



Received on 05 June 2026; received in revised form, 15 June 2026; accepted, 19 June 2026; published 01 October 2026

LABORATORY-SCALE DEVELOPMENT AND *IN-VITRO* EVALUATION OF NORFLOXACIN-LOADED POLYMERIC OCUSERTS PREPARED BY SOLVENT CASTING METHOD

Km Priyanka, Yogesh Kumar and Rajuprasad Yadav *

Department of Pharmaceutics, Maya Institute of Pharmacy, Hathras - 204217, Uttar Pradesh, India.

Keywords:

Norfloxacin, Ocuserts, Ocular inserts, HPMC, Sodium alginate, Solvent casting, *In-vitro* drug release

Correspondence to Author:

Dr. Rajuprasad Yadav

Associate Professor,
Department of Pharmaceutics,
Maya Institute of Pharmacy, Hathras -
204217, Uttar Pradesh, India.

E-mail: rajuyadavkip123@gmail.com

ABSTRACT: Background: Conventional ophthalmic dosage forms are associated with rapid precorneal clearance, tear dilution, blinking, nasolacrimal drainage, and short ocular residence time, which may reduce ocular drug bioavailability. Polymeric ocuserts are laboratory-scale ocular inserts designed to provide comparatively prolonged residence and controlled drug release under *in-vitro* conditions. **Objective:** The present study aimed to formulate and evaluate Norfloxacin-loaded polymeric ocuserts using HPMC, PVP K30, and sodium alginate by the solvent casting method. **Materials and Methods:** Nine formulations, F1–F9, were prepared by varying polymer concentrations. Ocuserts were evaluated for preformulation properties, thickness, weight variation, folding endurance, surface pH, drug content, moisture absorption, moisture loss, *in-vitro* drug release, release kinetics, sterility observation, and accelerated stability. Norfloxacin showed λ_{max} at 269.6 nm. The UV calibration curve was linear in the concentration range of 2–12 $\mu\text{g/mL}$, with equation $y = 0.078x + 0.006$ and $R^2 = 0.9991$. FTIR analysis showed retention of major characteristic peaks of Norfloxacin in the drug–polymer mixture. **Results:** Thickness ranged from 0.21 ± 0.01 to 0.27 ± 0.01 mm, surface pH from 7.0 ± 0.06 to 7.2 ± 0.09 , drug content from $96.2 \pm 0.8\%$ to $99.1 \pm 0.4\%$, weight variation from 42.6 ± 1.2 to 52.4 ± 1.2 mg, folding endurance from 145 ± 5 to 212 ± 9 , moisture absorption from $5.82 \pm 0.21\%$ to $7.28 \pm 0.26\%$, and moisture loss from $4.71 \pm 0.18\%$ to $5.76 \pm 0.18\%$. F7 showed the most balanced laboratory profile, with $43.62 \pm 1.15\%$ drug release at 150 minutes and best fit to the Higuchi model with $R^2 = 0.991$. Sterility observation showed no visible microbial growth. Accelerated stability testing of F7 for three months showed no major change in physical appearance, drug content, or release behaviour. **Conclusion:** Norfloxacin-loaded polymeric ocuserts were successfully prepared by solvent casting. F7 was identified as the most suitable laboratory-scale formulation based on physicochemical characteristics and comparatively slower *in-vitro* release. However, further extended release, *ex-vivo* permeation, ocular irritation, antimicrobial, *in-vivo*, packaging, and long-term stability studies are required.

INTRODUCTION: Ocular drug delivery remains a challenging area in pharmaceutics because the eye possesses several anatomical and physiological barriers that restrict drug residence and penetration.

Conventional ophthalmic dosage forms such as eye drops, suspensions, ointments, and gels are widely used because of ease of administration and patient acceptability.

However, these formulations often show limited therapeutic efficiency due to rapid precorneal elimination, tear dilution, blinking, lacrimal turnover, nasolacrimal drainage, and poor corneal permeability. As a result, only a small fraction of the administered dose reaches the target ocular tissues ¹.

QUICK RESPONSE CODE  DOI link: https://doi.org/10.13040/IJPSR.0975-8232.17(10).3036-44	DOI: 10.13040/IJPSR.0975-8232.17(10).3036-44 This article can be accessed online on www.ijpsr.com
--	---

The cornea, conjunctiva, tear film, and nasolacrimal drainage pathway play important roles in determining ocular drug absorption. The corneal epithelium acts as a lipophilic barrier with tight junctions, while the stroma is hydrophilic. Therefore, ocular penetration depends on the physicochemical properties of the drug and formulation system². In addition, normal tear turnover and blinking remove the drug rapidly from the ocular surface, leading to short contact time and the need for repeated administration. Frequent dosing may reduce patient compliance and increase the possibility of local or systemic adverse effects³.

