Iraqi Journal of Pharmacy 22(4) (2025) 186-192

Online ISSN: 2664-2522

Print ISSN: 1680-2594

Iraqi Journal of Pharmacy

Journal homepage: https://iphr.uomosul.edu.iq/

Research Article:

A Comparative Study of Levofloxacin Tablet from Brand and Generic Companies Available in Iraq: A Pharmaceutical Evaluation

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Article Information

Article history:

Received on: 12 July 2025
Revised on: 05 September 2025
Accepted on: 11 September 2025
Published on: 01 December 2025

Keywords:

Levofloxacin, Physicochemical properties, Dissolution profile, Disintegration time, pH-dependent solubility

Abstract

Background and objectives : Since levofloxacin is a commonly used antibiotic, it is necessary to ensure therapeutic equivalency across different market formulations. The physicochemical properties of six brands of 500 mg Levofloxacin tablets were assessed in this study. These properties included weight uniformity, friability, hardness, disintegration time, dissolution profiles at various PH buffers, and similarity factor study. **Methods:** Pharmacopeial compliance was assessed for six Levofloxacin tablet brands (S1–S6). Weight variation, hardness, disintegration time, and friability were all assessed. Using USP equipment, dissolution profiles were assessed over a 30-minute period in phosphate buffer solutions with pH values of 4.5 and 6.8. **Results:** Weight uniformity analysis revealed mean tablet weights ranging from 498.61 mg (S6) to 527.45 mg (S2), with S1 demonstrating the lowest variability (SD = 1.75 mg) and S4 the highest (SD = 3.99 mg). Friability tests confirmed all formulations complied with pharmacopeial limits (≤1%), with values between 0.08% and 0.09%, indicating robust mechanical strength. Hardness measurements (6.46–8.10 kg/cm²) fell within acceptable ranges, though variability was higher for S1 (SD = 0.56) and S2 (SD = 0.83). Disintegration times (5.5–10 minutes) met regulatory standards (≤15 minutes), with S1 showing the fastest breakdown. Dissolution studies in pH 4.5 buffer revealed that all brands except S6 achieved ≥95% drug release within 30 minutes, with S1 exhibiting the fastest release (98.8%). In a pH 6.8 buffer, dissolution improved significantly, with S1 and S2 reaching near-complete release (>99%) by 30 minutes, while S6 lagged (94.9%). The pH-dependent solubility of levofloxacin was evident, with faster and more complete dissolution observed at pH 6.8. In vitro dissolution studies showed that only S2 met the similarity (f_2 > 50) criteria in relation to the reference product (S1) at pH 4.5 and 6.8. S5 showed similarity with S1 only at pH 4.5, while S3, S4 and S6 failed similarity at both pH, showing diverse release profiles with less predictable behavior. **Conclusion:** These results show that different brands have different levels of manufacturing quality, with some showing better consistency in terms of weight, hardness, and dissolution. Even though every formulation complied with pharmacopeial requirements, variations in performance, especially in dissolution, could affect bioavailability. The study emphasizes how crucial strict quality control is to guaranteeing therapeutic equivalency between brands, particularly for critical-dose antibiotics like levofloxacin.

1. Introduction

The pharmaceutical evaluation of tablet formulations-whether brand-name or generic represents a critical quality control measure to ensure therapeutic efficacy, patient safety, and regulatory compliance (1,2). This comprehensive assessment involves multiple standardized tests that examine both physical and chemical characteristics of solid dosage forms. Common pharmaceutical evaluation measures for these tablets, include uniformity of weight, hardness, friability, and disintegration time. Dissolution corroborates drug releases uniformly in vitro, reflecting bioavailability. Post-marketing investigation continues essential to screen action, particularly for locally manufactured generics, guaranteeing they supply equivalent therapeutic ending to their brand-name corresponding items (2–4).

For brand product manufacturers (e.g. Tavanic), perform rigorous in-process quality control protocols. These globally recognized brands usually validate outstanding batch-to-batch consistency in crucial parameters (5). Weight variation tests, hardness measurements, and friability results are frequently checked, demonstrating incomparable durability during handling and transport (6–8).

