ISSN: 3049-8074

Research Article

Journal of Clinical Medicine & Health Care

Formulation & Characterisation of Sulfacetamide Sodium Ophthalmic Gel

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Received: March 01, 2025; **Accepted:** March 11, 2025; **Published:** March 14, 2025

ABSTRACT

The present study focuses on the formulation and characterization of an ophthalmic gel containing Sulphacetamide Sodium, a sulfonamide antibiotic, to enhance its ocular retention time and bioavailability. Sulphacetamide Sodium is conventionally used as eye drops, which suffer from rapid elimination and poor therapeutic efficacy. To overcome this limitation, ophthalmic gels were formulated using different polymers, including Hydroxypropyl Methylcellulose (HPMC) K100, Carbopol, and Sodium Alginate, both individually and in combination. The compatibility of the drug with excipients was confirmed through FT-IR studies. The prepared gels exhibited clarity, a pH close to 7.4, and drug content within acceptable limits. Antimicrobial efficacy was demonstrated by zones of inhibition, and all formulations passed sterility testing. Among the various formulations, F4, containing HPMC K100 and Carbopol at 0.5% each, exhibited an optimized drug release of 99.75% by the end of six hours. The study concludes that the combination of HPMC K100 and Carbopol is optimal for sustaining drug release over six hours, making it a promising formulation for improved ocular drug delivery.

Keywords: Ophthalmic Gel, Sulphacetamide sodium, Sustained Drug Release, HPMC K100 and Carbopol

Introduction

Ophthalmic drug delivery presents significant challenges due to the unique anatomical and physiological barriers of the eye, which limit drug absorption and retention [1]. Sulphacetamide sodium, a sulfonamide antibiotic, is commonly used in the treatment of bacterial eye infections, typically administered as eye drops. However, conventional eye drops suffer from rapid elimination due to tear turnover, blinking, and nasolacrimal drainage, leading to poor bioavailability and frequent dosing requirements [2]. This frequent administration can reduce patient compliance and therapeutic effectiveness [3].

To address these limitations, ophthalmic gels have been explored as an alternative drug delivery system. Gels provide increased ocular retention time, sustained drug release, and improved therapeutic outcomes by enhancing drug contact with the ocular surface [4]. The present study focuses on the formulation and characterization of ophthalmic gels containing sulphacetamide sodium, utilizing different polymers-Hydroxypropyl Methylcellulose (HPMC) K100, Carbopol, and Sodium Alginate-individually and in combination, to achieve controlled and prolonged drug release [5].

The formulations were evaluated for physicochemical properties, sterility, antimicrobial activity, and in vitro drug release profiles. Among the various formulations studied, the combination of HPMC K100 and Carbopol at 0.5% each demonstrated optimized drug release over six hours, suggesting its potential as an effective ophthalmic gel formulation for enhanced ocular drug delivery [6]. This research aims to contribute to the development of an improved ophthalmic gel system that enhances patient compliance and therapeutic efficacy for bacterial eye infections [7].

Materials and Methods

Materials

Sulfacetamide sodium was obtained from Cipla Limited, Mumbai, India. Sodium chloride, hydrochloric acid, and purified water were sourced from Merck Life Science Pvt. Ltd., India. The gelling agent, Carbopol 934, was procured from Lubrizol Advanced Materials, USA. All other excipients, including preservatives and stabilizers, were of commercial grade and sourced from reputable suppliers such as Sigma-Aldrich, USA, and Thermo Fisher Scientific, USA. All excipients used were of high pharmaceutical grade and were procured from authorized suppliers to ensure the quality and consistency of the formulation.

Citation: Vaseem Unnisa, Lakshmana Rao A, Naga Ramya Sree K, Mani Sankar K, Sri Divya K, et al. Formulation & Characterisation of Sulfacetamide Sodium Ophthalmic Gel . J Clin Med Health Care. 2025. 2(1): 1-6. DOI: doi.org/10.61440/JCMHC.2025.v2.16

Methodology

Determination of λmax of Sulfacetamide Sodium: To determine the λmax of Sulfacetamide sodium, 10 mg of Sulfacetamide sodium was dissolved in a few milliliters of distilled water. The solution was diluted suitably to obtain an absorbance in the range of 0-1. The solution was then scanned at wavelengths ranging from 200 nm to 400 nm using a UV-Visible Spectrophotometer to determine the λmax.