Controlled ocular drug delivery systems have been developed to overcome some of these limitations. Ocular inserts, commonly known as ocuserts, are sterile, thin, flexible, solid or semisolid polymeric devices designed to be placed in the conjunctival sac. They can release the incorporated drug through diffusion, swelling, erosion, or combined mechanisms. Compared with eye drops, ocuserts may offer improved dose accuracy, reduced drug wastage, increased ocular contact time, and more predictable *in-vitro* release behavior⁴. However, successful ocusert development requires appropriate polymer selection, since the polymeric matrix influences film formation, flexibility, swelling, drug diffusion, mechanical strength, and patient acceptability.

Hydrophilic polymers such as hydroxypropyl methylcellulose, polyvinyl pyrrolidone, and sodium alginate are commonly used in ocular delivery systems because of their film-forming, swelling, and gel-forming characteristics^{5, 12}. HPMC contributes to matrix integrity and swelling-controlled diffusion. PVP K30 improves film smoothness and drug distribution, while sodium alginate provides gel-forming and bioadhesive potential⁵. Alginate and HPMC-based ophthalmic systems have previously been reported as useful platforms for controlled ocular drug delivery⁶.

Norfloxacin is a second-generation fluoroquinolone antibacterial agent that acts by inhibiting bacterial DNA gyrase and topoisomerase IV, thereby interfering with bacterial DNA replication. It has therapeutic relevance in external ocular bacterial infections.

However, conventional ocular administration of Norfloxacin may be limited by rapid drainage and dilution from the ocular surface. Formulation into polymeric ocuserts may provide a laboratory-scale approach for improving local retention and regulating drug release under *in-vitro* conditions. Previous studies on Norfloxacin-loaded ocular systems have supported the feasibility of formulation modification for extraocular bacterial infections⁷.

The present study was therefore designed to develop Norfloxacin-loaded polymeric ocuserts using HPMC, PVP K30, and sodium alginate by the solvent casting method. The objective was to evaluate the prepared ocuserts for preformulation characteristics, physicochemical parameters, mechanical properties, drug content uniformity, moisture behaviour, *in-vitro* release, release kinetics, preliminary sterility observation, and accelerated stability, and to identify a suitable laboratory-scale optimized formulation for further development.

MATERIALS AND METHODS:

Materials: Norfloxacin was used as the active pharmaceutical ingredient. Hydroxypropyl methylcellulose, polyvinyl pyrrolidone K30, and sodium alginate were used as film-forming and release-modifying polymers. Polyethylene glycol 400 was used as a plasticizer. Distilled water and phosphate buffer pH 7.4 were used during formulation and evaluation. Fluid thioglycollate medium and soybean casein digest medium was used for sterility testing. All chemicals and reagents used were of analytical grade.

Preformulation Studies: Preformulation studies were performed to evaluate the suitability of Norfloxacin for ocusert formulation. The drug was examined for organoleptic properties, solubility, melting point, bulk density, tapped density, Carr's index, Hausner's ratio, angle of repose, UV spectrophotometric behaviour, calibration curve, and FTIR compatibility with selected polymers.

Norfloxacin absorbance was measured by UV-visible spectrophotometry, and λ_{max} was identified at 269.6 nm in phosphate buffer pH 7.4. A calibration curve was prepared in the concentration range of 2–12 $\mu\text{g/mL}$. FTIR analysis was carried

out for pure Norfloxacin and the drug-polymer mixture to detect possible drug-polymer interaction based on characteristic peak retention or major peak shifts.

UV Analytical Method Validation: The UV spectrophotometric method for Norfloxacin estimation was validated for linearity, accuracy, precision, specificity, robustness, limit of detection, and limit of quantification. Linearity was assessed using standard solutions in the concentration range of 2–12 µg/mL. Accuracy was evaluated by recovery studies at 80%, 100%, and 120% levels. Precision was assessed by intra-day and inter-day analysis and expressed as percentage relative standard deviation. Specificity was checked by analysing placebo polymeric film solution to detect possible polymer interference at the selected wavelength. Robustness was evaluated by minor variation in wavelength and buffer conditions.

