

Design, Optimization, and Evaluation of Moxifloxacin Nanosuspension

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Abstract: *The present study aimed to develop, optimize, and evaluate a Moxifloxacin nanosuspension to enhance its solubility, stability, and controlled release profile. A preformulation study was conducted, assessing organoleptic properties, melting point, solubility, UV absorption characteristics, and drug-excipient compatibility via FTIR, confirming the purity and suitability of Moxifloxacin for nanosuspension formulation. The nanosuspension was prepared by the solvent diffusion method using ethanol as the organic phase and an aqueous phase containing Pluronic, Polysorbate 80, and Benzalkonium chloride as stabilizers. Various formulations (F1–F9) were prepared and evaluated for pH, viscosity, drug content, particle size, polydispersity index (PDI), and zeta potential. All formulations displayed acceptable pH (6.82–6.90) and viscosity (14.8–16.4 cP), with drug content ranging from 93.5% to 99.5%, indicating high encapsulation efficiency. F7 was identified as the optimized formulation due to its highest drug content (99.5%) and balanced physicochemical properties. In vitro drug release studies demonstrated a sustained release pattern, suggesting prolonged drug availability. Stability studies conducted under ICH conditions over three months confirmed the formulation's stability without significant changes in critical quality attributes. Overall, the developed nanosuspension exhibits promising potential for improved therapeutic delivery of Moxifloxacin, suitable for topical or systemic administration.*

Keywords: *Moxifloxacin, nanosuspension, solvent diffusion, controlled release, particle size, zeta potential, in vitro release, stability study*

I. INTRODUCTION

Moxifloxacin, a fourth-generation fluoroquinolone antibiotic, exhibits broad-spectrum activity against a variety of Gram-positive and Gram-negative bacteria, making it widely employed in the treatment of respiratory, ophthalmic, and skin infections. Despite its potent antibacterial efficacy, Moxifloxacin is characterized by limited aqueous solubility, which may result in suboptimal bioavailability and therapeutic performance when administered in conventional dosage forms.[1,2] This poses significant challenges in achieving and maintaining effective drug concentrations at the target site, necessitating frequent dosing and potentially leading to patient non-compliance.

Nanosuspension technology has emerged as a promising strategy to overcome solubility and dissolution limitations of poorly water-soluble drugs. Nanosuspensions are colloidal dispersions consisting of pure drug nanoparticles stabilized by suitable surfactants or polymers. By reducing the particle size to the nanometer range, nanosuspensions significantly enhance the surface area, thereby improving the dissolution rate and absorption of the drug. Additionally, they offer advantages such as improved bioavailability, reduced dose frequency, and the potential for controlled drug release.[3,4] The solvent diffusion method is one of the most efficient techniques for nanosuspension preparation, facilitating spontaneous formation of nanosized particles through rapid diffusion of a water-miscible organic phase into an aqueous medium under controlled conditions. The selection of appropriate stabilizers plays a critical role in ensuring uniform particle distribution and preventing aggregation.[5]

In this study, an attempt was made to formulate and optimize a Moxifloxacin nanosuspension using the solvent diffusion technique, employing Pluronic and Polysorbate 80 as stabilizers along with Benzalkonium chloride for additional stabilization. The prepared nanosuspensions were evaluated for key parameters such as particle size, polydispersity index (PDI), zeta potential, pH, viscosity, drug content, and in vitro release behavior. Furthermore,



stability studies were conducted under various storage conditions following ICH guidelines to assess the long-term integrity of the formulations. This work aims to develop a robust nanosuspension system capable of enhancing the solubility, stability, and controlled release of Moxifloxacin, thereby improving its therapeutic effectiveness and patient compliance.[6]

II. MATERIALS AND METHODS

The pre-formulation study of Moxifloxacin nanosuspension involved evaluating its organoleptic properties, including color, odor, and appearance, through visual inspection to confirm its identity and quality. The melting point was determined using the capillary tube method with a digital apparatus, aiding in assessing drug purity. Solubility studies were carried out in various solvents by the shake-flask method to support formulation design. UV spectroscopic analysis was performed to determine the characteristic absorption and λ max of Moxifloxacin, followed by constructing a standard calibration curve to establish linearity between concentration and absorbance. Drug-excipient compatibility was evaluated using FTIR spectroscopy, ensuring no significant interactions that could affect formulation stability, with FTIR also confirming the presence of key functional groups in Moxifloxacin. This comprehensive pre-formulation analysis provided essential data for developing a stable and effective nanosuspension.

The nanosuspension of Moxifloxacin was prepared by the solvent diffusion method, where the drug was first dissolved in ethanol to form the organic phase. Separately, the aqueous phase was prepared by dissolving stabilizers such as Pluronic, Polysorbate 80, and Benzalkonium chloride in distilled water. The organic phase was then added dropwise into the aqueous phase under high-speed homogenization, leading to rapid solvent diffusion and spontaneous precipitation of nanosized drug particles. This dispersion was further sonicated to reduce particle size and ensure uniformity. The resulting nanosuspension was subjected to solvent evaporation under reduced pressure to eliminate residual solvent and then stored under controlled conditions for subsequent evaluation.[7,8]