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How to cite:

Ibrahim, H., F., (2025). A Comparative Study of Levofloxacin Tablet from Brand and Generic Companies Available in Iraq: A Pharmaceutical Evaluation. Iraqi J. Pharm. 22(4), 186-192.

DOI: https://doi.org/10.33899/iraqij.p.2025.162710.1158

Generic manufacturers must maintain good quality measures comparable to the brand, perhaps slightly wider acceptable variations (9,10). Although compatible with regulatory desires, generic products occasionally show slightly broader weight variations, disintegration, and friability (11,12). These negligible alterations originated from using additives in preformulations or variations in processing steps allowable under regulatory guidelines (13,14).

Regulatory bodies worldwide, including Iraq's Ministry of Health, require generic manufacturers to validate pharmaceutical bioequivalence via comprehensive testing (15,16). While therapeutic bioequivalence is postulated for generics granted via legal pathways, some healthcare settings insist predilection for brand products in critical care situations due to their supported track record of consistency (17,18).

Levofloxacin is a broad-spectrum fluoroquinolone antibiotic used in Iraq for treating bacterial infections (19,20). This study compares the pharmaceutical quality of brand-name and generic levofloxacin tablets available in the Iraqi market, evaluating their compliance with international pharmacopeial standards. The tested products include Tavanic (Sanofi, France), Levoxime (World Medicine, UK), Uniflox (United Pharmaceuticals, Jordan), LevoxacineAwa (Awamedica, Iraq), Levosam (SDI, Iraq), and Levobran (Brawn, India). These tablets were purchased from the local market and tested for critical quality attributes such as weight uniformity, hardness, friability, disintegration time, and dissolution profile.

2. Materials and Methods

2.1. Formulation used

Levofloxacin tablets in the Iraqi market include both international brand-name products and locally manufactured generics or imported from a generic company. Brand-name product (Tavanic) is produced by a well-known company with high obedience to Good Manufacturing Practices, usually displaying excellent consistency in weight, hardness, and dissolution rate. Generic products (Levoxime, Uniflox, LevoxacineAwa, Levosam, and Levobran) must meet bioequivalent pharmacopeia standards but may demonstrate marginal dissimilarities due to excipient or manufacturing processing.

Table 1. Levofloxacin tablets from brand and generic companies available in Iraq

No.	Name	Manuf-acturer	Origin	Batch no.	Exp.
s1	Tavanic	Sanofi	France	2ma9e	2026/03/01
s2	Levoxime	World medicine	UK	10200252	2026/01/01
s3	Uniflox	United pharmacy-euticals	Jordan	093c	2027/03/01
s4	Levoxacine -Awa	Awamedica	Iraq	BL2019	2026/01/01
s5	Levosam	SDI	Iraq	1	2026/01/01
s6	Levobran	brawn	India	BNT1121003	2025/10/01

2.2. Tablet weight variation test

The uniformity of weight test started using 20 tablets. Each tablet's weight is recorded. The mean weight of the tablets is then calculated. No more than two tablets may deviate from the average weight by more than ±5% for uncoated tablets weighing ≥500 mg.

2.3. Tablet hardness test

The tablet YD-1 hardness tester (Lpmie) is used to do a hardness test. The hardness test was conducted for 10 tablets with each tablet loaded between the edges of the hardness tester at center. The machine is then pressed, applying compressive force until the tablet fractures. The force recorded to break the tablet in kilograms per square centimeter (kg/cm²) is reflective of hardness. The typical forces for tablet break should fall between 4–10 kg/cm² for conventional tablets.