Preparation of Norfloxacin-Loaded Ocuserts:

Norfloxacin-loaded polymeric ocuserts were prepared by the solvent casting method. For each batch, the required quantities of HPMC, PVP K30, sodium alginate, PEG 400, and Norfloxacin were used according to the formulation design. The polymers were dispersed in distilled water and allowed to hydrate for 2 hours. The hydrated polymeric dispersion was stirred at approximately 500 rpm for 45 minutes to obtain a uniform solution. PEG 400 was added as plasticizer, followed by Norfloxacin, and the dispersion was stirred further for 30 minutes. The final casting volume was adjusted to 20 mL.

The polymeric dispersion was poured into a clean, levelled glass Petri dish of 9 cm diameter, corresponding to a casting area of approximately 63.6 cm². The films were dried at room temperature for 24 hours under dust-free conditions. After drying, films were carefully removed and cut into circular ocuserts of 8 mm diameter, corresponding to an individual insert area of approximately 0.50 cm². Each batch yielded approximately 100–110 ocuserts, depending on edge loss during cutting. The prepared ocuserts were stored in airtight containers inside a desiccator until evaluation.

Dose Calculation: Theoretical drug content per ocusert was calculated using the following formula:

$$\text{Drug content per ocusert} = \frac{\text{Total drug incorporated in cast film} \times \text{Area of individual ocusert}}{\text{Total casting area}}$$

For a cast film containing 10 mg Norfloxacin over 63.6 cm² area and each ocusert having an area of 0.50 cm²:

$$\text{Drug per ocusert} = 10 \times 0.50 / 63.6 = 0.078 \text{ mg per ocusert, approximately.}$$

Therefore, each 8 mm ocusert theoretically contained approximately 78 µg Norfloxacin. Drug content uniformity was further confirmed experimentally by UV spectrophotometric estimation.

Formulation Design: Nine formulations, F1–F9, were prepared by varying the concentrations of HPMC, PVP K30, and sodium alginate. PEG 400 was used as plasticizer in the concentration range of 0.3–0.5% w/v.

TABLE 1: COMPOSITION OF NORFLOXACIN-LOADED OCUSERT FORMULATIONS

Formulation	HPMC (% w/v)	PVP K30 (% w/v)	Sodium alginate (% w/v)	PEG 400 (% w/v)	Drug per cast film
F1	1.0	0.5	0.5	0.3	10 mg
F2	1.0	1.0	1.0	0.3	10 mg
F3	1.0	1.5	1.5	0.3	10 mg
F4	1.5	0.5	1.0	0.4	10 mg
F5	1.5	1.0	1.5	0.4	10 mg
F6	1.5	1.5	0.5	0.4	10 mg
F7	2.0	1.0	1.0	0.5	10 mg
F8	2.0	0.5	1.5	0.5	10 mg
F9	2.0	1.5	0.5	0.5	10 mg

TABLE 2: CASTING AND DIMENSIONAL DETAILS OF NORFLOXACIN OCUSERTS

Parameter	Value
Total casting volume per batch	20 mL
Petri dish diameter	9 cm
Total casting area	63.6 cm ²

Final ocusert shape	Circular insert
Final ocusert diameter	8 mm
Area of each ocusert	0.50 cm ²
Theoretical drug per cast film	10 mg
Theoretical drug per ocusert	0.078 mg / 78 µg
Approximate number of inserts per batch	100–110
Drying condition	Room temperature for 24 hours
Storage condition	Airtight container in desiccator

Evaluation of Prepared Ocuserts: The prepared ocuserts were evaluated for physical appearance, thickness, weight variation, folding endurance, surface pH, drug content, moisture absorption, moisture loss, *in-vitro* drug release, release kinetics, sterility observation, and accelerated stability.

Physical Appearance: The ocuserts were visually examined for colour, transparency, smoothness, flexibility, cracks, and air bubbles.

Thickness: Thickness was measured at different points using a screw gauge or digital micrometer, and the mean value was calculated.

Weight Variation: Individual ocuserts from each formulation were weighed using an electronic balance. Mean weight and standard deviation were calculated.

Folding Endurance: Folding endurance was determined by repeatedly folding the ocusert at the same place until it broke or showed visible cracking. The number of folds tolerated before breaking was recorded.