Preparation of Phosphate Buffer pH 7.4: A phosphate buffer with a pH of 7.4 was prepared by mixing 39.1 mL of 0.2 M sodium hydroxide (8 g in 1000 mL water) with 50 mL of 0.2 M potassium dihydrogen phosphate (27.218 g in 1000 mL water). The mixture was then diluted to a final volume of 200 mL with distilled water to achieve a phosphate buffer of pH 7.4.

Calibration Curve of Sulfacetamide Sodium in Phosphate Buffer pH 7.4: A primary stock solution was prepared by dissolving 100 mg of Sulfacetamide sodium in sodium hydroxide in a 100 mL volumetric flask and making the volume up to 100 mL with phosphate buffer. From this stock solution, 10 mL was transferred to another volumetric flask and diluted up to 100 mL with phosphate buffer to obtain a secondary stock solution. The secondary stock solution was then diluted further to produce concentrations of 2, 4, 6, 8, and 10 µg/mL. The absorbance of these solutions was measured at 256 nm using a UV-Visible Spectrophotometer.

Drug-Excipient Compatibility Study: To assess the compatibility of Sulfacetamide sodium with the excipients, physical mixtures of the drug and excipients were prepared in predetermined ratios. Fourier Transform Infrared (FTIR) spectroscopy was conducted to identify any potential interactions between Sulfacetamide sodium and the excipients. The absence of any new peaks or significant shifts in the spectra suggested that the excipients were compatible with Sulfacetamide sodium.

Preparation of Gels: The required quantities of polymers were separately weighed and kept for swelling overnight in distilled water. The polymers were dissolved (heated if necessary) using a magnetic stirrer. An aqueous solution of Sulfacetamide sodium was then added to the polymeric solution with continuous stirring. Benzalkonium chloride was added to the resulting solution as a preservative. The pH of the gel was adjusted to 7.4 using 0.1 N sodium hydroxide or 0.1 N hydrochloric acid. The gel formulations are presented in Table 1.

Table 1: Formulation of Gels with Individual Polymers

Formulation	F1	F2	F3	F4	F5	F6
Sulfacetamide sodium (g)	15	15	15	15	15	15
HPMC K100 (g)	-	1	-	0.5	-	0.5
Carbopol (g)	1	-	-	0.5	0.5	-
Sodium Alginate (g)	-	-	1	-	0.5	0.5
Benzalkonium Chloride (g)	0.02	0.02	0.02	0.02	0.02	0.02
Water (q.s)	100 mL	100 mL	100 mL	100 mL	100 mL	100 mL

Sterilization of Ophthalmic Formulation: Once prepared, the ophthalmic gel formulations were sterilized by autoclaving at 121°C for 15 minutes. After sterilization, the formulations were stored in aseptic conditions until use.

Evaluation

The following tests were conducted to evaluate the prepared ophthalmic gels:

Clarity Test: Each formulation was visually inspected for clarity. The formulations were observed under good lighting and placed against both a black and white background. A swirling motion was applied to check for any visible particulates or cloudiness.

pH Determination: The pH of each formulation was measured using a digital pH meter, which was calibrated with pH 4 and pH 7 buffers. The pH was recorded immediately after preparation.

