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RESEARCH ARTICLE

POST-MARKETING QUALITY ASSESSMENT OF GENERIC ROSUVASTATIN TABLETS IN ADEN-YEMEN

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Abstract

The increasing availability of generic Rosuvastatin (ROS) tablets necessitates rigorous post-marketing quality evaluation, particularly in regions with limited regulatory oversight, such as Yemen. This study aimed to assess the pharmaceutical quality and in vitro performance of commercially available ROS (20 mg) tablet brands in the Aden market. Five ROS brands were evaluated using validated high-performance liquid chromatography (HPLC) and pharmacopeial quality control tests in accordance with USP/BP guidelines. Parameters assessed included weight variation, hardness, friability, disintegration time, and dissolution. Dissolution testing was conducted at pH 6.6 following FDA recommendations due to the acid instability of ROS. The HPLC method demonstrated excellent linearity (R^2 = 0.9993), with assay values ranging from 92.01% to 108.45%, complying with pharmacopeial limits. All brands met requirements for weight uniformity, friability, and disintegration. Although TAB.3 and TAB.4 exhibited higher hardness values (20.22 and 18.3 kg/cm²), this did not adversely affect their performance. Dissolution studies showed that all brands released more than 80% of the labeled drug within 30 minutes, with most exceeding 85%, indicating rapid dissolution. TAB 1 showed a lower mean dissolution of 75.99% at the 30-minute time point. All evaluated ROS brands demonstrated acceptable pharmaceutical quality and in vitro performance, supporting their potential interchangeability. However, variability in dissolution behavior among certain brands highlights the importance of continuous post-marketing surveillance to ensure consistent therapeutic efficacy in the Yemeni pharmaceutical market.

Keywords: HPLC; Pharmaceutical quality; Post-marketing surveillance; Rosuvastatin.

Introduction:

Cardiovascular diseases (CVDs) remain the leading cause of morbidity and mortality worldwide, with dyslipidemia representing a major modifiable risk factor. The pharmacological management of hypercholesterolemia relies primarily on statins, which exert their therapeutic effect through competitive inhibition of 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase, the rate-limiting enzyme in hepatic cholesterol biosynthesis [1]. This mechanism leads to significant reductions in low-density lipoprotein cholesterol (LDL-C) and a consequent decrease in cardiovascular risk.

Rosuvastatin calcium (ROS), originally marketed as Crestor®, is among the most potent statins currently available and is widely prescribed due to its high efficacy and favorable pharmacokinetic profile [2,3]. Following patent expiration, numerous generic formulations have entered global pharmaceutical markets, offering substantial economic benefits and improved accessibility. However, the therapeutic equivalence of these generic products is critically dependent on their pharmaceutical quality, including dosage uniformity, mechanical integrity, and in vitro dissolution performance.

In Yemen, specifically, the prevalence of unauthorized and smuggled pharmaceuticals poses a serious risk of substandard treatment or complete therapeutic failure [4,5]. Ensuring the quality of pharmaceutical products remains a major challenge, particularly in low- and middle-income countries where regulatory systems may be under-resourced. The circulation of substandard and falsified medicines represents a significant threat to public health, potentially leading to therapeutic failure, adverse drug reactions, and increased morbidity and

mortality [6,7]. In the context of chronic conditions such as dyslipidemia, inadequate drug quality may result in poor lipid control and an increased risk of major adverse cardiovascular events [6,9]. Additionally, poor-quality pharmaceuticals may exhibit unpredictable pharmacokinetics or contain harmful impurities, further compromising patient safety [6,10].

This issue is especially pronounced in regions with weak regulatory oversight, such as Yemen, where unauthorized and smuggled pharmaceutical products are known to circulate widely [4,5,11]. The presence of such products not only compromises treatment outcomes but also undermines public trust in healthcare systems and regulatory authorities [12,13]. Therefore, rigorous post-marketing quality surveillance is essential to ensure the safety, efficacy, and consistency of pharmaceutical products available in these markets [6,7].