2.4. Tablet friability test

The friability test is used to measure the resistance of tablets to chipping, abrasion, or breakage when exposed to mechanical stress during handling and transportation. The procedure starts using 20 pre-weighed intact tablets. The tablets are then loaded into the drum of a friability tester (Roche friabilator), which rotates at a speed of 25 rpm for 4 minutes. Once the rotation is complete, the tablets are removed, and any particles are brushed off. The tablets were weighed again, and the weight loss is calculated using the following formula. The test is acceptable if the weight loss does not exceed 1%.

$$\textbf{Friability}\ (\%) = \frac{\textbf{Initial weight} - \textbf{Final weight}}{\textbf{Initial weight}} \times \mathbf{100}$$

2.5. Tablet disintegration test

The disintegration test is used to determine the time it takes for a tablet to break down into granules under certain conditions, confirm its ability to release the active ingredient for absorption. The test was conducted using a disintegration apparatus (BJ-2), typically made up of six

cylindrical glass tubes with mesh bottoms, immersed in a water bath maintained at 37±2°C and 0.1N HCl. Each tablet was placed in one glass tube, and the glass tube was lowered into the bath and started moving up and down (at a speed 28–32 cycles per minute). The test was continued until all tablets disintegrated completely, with no residue remaining on the mesh. The disintegration times for the six tablets were recorded, and the test was repeated for six tablets to ensure consistency. The tablets must disintegrate within 15–30 minutes.

2.6. Tablet dissolution test

Six tablets from each brand were chosen at random to conduct the dissolution test using type 2 paddle apparatus (OLABO\BK-RC6, USA), and each tablet was placed in one of the six vessels of a U.S. type 2 paddle apparatus. The test's dissolving medium was 900 ml of phosphate buffer solution (PH 4.5 and PH 6.8). To prepare this buffer, 27.218 g of potassium dihydrogen phosphate was dissolved in 800 ml of distilled water to create the first dissolution medium, which had a pH of 4.5. The mixture was then diluted with distilled water to 1000 ml (0.2M). While, for pH of 6.8, a 7.956g of potassium phosphate dibasic and 7.393 g of potassium phosphate monobasic were dissolved in 800 ml of distilled water to create the second dissolution medium, which had a pH of 6.8. Distilled water was then added to bring the volume to 1L. A sensitive pH meter was used to check both phosphate buffer solutions.

The dissolution apparatus was configured with a temperature of 37 ± 0.5°C and a paddle rotation speed of 50 RPM. At 5, 10, 15, 20, 25, and 30 minute intervals after the test began, 5 mL samples were taken out and replaced with new dissolving media. A 0.45 µm membrane filter was used to filter the extracted samples. A UV-visible Electronic Spectrophotometer (Thermo FisherScientific), was used to analyze the filtrated levofloxacin solution after dilution at levofloxacin λmax. At the two pH values, the percentage of levofloxacin dissolution was computed. Within 30 minutes, at least 80% of the labeled amount must be released for it to be accepted.

2.6.1 Determination of levofloxacin lambda max and calibration curve:

A 1000 µg/mL levofloxacin stock solution was prepared in order to calculate the drug's λmax. A UV-visible spectrophotometer was then used to scan between 200 and 400 nm after 10 mL of the stock solution had been diluted with buffer to 100 mL. Serial dilutions were made from the stock solution (10, 20, 40, 60, 80, and 100 µg/mL) and examined at levofloxacin λ_{max} (295 nm) in order to create the calibration curve for the two pH. At pH 4.5,the R^2 value is 0.9995, and the correlation equation was y=0.067x+0.015. the R^2 value at pH 6.8 is 0.9991 ,and the correlation equation was y=0.035X+0.008.

2.7. Similarity factor study

The similarity factor (f_2) is calculated for the samples, to compare two dissolution profiles (e.g., test versus reference product) using the following equation.

$$f_2 = 50 * \log\left\{\left[1 + \frac{1}{n}\sum_{t=1}^{n}(Rt - Tt)^2\right]^{-0.5} * 100\right\}$$

*Where: n = number of time points, Rt = percent drug dissolved from the **reference** at time t, Tt = percent drug dissolved from the **test** at time t.*

If $f_2 \geq 50$, the two profiles are considered similar (less than 10% difference on average), but If $f_2 < 50$, the profiles are not similar.

2.8. Statistical analysis

The data were expressed as mean and standard deviation. A GraphPad Software (Prism 11.5, USA) used to complete this step. One-way analysis of variance (ANOVA), followed by Turkey multiple comparison tests, was used to identify the statistically different group. When the P value ≤ 0.05, the difference is considered significant. Because weight of each tablet fall within normal acceptable values, the weight variation were based on mean and standard deviation instead of using the standard quality control criteria for weight variations.