Determination of Percent Drug Content: To determine the drug content, accurately weighed quantities of the gel equivalent to 30 mg of Sulfacetamide sodium were added to 100 mL of distilled water in stoppered conical flasks. The solution was filtered and diluted appropriately, and the drug content was assayed using a UV-Vis spectrophotometer at 256 nm. The amount of drug was calculated using the following formula:

$$\text{Amount of drug} = \frac{\text{Concentration X dilution factor X volume of dissolution}}{1000}$$

$$\text{Percent drug content} = \left(\frac{\text{Actual amount present}}{\text{Amount expected}}\right) \times 100$$

In-Vitro Drug Diffusion Study: In-vitro drug release studies were conducted using a Franz diffusion cell apparatus. An egg membrane, isolated by placing it in dilute HCl, was used to study the in-vitro diffusion of the formulations. The receptor chamber was filled with freshly prepared phosphate buffer (pH 7.4), and the donor compartment was loaded with 1 g of the formulation. Aliquots of the receptor medium were withdrawn at specific time intervals and replenished with fresh medium. The drug content in the aliquots was measured spectrophotometrically.

Sterility Test: The sterility of the formulation was evaluated using three sets of agar media. The first set served as a negative control, using sterile media. The second set was the positive control, inoculated with Staphylococcus aureus. The third set was the test, containing 1 g of the sterile optimized formulation. The formulation was diluted with 100 mL of sterile water for injection, and 10 mL of the test solution was added to each medium. The samples were incubated at 20-25°C for 14 days. The absence of bacterial growth indicated the sterility of the formulation.

Anti Bacterial Activity: The antibacterial activity of the formulations was determined using the agar diffusion method. Standard Petri dishes containing medium to a depth of 0.5 cm were prepared. The inoculum (0.5 mL) was spread over the surface of the agar, and the plates were dried at 35°C for 15 minutes before placing the formulation. Bores of 0.5 cm in diameter were created, and 100 mg of the formulation was added to the bores. After incubation at 35°C for 24 hours, the zone of inhibition around each bore was measured.

Results and Discussion

Absorption maximum of Sulfacetamide Sodium

Absorption maximum of Sulfacetamide Sodium pure sample was found to be at 256nm using UV-visible spectrophotometer

Construction of calibration curve of Sulfacetamide Sodium

The data standard graph of Sulfacetamide Sodium has shown good linearity over a concentration range of 0-10µg/ml with R2 value of 0.997. The equation was y =0.063x. This was utilized in the estimation of Sulfacetamide Sodium samples.

Table 2: Absorbance Values of Sulfacetamide Sodium

Concentration (µg/ml)	Absorbance
0	0
2	0.089
4	0.238
6	0.362
8	0.486
10	0.604

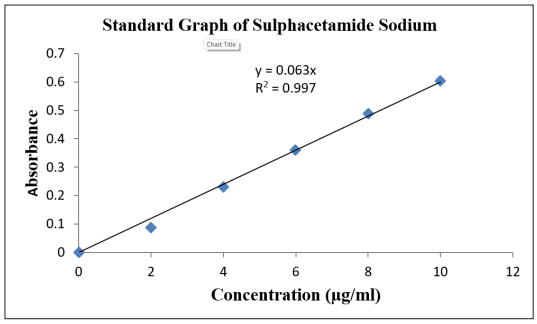

Figure 1: Standard Graph of Sulfacetamide Sodium

Drug Excipient Compatability-FTIR Spectroscopy

The functional groups present in the drug were identified. The FTIR of Sulfacetamide sodium showed intense bands at 3379cm-1, 1736cm-1, 1226cm-1, 1592cm-1 and 823cm-1 corresponding to the functional groups NH, C=O, C=H Stretching in Benzene, C-N, C=C Stretching and C=C Bending respectively. The wavenumbers of drug were compared with the IR spectrum of drug with polymers. The resulted peaks observed in FTIR are presented in Table No.17. The FTIR spectra of Sulfacetamide, Sulfacetamide with polymer mixture were given in Figure 2 and Figure 3.

The results revealed that there was no significant disturbance in the principle peaks of pure drug Sulfacetamide. From the interpretation it was understood that there was no major shifting in the frequencies of Sulfacetamide which indicated that there is no chemical interaction in the formulations. This further confirms the integrity of pure drug and compatability of it with Excipients.