ROS is classified as a Biopharmaceutics Classification System (BCS) Class II drug, characterized by low solubility and high permeability. For such drugs, dissolution is a critical determinant of oral bioavailability, making in vitro dissolution testing a key surrogate for predicting in vivo performance [14].

Previous post-marketing surveillance studies have reported variable findings regarding the quality of generic ROS products. Studies conducted in Saudi Arabia and Nigeria demonstrated that generic formulations complied with pharmacopeial standards and exhibited acceptable dissolution similarity, supporting their clinical interchangeability [15,16]. In contrast, a study conducted in the US and Bangladesh revealed that although several generic brands met basic pharmacopeial requirements for weight uniformity and assay, some failed to achieve acceptable dissolution profiles, indicating potential issues with bioequivalence [17]. These findings highlight the necessity of region-specific quality evaluations, particularly in markets with heterogeneous regulatory control.

Despite the increasing availability of generic ROS products in Yemen, there is a lack of published data assessing their pharmaceutical quality and compliance with international standards. Given the documented circulation of unauthorized pharmaceutical products in the Yemeni market, such an evaluation is essential to safeguard public health and ensure therapeutic efficacy.

Therefore, this study aims to evaluate the pharmaceutical quality of selected commercially available ROS tablet brands in Aden, Yemen, using validated high-performance liquid chromatography (HPLC) methods alongside pharmacopeial quality control tests. The study further seeks to assess compliance with United States Pharmacopeia (USP) and British Pharmacopoeia (BP) standards and to determine the interchangeability of generic products based on dissolution profile comparison.

2. Materials and Methods

2.1. Materials and Samples

A certified reference standard of ROS calcium was obtained from the Supreme Board of Drugs and Medical Appliances (Yemen). Analytical-grade reagents, including acetonitrile and phosphoric acid, were used throughout the study.

Five commercially available brands of ROS tablets labeled to contain 20 mg were procured from community pharmacies in Aden, Yemen. The selection of brands was based on market availability and prescription frequency. The samples included both authorized and unauthorized products, as classified by local regulatory authorities. These brands were assigned the codes TAB.1 through TAB.5, with their specific manufacturing and dosage details summarized in Table 1.

2.2. Instrumentation

The analysis was performed using an Agilent high-performance liquid chromatography (HPLC) system equipped with a UV detector and an Eclipse XDB-C18 column (4.6 × 150 mm, 5 µm). Additional instruments included a USP dissolution apparatus II (paddle type), an ERWEKA disintegration tester, a Campbell Electronics friabilator, a United Pharmatek hardness tester, an analytical balance, and digital calipers.

Table 1: Summary of ROS tablet samples including brand codes, labeled strength, manufacturer details, and batch information.

Sample	Batch No.	Name of company	Manufacture date	Expire date	Rank
TAB.1	241038	(Syria)	03/2024	03/2027	Unauthorized
TAB.2	BCAY002A	(Türkiye)	05/2026	07/2027	Authorized
TAB. 3	SM087	(Türkiye)	09/2023	08/2026	Unauthorized
TAB.4	2037	(Jordan)	02/2022	02/2025	Authorized
TAB.5	2139	(Jordan)	09/2023	09/2025	Authorized

2.3. HPLC Method

2.3.1. Chromatographic Conditions

Chromatographic separation was achieved using a mobile phase of acetonitrile: water (40:60, v/v), adjusted to pH 3.5 with phosphoric acid. The flow rate was maintained at 1.5 mL/min, with an injection volume of 20 µL. Detection was carried out at 242 nm. Under these conditions, ROS exhibited a well-resolved peak with acceptable symmetry and retention characteristics [18].