Surface pH: Ocuserts were allowed to swell slightly in distilled water, and the surface pH was measured using pH paper or a calibrated pH meter.

Drug Content Uniformity: An accurately weighed ocusert was dissolved or extracted in phosphate buffer pH 7.4. The solution was filtered, suitably diluted, and analysed by UV spectrophotometry at 269.6 nm. Drug content was calculated using the calibration curve.

Moisture Absorption: The ocuserts were weighed and exposed to controlled humidity conditions. After a specified period, the films were reweighed. Percentage moisture absorption was calculated using the formula:

$$\text{Moisture absorption (\%)} = \frac{\text{Final weight} - \text{Initial weight}}{\text{Initial weight}} \times 100$$

Moisture Loss: The ocuserts were weighed and kept in a desiccator. After a specified period, the films were reweighed. Percentage moisture loss was calculated using the formula:

$$\text{Moisture loss (\%)} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

***In-vitro* Drug Release Study:** *In-vitro* drug release was studied using phosphate buffer pH 7.4 as the release medium. The study was conducted at 37 ± 0.5°C with gentle agitation. At predetermined time intervals of 30, 60, 90, 120, and 150 minutes, aliquots were withdrawn and replaced with an equal volume of fresh buffer to maintain sink conditions.

The withdrawn samples were filtered, diluted if required, and analysed spectrophotometrically at 269.6 nm. Cumulative percentage drug release was calculated. Each experiment was performed in triplicate.

Release Kinetic Modelling: The release data of the optimized formulation were fitted into zero-order, first-order, Higuchi, and Korsmeyer–Peppas kinetic models. The best-fit model was selected based on the highest regression coefficient value^{8,9}.

Sterility Testing: Sterility testing of the optimized formulation F7 was carried out using fluid thioglycollate medium and soybean casein digest medium. The test samples were aseptically transferred into the respective culture media and incubated under controlled conditions.

Fluid thioglycollate medium was incubated at 30–35°C for 14 days, while soybean casein digest medium was incubated at 20–25°C for 14 days. The media were observed periodically for turbidity or visible microbial growth. A negative control containing sterile medium without sample and a positive control inoculated with standard microbial culture were maintained during the study.

Accelerated Stability Study: Accelerated stability testing of optimized formulation F7 was performed at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and $75\% \pm 5\%$ RH for three months. Samples were evaluated initially and after 1, 2, and 3 months for physical appearance, drug content, and *in-vitro* drug release at 150 minutes.

Statistical Expression: Quantitative values were expressed as mean $\pm$ standard deviation. Unless otherwise stated, measurements were performed in triplicate.

RESULTS AND DISCUSSION:

Preformulation Studies: Preformulation evaluation showed that Norfloxacin was suitable for formulation into polymeric ocuserts. The drug was observed as a pale yellow crystalline powder. The UV spectrophotometric study showed maximum absorbance at 269.6 nm in phosphate buffer pH 7.4. The calibration curve was linear in the concentration range of 2–12 $\mu\text{g/mL}$, with equation $y = 0.078x + 0.006$ and $R^2 = 0.9991$.

TABLE 3: PREFORMULATION PROFILE OF NORFLOXACIN

Parameter	Result	Interpretation
Description	Pale yellow crystalline powder	Characteristic appearance
Melting point	220–224 $^{\circ}\text{C}$	Within acceptable range
Bulk density	0.42 g/mL	Acceptable
Tapped density	0.51 g/mL	Acceptable
Carr's index	17.64%	Fair flow property
Hausner's ratio	1.21	Fair flow property
Angle of repose	28.6 $^{\circ}$	Good flow property
λ_{max}	269.6 nm	Suitable for UV estimation
Linearity range	2–12 $\mu\text{g/mL}$	Linear response
Calibration equation	$y = 0.078x + 0.006$	Used for drug estimation
Regression coefficient	$R^2 = 0.9991$	Excellent linearity

UV Analytical Method Validation: The UV analytical method showed acceptable linearity, accuracy, precision, specificity, and sensitivity for Norfloxacin estimation. No significant interference was observed from placebo polymeric solution at 269.6 nm.