Table 3: Principle IR Peaks of Sulfacetamide Sodium

Drug	Drug + Polymers	Functional group
3371	3379	Amine (NH)
1743	1736	C=O
3265	2912	C-H Stretching in Benzene
1264	1226	C-N
1591	1592	C=C Stretching
816	823	C=C Bending

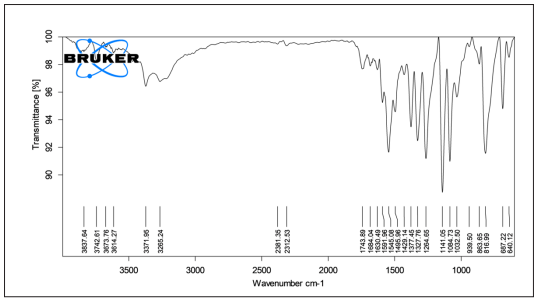

Figure 2: FTIR of Sulfacetamide Sodium

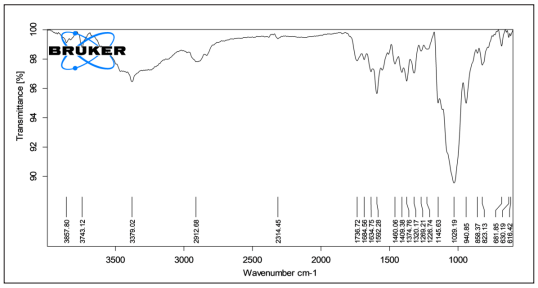

Figure 3: FTIR of Sulfacetamide Sodium with Polymers

Evaluation of Ophthalmic Gel Formulation

Clarity: On careful visual inspection against dark and white background, all the prepared ophthalmic gel formulations were found to be free from any suspended particulate matter.

Table 4: Appearance of the Formulations

S. No	Formulation code	Appearance
1.	F1	Clear
2.	F2	Clear
3.	F3	Clear
4.	F4	Clear
5.	F5	Clear
6.	F6	Clear

pH Determination: The pH of the prepared gels was found to be in the range of 7.40-7.64 with a standard deviation of 0.025 to 0.197. All the formulations have shown a pH with not much deviation.

Table 5: pH of the Formulations

S. No	Formulation code	Observed pH (±S.D.)
1	F1	7.53±0.025
2	F2	7.46±0.134
3	F3	7.56±0.178
4	F4	7.44±0.197
5	F5	7.64±0.115
6	F6	7.40±0.145

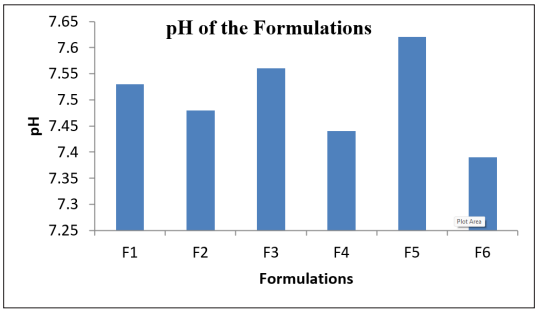

Figure 4: pH of the Formulation

Drug Content of Sulfacetamide Sodium: The drug content of the prepared gels was found to be in the range 96-99 indicating the application of the present method for the preparation of gels with high content uniformity.

Table 6: Drug Content of Sulfacetamide Sodium

Formula	Drug/Polymer (w/w)	Assay
F1	Sulfacetamide Sodium /Carbopol	97.63 ± 0.91
F2	Sulfacetamide Sodium /HPMC K100	96.02 ± 0.24
F3	Sulfacetamide Sodium / Sodium Alginate	98.35 ± 1.47
F4	Sulfacetamide Sodium /Carbopol/ HPMC K100	95.18 ± 0.37
F5	Sulfacetamide Sodium / Carbopol/ Sodium Alginate	99.34±0.27
F6	Sulfacetamide Sodium / HPMC K100 / Sodium Alginate	98.33±0.36

In-Vitro Drug Diffusion Study: From the in vitro results it was observed that percentage release of the drug from the developed formulations F1 (91.49%), F2 (66.87%), F3 (78.97%), F4 (99.75%), F5 (59.83%), and F6 (63.50%) as shown in Table 7.