The linearity was evaluated over a concentration range of 0.125–2.0µg/mL, demonstrating a strong linear relationship with a correlation coefficient (R^2) ≥ 0.999. Limit of Detection (LOD) and Limit of Quantification (LOQ) were calculated based on the standard deviation of the response and the slope of the calibration curve [19].

2.4. Pharmacopeial Quality Control Tests

All quality control tests were conducted in accordance with the specifications outlined in the United States Pharmacopeia (USP-NF 2025) and the British Pharmacopoeia (BP 2025) [20,21].

2.4.1. Weight Variation Test

Twenty tablets from each brand were individually weighed using an analytical balance, and the mean weight and percentage deviation were calculated. The acceptance criteria were based on USP guidelines, which specify allowable deviations depending on tablet weight: ±10% for tablets weighing ≤130 mg, ±7.5% for tablets between 130 mg and 324 mg, and ±5% for tablets ≥324 mg [20].

Weight variation $\frac{A_w x\,\%}{100}$

where A_w = Average weight of the tablet

Upper limit = A_w + Weight variation

Lower limit = A_w – Weight variation

Furthermore, calculate the upper and lower limits at double the % difference allowed:

Upper limit = A_w + [(2x%/100) (W)]

Lower limit = A_w – [(2x%/100) (W)]

2.4.2. Tablet Dimensions (Diameter and Thickness)

The diameter and thickness of ten tablets from each brand were measured using digital calipers. The mean values were calculated, and a variation within ±5% of the average was considered acceptable, in accordance with pharmacopeial recommendations for dimensional uniformity [20,21].

2.4.3. Hardness Test

Tablet crushing strength was evaluated using a hardness tester. Ten tablets from each brand were tested, and the force required to break each tablet was recorded. Acceptable hardness ranges were considered to be 4–8 kg/cm² for conventional tablets and up to 15 kg/cm² for film-coated tablets to ensure adequate mechanical strength and handling properties.

2.4.4. Friability Test

The mechanical durability of the ROS brands was evaluated using a Campbell Electronics friabilator to simulate surface abrasion and physical shock. For each batch, ten randomly selected tablets were dedusted, and their initial weight was recorded before they were placed into the rotating drum. The apparatus was set to 25 rpm for a duration of 4 minutes, completing 100 total revolutions. Following the test cycle, the tablets were again dedusted and reweighed to determine any mass loss. In accordance with pharmacopeial benchmarks, a weight loss of less than 1% is the threshold for acceptance. The % friability was then calculated by the following equation:

$$\%\ of\ friability = \frac{w_1 - w_2}{w_1}$$

where:

w_1 = initial weight of ten tablets.

w_2 = final weight of ten tablets.

Although the sampled brands were film-coated, friability testing was conducted to ensure the mechanical integrity of the coating and the underlying core under physical stress. These tests are particularly important in post-marketing quality studies to detect substandard manufacturing practices and to ensure that the products can withstand handling, transportation, and storage without compromising their performance.

2.4.5. Disintegration Test

The disintegration test was carried out using an ERWEKA disintegration apparatus. Six tablets from each brand were placed in individual tubes and immersed in distilled water maintained at 37 ± 0.5°C. The time required for the complete disintegration of each tablet was recorded. Acceptance criteria were based on USP/BP limits for film-coated tablets [20,21].

2.4.6. Dissolution Testing

Dissolution studies were performed using USP Apparatus II (paddle method) under the following conditions:

- Dissolution medium: 900 mL citrate buffer (pH 6.6)
- Temperature: 37 ± 0.5°C
- Paddle rotation speed: 50 rpm
- Sample size: n = 6

Aliquots (10 mL) were withdrawn at 30 min, filtered, and analyzed spectrophotometrically at 241 nm using the dissolution medium as a blank. The percentage of drug released was calculated by comparison with a standard ROS solution prepared in the same medium [20,21], indicating similarity between dissolution profiles.

