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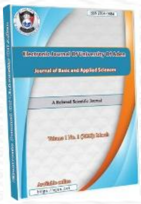

RESEARCH ARTICLE

IMPACT OF STORAGE CONDITIONS ON THE PHYSIOCHEMICAL STABILITY OF IN USE MOXIFLOXACIN EYE DROPS SOLUTION IN ADEN CITY

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Abstract

Moxifloxacin hydrochloride (MOX) ophthalmic solution is a critical fourth-generation fluoroquinolone. Moxifloxacin hydrochloride is a synthetic, fourth-generation fluoroquinolone that has become a widely used standard in ophthalmology for treating bacterial conjunctivitis and other ocular infections. The reality is, many patients continue to use these costly drops long after the recommended discard date. The study focused on assessing the physicochemical stability as pH, osmolality, refractive index, and color of three common MOX solutions, the original brand (Vigamox®) and two generic versions (Indian and Pakistani) over a 60-days simulated in-use period under three storage scenarios common in Aden, Yemen, to determine their suitability for continued use and to inform local patient safety guidelines. Three simulated common storage realities: Condition I (ideal, 21.0±1.8 ^{0}C): Continuous A/C; Condition II (Common, 29.4±2.9 ^{0}C): Intermittent A/C with power outages often exceeding 16 hours daily; and Condition III (Harsh, 33.4±2.3 ^{0}C): Non A/C storage, using only a ceiling fan. Samples were checked at baseline, one, two weeks, one month and two months. the simulated patient use done by opening and closing the bottles three times daily for the initial ten days. The results revealed the Stability was largely maintained under Condition I and Condition II (though the Pakistani generic's pH dipped slightly by day 60 in Condition II). However, under the high-stress Condition III: After two months, both generics showed clear signs of accelerated degradation. Their pH levels dropped below the USP acceptability threshold (<6.8), risking increased ocular irritation and reduced preservative efficacy. they became visibly darker, and, notably, the Pakistani generic's osmolality went marginally hypertonic (>320 mOsmol/kg), with the Refractive Index (RI) showing an unacceptable increase (>1.333), indicating significant solvent loss or solute buildup. Storing MOX ophthalmic solutions, especially the generics, under high temperature conditions a reality in hot climates seriously compromises their physicochemical integrity.

Keywords: Moxifloxacin hydrochloride; Physicochemical stability; In-use stability; Storage conditions.

1. Introduction

Bacteria are pervasive, and their vast diversity constantly requires us to find and use effective antimicrobial agents [1]. Moxifloxacin hydrochloride is a synthetic, fourth-generation fluoroquinolone that has become a widely used standard in ophthalmology for treating bacterial conjunctivitis and other ocular infections [2]. Its dual action against DNA gyrase and topoisomerase IV makes it particularly favored for its broad-spectrum coverage, even managing pathogens that are resistant to older quinolones [3].

MOX is distinguished by specific structural modifications that optimize both its pharmacological performance and physicochemical stability. The core pharmacophore, consisting of the C-3 carboxyl (-COOH) and C-4 keto (=O) groups, is essential for binding to bacterial DNA-gyrase and topoisomerase IV via a magnesium-ion bridge; however, the C-3 position is particularly sensitive to thermal stress, where decarboxylation can occur, leading to a complete loss of antimicrobial activity and a measurable shift in the formulation's pH (figure 1) . Potency is further enhanced by the C-6 fluorine substituent, which increases affinity for target enzymes and facilitates superior cell membrane penetration. A defining feature of this fourth-generation fluoroquinolone is the C-8 methoxy (-OCH_3) group, which broadens the spectrum of activity against anaerobes and Gram-positive pathogens. Additionally, the bulky C-7 diazabicyclononyl side chain increases the molecule's lipophilicity a critical factor for effective corneal penetration in ophthalmic applications while its steric hindrance prevents recognition by bacterial efflux pumps, thereby overcoming common resistance mechanisms. These features, complemented by the N-1 cyclopropyl ring, ensure the broad spectrum efficacy and robust clinical profile characteristic of MOX [4].