3. Results

3.1. Weight variation results

The physicochemical properties of levofloxacin (500mg) tablets purchased from local market from six manufacturers were estimated, including uniformity of weight, friability, hardness, and disintegration time. The mean weights of the tablets ranged from 498.61±3.07 mg (s6) to 527.45±3.06 mg (s2). The standard deviation values, which indicate the variability in tablet weights, varied from 1.75 mg (s1) to 3.99 mg (s4). Notably, s1 showed the minimal variability, proposing the greatest reliable tablet weight, while s4 demonstrated the greatest variability. These results highlight differences in the weight uniformity between manufacturers, with s1 and s3 exhibiting relatively tighter control (lower standard deviations) compared to s4 and s6, which exhibited the highest variability (**Figure 1A**).

3.2. Friability results

The levofloxacin tablets from six manufacturers were subjected to a friability test to evaluate their resistance to abrasion and breakage, with all formulations complied with the pharmacopeial limit of ≤1% friability. The mean friability values ranged from 0.08% to 0.09%; the variability between manufacturers is negligible. Notably, s4, s5, and s6 have shown the least variability (SD = 0.002), suggesting high consistency in friability testing (**Figure 1B**).

3.3. Hardness results

The levofloxacin tablets from six manufacturers were subjected to hardness to assess their mechanical strength and resistance to chipping or breaking. The mean hardness values ranged from the softest 6.46 kg/cm² (s1) to the hardest 8.10 kg/cm² (s6), all formulations fell within the typical acceptable range for tablet hardness (usually 4–10 kg/cm²). The standard deviation values, reflecting variability in hardness, were lowest for s3, s4, s5, and s6, indicating consistent tablet hardness in these manufacturers. In contrast, s1 (0.56) and s2 (0.83) demonstrated greater variability (**Figure 1C**).

3.4. Disintegration results

The disintegration time of levofloxacin tablet products (s1 to s6) was estimated to assess their breakdown into particles in aqueous conditions, a critical factor for drug dissolution. The disintegration times (ranged 5.5 minutes to 10 minutes), with s1 being the fastest disintegration and s6 the slowest, whereas the remaining products (s3 to s6) expressed the lowest variability, suggesting more consistent disintegration, highlight their reliability in meeting quality standards (**Figure 1D**).

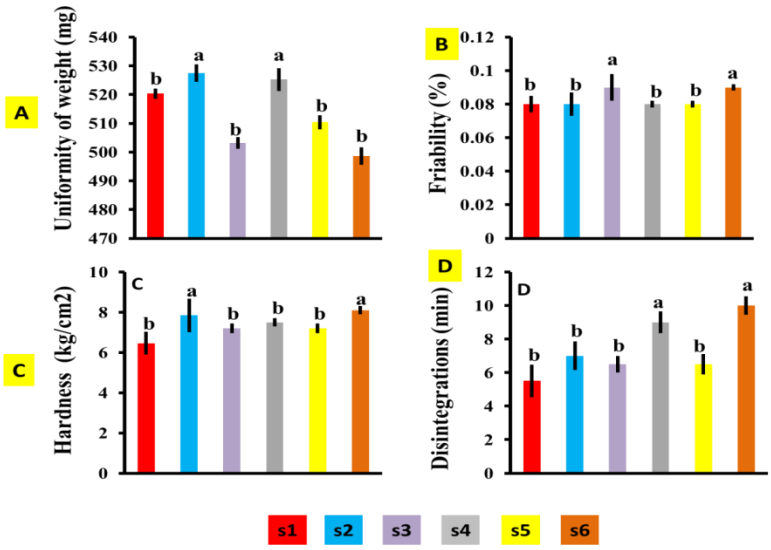

Figure 1. Physical characterization of tablets of the six manufacturers testing weight (A), friability (B), hardness (C), and disintegration (D). The histogram bar represents mean and standard deviation, similar letters indicate non-significant difference, different letters indicate significant differences at p value less than 0.05 using One way ANOVA with post-hoc Tukey.