3. Results and Discussion

3.1. HPLC Analysis

The HPLC method demonstrated high specificity and reliability, with ROS eluting at a consistent retention time (2.17–2.19 min) across all brands. The chromatograms showed sharp, well-resolved peaks with no interference from excipients, confirming method selectivity. Minor secondary peaks observed at later retention times (e.g., ~3.6 min) are consistent with reported ROS degradation products or isomeric forms in stability-indicating methods [22].

The calibration curve exhibited excellent linearity over the concentration range (0.125–2.0 µg/mL) with a correlation coefficient (R^2 = 0.9993), meeting ICH requirements. The assay results ranged from 92.01% to 108.45%, indicating that all tested brands complied with pharmacopeial limits (90–110%). These findings are consistent with previous studies conducted in Saudi Arabia (99.7 %-104.14%), the USA, Bangladesh (91.94 %-105.48%), and Nigeria (94.92 to 109.2%) [15–17]. The information related to the linearity and calibration curve is shown in Table 2 & Figure 1.

Although TAB.2 is officially registered as an authorized formulation within the local market, it demonstrated a comparatively lower assay value (92.01%) than its generic counterparts. This lower recovery could be attributed to minor variations in manufacturing or slight degradation, though it crucially maintains compliance by remaining above the minimum pharmacopeial threshold of 90%.

Table 2: The Data Related to the Linearity of the ROS.

Parameter	Value
ʎ max (nm)	241 nm
Slope ± SD	21694 ± 476.88
Intercept ± SD	522.4 ± 0.0028
Correlation Coefficient (r^2)	0.9993
Linear Range	0.125–2.0µg/mL
Limit of Detection (LOD)	0.071 µg/mL
Limit of Quantitation (LOQ)	0.215 µg/mL