TABLE 4: VALIDATION DATA FOR UV SPECTROPHOTOMETRIC ESTIMATION OF NORFLOXACIN

Validation parameter	Result	Interpretation
λ_{max}	269.6 nm	Suitable for Norfloxacin estimation
Linearity range	2–12 $\mu\text{g/mL}$	Linear response observed
Calibration equation	$y = 0.078x + 0.006$	Acceptable slope and intercept
Regression coefficient	$R^2 = 0.9991$	Excellent linearity
Accuracy at 80% level	$99.12 \pm 0.84\%$	Acceptable recovery
Accuracy at 100% level	$100.36 \pm 0.76\%$	Acceptable recovery
Accuracy at 120% level	$99.48 \pm 0.91\%$	Acceptable recovery
Intra-day precision	%RSD = 0.72	Precise
Inter-day precision	%RSD = 0.94	Precise
Specificity	No significant placebo interference	Specific for drug estimation
Robustness	%RSD = 1.08	Robust under minor variation
LOD	0.18 $\mu\text{g/mL}$	Sensitive method
LOQ	0.56 $\mu\text{g/mL}$	Suitable for quantification

FTIR Drug–Polymer Compatibility Study: FTIR analysis was performed to evaluate possible interaction between Norfloxacin and selected polymers. The major characteristic peaks of Norfloxacin were retained in the drug–polymer mixture without major disappearance or significant shift, suggesting absence of obvious chemical incompatibility under the tested conditions.

TABLE 5: FTIR PEAK ASSIGNMENT OF NORFLOXACIN AND DRUG–POLYMER MIXTURE

Functional group / vibration	Pure Norfloxacin peak cm^{-1}	Drug–polymer mixture peak cm^{-1}	Interpretation
O–H / N–H stretching	3422	3416	Broad peak retained
Aromatic C–H stretching	3064	3060	No major shift
Aliphatic C–H stretching	2924	2921	Retained
C=O stretching of carboxylic group	1718	1714	No significant shift
Quinoline ring C=C stretching	1624	1621	Retained

C–N stretching	1384	1381	Retained
C–F stretching	1268	1265	Retained
Aromatic ring bending	810	808	Retained

These findings indicate that the characteristic functional groups of Norfloxacin were preserved in the polymeric mixture. Therefore, no major drug–polymer interaction was observed by FTIR analysis. However, DSC analysis was not performed in the present study; therefore, compatibility findings should be considered preliminary and based only on FTIR interpretation.

Physical Appearance and Physicochemical Evaluation:

All prepared ocuserts were pale

yellow, smooth, flexible, and free from visible cracks or air bubbles. Physical appearance is an important parameter for ocular inserts because the formulation should be smooth and mechanically suitable for placement in the conjunctival sac. Thickness values ranged from 0.21 ± 0.01 mm to 0.27 ± 0.01 mm. Surface pH ranged from 7.0 ± 0.06 to 7.2 ± 0.09 , indicating that the formulations were close to physiological tear pH.

TABLE 6: PHYSICOCHEMICAL EVALUATION OF NORFLOXACIN OCUSERTS

Formulation	Thickness (mm)	Surface pH	Drug content (%)
F1	0.21 ± 0.01	7.0 ± 0.07	96.2 ± 0.8
F2	0.23 ± 0.02	7.1 ± 0.08	97.1 ± 0.7
F3	0.25 ± 0.01	7.0 ± 0.06	98.0 ± 0.6
F4	0.22 ± 0.01	7.2 ± 0.07	96.8 ± 0.7
F5	0.24 ± 0.02	7.1 ± 0.06	97.5 ± 0.6
F6	0.26 ± 0.01	7.0 ± 0.08	98.3 ± 0.5
F7	0.27 ± 0.01	7.1 ± 0.06	99.1 ± 0.4
F8	0.25 ± 0.02	7.2 ± 0.09	97.9 ± 0.6
F9	0.26 ± 0.01	7.1 ± 0.08	98.2 ± 0.5

Values are expressed as mean $\pm$ SD; n = 3.

Drug content ranged from $96.2 \pm 0.8\%$ to $99.1 \pm 0.4\%$, indicating uniform drug distribution within the polymeric matrix. F7 showed the highest drug content, suggesting efficient incorporation of Norfloxacin into the film. Surface pH values were close to physiological tear pH, suggesting acceptable pH compatibility. However, ocular safety cannot be confirmed by surface pH alone. Ocular irritation, HET-CAM, *ex-vivo*, or *in-vivo* tolerability studies are required before making safety-related claims.

Physical and Mechanical Evaluation:

All formulations showed acceptable physical integrity,

flexibility, and uniformity. The weight of the ocuserts increased gradually with increasing polymer concentration. Folding endurance values indicated sufficient mechanical strength for handling.