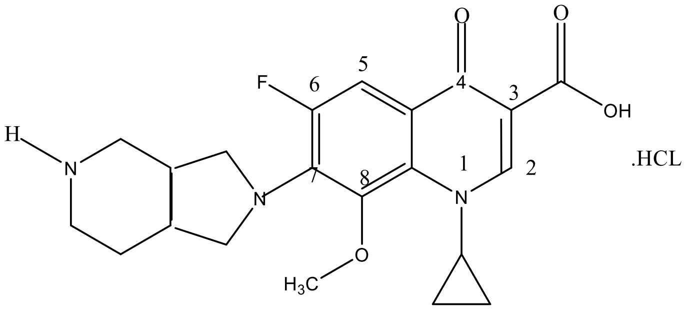

Fig. 1: Chemical Structure of MOX HCl

The stability of the drug formulation, particularly the in use stability for multi dose ophthalmic products, is a critical factor for achieving patient safety and ensuring successful treatment. This necessity demands the maintenance of specific physicochemical properties like pH, osmolality, and sterility to guarantee drug potency, maximum absorption, and, crucially, patient comfort by preventing irritation [5].

Given the clinical importance of preserving stability, especially in hot climates, the recommended in-use period is typically kept very short (e.g., 28 days) after opening to limit the risk of both microbial contamination and chemical breakdown . Degradation can lead to a shift in pH and osmolality, resulting in ocular irritation, stinging, and poor patient compliance [6]. More critically, chemical breakdown can lower drug potency and potentially create toxic degradation byproducts, thus compromising the drug's antimicrobial efficacy and patient safety [7].

The study specifically addresses to the stability of the physicochemical integrity of these products to determine if they remain clinically safe and effective under the demanding storage realities of Aden.

Unfortunately, in resource limited settings, patients often overlook this advice for two main reasons. First, a single course of treatment rarely requires the full volume of eye drops. Second, and perhaps more importantly, the high cost of the medication often compels patients to try and save and reuse the remainder.

Aden city presents an inherently challenging environment. It is characterized by high ambient temperatures and elevated humidity, which is significantly worsened by frequent and prolonged electricity outages often exceeding 16 hours a day. These factors create extremely harsh storage conditions that can drastically accelerate chemical degradation and solvent evaporation, potentially compromising product stability far sooner than expected.

The study, therefore, aimed to investigate the physicochemical stability as pH, osmolality, refractive index, and color of the original brand and two generic MOX solutions over a two month post opening period. Three specifically simulated storage conditions used that are highly representative of the actual local climate in Aden. The other aim also findings will provide much needed, evidence based recommendations for both drug storage protocols and patient education in hot, unpredictable environments.

2. Methodology

2.1. Samples and Storage Conditions

Three commercially available ophthalmic MOX solutions selected based on a survey of what doctors were prescribing and what was being dispensed most frequently in Aden’s pharmacies and eye clinics:

1. Original Brand (Vigamox®): Used as the reference standard Batch No. VH394A.
2. Generic N (Indian Product): Very popular and cost-effective Batch No. 25DA29.
3. Generic T (Pakistani Product): Moderately priced Batch No. (10) OP193.

All samples were purchased pre-packaged from local pharmacies and stored outside their original paper cartons to accurately reflect local storage practices

Condition I (Ideal): Continuous A/C in the room. Mean Temperature (Mean±SD) 21.0±1.8 ^{0}C Mean RH (Mean±SD) 43.5±5.5% .

