brands (R, S, T, U, V, and W) were obtained, and the percentage of drug released at 5, 10, 15, 30, 45, and 60 minutes was calculated using Microsoft Excel. The similarity factor (f2) between the dissolution profiles of the generic brands (S, T, U, V, and W) and the innovator brand (R) was determined using the similarity factor formula in Microsoft Excel.[24]

$$f2 = 50 \log \{(1+\tfrac{1}{n}\textstyle\sum_{i=1}^{n}(R_t - T_t)^2)^{-0.5} X 100\} \quad (3)$$

Where;

$f2$ = Similarity factor
n = number of observations
R_t = Average percentage drug dissolved from the reference formulation
T_t = Average percentage drug dissolved from test formulation

$$f1 = \left\{ \frac{\sum_{t\ 1}^{n} |R_t - T_t|}{\sum_{t=1}^{n} R_t} \right\} X\ 100 \quad (4)$$

Where;

$f1$ = Difference factor
n = number of observations
R_t = Average percentage drug dissolved from the reference formulation at time t
T_t = Average percentage drug dissolved from test formulation at time t

Determination of percentage purity

From each brand, an amount equivalent to 10 mg of rosuvastatin was accurately weighed and transferred into a 100 mL volumetric flask. Twenty milliliters of methanol were added, the mixture was shaken thoroughly, and then sonicated for 15 minutes. The volume was adjusted to 100 mL with methanol, and the solution was filtered. From the filtrate, 1 mL was transferred into a 50 mL volumetric flask and diluted to volume with methanol. The resulting solutions were placed in labeled sample bottles, and their absorbance was measured using a UV spectrophotometer at wavelength of 241 nm.[21] The potency of each brand was calculated using the following formula.

$$Percentage\ Purity = \frac{concentration\ of\ sample}{concentration\ of\ standard} X 100 \quad (5)$$

The sample concentrations were determined from the prepared calibration curve of the reference standard.

RESULTS

The six (6) brands of rosuvastatin 20 mg tablets used in this study were all obtained from retail pharmacy outlets in Mushin, Lagos, Nigeria and were all still within their respective stipulated shelf-lives assigned by the manufacturers when the quality assessments procedures were done.

Table 1: Samples and packaging information

Brand code	Batch number	Production date	Expiry date
R	02247162	12/23	11/26
S	WG21541	08/23	07/26
T	B01573	12/22	11/25
U	01230485	04/23	03/26
V	067756	12/22	11/25
W	H21451	11/23	10/26

Table 1 shows the sample codes and packaging information, Table 2 shows the evaluation of different physicochemical parameters of different brands of Rosuvastatin tablets in Lagos, Nigerian market, while Table 3 shows similarity factor and difference factor between dissolution profiles of the generic brands and the innovator brand. Figure 1 depicts the dissolution profile of all the brands of rosuvastatin.

Table 2: Physicochemical parameters of different brands of Rosuvastatin tablets

Sample code	Deviation in weight (%)	Hardness (KgF)	Friability (%)	% Purity
S	0.14	5.75 ± 0.55	0.00	71.60
R	0.15	5.33 ± 0.97	0.00	100.00
T	0.10	5.70 ± 0.41	0.00	131.20
U	0.32	5.67 ± 1.50	0.00	30.30
V	0.15	6.17 ± 0.75	0.00	79.40
W	0.12	5.83 ± 0.61	0.00	66.00