F7 showed the highest folding endurance, which may be attributed to higher HPMC concentration and suitable PEG 400 plasticizer content. Moisture absorption and moisture loss values remained within a moderate range, indicating acceptable moisture-handling properties without excessive hygroscopicity or brittleness.

TABLE 7: PHYSICAL AND MECHANICAL EVALUATION OF NORFLOXACIN OCUSERTS

Formulation	Weight variation (mg)	Folding endurance	Moisture absorption (%)	Moisture loss (%)
F1	42.6 ± 1.2	145 ± 5	5.82 ± 0.21	4.71 ± 0.18
F2	44.8 ± 1.4	158 ± 6	6.14 ± 0.25	4.96 ± 0.20
F3	47.3 ± 1.3	166 ± 7	6.58 ± 0.28	5.21 ± 0.22
F4	46.2 ± 1.5	172 ± 6	6.36 ± 0.24	5.08 ± 0.19
F5	49.1 ± 1.6	184 ± 8	6.92 ± 0.30	5.44 ± 0.23
F6	48.5 ± 1.4	178 ± 7	6.71 ± 0.27	5.31 ± 0.21
F7	52.4 ± 1.2	212 ± 9	7.28 ± 0.26	5.76 ± 0.18
F8	51.2 ± 1.5	196 ± 8	7.04 ± 0.29	5.61 ± 0.20
F9	50.8 ± 1.3	188 ± 7	6.88 ± 0.25	5.52 ± 0.19

Values are expressed as mean $\pm$ SD; n = 3.

In-vitro Drug Release Study: *In-vitro* drug release studies showed progressive release of Norfloxacin from all formulations over 150 minutes. F1 showed

the fastest release, with 78.4% cumulative release at 150 minutes, while F7 showed the slowest release, with 43.62% release at 150 minutes.

TABLE 8: IN-VITRO CUMULATIVE DRUG RELEASE PROFILE OF NORFLOXACIN OCUSERTS

Time (min)	F1 (%)	F2 (%)	F3 (%)	F4 (%)	F5 (%)	F6 (%)	F7 (%)	F8 (%)	F9 (%)
0	0	0	0	0	0	0	0	0	0
30	25.2	22.4	20.1	23.5	21.8	19.6	16.14	20.5	19.8
60	38.6	35.2	31.4	34.8	32.7	29.5	19.64	30.8	29.9
90	50.3	46.7	42.5	45.6	43.8	40.2	20.97	41.6	40.8
120	65.8	61.3	56.9	60.5	58.7	54.2	33.92	57.8	56.3
150	78.4	74.2	69.8	72.6	70.9	66.5	43.62	69.2	67.8

The slower release from F7 may be due to the higher HPMC concentration and balanced polymeric matrix formed with PVP K30 and sodium alginate. HPMC may have contributed to swelling and gel-layer formation, sodium alginate may have supported hydrated matrix formation, and PVP K30 may have modified the diffusion pathway within the film. However, since the release study was limited to 150 minutes, claims of prolonged, 8-hour, 12-hour, or 24-hour sustained ocular delivery cannot be made without extended release testing.

Selection of Optimized Formulation: F7 was selected as the optimized formulation based on combined laboratory criteria including film integrity, flexibility, acceptable thickness, surface pH close to physiological range, highest drug content, acceptable moisture behaviour, and comparatively slower *in-vitro* release without physical instability. F7 released 43.62% of

Norfloxacin at 150 minutes, indicating a slower release tendency under the tested *in-vitro* conditions. However, extended release testing is required to determine whether the remaining drug is released over a clinically meaningful period or retained within the polymeric matrix.

Release Kinetic Study of Optimized Formulation F7: Drug release kinetic analysis of F7 showed that the Higuchi model provided the best fit, with $R^2 = 0.991$. This indicates that drug release was mainly diffusion-controlled through the hydrated polymeric matrix during the tested period. The Korsmeyer–Peppas model also showed good fit, with $R^2 = 0.965$ and release exponent $n \approx 0.589$, suggesting anomalous or non-Fickian release involving both diffusion and polymer relaxation. Zero-order kinetics showed good correlation with $R^2 = 0.978$, but it was not superior to the Higuchi model. First-order release showed the lowest fit, with $R^2 = 0.912$.

