

Evaluating the Cost-Effectiveness of Generic Artificial Tears Eye Drops: A Comparative Analysis of Dosing Variations

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ABSTRACT

Background: Dry eye Disease (DED) is a prevalent condition that significantly impacts quality of life and productivity. Artificial tears are a common treatment for DED, but differences in bottle design and manufacturing can lead to variability in drop volume, resulting in inconsistent dosing and increased healthcare costs. This study aimed to compare the dosing variations and cost-effectiveness of generic artificial tears eye drops.

Methodology: Six brands of generic artificial tears were evaluated for quality and cost-effectiveness. The brands underwent organoleptic evaluation, pH measurement, viscosity determination, and sterility testing. A comparative economic analysis was conducted to evaluate the number of drops per bottle, drop volume, cost per year, and cost-effectiveness.

Results: All six brands met the acceptable standards for ophthalmic solutions, with clear and colourless appearances. However, the actual volume of the eye drops in each bottle was not consistent with the labelled volume for all brands. The number of drops per bottle and drop volume varied between the vertical and horizontal positions among brands. The cost per year ranged from N 38,000 to N 154,000, and the cost-effectiveness ranged from N 13,620 to N 55,197. Brand E was the most cost-effective option.

Conclusions: Our study reveals that brand and dispensing position substantially affect the number of drops per bottle, potentially leading to inaccurate medication quantity estimates. This discrepancy may cause patients to experience stockouts or accumulate excess medication, compromising treatment efficacy and safety.

1. Introduction

Dry eye disease (DED) is a complex and prevalent condition that significantly impacts quality of life and productivity, affecting up to 50% of the global population¹. The economic burden of DED is substantial, with estimated annual costs ranging from billions to trillions of dollars². Effective management of DED relies heavily on topical therapeutics, particularly artificial tears eye drops, which provide essential lubrication and hydration to the ocular

surface³. Artificial tears come in various formulations, including preservative-free and preserved formulations, with different active ingredients such as carboxymethylcellulose, hyaluronic acid, or glycerine^{1,4,5}. Given the long-term treatment requirements for many patients with DED, the cost of brand-name artificial tears can be prohibitively expensive^{6,7}. Generic artificial tears may offer a more affordable option, improving patient adherence and treatment outcomes⁸. In addition to

economic benefits, generic artificial tears may also enhance accessibility for patients with DED^{7,8}.

Despite the widespread use of generic formulations, significant variability exists in eye drop bottle design and manufacturing standards. This variability leads to inconsistent drop volumes and unpredictable bottle exhaustion, which may compromise medication adherence and treatment efficacy. Furthermore, while the impact of dispensing angles on medication delivery has been explored in glaucoma treatments⁹, there is a paucity of data specifically comparing the physical quality, dosing variations, and long-term cost-effectiveness of generic artificial tears within the Nigerian pharmaceutical market.

This study seeks to address these gaps by comparing the dosing variations and cost-effectiveness of generic artificial tears eye drops, providing insights into their therapeutic equivalence and economic implications for patients and healthcare systems. The analysis will contribute to the growing body of evidence on DED management and the role of generic artificial tears in clinical practice.

2. Methodology

Sample collection

The selection of samples followed a purposive sampling technique to reflect the most commonly prescribed and commercially available generic artificial tears in the Federal Capital Territory of Nigeria. Six distinct brands were identified based on their availability in reputable pharmaceutical retail outlets. Brands were as well selected to cover variety of active pharmaceutical ingredients (API). Following purchase, all samples were immediately transferred to a controlled environment maintained at a temperature not exceeding 30 °C to prevent thermal degradation prior to analysis. All analysis was determined in triplicate and results expressed as mean \pm standard deviation where applicable.

Quality Assessment

The brands underwent a comprehensive assessment, which included organoleptic evaluation, pH measurement, viscosity determination, and sterility testing.

Organoleptic assessment involved visual inspection for colour and clarity against a visual inspection board with a black and white under bright light⁹. This helped to detect any visible particulate matter or contamination.

The pH levels of the eye drops were measured using a calibrated pH meter (Mettler Toledo; Type 8603, Switzerland) to ensure that they fell within the acceptable

range for ophthalmic solutions².

Viscosity was determined using a Brookfield viscometer (NDJ-85, USA) to assess the flow properties of the eye drops².

Sterility testing was conducted to ensure the absence of microbial contamination, by inoculating 1 mL of each sample into fluid thioglycolate agar, soybean digest medium, and Sabouraud dextrose broth, then incubating for 72 hours to check for microbial growth, using *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *Candida albican* as positive controls⁹.

Comparative Economic Analysis

The study compared the economic viability of each brand by evaluating several key parameters, including the number of drops per bottle, drop volume, cost per year, and cost effectiveness.

To determine the number of drops per bottle, the bottles were held at 90 °(vertical) and 45 ° (horizontal) to simulate real-world usage, and the drops were counted and measured¹⁰.

Drops per mL was determined by dividing the number of drops in a bottle by the filled volume.

Drop volume was the reciprocal of the drops per mL¹⁰.