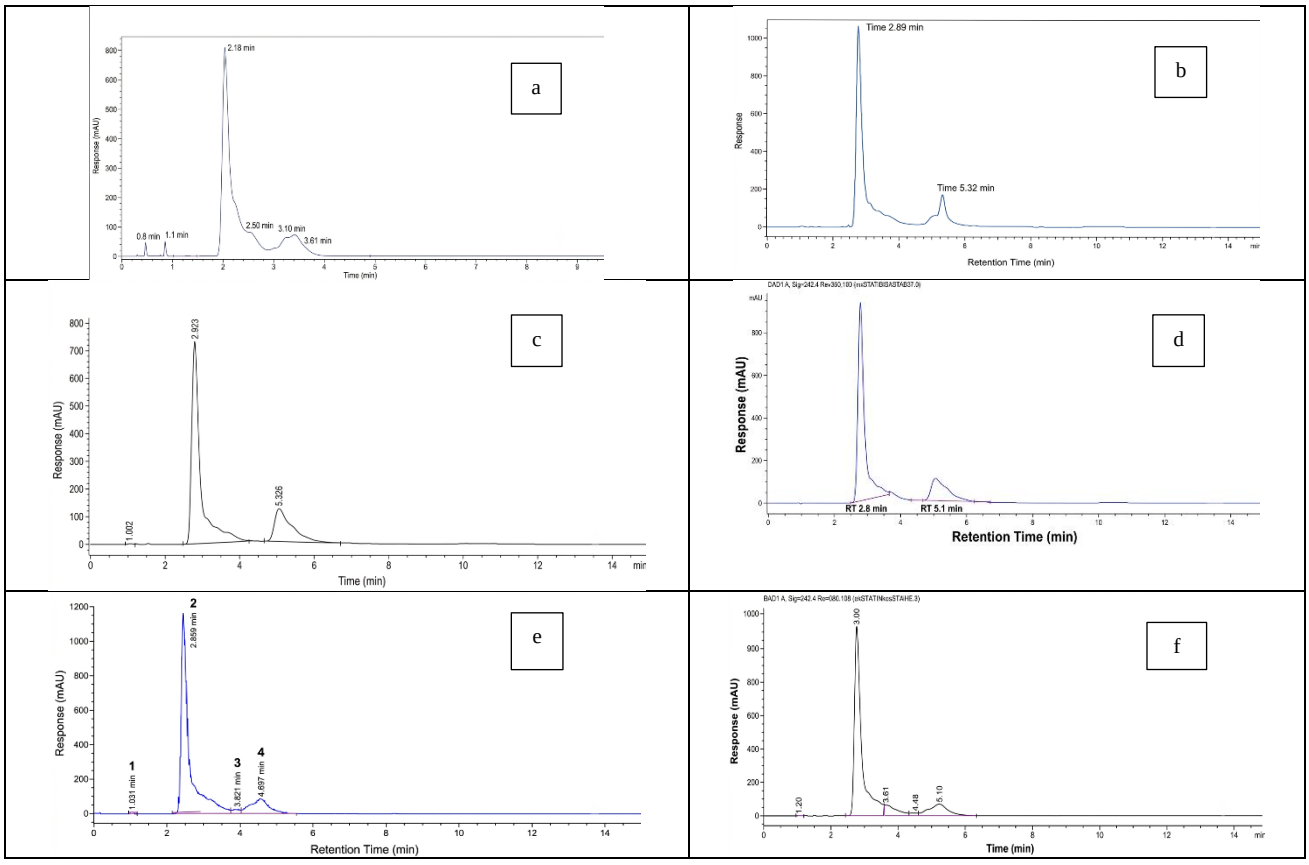

Fig. 1: The Chromatogram of the (a) Standard of ROS (b) TAB.1, (c) TAB.2, (d) TAB.3, (e) TAB.4,(f) TAB.5

Table 3: Assay Results of Five Commercial Brands of ROS Tablets Using RP-HPLC.

Samples	HPLC Assay (%) ± RSD
TAB.1	100.24 ± 1.52
TAB.2	92.01 ± 1.71
TAB.3	102.31 ± 0.455
TAB.4	101.52 ± 0.36
TAB.5	108.45 ± 1.43

3.2. Physicochemical Quality Evaluation

All tested brands complied with pharmacopeial specifications for weight variation, dimensions, friability, and disintegration time, indicating good manufacturing consistency. The low relative standard deviation (RSD < 2%) observed across all brands confirms uniformity of dosage units.

Notably, TAB.3 (unauthorized) and TAB.4 (authorized) exhibited significantly higher hardness values (20.22 and 18.3 kg/cm², respectively) compared to previously reported ranges in Saudi Arabia (8.15–8.85 kg/cm²) and Nigeria (11.30 kg/cm²). Despite this, both brands demonstrated rapid disintegration and acceptable dissolution profiles, except for TAB.2, where the dissolution percentage was below 80% but within the USP range. This suggests that the formulations were adequately optimized, likely through the use of efficient disintegrants and appropriate excipient composition, enabling effective tablet breakup and drug release despite high compression forces. These findings support the concept that hardness alone is not a definitive predictor of dissolution behavior in film-coated tablets. The results of the quality control tests are summarized in Table 4.

3.3. Dissolution Studies

All evaluated brands met pharmacopeial requirements by releasing more than 80% of the labeled drug content within 30 minutes, with acceptable variability. In accordance with FDA recommendations, dissolution testing was conducted at pH 6.6 because ROS are acid-instable at lower pH values [23].

Most brands (TAB.2–TAB.5) were classified as rapidly dissolving (>85% drug release within 30 min), consistent with findings from Saudi Arabia, where dissolution ranged from 95.57% to 97.54%. Similarly, studies from Nigeria reported that all brands released more than 80% of drug content within 20 minutes, indicating rapid and efficient dissolution. However, in Bangladesh, several brands failed to meet in vitro bioequivalence criteria (f_1/f_2), despite passing basic pharmacopeial tests, highlighting variability among generic products.

The in vitro dissolution profiles of the evaluated formulations reveal notable variations between the brands, independent of their official registration status.