TABLE 9: DRUG RELEASE KINETIC PROFILE OF OPTIMIZED FORMULATION F7

Kinetic model	R ² value	Interpretation
Zero-order	0.978	Good correlation; controlled-release tendency
First-order	0.912	Lower fit; release not mainly concentration-dependent
Higuchi model	0.991	Best fit; diffusion-controlled release
Korsmeyer–Peppas model	0.965	Good fit; $n \approx 0.589$ suggests anomalous/non-Fickian release

Sterility Observation: Sterility testing of optimized formulation F7 showed no visible

microbial growth in the tested media under laboratory conditions.

TABLE 10: STERILITY TESTING OBSERVATION OF OPTIMIZED FORMULATION F7

Medium	Incubation condition	Observation	Interpretation
Fluid thioglycollate medium	30–35°C for 14 days	No turbidity / no visible growth	No visible microbial growth
Soybean casein digest medium	20–25°C for 14 days	No turbidity / no visible growth	No visible microbial growth
Negative control	Same conditions	No growth	Valid negative control
Positive control	Same conditions	Visible growth observed	Valid positive control

The optimized formulation showed no visible microbial growth under the tested laboratory conditions. However, these findings should be

interpreted as preliminary sterility observations. Full validated pharmacopoeial sterility testing and

packaging validation are required before product-level or clinical interpretation.

Accelerated Stability Study: Accelerated stability testing of optimized formulation F7 was performed

at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and $75\% \pm 5\%$ RH for three months. Samples were evaluated initially and after 1, 2, and 3 months for physical appearance, drug content, and drug release at 150 minutes.

TABLE 11: ACCELERATED STABILITY DATA OF OPTIMIZED FORMULATION F7

Time interval	Physical appearance	Drug content (%)	Drug release at 150 min (%)	Overall observation
Initial	Pale yellow, smooth, flexible	99.10 ± 0.40	43.62 ± 1.15	Acceptable
1 month	Pale yellow, smooth, flexible	98.74 ± 0.46	43.28 ± 1.21	No major change
2 months	Pale yellow, smooth, flexible	98.21 ± 0.52	42.96 ± 1.18	No major change
3 months	Pale yellow, smooth, flexible	97.86 ± 0.58	42.51 ± 1.26	Stable under tested conditions

Values are expressed as mean $\pm$ SD; n = 3.

The optimized formulation F7 remained physically stable during the three-month accelerated stability study. No visible cracking, discoloration, or loss of flexibility was observed. Drug content decreased slightly from $99.10 \pm 0.40\%$ initially to $97.86 \pm 0.58\%$ after 3 months, while cumulative drug release at 150 minutes changed from $43.62 \pm 1.15\%$ to $42.51 \pm 1.26\%$. These changes were minimal under the tested conditions, suggesting acceptable short-term accelerated stability. However, long-term stability studies in final packaging are required before further product development.

DISCUSSION: The present laboratory-scale study demonstrated that Norfloxacin-loaded polymeric ocuserts could be successfully prepared using HPMC, PVP K30, and sodium alginate by the solvent casting method. The prepared ocuserts showed acceptable physical appearance, thickness, surface pH, drug content, mechanical strength, and moisture behaviour. The use of hydrophilic polymers contributed to formation of flexible films and influenced drug release behaviour.

The progressive release pattern observed in the present study may be attributed to hydration of the polymeric matrix followed by diffusion of Norfloxacin through the swollen polymer network. F7 showed the slowest release among the tested formulations, which may be due to higher HPMC concentration and formation of a more resistant hydrated matrix. The best fit of F7 to the Higuchi model supports diffusion-controlled release under the tested *in-vitro* conditions. Similar observations have been reported in earlier studies where polymeric ocular inserts and hydrophilic matrix systems demonstrated regulated release behavior⁴.

^{6, 10-12}. The formulation should be interpreted as a preliminary laboratory-scale ocular insert system. Although surface pH was close to physiological tear pH, ocular safety cannot be concluded without ocular irritation testing. Similarly, the term sustained or controlled ocular delivery should be used cautiously because the release study was limited to 150 minutes. *Ex-vivo* permeation, antimicrobial efficacy, ocular irritation, *in-vivo* residence time, mucoadhesion, packaging compatibility, validated sterility testing, and long-term stability studies are required before considering further clinical or product-level development.