Number of bottles per year was calculated based on the assumption of six-hourly administration to both eyes (8) multiplied by the number of days in a year (364.2; accounting for leap years), divided by the number of drops per bottle¹⁰.

Cost per year was calculated by multiplying the cost price of the medication (in naira) by the number of bottles per year¹¹.

The cost-effectiveness of each brand was extrapolated by dividing the cost per year by the Ocular Surface Disease Index (2.79); based on the mean difference in the tear volume increase between an artificial tears eye drop and placebo reported in authentic literature^{4,12}.

3. Results

Table 1. Some information about the brands of artificial tears eye drops analysed

	LCV (mL)	API	BN	NRN	MD	ED	CO
A	15	HPMC	L2KN2	-	08/24	07/26	USA
B	10	Na CMC	D25B34	B4-9606	02/25	22/27	Indian
C	10	Na hyaluronate	306776	-	-	02/26	Germany
D	10	HPMC	D25E38	B4-9924	05/25	04/27	India
E	10	HPMC	14E0128	A1-1063	05/25	04/28	Nigeria
F	10	HPMC	SL2410	04-9779	12/24	12/27	Macau

*LCV =label claim volume, API=active pharmaceutical ingredient, BN=batch number, NRN=NAFDAC registration number, MD=manufacturing date, ED=expiry date, CO=country of origin.

Table 2. Some organoleptic, pH, and viscosity data for brands of artificial eye drops analysed

	Colour	Clarity	pH (SD)	Viscosity (cP)
A	Colourless	Clear	7.20 (0.00)	4.52±0.85
B	Colourless	Clear	7.23 (1.51)	25.85±1.22
C	Colourless	Clear	7.30 (2.23)	6.14±2.01
D	Colourless	Clear	5.70 (0.00)	12.10±0.55
E	Colourless	Clear	6.93 (0.02)	9.77±1.02
F	Colourless	Clear	6.93 (0.51)	10.59±0.44

Table 3. sterility testing data for brands of artificial tears eye drops tested

	Liquid thioglycolate medium	Soyabean casein medium	Sabouraud dextrose broth
A	-	-	-
B	-	-	-
C	-	-	-
D	-	-	-
E	-	-	-
F	-	-	-

*absence of microbial growth (-)

Table 4. Vertical drop volume and annual cost analysis for generic artificial eye drops analysed

	AV (mL)	DPB	DPM	DV (mL)	BPY	CPY (N)	CE (N)
A	17±0.02	277±3.01	16	0.06	11	154,000	55,197
B	11±0.00	166±5.11	15	0.07	18	72,000	22,806
C	11±0.01	164±2.91	15	0.07	18	90,000	32,258
D	12±0.01	263±2.42	22	0.05	11	47,850	17,150
E	11±0.00	154±2.51	14	0.07	19	38,000	13,620
F	12±0.01	244±4.11	20	0.05	12	78,000	27,956

*AV=actual volume of eye drops in bottle, DPB=number of drops per bottle, DPM=drops per mL, DV=drops volume, BPY=number of bottles per year, CPY=cost per year in naira, CE=cost effectiveness in naira. Values are expressed as mean ±SD where applicable

Table 5. Horizontal drop volume and annual cost analysis for generic artificial eye drops analysed

	AV (mL)	DPB (SD)	DPM	DV (mL)	BPY	CPY	CE
A	17±0.02	293±2.22	17	0.06	10	140,000	50,179
B	11±0.00	205±2.90	19	0.05	14	56,000	20,071
C	11±0.01	169±1.09	15	0.07	17	85,000	30,465
D	12±0.01	267±6.02	22	0.05	11	47,850	17,150
E	11±0.00	156±3.04	14	0.07	19	38,000	13,620
F	12±0.01	218±1.88	18	0.06	13	84,500	30,287

*AV=actual volume of eye drops in bottle, DPB=number of drops per bottle, DPM=drops per mL, DV=drops volume, BPY=number of bottles per year, CPY=cost per year in naira, CE=cost effectiveness in naira. Values are expressed as mean ±SD where applicable

Quality Assessment

The results of the quality assessment are presented in Tables 1-3. All six brands met the acceptable standards for ophthalmic solutions, with clear and colourless appearances. The actual volume of the eye drops in each bottle was not consistent with the labelled volume for all brands. Their pH levels are within the acceptable range for an artificial eye drops with the exception of brand D (Table 2). The viscosity of the eye drops varied among the brands, ranging from 4.52 to 25.85 cP. Sterility testing confirmed the absence of microbial contamination in all six brands (Table 3).

Comparative Economic Analysis

The results of the comparative economic analysis are presented in Tables 4 and 5. The number of drops per bottle and drop volume varied between the vertical and horizontal positions among brands, ranging from 154 to 293 drops per bottle (Tables 4 and 5). The drop volume ranged from 0.05 to 0.07 mL, and the smaller drop volumes produces more drops per bottle; while the number of bottles required per year ranged from 10 to 19 bottles.

