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EVALUATION OF PHYSICAL PARAMETERS OF LOCALLY MANUFACTURED AND IMPORTED DEXAMETHASONE 0.1% OPHTHALMIC DROPS IN KABUL CITY

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ABSTRACT

Background: Dexamethasone 0.1% ophthalmic drops are widely used for ocular therapy. Physical parameters like drop volume, pH, and packaging integrity are critical for safe use. Objective: To evaluate the physical characteristics of locally manufactured and imported Dexamethasone 0.1% ophthalmic drops available in Kabul. Methods: Seven brands were collected from local pharmacies. Dropper calibration, total volume, pH, and labeling were evaluated according to British Pharmacopoeia (2023) standards. Results: Most samples met pharmacopeia standards. Samples F_6 failed volume criteria; samples F_2, F_4, F_5, and F_6 exceeded acceptable pH limits. Packaging deficiencies were noted in F_1 and F_3. Conclusion: While most drops were compliant, a few posed risks due to pH or volume deviations. Strict quality control is recommended.

KEYWORDS: Dexamethasone 0.1%, ophthalmic drops, physical evaluation, pH, dropper calibration.

INTRODUCTION

Ophthalmic formulations play a crucial role in the treatment and management of various ocular conditions. Among these, Dexamethasone 0.1% ophthalmic drops are widely used for their anti-inflammatory properties and therapeutic effectiveness in managing eye disorders, including conjunctivitis, uveitis, and postoperative inflammation. The efficacy and safety of ophthalmic drops are highly dependent not only on their active pharmaceutical ingredient but also on their physical characteristics**,** such as drop volume, pH, and packaging integrity. These parameters are essential to ensure

correct dosing, drug stability, and patient safety, as deviations may lead to ocular irritation, reduced drug efficacy, or instability of the formulation.[1] Several studies conducted internationally have evaluated the physical, chemical, and microbiological properties of ophthalmic preparations. These studies have highlighted the importance of quality control for ophthalmic drops**,** emphasizing parameters like pH, total volume, dropper calibration, and labeling.[2] However, there is a notable lack of local data in Afghanistan regarding the physical evaluation of commercially available Dexamethasone 0.1% ophthalmic drops. Considering the widespread use of these drops in Kabul and the absence of systematic local assessments, the present study aims to evaluate the physical quality of manufactured and imported Dexamethasone 0.1% ophthalmic drops available in the city. The study focuses on critical parameters, including packaging, labeling, dropper calibration, total volume, and pH, providing essential insights into their compliance with pharmacopeia standards and their suitability for safe ocular use. According to available literature, no specific research has been conducted in Afghanistan under the title *"Evaluation of Physical Parameters of Dexamethasone 0.1% Ophthalmic Drops."* However, similar studies have been carried out internationally.[3]

Research Problem and Significance

Ophthalmic medications such as Dexamethasone 0.1% eye drops must be carefully selected, formulated, stored, and administered to ensure safety and effectiveness. Any deviation in these processes may alter their physical parameters, including pH, viscosity, sterility, particle size, and dropper calibration factors that are critical for ocular comfort and drug stability. [4] For instance, an inappropriate pH can cause eye irritation and excessive tearing. Various factors, from raw materials and manufacturing methods to storage and packaging conditions, can affect these physical characteristics. [3] Therefore, evaluating such parameters is essential to maintain the quality and therapeutic reliability of ophthalmic products. This study was conducted in the pharmaceutical laboratories of Kabul University to assess the physical parameters of both imported and locally manufactured Dexamethasone 0.1% eye drops available in Kabul City. The research was motivated by concerns regarding improper packaging, unsuitable pH, and poor storage conditions in the local market. This evaluation aims to support regulatory authorities in identifying deficiencies in product quality and to help manufacturers implement better quality assurance practices.[5]

Objectives

The main objective of this study is to evaluate the physical quality of locally manufactured and imported Dexamethasone 0.1% ophthalmic drops and compare the findings with standard specifications.[6]

Specific objectives include

1. Assessment of labeling and visual appearance.
2. Measurement of pH levels.
3. Evaluation of dropper calibration accuracy.
4. Determination of fill volume.