Condition II : A/C room with planned power cuts (>16 h/day). Mean Temperature 29.4±2.9 ^{0}C Mean RH 56.0±4.0%

Condition III : Non-A/C room, only a ceiling fan, frequent power cuts. Mean Temperature 33.4±2.3 ^{0}C Mean RH 69.5±5.5%

2.2. Simulating Use and Testing Schedule

To replicate real world patient use and assess in use stability, a simulation of the prescribed dosage regimen was conducted for the initial 10 days of the study. Each bottle was opened and one drop was dispensed (discarded) three times daily (morning, afternoon, evening) for the first 10 days. The bottles were not refilled after dispensing; this process allowed us to test the impact of daily oxygen exposure, volume reduction, and potential air ingress, accurately reflecting natural use. The 10-day duration was chosen as it represents the typical maximum period for which a course of MOX is prescribed locally. Physical properties were then tested at five time points: time zero (T_0), 1 week, 2 weeks, 1 month (T_{30}), and 2 months (T_{60}).

2.3. Physicochemical Analysis

For all physicochemical measurements, each sample was analyzed in triplicate (n=3) at each time point, and the results are reported as the mean ± standard deviation (Mean±SD).

pH: Measured using a calibrated digital pH meter (pH 2006 meter [J.P.SELECTA,s.a.u] Serial No.4120600). Calibration was performed daily using certified pH 4.0, 7.0, and 10.0 buffers.

Sampling: Four separate bottles of each formulation were consumed per storage condition at each time point, totaling 60 bottles per product for pH measurement across all conditions and time points.

Osmolality: Measured with an osmometer (ADVANCED UNSTRUMENT.*INC*.[Model 3D3]).

Sampling: One entire bottle of each formulation was consumed per storage condition at each time point (5 time =15 bottles per product) [8].

Refractive Index (RI): Measured using a refractometer (ABBE Refractometer [Optic Ivymen] Serial No.820320100178) at 25 ^{0}C.

Sampling: One bottle of each formulation was used across all time points for each storage condition to monitor gradual change, as the measurement is non-destructive [9].

Color: Assessed via visual inspection against both white and black backgrounds to look for any signs of discoloration or darkening.

Assay (Drug Concentration): After the 60 days in Condition III, the remaining MOX concentration was measured using a UV-Spectrophotometer at λ max=293 nm and calculated by comparison to a previously established Calibration Curve based on a MOX reference standard.

2.4. Statistical Analysis

All quantitative data are presented as Mean±Standard Deviation (SD). Statistical analysis was performed using One-Way Analysis of Variance (ANOVA) to test for significant differences between the three storage conditions at each time point (from time zero – after two months). The Tukey's Post Hoc test was applied for multiple comparisons. A p-value<0.05 was considered statistically significant. We also calculated Effect Sizes (e.g., Cohen's d) for critical parameters to better interpret the magnitude of observed differences, and 95% Confidence Intervals (CI) are reported alongside mean values.

3. Results and Discussion

All formulations started well, with initial (time zero) pH values ranging between 7.08 and 7.10, safely within the limits set by the United States Pharmacopeia (USP).

According to the results in (table 1 and figure 2 a-c) throughout the 60 days study, we observed a gradual but consistent drop in pH across all samples. This decline was noticeably faster and more severe under the elevated temperature conditions

Table 1: pH changes of different brands at different conditions

Sample	Storage Condition	pH		ΔpH	p-value (T0 vs T60)	USP Limit (6.8–7.4)
		time zero (Mean±SD)	after two months (Mean±SD)			
Vigamox	I	7.10±0.02	6.97±0.03	−0.13	0.001†	Within
Vigamox	II	7.10±0.02	6.91±0.03	−0.19	0.012†	Within
Vigamox	III	7.10±0.02	6.84±0.03	−0.26	<0.001†	Within
Generic N	I	7.08±0.03	6.94±0.04	−0.14	0.009†	Within
Generic N	II	7.08±0.03	6.85±0.04	−0.23	<0.001†	Within
Generic N	III	7.08±0.03	6.79±0.04	−0.29	<0.001†	Below Limit
Generic T	I	7.09±0.01	6.89±0.03	−0.20	0.002†	Within
Generic T	II	7.09±0.01	6.81±0.03	−0.28	<0.001†	Within
Generic T	III	7.09±0.01	6.74±0.03	−0.35	<0.001†	Below Limit