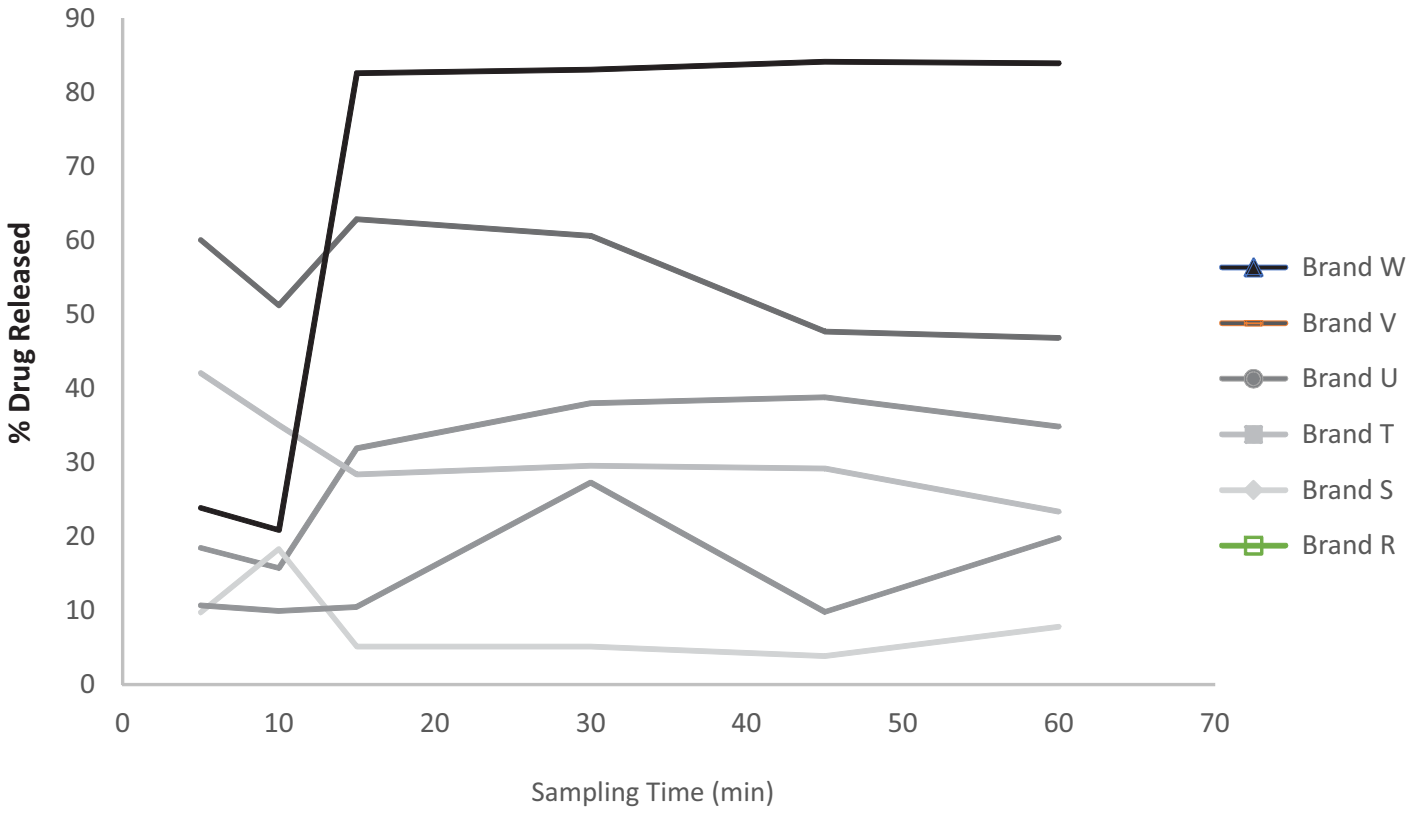

Figure 1: Dissolution profile of the brands of Rosuvastatin

Table 3: Similarity Factor and difference factor between dissolution profiles of the generic brands and the innovator brand

Brand Code	Similarity Factor	Difference Factor
Brand S	25	48
Brand T	17	68
Brand U	13	77
Brand V	10	87
Brand W	20	53

Innovator Brand- R

DISCUSSION

Ensuring the quality of drug products is essential to achieving the desired therapeutic response.[25] Tablets are composed of both active pharmaceutical ingredients (APIs) and excipients, and the performance of the final product depends on the integrity of both components.[26] Failure to comply with pharmacopeial standards may result in reduced bioavailability, compromised efficacy, and possible safety concerns.[27] This is particularly important in the case of statins such as rosuvastatin, which are widely prescribed for the management of hypercholesterolemia and prevention of cardiovascular diseases. Given their chronic use, any variation in quality among different brands can have long-term clinical consequences, including inadequate lipid control or increased risk of adverse effects. For this reason, comparative quality evaluation of innovator and generic products provides a practical means of verifying conformity to official monograph requirements and ensuring therapeutic equivalence. This study evaluated the quality of six brands of rosuvastatin tablets marketed in Mushin, Lagos, Nigeria, focusing on their physicochemical characteristics, dissolution behaviour, and percentage purity.