Research Questions

1. Are the ophthalmic drops physically intact and properly packaged?
2. Do the samples meet acceptable physical quality standards?

MATERIALS AND METHODS

Study Site

The study, titled "Evaluation of Physical Parameters of Dexamethasone 0.1% Ophthalmic Drops in Kabul City," was conducted in the Pharmaceutical Laboratories of the Faculty of Pharmacy, Kabul University, utilizing available laboratory equipment for all analyses.

Figure 1: Combined view of collected Dexamethasone 0.1% ophthalmic drop samples.

Sample Collection

As described in the study proposal, all available brands of Dexamethasone 0.1% ophthalmic drops in the Kabul City market were collected. A total of seven samples were obtained from various pharmacies across Kabul during a single collection period to ensure comprehensive representation of both imported and locally manufactured products.

Equipment and Materials

The following equipment and materials were used in this study:

- pH meter (Hanna, Italy): Used to determine the pH of all samples.
- Analytical balance (Biobase, China): Used for accurate measurement of drop volume.
- Magnifying glass: Employed for examining label details and visual characteristics.
- Graduated cylinder: Used to determine fill volume.
- Distilled water: Utilized for calibration and cleaning of instruments.
- Clean glass containers and droppers: Used for sample handling and measurement procedures.
- Labeling materials and gloves: Applied to ensure proper identification and safe handling of samples.

Methods

Physical Appearance: Packaging, labeling, and leaflet presence.

Dropper Calibration and Volume: Three bottles per brand, drops dispensed, total volume and individual drop volume measured.

pH Measurement: Calibrated pH meter; three bottles per brand; British Pharmacopoeia acceptable range: 5.0–6.0.

Data Analysis: Average ± standard deviation (SD) calculated; compared to pharmacopeia standards.

RESULTS

1. Physical Appearance of Dexamethasone Drops

Among the seven evaluated samples of Dexamethasone 0.1% ophthalmic drops, some deficiencies in labeling and packaging were observed. Specifically, sample F_1 (Dexamethasone 5 mL, Darou Pakhash) lacked the manufacturing date and the product leaflet, while sample F_3 (Dexamb 5 mL, Sina Darou) also lacked the manufacturing date.

Additionally, sample F_5 (MAXIDEX) did not display the company name on the packaging. All other samples met the required standards for labeling, including batch number, manufacturing and expiry dates, and country of origin.

Table 1: Physical Characteristics of Dexamethasone 0.1% Ophthalmic Drops.

No	Brand Name	Batch No	Company Name	MFG. Date	EXP. Date	MFG. Country
1	Dexamethasone 5ml	513	Darou Pakhash	**Unavailable**	03-2025	Iran
2	EPIDEXONE 5ml	2212374	Eipico	12-2022	12-2025	Egypt
3	Dexamb 5ml	409217	Sina Darou	**Unavailable**	09-2027	Iran
4	MEDIDEX 5ml	3503	Medipak limited	04-2024	04-2025	Pakistan
5	MAXIDEX 10ml	091914	**Unavailable**	04-2023	02-2025	Pakistan
6	Beenadex 3ml	1303024	Beena PHarma	03-2023	03-2027	Afghanistan
7	OPHTH -DEX 5ml	(10) op288	OpHth PHarma	01-2024	5-2026	Pakistan

2. Dropper Calibration of Dexamethasone 0.1% Samples (F_1–F_7)

For each brand, three individual bottles were tested. Drops were dispensed one by one into a graduated cylinder, counted, and the volume of each drop was measured.[7] The results, including mean drop volume (µL) and standard deviation (SD), are summarized in Table 2. All measured drop volumes fell within the FDA-specified acceptable range of 20–70 µL for commonly used ophthalmic preparations.

Table 2: Dropper Calibration of Dexamethasone 0.1% Samples (F_1–F_7).