Out of the formulations containing 1% of polymer, by the end of six hours, formulation F1 with carbopol as polymer has shown good release characteristics than those with HPMC K 100 and Sodium alginate.

When the combination of polymers were used, the F5 containing Carbopol and Sodium alginate each at 0.5% and F6 formulation containing HPMC K 100 and Sodium alginate each at 0.5% have shown a decrease in drug release may be due to hindrance of release by interaction of two polymers used in combination.

The formulation F4 containing HPMC K 100 and Carbopol each at 0.5% as polymer has shown a release of 99.75% by the end of 6th hour. Thus it is considered as optimised formulation as it has shown maximum drug release by the end of six hours.

Table 7: Cumulative Percentage of Drug Release

Time (hrs)	Cumulative % drug released					
	F1	F2	F3	F4	F5	F6
0.5	21.60±0.84	17.21±0.62	19.14±1.43	24.14±1.30	12.60±1.08	14.06±0.99
1	34.71±0.61	26.01±0.30	31.30±0.58	46.96±3.28	21.46±0.79	19.31±1.39
2	45.52±1.07	36.17±0.64	40.98±1.35	62.37±1.57	29.41±0.53	30.7±0.52
3	51.84±0.96	44.53±0.94	47.32±2.27	72.01±2.43	37.21±0.73	39.96±0.63
4	69.51±0.96	54.58±0.88	61.18±1.28	88.71±1.28	45.90±0.57	46.71±1.13
5	82.88±1.45	59.66±0.93	69.84±0.43	92.52±1.12	47.35±0.40	52.66±0.97
6	91.49±0.84	66.87±0.91	78.97±1.17	99.75±1.13	59.83±1.79	63.50±1.17

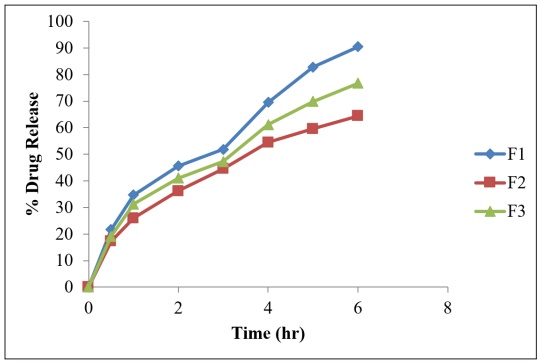

Figure 5: Drug Release of F1-F3 Formulations

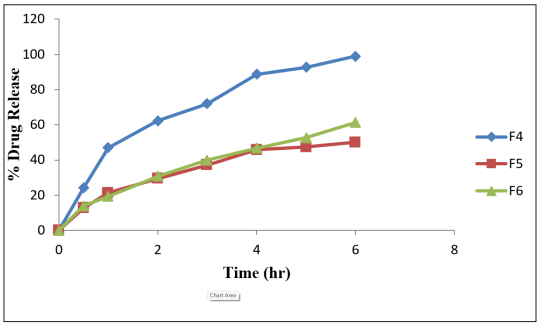

Figure 6: Drug Release of F4-F6 Formulations

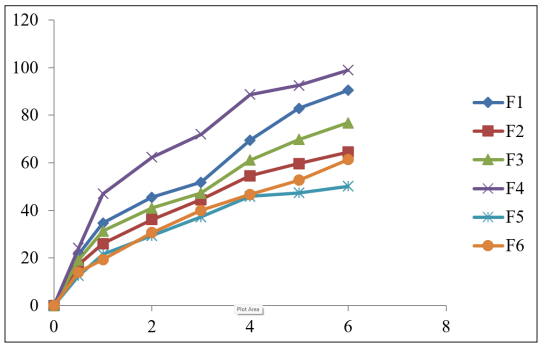

Figure 7: Cumulative Drug Release of F1-F6 Formulations

Sterility Test: The formulations showed no evidence of microbial growth when incubated for more than 7 days and cleared the sterility test.