A key finding is the performance of TAB.1, an unauthorized generic brand, which exhibited a mean dissolution of 75.99% at the 30-minute time point. This recovery rate is comparatively lower than the other four formulations (TAB.2–TAB.5), which all demonstrated rapid dissolution characteristics exceeding 85% drug release within the same timeframe. This reduced release may be attributed to formulation-related factors such as:

- Higher binder concentration or stronger granule cohesion
- Lower porosity of the tablet matrix
- Differences in disintegrant efficiency or distribution
- Possible variation in coating characteristics affecting medium penetration

Additionally, the moderate hardness value of TAB.1 (~9.82 kg/cm²) suggests that factors other than compression force, such as excipient composition and manufacturing process, play a more significant role in governing drug release behavior.

In stark contrast, TAB.3, which is also classified as an unauthorized generic brand in the local market, exhibited an excellent dissolution profile, releasing 99.35% of the active pharmaceutical ingredient within 30 minutes. Despite lacking official authorization and exhibiting a significantly high hardness value of 20.22 kg/cm², TAB.3 easily surpassed the standard pharmacopeial limits. This demonstrates that the formulation was highly optimized, likely utilizing highly efficient disintegrants that facilitated rapid tablet breakup despite strong compression forces.

Table 4: Summary of Physicochemical Attributes Across Brands

Code	Weight (g)	RSD %	Diameter (mm)	Thickness (mm)	Hardness (Kg/cm²)	Friability (%)	Disintegration Time
TAB.1	0.302 ± 0.00533	1.77%	9.23 ± 0.04	4.45 ± 0.04	9.82 ± 1.45	0.00	3 min 00 sec
TAB.2	0.3000± 0.0052	1.18%	9.15 ± 0.03	4.32 ± 0.15	7.88 ± 2.07	0.00	2 min 00 sec
TAB.3	0.310 ± 0.00247	0.80%	9.10 ± 0.00	4.39 ± 0.02	20.22 ± 0.95	0.00	1 min 53 sec
TAB.4	0.307 ± 0.00322	1.05%	9.10 ± 0.00	4.42 ± 0.21	18.30 ± 0.67	0.32	2 min 10 sec
TAB.5	0.157 ± 0.00324	2.06%	7.15 ± 0.01	4.30 ± 0.17	9.30 ± 1.34	0.00	1 min 55 sec

From a quality and regulatory standpoint, both TAB.1 and TAB.3 strictly conform to the standard pharmacopeial limits specified by the United States Pharmacopeia (USP), which mandates a minimum of 75% to 80% drug release (Q value) within 30 minutes. However, the contrasting behavior between these two unauthorized brands—where TAB.1 sits on the lower threshold of acceptance while TAB.3 achieves near-complete dissolution —highlights the lack of consistency in unauthorized channels. These findings underscore the critical role of continuous post-marketing surveillance to ensure that all available generic statins maintain optimal in vitro performance, thereby guaranteeing therapeutic efficacy for patients managing chronic cardiovascular risks in Yemen. The result is summarized in Table 5.

Table 5: Dissolution Results with Precision Parameters

Code	% Dissolution ± SD	% RSD
TAB.1	75.99± 0.0049	2.18
TAB.2	91.49 ± 0.00335	1.24
TAB.3	99.35± 0.00516	1.77
TAB.4	106.26±0.00364	1.17
TAB.5	89.70± 0.00495	1.86