Sample	Form	Dropper Calibration	Drops per mL	Mean ± SD (µL)	Result
F_{1a}	Eye drop	120 Drops	24	119 ± 3.31	Passed
F_{1b}	Eye drop	123 Drops	25		
F_{1c}	Eye drop	114 Drops	23		
F_{2a}	Eye drop	152 Drops	31	152.33 ± 2.05	Passed
F_{2b}	Eye drop	155 Drops	32		
F_{2c}	Eye drop	150 Drops	31		
F_{3a}	Eye drop	133 Drops	26	133 ± 1.63	Passed
F_{3b}	Eye drop	135 Drops	27		
F_{3c}	Eye drop	131 Drops	26		
F_{4a}	Eye drop	133 Drops	26	135.33 ± 2.50	Passed
F_{4b}	Eye drop	138 Drops	27		
F_{4c}	Eye drop	135 Drops	27		
F_{5a}	Eye drop	96 Drops	20	96 ± 1.63	Passed
F_{5b}	Eye drop	94 Drops	20		
F_{5c}	Eye drop	98 Drops	20		
F_{6a}	Eye drop	190 Drops	34	186 ± 2.94	Passed
F_{6b}	Eye drop	185 Drops	33		
F_{6c}	Eye drop	183 Drops	33		
F_{7a}	Eye drop	159 Drops	33	156 ± 3.74	Passed
F_{7b}	Eye drop	155 Drops	32		
F_{7c}	Eye drop	154 Drops	32		

3. Drop Volume and Standard Deviation of Dexamethasone 0.1% Ophthalmic Drops (F_1–F_7)

For each brand of Dexamethasone 0.1% ophthalmic drops, three individual bottles were selected. Drops from each bottle were dispensed into a graduated cylinder, and the total volume of each sample was measured.[8] According to the British Pharmacopoeia (2023), the acceptable deviation for a 5 mL bottle is ±10%. The results showed that among the seven tested brands, six samples met the acceptable volume criteria, while sample F_6 was rejected due to exceeding the acceptable volume range.

Table 3: Drop Volume of Dexamethasone 0.1% Samples (F_1–F_7).

No.	Form	Sample	Total Volume (mL)	Average ± SD (mL)	Result
F_1	Eye Drop	F_{1a}	4.9	5 ± 0.081	Passed
	Eye Drop	F_{1b}	5.0		
	Eye Drop	F_{1c}	5.1		
F_2	Eye Drop	F_{2a}	4.9	4.83 ± 0.081	Passed
	Eye Drop	F_{2b}	4.8		
	Eye Drop	F_{2c}	4.8		
F_3	Eye Drop	F_{3a}	4.9	4.96 ± 0.081	Passed
	Eye Drop	F_{3b}	5.0		
	Eye Drop	F_{3c}	5.0		
F_4	Eye Drop	F_{4a}	5.0	4.85 ± 0.382	Passed
	Eye Drop	F_{4b}	4.8		
	Eye Drop	F_{4c}	4.75		
F_5	Eye Drop	F_{5a}	4.8	4.8 ± 0.01	Passed
	Eye Drop	F_{5b}	4.8		
	Eye Drop	F_{5c}	4.8		
F_6	Eye Drop	F_{6a}	5.7	5.5 ± 0.382	**Rejected**
	Eye Drop	F_{6b}	5.5		
	Eye Drop	F_{6c}	5.3		
F_7	Eye Drop	F_{7a}	4.9	4.83 ± 0.081	Passed
	Eye Drop	F_{7b}	4.8		
	Eye Drop	F_{7c}	4.8		

4. pH and Standard Deviation of Dexamethasone 0.1% Ophthalmic Drops (F_1–F_7)

The pH of seven brands of Dexamethasone 0.1% ophthalmic drops was measured using a calibrated pH meter (Hanna, Italy) according to British Pharmacopoeia (2023) standards. Three bottles per brand were tested. [9] As shown in Table 4, samples F_1, F_3, and F_7 were within the acceptable range of 5.0–6.0 and passed the test, while samples F_2, F_4, F_5, and F_6 exceeded this range and were rejected. These results emphasize the importance of regular quality control for marketed ophthalmic formulations.

Table 4: pH and SD of Dexamethasone 0.1% Eye Drops (F_1–F_7).