The cost per year ranged from N38,000 to N154,000, and the cost-effectiveness ranged from N13,620 to N55,197 (Tables 4 and 5). Brand E was the most cost-effective option, with a cost-effectiveness of N13,620, while Brand A was the least cost-effective option, with a cost-effectiveness of N55,197.

4. Discussion

Artificial eye drops are a common treatment for dry eye syndrome, and their widespread use necessitates evaluation of their quality and cost-effectiveness. This study assessed the packaging integrity, sterility, pH, and viscosity of various artificial tear products and examined the impact of bottle angle on drop size, volume, and cost.

All products demonstrated satisfactory packaging integrity, with no signs of compromise or damage, ensuring the sterility of the eye drops. The samples were clear, colourless, and free of particulate matter, indicating a successful membrane filtration process and adherence to stringent manufacturing standards⁹.

The pH of artificial tears eye drops typically ranges from 6.5 to 7.8 which is close to the natural pH of human tears (~7.0-7.4)^{2,13}. The pH of tears among dry eye patients has been reported to be around 7.46. Some artificial tears may have a slightly broader pH range, but most formulations aim to stay within this neutral to slightly alkaline range to maintain ocular surface health, minimize irritation, and

ensure compatibility with the eye's natural environment². Extreme pH levels in eye drops can cause ocular discomfort, increased tearing, and potentially lead to epiphora, a condition characterized by excessive tear production⁹. This is because altered pH levels can lead to drug degradation, compromising the safety and efficacy of the treatment¹. In addition, the excessive tearing triggered by irritation can quickly flush out the artificial tears, reducing their bioavailability⁵.

Viscosity plays a crucial role in the comfort and efficacy of artificial tears. Our study found that all artificial tears had a viscosity below 30 cP at a shear rate of 100/s, which is consistent with previous research². The ideal artificial tear formulation should balance high viscosity at low shear rates for prolonged ocular retention and low viscosity at high shear rates for comfortable blinking⁶.

While some may argue that overfilling eye drop bottles is a strategy to reduce waste and optimize product usage, the reality is that inconsistent volumes can have serious consequences. These include inaccurate dosing, which can compromise treatment efficacy and safety, treatment failure, increased costs, patient non-adherence, and regulatory issues^{6,11,14}. To ensure effective treatment, patient safety, and regulatory compliance, it is essential to prioritize accurate labelling and consistency of eye drop volumes.

The section on cost-effectiveness and bottle design is also noteworthy, as it highlights the potential for significant cost savings by optimizing bottle design and dispensing position. Our study found significant differences in drop count, volume and annual costs among various brands, which were influenced by the dispensing position. The US FDA guideline of approximately 20 drops/mL (or 0.05 mL/drop) was not met by some brands regardless of the dispensing method¹⁰. The design of the dropper bottle and tip, solution viscosity, and dispensing angle all impact drop size¹⁴. Using a dropper tip with a smaller orifice diameter may help produce consistent, smaller-volume drops.

While Brand E appeared to be the most cost-effective option in this analysis, these findings should be interpreted as preliminary observations rather than definitive market rankings. Relying solely on the purchase price without considering drop volume and annual bottle requirements may lead to inaccurate medication quantity estimates. This potential for inaccuracy could result in patients experiencing unexpected stockouts or accumulating excess

medication.

Our findings observed that dispensing artificial tears horizontally may result in a higher number of drops per bottle for certain brands compared to vertical dispensing. While this suggests a potential for cost savings of up to N14,000 per year for specific products, this must be weighed against clinical safety. Although all brands passed initial sterility testing, existing literature suggests that the prolong use of a single bottle, necessitated by higher drop counts, may increase the risk of microbial contamination over time¹. While our study did not directly measure contamination rates post-opening, this remains a critical consideration for healthcare providers when advising patients on bottle longevity.

5. Study Limitations

While this study provides valuable insights into the quality and cost effectiveness of generic artificial tears, several limitations must be acknowledged.

Small Sample Size: This analysis was limited to six generic brands available in the Federal Capital Territory. Consequently, the results may not be generalizable to the entire range of artificial tear products available globally or in other regional markets.

Statistical Constraints: The variability observed in drop volumes and costs was reported as mean values; however, due to the sample size, formal longitudinal statistical modelling was not conducted to confirm long-term trends.

Economic Assumptions: The cost-effectiveness analysis relied on the assumption of a fixed six-hourly administration schedule to both eyes. In real-world clinical settings, patient adherence and varying dosing frequencies prescribed by physicians may significantly alter annual costs.

Statistic Quality Assessment: Quality parameters such as pH and viscosity were measured at a single point in time under controlled storage conditions (30 °C). The study did not evaluate how these properties might change after the bottle is opened or when exposed to fluctuating environmental temperatures during patient use

Lack of Clinical Correlation: The study focused on the physical and economic properties of the medications. Further research is required to correlate these findings with actual patient comfort and therapeutic efficacy outcomes in a clinical population.

6. Conclusion

Overall, the study provides valuable insights into the quality and cost-effectiveness of artificial tears and highlights the need for careful consideration of these factors in clinical practice.

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