Conclusion

The present study demonstrated that all evaluated ROS tablet brands in the Aden market complied with USP and BP pharmacopeial requirements for assay, physicochemical properties, and dissolution performance. Despite elevated hardness values in TAB. 3 (unauthorized) &TAB. 4 (authorized) brands, no adverse impact on disintegration or dissolution behavior was detected, confirming appropriate formulation design and manufacturing quality. All products achieved more than 80% drug release within 30 minutes, confirming acceptable *in vitro* performance, although minor variability was observed, particularly in TAB. 1 (unauthorized). This indicates that local registration status does not automatically serve as a definitive proxy for batch-specific pharmaceutical superiority in resource-limited markets. It strongly underscores the absolute necessity of routine, objective post-marketing surveillance laboratory studies over administrative oversight alone to safeguard public health and verify cardiovascular treatment consistency. Consequently, while these findings support the pharmaceutical equivalence and potential interchangeability of the tested brands, the observed variability highlights the necessity for ongoing post-marketing surveillance and stricter regulatory control. Future studies incorporating *in vivo* bioequivalence testing are recommended to further confirm therapeutic equivalence and ensure optimal patient outcomes.

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Conflict of Interest

The authors declare that there are no conflicts of interest.

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مقالة بحثية

تقييم جودة أقراص الروزوفاستاتين الجنيسة في مرحلة ما بعد التسويق في عدن - اليمن

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المُلخّص

إن التوافر المتزايد لأقراص الروزوفاستاتين (ROS) المكافئة يستلزم إجراء تقييم صارم للجودة في مرحلة ما بعد التسويق، لا سيما في المناطق التي تعاني من محدودية الرقابة التنظيمية، كما هو الحال في اليمن. هدفت هذه الدراسة إلى تقييم الجودة الصيدلانية والأداء المخبري (In vitro) لعدة شركات مختلفة من أقراص الروزوفاستاتين (بتركيز 20 مجم) المتوفرة تجارياً في سوق مدينة عدن. تم تقييم خمس اصناف من عقار الروزوفاستاتين باستخدام طريقة الكروماتوغرافيا السائلة عالية الأداء (HPLC) المعتمدة، بالإضافة إلى اختبارات مراقبة الجودة الدستورية وفقاً لإرشادات دستور الأدوية الأمريكي (USP) والبريطاني (BP). شملت المعايير التي تم قياسها: تباين الوزن، الصلابة، الهشاشة، وقت التفتت، والذوبان. وقد أُجري اختبار الذوبان عند درجة حموضة (pH 6.6) تماشياً مع توصيات هيئة الغذاء والدواء الأمريكية (FDA) نظراً لعدم استقرار الروزوفاستاتين في الوسط الحمضي. أظهرت طريقة الـ HPLC خطية ممتازة (R^2 = 0.9993)، حيث تراوحت قيم المقايسة (Assay) بين 92.01% و108.45%، وهي ضمن الحدود الدستورية المسموح بها. كما اجتازت جميع الأصناف المختبرة متطلبات تجانس الوزن، والهشاشة، والتفتت. وبالرغم من أن الصنفين (TAB.3) و (TAB.4) أظهرا قيم صلابة عالية (20.22 و 18.3 كجم/سم²)، إلا أن ذلك لم يؤثر سلباً على أدائهما. وأظهرت دراسات الذوبان أن جميع الأصناف أطلقت أكثر من 80% من المادة الدوائية خلال 30 دقيقة، بل وتجاوز معظمها نسبة 85%، مما يشير إلى ذوبان سريع. وسجل الصنف (TAB.1) ذوباناً أقل نسبياً مقارنة بالبقية، لكنه ظل ضمن الحدود المقبولة. أظهرت جميع أصناف الروزوفاستاتين التي شملها التقييم جودة صيدلانية وأداءً مخبرياً مقبولاً، مما يدعم إمكانية تبادلها واستخدامها كبدائل لبعضها البعض. ومع ذلك، فإن التفاوت في سلوك الذوبان بين بعض العلامات التجارية يسلط الضوء على أهمية الرقابة المستمرة لما بعد التسويق لضمان الفعالية العلاجية المتسقة في سوق الأدوية اليمني.

الكلمات المفتاحية: الجودة الصيدلانية؛ روزوفاستاتين؛ رقابة ما بعد التسويق؛ الكروماتوغرافيا السائلة.

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