The uniformity of weight is an important indicator of dose consistency. All six brands complied with the British Pharmacopoeia (BP) specification, suggesting that the manufacturing processes employed by the producers are adequately controlled to yield tablets of consistent weight. This is crucial in preventing under-dosing or overdosing, which could compromise therapeutic outcomes.

Tablet hardness and friability provide insights into the mechanical strength of formulations. All the tested brands exhibited hardness values within acceptable limits, ranging from 5.33 to 6.17 KgF (Table 2). The hardness of oral tablets is usually between 4 and 8 kg/F.[16] These values indicate that the tablets are sufficiently robust to withstand handling, packaging, and transportation without compromising their structural integrity. Similarly, friability values were below the maximum threshold of 1 %, further confirming the mechanical stability of the brands. Such results are indicative of good formulation design and appropriate excipient selection.

Dissolution testing revealed notable variations among the brands. According to the BP specification, not less than 80 % of the rosuvastatin should be released within 30 minutes. While the innovator brand (R) demonstrated rapid and consistent drug release (above 80 % at 30 minutes), most of the generic brands failed to meet this requirement, with dissolution rates ranging between 5.15% and 60.61 % at 30 minutes. This poor dissolution performance raises concerns about the bioavailability of these generics, as suboptimal release may reduce systemic exposure and compromise clinical effectiveness. Such disparities highlight the need for stringent post-marketing surveillance to ensure therapeutic equivalence of generic products.

The similarity (f2) and difference (f1) factors further confirmed the lack of equivalence between the innovator and most of the tested generics (Table 3). None of the generics attained an *f*2 value above 50, indicating that their dissolution profiles were not comparable to the innovator. This suggests that despite compliance with

basic physicochemical parameters, several generic brands may not provide the same therapeutic outcomes as the reference product.

Percentage purity analysis showed the widest variability among all the tests conducted (Table 1). Only the innovator brand (100 %) fell within the BP specification of 98-102 %. The generics demonstrated markedly inconsistent results, with values ranging from as low as 30.3 % (Brand U) to as high as 131.2 % (Brand T). These deviations suggest either substandard manufacturing practices, poor-quality raw materials, or errors in formulation processes such as incorrect API loading. Such inconsistencies not only threaten therapeutic effectiveness but may also lead to adverse events, particularly in patients requiring long-term statin therapy. Products with low purity could result in treatment failure, while excessively high purity may increase the risk of dose-dependent adverse effects, including hepatotoxicity and myopathy.

Overall, while all brands satisfied compendial requirements for physical parameters, significant variation was observed in dissolution performance, which is at variance to the report of Ajima *et. al.*[28] These findings underscore the fact that meeting physical quality tests alone does not guarantee bioequivalence. The inconsistency among the tested generics highlights the urgent need for regulatory agencies to intensify post-market surveillance and enforce stricter quality assurance measures. Strengthening local quality control practices will not only safeguard patient health but also improve confidence in generic medicines available in the Nigerian market.

CONCLUSION

This study provides a comprehensive evaluation of the quality of rosuvastatin tablets from six different brands, with particular emphasis on physicochemical properties, dissolution behavior, and percentage purity. While all brands met the British Pharmacopoeia (BP) requirements for basic physical characteristics, marked disparities were observed in dissolution performance and active ingredient content. Importantly, only the innovator brand achieved the BP dissolution criterion of releasing more than 80% of the drug within 30 minutes, raising concerns about the bioavailability and therapeutic reliability of most generic alternatives. The wide variability in percentage purity, ranging from 30.3 % to 131.2 %, further underscores potential inconsistencies in manufacturing practices and raw material quality. Collectively, these findings highlight the urgent need for strengthened post-marketing surveillance and more rigorous regulatory oversight to ensure that all marketed rosuvastatin formulations consistently meet pharmacopeial standards. Such measures are essential to safeguard patient safety, maintain therapeutic efficacy, and uphold confidence in generic medicines.

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