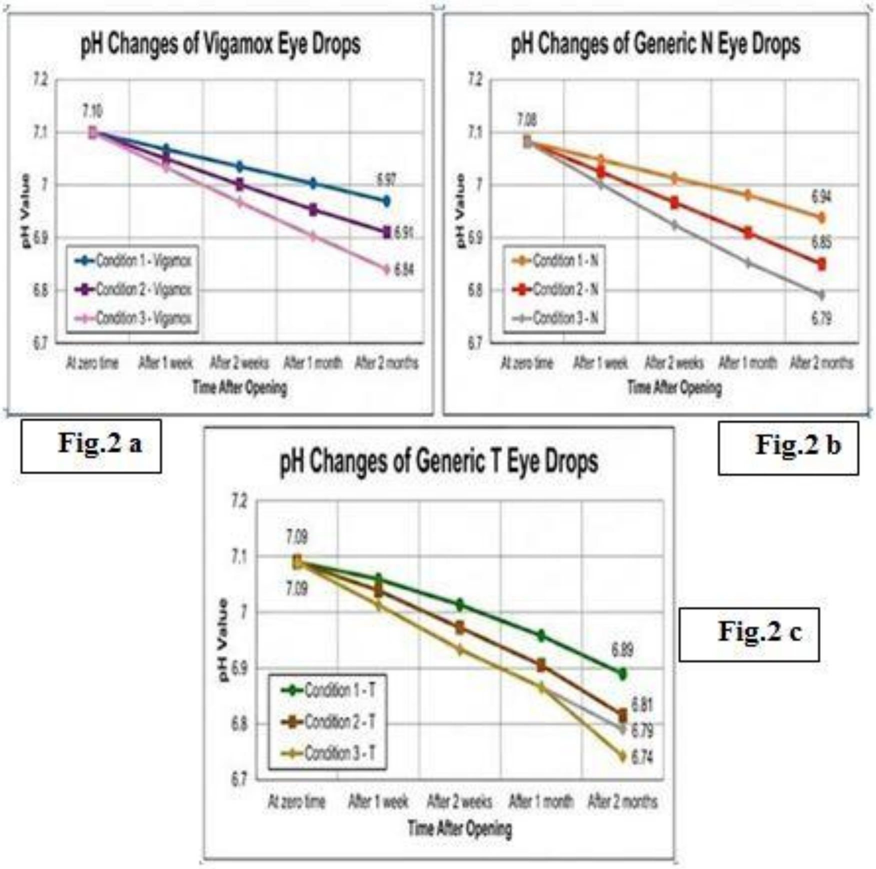

Fig.2 a

Fig.2 b

Fig.2 c

Fig. 2: pH Changes of MOX at Different Storage Conditions

This downward drift in pH suggests either the buffering system is failing or acidic degradation products are forming, likely from accelerated hydrolysis or oxidation at high temperatures [10]. Critically, the Pakistani and Indian generics failed the USP specification under the harshest Condition III, indicating a major breakdown in the formulation’s integrity. The fact that the Original Brand (Vigamox) remained stable points towards a better or more robust buffering system. The important note that a lower pH could potentially lead to increased ocular irritation, stinging, and discomfort upon instillation and might compromise the preservative system's effectiveness [11]. Furthermore, pH stability is crucial for the optimal function of the preservative (often benzalkonium chloride), and a significant shift may compromise the formulation's anti-microbial protection, especially in a multi-dose product. The failure of the generics to meet the pH specification (pH<6.8) under Condition III places them outside the regulatory acceptance criteria for ophthalmic safety, a finding with direct clinical relevance.