Sample	Form	Bottle	pH	Average ± SD	Result
F_1	Eye Drop	F_{1a}	5.68	5.66 ± 0.016	Passed
		F_{1b}	5.66		
		F_{1c}	5.64		
F_2	Eye Drop	F_{2a}	6.90	6.91 ± 0.014	**Rejected**
		F_{2b}	6.92		
		F_{2c}	6.91		
F_3	Eye Drop	F_{3a}	5.74	5.73 ± 0.014	Passed
		F_{3b}	5.72		
		F_{3c}	5.73		
F_4	Eye Drop	F_{4a}	7.27	7.30 ± 0.016	**Rejected**
		F_{4b}	7.30		
		F_{4c}	7.33		
F_5	Eye Drop	F_{5a}	6.99	7.01 ± 0.016	**Rejected**
		F_{5b}	7.03		
		F_{5c}	7.01		
F_6	Eye Drop	F_{6a}	6.45	6.453 ± 0.006	**Rejected**
		F_{6b}	6.45		
		F_{6c}	6.46		
F_7	Eye Drop	F_{7a}	6.02	5.99 ± 0.024	Passed
		F_{7b}	5.96		
		F_{7c}	5.99		

The main findings are summarized as follows:

1. Physical Appearance

Seven samples were examined for packaging and appearance.

- Sample F_1 lacked the Manufacturing Date (MFG Date).
- Sample F_3 lacked the Manufacturing Date (MFG Date).
- Sample F_1 did not include a product leaflet.
- All other samples met the standards for appearance, labeling, and packaging.

2. Dropper Calibration and Volume

Each brand was tested with three individual bottles. Dropper calibration and total volume measurements showed:

- Samples F_1, F_2, F_3, F_4, F_5, and F_7 were within the acceptable volume range (4.5–5.5 mL) according to the British Pharmacopoeia (2023) and passed.
- Sample F_6 exceeded the acceptable range and was rejected.

3. pH Measurement

The pH of each sample was measured using a calibrated pH meter (Hanna, Italy). According to the British Pharmacopoeia, the acceptable pH range for ophthalmic drops is 5.0–6.0.

- Samples F_1, F_3, and F_7 were within the acceptable range and passed.
- Samples F_2, F_4, F_5, and F_6 had pH values exceeding the acceptable limits and were rejected.

DISCUSSION

This study evaluated the physical parameters of manufactured and imported Dexamethasone 0.1% ophthalmic drops in Kabul, highlighting their regulatory importance. While similar studies have been conducted internationally, none exist in Afghanistan. International studies highlight the importance of monitoring pH, drop volume, and packaging for ocular safety**.** Our findings emphasize the need for regular quality control in local markets.[10]

Limitations

This study focused solely on the physical parameters (drop volume, pH, and packaging) of Dexamethasone 0.1% ophthalmic drops. Chemical composition, preservative content, microbiological stability, and long-term storage effects were not evaluated. Additionally, the study sample was limited to seven brands available in Kabul City, which may not represent all products in Afghanistan. Future studies should include chemical analysis, microbiological testing, and a broader range of samples to provide a comprehensive quality assessment.

CONCLUSION

This study evaluated the physical parameters of locally manufactured and imported *Dexamethasone 0.1% ophthalmic drops* available in Kabul to determine their compliance with pharmacopeia standards and suitability for safe ocular use. Ophthalmic drops, due to their direct contact with sensitive eye tissues, require strict control of quality attributes such as pH, drop volume, and packaging integrity. The results revealed that while most samples complied with pharmacopeia specifications, a few exhibited deviations in pH or drop volume and showed packaging deficiencies. Such variations may compromise product stability and increase the risk of ocular irritation. Therefore, continuous quality surveillance and adherence to Good Manufacturing Practices (GMP) are essential to ensure the safety and therapeutic efficacy of ophthalmic preparations available in the local market.

Recommendations

- Strict quality control and regular monitoring of ophthalmic formulations should be implemented.
- Manufacturers and importers must ensure proper labeling, packaging, and compliance with volume and pH standards.
- End-users, including pharmacies and healthcare providers, should verify the quality of ophthalmic drops before dispensing or administration.

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