Table 8: Sterility Test Data of Prepared in Situ Gels

Formulation	Days of incubation					
	1	2	3	4	5	6
F1	-	-	-	-	-	-
F2	-	-	-	-	-	-
F3	-	-	-	-	-	-
F4	-	-	-	-	-	-
F5	-	-	-	-	-	-
F6	-	-	-	-	-	-

*-ve sign indicates no growth.

Antibacterial Activity: Antimicrobial efficacy study was performed on formulations using Gram +ve S. aureus and Gram -ve E. coli organism. Clear zones showing inhibited zone of growth were observed. The zone of inhibition of the formulations were shown in the Table 10. The study indicated Sulfacetamide Sodium retained its antimicrobial activity when formulated as gel forming ophthalmic system against both selected S. aureus and E. coli.

Table 9: Zone of Inhibition of Prepared in Situ Gels

Microorganism	Zone of Inhibition(mm)						
	Standard (Pure Drug)	F1	F2	F3	F4	F5	F6
S. aureus	29	28	28	27.5	25.5	28.5	26
E. coli.	30	27.5	28.5	29.5	27.5	28	27.5

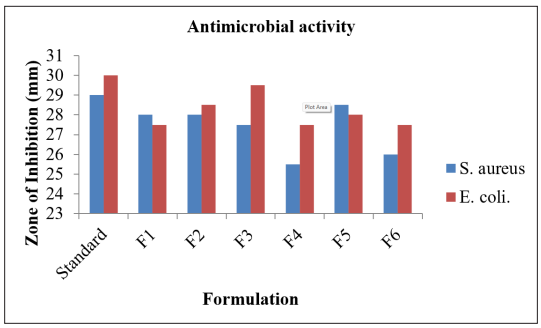

Figure 8: Zone of Inhibition of Prepared in Situ Gels

Discussion

In this study, the absorption maximum (λmax) of Sulfacetamide Sodium was determined to be at 256 nm using UV-visible spectrophotometry, which aligns with literature values for Sulfacetamide Sodium. The calibration curve constructed over the concentration range of 0-10 µg/ml exhibited excellent linearity ($R^2 = 0.997$), confirming the reliability and accuracy of the UV method for drug quantification. FTIR studies indicated no significant interactions between the drug and the excipients (Carbopol, HPMC K100, Sodium Alginate), as evidenced by the absence of shifts in the characteristic peaks of the drug. This suggests that the excipients used in the formulations are compatible with Sulfacetamide Sodium, supporting the integrity and stability of the drug in the formulations.

The physical evaluation of the formulations revealed that all gels were clear, with no particulate matter, and had pH values ranging from 7.40 to 7.64, making them suitable for ocular use. The drug content in the formulations was consistent, ranging from 96.02% to 99.34%, ensuring uniformity and accurate dosing. The in-vitro drug release study showed that formulation F4 (containing Carbopol and HPMC K100) exhibited the highest cumulative drug release (99.75%) at the 6-hour mark, suggesting that this formulation provides an optimal balance of gel formation and drug release. Other formulations, especially those containing combinations of polymers (F5 and F6), displayed slower drug release, which could be attributed to the gel network's increased viscosity and possible interactions between the polymers.

Conclusion

The results from this study demonstrate that Sulfacetamide Sodium ophthalmic gel formulations exhibit promising characteristics for effective ocular drug delivery. Formulation F4, containing Carbopol and HPMC K100, stands out as the optimal formulation due to its high drug release (99.75%) within 6 hours, indicating its potential for sustained ocular delivery. The drug's antimicrobial activity against both S. aureus and E. coli, combined with the formulations' sterility and uniform drug content, further supports their suitability for ocular therapy. The compatibility of Sulfacetamide Sodium with commonly used excipients ensures the stability and safety of these formulations. Overall, these ophthalmic gels offer a reliable, controlled drug delivery system for treating ocular infections, providing both efficacy and safety for patients.

Conflict of Interests

The authors declared no conflicts of interest.

Acknowledgements

Authors would like to express their gratitude to V. V. Institute of Pharmaceutical Sciences, Gudlavalleru, for offering essential facilities and resources to conduct this research.

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