Osmolality as in the table (2) remained largely stable for all products in Condition I and Condition II, confirming they maintained isotonicity within the desired 290–320 mOsmol/kg range.

Table 2: the osmolality changes

Sample	Storage Condition	Osmolality at time zero	Osmolality after two months	Ideal Range (290–320)
Vigamox	III	~305	~312	Within
Generic N	III	~302	~318	Within
Generic T	III	307	**324**	**Marginally Hypertonic**

The slight increase in the Pakistani generic’s osmolality (324 mOsmol/kg) under Condition III represents a significant clinical concern, indicating a shift toward a hypertonic state. This phenomenon is likely attributable to solvent evaporation or the accumulation of degradation products that increase solute concentration. While the deviation appears subtle, hypertonic ophthalmic solutions can induce patient discomfort and corneal irritation. Furthermore, such tonicity shifts may impair drug absorption by inducing osmotic water efflux from corneal cells [12], highlighting the vulnerability of certain generic formulations to extreme environmental stress.

This change in Osmolality, coupled with the RI increase, strongly suggests solvent evaporation accelerated by the harsh thermal stress under Condition III, a phenomenon often exacerbated by a sub optimal cap seal. Generic T's osmolality exceeded the ideal physiological range, representing an unacceptable physicochemical change.

The Refractive Index (RI) is a sensitive indicator of changes in solute concentration. While all samples were stable in Condition I and II, we observed a critical deviation in Condition III as mentioned in table 3.

Table 3: refractive index changes

B Sample	Storage Condition	RI at T0	RI at T60	Acceptable Range (1.331–1.333)
Vigamox	III	1.332	1.333	Within
Generic N	III	1.332	1.333	Within
Generic T	III	1.332	1.335	Unacceptable Deviation

The significant jump in RI for the Pakistani generic to 1.335 under Condition III is strong proof that a fundamental and unacceptable change in the solution's chemistry has occurred. Since RI correlates directly with solute concentration, this change probably results from accelerated solvent loss or the build-up of heavier degradation products due to severe thermal stress. This deviation from the acceptable range (1.331–1.333) means Generic T physical specifications were critically compromised, rendering it unacceptable for continued use. This data strongly supports the pH findings, confirming the complete breakdown of the formulation’s physical specifications.

Color stability, determined by simply looking at the samples, is a macro-level sign of advanced chemical degradation (the formation of chromophores).

Condition I & II: All products kept their original clear yellow color throughout the study.

Condition III: The original brand (Vigamox) showed only a very slight increase in yellow intensity. Both Generic N and Generic T became noticeably darker.

While color change isn't the first sign of degradation, the marked darkening of the generics in Condition III confirms that high stress accelerates chemical reactions, producing a significant amount of colored byproducts. This visual change is a powerful, macroscopic warning sign that the formulation's integrity has been severely lost.

The degradation patterns observed in this study, particularly the pronounced pH decline and osmolality shifts, align with established literature regarding the susceptibility of fluoroquinolones to hydrolysis and oxidation processes known to be accelerated by thermal stress and light exposure [13–18]. However, the data provide distinct empirical evidence that real-world storage environments in hot climates, such as Aden, exert stress exceeding that of standard controlled laboratory conditions. This multi-stress context revealed a critical disparity in formulation robustness: while the innovator brand (Vigamox) maintained all quality attributes, the generic alternatives exhibited significant physicochemical breakdown, failing to meet USP specifications for pH, refractive index, and osmolality.

These failures strongly suggest that the buffering capacity and packaging integrity of the tested generics offer insufficient protection against harsh environmental factors compared to the innovator product, thereby highlighting the potential limitations of relying solely on standard ICH stability protocols for products distributed in extreme climatic zone

MOX Drug Potency (Assay) and Packaging Observations

To determine the initial concentration of MOX in each product, we performed an Assay on fresh, unopened samples (time zero) using a UV-Spectrophotometer against a reference standard.