3.5. Dissolution results

The dissolution at pH 4.5 demonstrated that all formulations eventually delivered high drug release percentage (over 87%) within the acceptable time (30-minutes), however, the rate of dissolution varies (**Figure 2**).
Initial release: fastest s1 constantly showed the most rapid drug release in the initial and middle stages of the test.
Initial release: Slowest s3 and s4 were the slowest in the initial stages of the test, though later accelerated. Uniform release: s5 and S6 demonstrated a steady release across the time.

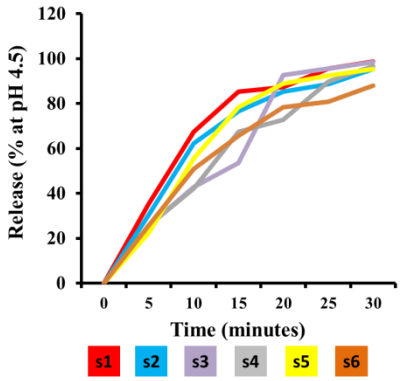

Figure 2. Cumulative percentage of release of the six manufacturers at pH 4.5.

The dissolution test at pH 6.8 revealed distinctive values in the rate of release between the six manufacturers at pH 4.5, with all formulations achieved high release rate (>94% at 30min), however, their initial release varies widely (**Figure 3**).

Fast releasing: s2 and **s1** were quickly dissolved formulations, with the majority of the drug released within the first 5-10 minutes. **Delayed release: s5** and **s6** show a pronounced delayed release profile. **Lag profiles: s3** and **s4** demonstrated a lag phase accompanied by fast release rate.

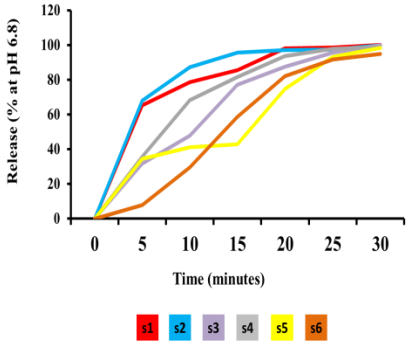

Figure 3. Cumulative percentage of release of the six manufacturers at pH 6.8.

3.6. Similarity factors results

By employing the similarity factor (f_2), dissolution profiles at two media (pH 4.5 and pH 6.8) were analyzed. Dissolution profiles are considered comparable based on regulatory standards when the f_2 value falls between 50 and 100. S2 (f_2 = 62.10) and S5 (f_2 = 54.83) showed similarity to the reference product (S1), while S3, S4, and S6 showed lack of similarity with f_2 values of 38.37, 41.53, and 42.65, respectively, at pH 4.5. While at pH 6.8 S3, S4, S5, and S6 produced f_2 values of (35.54, 44.17, 27.48, and 23.68, respectively), below the acceptance threshold(<50), only S2 (f_2 = 62.39) satisfied the similarity requirement with the reference S1. These results suggest greater robustness under changing physiological conditions, as only S2 among the tested formulations retained dissolution similarity with the reference product across both pH conditions (**Table 2**).

Table 2. Similarity factors of the formulations used.

Similarity factor	Sample	F_2 value	Interpretation
pH 4.5	S2	**62.1**	Similar (≥50)
	S3	38.37	Not similar
	S4	41.53	Not similar
	S5	**54.83**	Similar (≥50)
	S6	42.65	Not similar
	S2 and S5 show similarity with the reference profile (s1).		
pH 6.8	**Sample**	**F_2 value**	**Interpretation**
	S2	**62.39**	Similar (≥50)
	S3	35.54	Not similar
	S4	44.17	Not similar
	S5	27.48	Not similar
	S6	23.68	Not similar
	Only S2 is similar to the reference profile (s1).		

4. Discussion

The Result indicated variation in physicochemical properties and release parameters between brand and generic products; these differences could potentially affect the action perhaps due to variation between the manufacturing processes and in process quality control steps, resulting in inconsistency between brand-name and generic products, reflecting fundamental disparities in production capabilities and quality assurance systems. Acoording to pharmacopeial standards, the results of the brand and generic products are within the accepted limits for all tests in this research.