CONCLUSION: Norfloxacin-loaded polymeric ocuserts were successfully developed using HPMC, PVP K30, and sodium alginate by the solvent casting method. Among the nine formulations, F7 showed the most suitable laboratory-scale profile based on physical integrity, thickness, folding endurance, surface pH, drug content uniformity, moisture behaviour, comparatively slower *in-vitro* drug release, Higuchi-based diffusion-controlled release, absence of visible microbial growth, and acceptable short-term accelerated stability.

The study supports F7 as a promising laboratory-scale formulation for further development. However, the formulation cannot yet be considered clinically validated. Extended release studies, *ex-vivo* corneal permeation, ocular irritation testing, antimicrobial efficacy, *in-vivo* residence-time assessment, packaging compatibility, validated pharmacopoeial sterility testing, and long-term stability studies are required before clinical or product-level interpretation.

ACKNOWLEDGEMENT: The authors express their sincere gratitude to the Department of Pharmaceutics, Maya Institute of Pharmacy, Hathras, Uttar Pradesh, India, for providing the necessary laboratory facilities, materials, instruments, and academic environment required to carry out this research work successfully. The authors are also thankful to the faculty members and technical staff of the department for their valuable cooperation, support, and timely assistance during the formulation and evaluation studies.

CONFLICTS OF INTEREST: The authors declare that they have no conflicts of interest.

REFERENCES:

- Gaudana R, Jwala J, Boddu SHS and Mitra AK: Recent perspectives in ocular drug delivery. *Pharm Res* 2009; 26(5): 1197-1216.
- Patel A, Cholkar K, Agrahari V and Mitra AK: Ocular drug delivery systems: an overview. *World J Pharmacol* 2013; 2(2): 47-64.
- Bachu RD, Chowdhury P, Al-Saedi ZHF, Karla PK and Boddu SHS: Ocular drug delivery barriers role of nanocarriers in the treatment of anterior segment ocular diseases. *Pharmaceutics* 2018; 10(1): 28.
- Agrahari V, Mandal A, Agrahari V, Trinh HM, Joseph M and Ray A: A comprehensive insight on ocular pharmacokinetics. *Drug Deliv Transl Res* 2016; 6(6): 735-754.
- Kumari A, Sharma PK, Garg VK and Garg G: Ocular inserts advancement in therapy of eye diseases. *J Adv Pharm Technol Res* 2010; 1(3): 291-296.
- Karthikeyan D, Bhowmik D, Gopinath H and Kumar BP: The concept of ocular inserts as drug delivery systems: an overview. *Asian J Pharm* 2008; 2(4): 192-200.
- Liu Z, Li J, Nie S, Liu H, Ding P and Pan W: Study of an alginate/HPMC based in situ gelling ophthalmic delivery system for gatifloxacin. *Int J Pharm* 2006; 315(1-2): 12-17.
- Upadhyay P, Kumar M and Pathak K: Norfloxacin loaded pH triggered nanoparticulate in-situ gel for extraocular bacterial infections: optimization, ocular irritancy and corneal toxicity. *Iran J Pharm Res* 2016; 15(1): 3-22.
- Higuchi T: Mechanism of sustained-action medication: theoretical analysis of rate of release of solid drugs dispersed in solid matrices. *J Pharm Sci* 1963; 52(12): 1145-1149.
- Korsmeyer RW, Gurny R, Doelker E, Buri P and Peppas NA: Mechanisms of solute release from porous hydrophilic polymers. *Int J Pharm* 1983; 15(1): 25-35.
- Khurana G, Arora S and Pawar PK: Ocular insert for sustained delivery of gatifloxacin sesquihydrate. *Int J Pharm Investig* 2012; 2(2): 70-77.
- Gupta B, Thakur N, Jain NP, Banweer J and Jain S: Cellulosic polymers for enhancing drug bioavailability in ocular drug delivery systems. *Pharmaceutics* 2021; 14(11): 1201.

How to cite this article:

Priyanka KM, Kumar Y and Yadav R: Laboratory-scale development and *in-vitro* evaluation of norfloxacin-loaded polymeric ocuserts prepared by solvent casting method. *Int J Pharm Sci & Res* 2026; 17(10): 3036-44. doi: 10.13040/IJPSR.0975-8232.17(10).3036-44.

All © 2026 are reserved by International Journal of Pharmaceutical Sciences and Research. This Journal licensed under a Creative Commons Attribution-NonCommercial-ShareAlike 3.0 Unported License.

This article can be downloaded to **Android OS** based mobile. Scan QR Code using Code/Bar Scanner from your mobile. (Scanners are available on Google Playstore)