Table 4: drug potency changes

Sample	Drug Potency (Assay)	USP Acceptance Limit (≥90.0%)
Vigamox (Original Brand)	98.99%	Within Limit
Generic T (Pakistani Product)	96.2%	Within Limit
Generic N (Indian Product)	92.4%	Within Limit

These initial Assay results highlight a significant pre-existing difference in drug potency even before the in-use period began. While all products met the USP minimum (≥90%) as seen in table (4)., the Original Brand (Vigamox) showed superior initial quality at 98.99%. The generic products started with notably lower initial concentrations: the Pakistani Generic T at 96.2% and the Indian Generic N lowest at 92.4%.

Fig. 3: Primary Packaging and Container-Closure Integrity for MOX Formulations

This lower initial potency starting much closer to the minimum acceptable limit is a major factor that likely contributed to the poor performance of the generics under stress. A lower starting concentration, combined with the accelerated degradation (critical pH drop and color darkening) seen after two months, strongly suggests these generic formulations have a much smaller margin for error regarding stability and efficacy over the in-use period.

Furthermore and according to figure (3), looking closely at the packaging provided extra context for the products' vulnerabilities. The Pakistani Generic T came in a transparent bottle, unlike the opaque/colored containers used for Generic N and Vigamox. Transparent packaging risks photolytic degradation (light-induced breakdown), which could certainly contribute to the physical deterioration observed (e.g., color darkening and RI change). Additionally, the cap on the Pakistani Generic T seemed less securely sealed than the others, potentially allowing for greater solvent evaporation (leading to hypertonicity and RI changes) and oxygen exposure (accelerating chemical oxidation).

The totality of the physicochemical data demonstrates, beyond doubt, that storage conditions directly and significantly affect the quality and stability of MOX eye drops once they are opened. The progressive degradation shown by the critical pH drop, unacceptable RI changes, and noticeable color darkening is fastest and most severe at high temperatures (Condition III).

The original brand (Vigamox®) consistently proved its superior physical stability, staying within all USP and physiological limits, even under the most extreme thermal stress. This implies that its formulation (excipients, buffering system) and/or packaging are simply more robust than the generics.

In stark contrast, the generic products (N and T) experienced critical failures across multiple key parameters (pH, RI, and Osmolality) under the high-stress Condition III. These failures mean we cannot guarantee the quality, and by extension, the safety and efficacy, of these formulations when they are stored in the non A/C environments so common in hot climates.

4. Conclusion

To conclude, our study provides solid scientific evidence that high ambient temperatures and inadequate storage (Conditions II and III) compromise the physical stability of MOX ophthalmic solutions, with the generic formulations being disproportionately affected. The initial Assay (time zero) already pointed to a pre-existing quality difference, with generics starting at a lower potency (N at 92.4%), leaving them with a reduced margin for stability. This lower starting quality, combined with subsequent physical failures (critical pH drop and unacceptable RI rise), clearly highlights the generics' accelerated degradation. Furthermore, the observation of a transparent bottle and a potentially poor cap seal on the Pakistani generic suggests that packaging design is a critical, yet often overlooked, factor influencing product stability in harsh climates. Ultimately, we must ensure patients and healthcare providers are thoroughly educated on the vital necessity of adhering to storage instructions to guarantee the drug's safety and efficacy throughout the in-use period.

5.Recommendations for Clinical Practice and Patient Safety

Based on our findings, we must address the significant public health risks associated with using degraded solutions. We strongly recommend that:

1. Healthcare Providers emphasize the critical need to discard multi-dose ophthalmic solutions strictly within 28 days (or the manufacturer's specified period) after opening, irrespective of remaining volume, and highlight the A/C or cool storage requirement.
2. Pharmacists should prioritize dispensing the branded product or Generic N over Generic T in non A/C settings due to its superior packaging and stability profile.

Local Regulatory Bodies consider issuing specific patient advisories regarding the proper storage of multi-dose ophthalmic preparations in high-temperature environments.