The weight variability is well accepted with brand manufacturers (Sanofi, Tavanic^{R}), perhaps because brand companies have established precise and advanced manufacturing technologies, such as high-precision filling systems, optimized granule formulations ensuring excellent flow properties, and integrated into tablet compression machines, ensuring remarkable consistency. The generic companies might lack equivalent technological infrastructure and less well maintained and sophisticated equipment, resulting in weight variabilities. In addition, properly maintained environmental control (temperature, humidity, and lighting) in the production environment will ultimately affect the powder flow properties and machine compressibility. These environmental parameters might well be restricted in brand versus generic (21–23).

Alongside variation in weight, these differences in manufacturing process will definitely lead to variation in hardness and friability. In addition, hardness also affected by the type of excipients used, especially the selected binders (povidone or hydroxypropyl methylcellulose) and lubricants (magnesium stearate) in controlled ratios, which is highly controlled in brand manufacturers. In contrast, generic companies might express either lower hardness values (potentially risking friability) or excessive hardness (possibly delaying disintegration), often due to excipient substitutions aimed at cost reduction or regional availability constraints (24).

Branded products like Tavanic (Sanofi) revealed more consistent and complete dissolution across pH due to their optimized formulations incorporating selected pH-modifiers that maintain drug solubility across the gastrointestinal pH gradient. When comparing the dissolution profiles of the brand-name levofloxacin tablets (S1) and their generic analogs (S2–S6), it was observed that only S2 achieved similarity (f_2 > 50) under both pH 4.5 and pH 6.8 circumstances. This suggests that S2 may be bioequivalent because it shows a dissolution profile similar to the reference in both intestinal and gastric environments. S5 only displayed similarity at pH 4.5, indicating inconsistent release behavior, whereas S3, S4, and S6 did not meet similarity criteria at either pH value. From a clinical perspective, the robustness of S2 across physiological pH ranges implies predictable absorption and therapeutic efficacy, consistent with the brand product. Generic formulations lacking dissolution similarity may provide

variable plasma levels, potentially reducing antibacterial effectiveness or contributing to resistance. Therefore, S2 appears to be the most reliable generic alternative to the brand-name levofloxacin tablet in terms of dissolution performance and likelihood of therapeutic equivalence (25). This variation is related to variation in excipient, manufacturing process, and buffering agents vary between formulations that influence the drug's ionization state and solubility at critical pH points (26).

The pH 4.5 buffer showed inter-product variability as it approaches levofloxacin's isoelectric point, where slight differences have amplified effects on solubility. At pH 6.8, closer to the drug's optimal solubility range revealed consistency. These dissolution variations, while potentially minor *in vitro*, could translate to variable absorption rates *in vivo*, principally for patients with altered GIT physiology (27).

5. Conclusion

This study of the analysis of six levofloxacin 500 mg tablet brands revealed that while all products met the standards, modulating bioavailability and clinical response. The study revealed marked variation in manufacturing consistency. The S1 formulation revealed superior overall quality test results, indicated by the low weight variation, rapid disintegration, and ideal dissolution rate across both pH conditions. Of the levofloxacin generics characterized, only S2 showed dissolution similarity (f_2) to the brand product (S1) at pH 4.5 and pH 6.8; this is indicative of similar performance throughout the physiological ranges. The results indicate that S2 can be regarded as the best generic drug candidate for bioequivalence.

6. Acknowledgment

The researcher would like to express their special thanks to the pharmaceutics department at Pharmacy College/Mosul University for nourishing this work with supplies and facilities that enable the completion of this research.