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مقالة بحثية

تأثير ظروف التخزين على الثبات الفيزيائي-الكيميائي لمحاليل قطرات العين موكسيفلوكساسين قيد الاستخدام في مدينة عدن

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المُلخّص

يُعد محلول موكسيفلوكساسين هيدروكلوريد (MOX) العيني من الفلوروكينولونات المهمة من الجيل الرابع. ويُعد موكسيفلوكساسين هيدروكلوريد مركبًا اصطناعيًا من الجيل الرابع من الفلوروكينولونات، وقد أصبح معيارًا واسع الاستخدام في طب العيون لعلاج التهاب الملتحمة البكتيري وعدوى العين الأخرى. في الواقع، يستمر العديد من المرضى في استخدام هذه القطرات المكلفة لفترة طويلة بعد تاريخ التخلص الموصى به. ركزت هذه الدراسة على تقييم الثبات الفيزيائي-الكيميائي — مثل الرقم الهيدروجيني (pH)، والأسمولالية، ومعامل الانكسار، واللون — لثلاثة محاليل شائعة من موكسيفلوكساسين: العلامة التجارية الأصلية (Vigamox®) ونسختين جنيسيتين (هندية وباكستانية)، وذلك على مدى فترة استخدام محاكية لمدة 60 يومًا تحت ثلاث سيناريوهات تخزين شائعة في عدن، اليمن، بهدف تحديد مدى ملاءمتها للاستمرار في الاستخدام وتقديم إرشادات لسلامة المرضى محليًا. تمت محاكاة ثلاث حالات تخزين شائعة: الحالة الأولى (مثالية، 21.0±1.8 °م): تكييف هواء مستمر؛ الحالة الثانية (شائعة، 29.4±2.9 °م): تكييف متقطع مع انقطاع كهربائي يتجاوز غالبًا 16 ساعة يوميًا؛ الحالة الثالثة (قاسية، 33.4±2.3 °م): تخزين بدون تكييف باستخدام مروحة سقف فقط. تم فحص العينات عند خط الأساس، وبعد أسبوع، وأسبوعين، وشهر، وشهرين. وتمت محاكاة الاستخدام من قبل المرضى من خلال فتح وإغلاق العبوات ثلاث مرات يوميًا خلال الأيام العشرة الأولى. كشفت النتائج أن الثبات تم الحفاظ عليه إلى حد كبير في الحالة الأولى والحالة الثانية (مع ملاحظة انخفاض طفيف في الرقم الهيدروجيني للنسخة الباكستانية بحلول اليوم 60 في الحالة الثانية). ومع ذلك، تحت الحالة الثالثة عالية الإجهاد: بعد شهرين، أظهرت كلتا النسختين الجنيسيتين علامات واضحة على تدهور متسارع. انخفضت مستويات الرقم الهيدروجيني إلى ما دون حد القبول وفق دستور الأدوية الأمريكي (<6.8) (USP)، مما يزيد من خطر تهيج العين ويقلل من فعالية المواد الحافظة. كما أصبح لونها أكثر قتامة بشكل ملحوظ، ولوحظ أن الأسمولالية في النسخة الباكستانية أصبحت مفرطة التوتر بشكل طفيف (>320 mOsmol/kg)، مع زيادة غير مقبولة في معامل الانكسار (>1.333)، مما يشير إلى فقدان كبير في المذيب أو زيادة في تركيز المذاب. إن تخزين محاليل موكسيفلوكساسين العينية، خاصة النسخ الجنيسية، تحت ظروف درجات حرارة مرتفعة — وهي واقع في المناخات الحارة — يؤثر بشكل خطير على سلامتها الفيزيائية-الكيميائية.

الكلمات المفتاحية: موكسيفلوكساسين هيدروكلوريد؛ الثبات الفيزيائي-الكيميائي؛ ثبات المنتج أثناء الاستخدام؛ ظروف التخزين.

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