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دراسة مقارنة لأقراص ليفوفلوكساسين من الشركات ذات العلامة التجارية والأدوية الجنيسة المتوفرة في العراق: تقييم صيدلاني

الخلفية والأهداف: بما أن الليفوفلوكساسين مضاد حيوي شائع الاستخدام، فمن الضروري ضمان التكافؤ العلاجي بين تركيبات السوق المختلفة. في هذه الدراسة، تم تقييم الخصائص الفيزيائية والكيميائية لستة أنواع من أقراص الليفوفلوكساسين بتركيز 500 ملغ. وشملت هذه الخصائص تجانس الوزن، والهشاشة، والصلابة، وزمن التفكك، وأنماط الذوبان في محاليل تنظيمية مختلفة ذات درجة حموضة (PH)، ودراسة عامل التشابه. **الطريقة:** تم تقييم الامتثال لدستور الأدوية لستة أنواع من أقراص الليفوفلوكساسين (S1-S6). تم تقييم تباين الوزن، والصلابة، وزمن التفكك، والهشاشة. باستخدام معدات USP، تم تقييم أنماط الذوبان على مدار 30 دقيقة في محاليل تنظيمية فوسفاتية ذات درجة حموضة (pH) تتراوح بين 4.5 و6.8. **النتائج:** كشف تحليل تجانس الوزن عن متوسط أوزان أقراص يتراوح بين 498.61 ملغ (S6) و527.45 ملغ (S2)، حيث أظهر S1 أقل تباين (الانحراف المعياري = 1.75 ملغ) وS4 أعلى تباين (الانحراف المعياري = 3.99 ملغ). أكدت اختبارات قابلية التفتت امتثال جميع التركيبات للحدود الدستورية (≥1%)، بقيم تتراوح بين 0.08% و0.09%، مما يدل على متانة ميكانيكية عالية. جاءت قياسات الصلابة (8.10-6.46 كجم/سم²) ضمن النطاقات المقبولة، مع أن التباين كان أعلى في S1 (الانحراف المعياري = 0.56) وS2 (الانحراف المعياري = 0.83). استوفت أوقات التفكك (10-5.5 دقائق) المعايير التنظيمية (≤15 دقيقة)، حيث أظهر S1 أسرع تفكك. أظهرت دراسات الذوبان في محلول منظم بدرجة حموضة 4.5 أن جميع العلامات التجارية باستثناء S6 حققت ≤ 95% من إطلاق الدواء في غضون 30 دقيقة، حيث أظهر S1 أسرع إطلاق (98.8%). في محلول منظم بدرجة حموضة 6.8، تحسن الذوبان بشكل ملحوظ، حيث وصل S1 وS2 إلى إطلاق شبه كامل (>99%) في 30 دقيقة، بينما تأخر S6 (94.9%). كانت قابلية الذوبان المعتمدة على درجة الحموضة لليفوفلوكساسين واضحة، مع ملاحظة ذوبان أسرع وأكثر اكتمالاً عند درجة حموضة 6.8. أظهرت دراسات الذوبان في المختبر أن S2 فقط استوفى معايير التشابه (f_2 > 50) فيما يتعلق بالمنتج المرجعي (S1) عند درجة حموضة 4.5 و6.8. أظهر S5 تشابهًا مع S1 فقط عند درجة حموضة 4.5، بينما فشلت S3 وS4 وS6 في التشابه عند كلا الرقمين الهيدروجينيين، مما أظهر أنماط إطلاق متنوعة مع سلوك أقل قابلية للتنبؤ. **الخلاصة:** تُظهر هذه النتائج اختلافًا في جودة التصنيع بين العلامات التجارية المختلفة، حيث يُظهر بعضها اتساقًا أفضل من حيث الوزن والصلابة والذوبان. ورغم استيفاء جميع التركيبات لمتطلبات دستور الأدوية، إلا أن اختلافات الأداء، وخاصةً في الذوبان، قد تؤثر على التوافر البيولوجي. وتُؤكد الدراسة على أهمية رقابة الجودة الصارمة لضمان التكافؤ العلاجي بين العلامات التجارية، وخاصةً للمضادات الحيوية ذات الجرعات الحرجة مثل الليفوفلوكساسين.

الكلمات المفتاحية: ليفوفلوكساسين، الخواص الفيزيائية والكيميائية، نمط الذوبان، زمن التفكك، الذوبان المعتمد على الرقم الهيدروجيني.