Table 1: Composition of formulation

Materials	F1	F2	F3	F4	F5	F6	F7	F8	F9
Moxifloxacin	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Polymer	1.0	1.0	1.0	0.15	0.15	0.15	0.2	0.2	0.2
Plb 80	0.3	0.4	0.5	0.3	0.4	0.5	0.3	0.4	0.5
Benz chlo	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%
D. water	Q.s	Q.s	Q.s	Q.s	Q.s	Q.s	Q.s	Q.s	Q.s

The prepared Moxifloxacin nanosuspension was characterized to ensure its quality, stability, and performance. Particle size and polydispersity index (PDI) were measured by dynamic light scattering (DLS), revealing the size distribution and homogeneity, where a lower PDI indicated uniform particles. Zeta potential analysis determined the surface charge, with values beyond ± 30 mV suggesting good electrostatic stability, minimizing aggregation risks. The pH was recorded using a digital pH meter to confirm physiological compatibility. Viscosity measurements were performed with a Brookfield viscometer to assess the formulation's flow behavior, crucial for ease of administration and shelf-life. In vitro drug release studies employed the dialysis membrane method, tracking the sustained release profile over time. Finally, a stability study following ICH guidelines evaluated the formulations under refrigerated, room temperature, and accelerated conditions for three months. Regular assessments of particle size, PDI, zeta potential, pH, viscosity, drug content, and release behavior ensured detection of any significant changes, helping establish the nanosuspension's optimal storage conditions and projected shelf life.[9-14]

III. RESULT AND DISCUSSION

The preformulation and formulation evaluation of Moxifloxacin nanosuspensions demonstrated promising outcomes. The organoleptic assessment confirmed that all formulations (F1–F9) were consistently white, odorless, and crystalline, with melting points around 240 °C, indicating the purity and integrity of the drug substance. The physicochemical evaluations revealed that the pH of all nanosuspensions remained within a narrow and acceptable range (6.82–6.90), suggesting compatibility with physiological conditions and minimizing the risk of irritation upon administration. The



viscosity values, ranging from 14.8 to 16.4 cP, indicated suitable flow properties that facilitate ease of handling and administration. Drug content analysis showed high encapsulation efficiency, with values between 93.5% and 99.5%, highlighting the successful incorporation of Moxifloxacin into the nanosuspensions without significant loss. Among the batches, F7 exhibited the highest drug content (99.5%) with optimal viscosity and pH, suggesting its potential as a stable formulation. The in vitro drug release profile demonstrated a sustained release behavior, ensuring prolonged availability of the drug, which is advantageous for maintaining therapeutic concentrations over time. Overall, these findings indicate that the developed nanosuspension formulations possess desirable physicochemical properties and controlled release profiles, making them promising candidates for effective topical or systemic delivery of Moxifloxacin.

Table 1: Organoleptic Properties of Moxifloxacin

Formulation	Color	Odor	Appearance	Melting Point (°C)
F1	White	Odorless	Crystalline	240.2
F2	White	Odorless	Crystalline	240.5
F3	White	Odorless	Crystalline	240.0
F4	White	Odorless	Crystalline	239.8
F5	White	Odorless	Crystalline	240.1
F6	White	Odorless	Crystalline	240.3
F7	White	Odorless	Crystalline	239.9
F8	White	Odorless	Crystalline	240.4
F9	White	Odorless	Crystalline	240.2

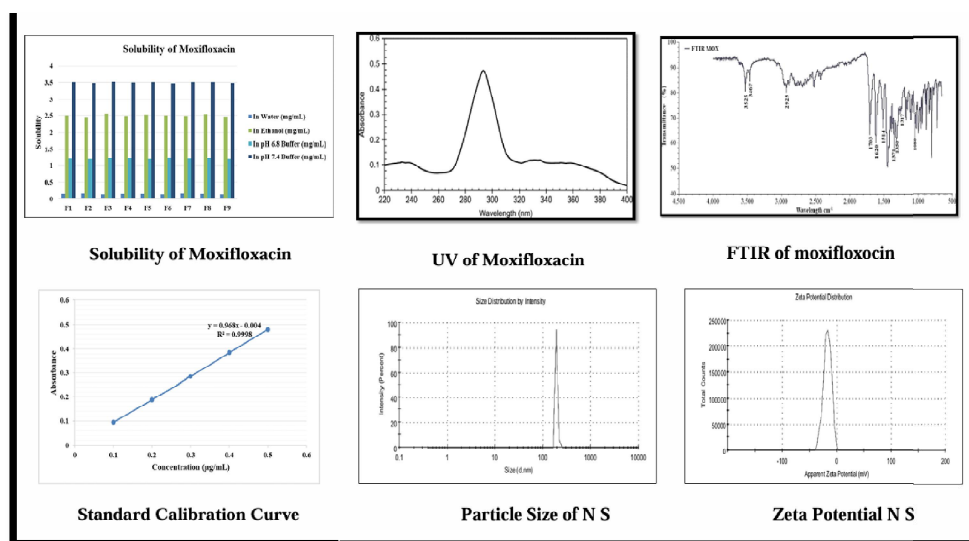


Fig 1 Evaluation of drug and formulation



Table 2: Evaluation of formulation

Formulation	pH	Viscosity (cP)	Drug Content (%)
F1	6.85	15.2	98.5
F2	6.88	16.4	97.0
F3	6.90	14.8	95.0
F4	6.84	15.1	99.0
F5	6.87	14.9	97.5
F6	6.86	16.0	94.0
F7	6.89	15.5	99.5
F8	6.82	15.3	96.8
F9	6.85	16.2	93.5

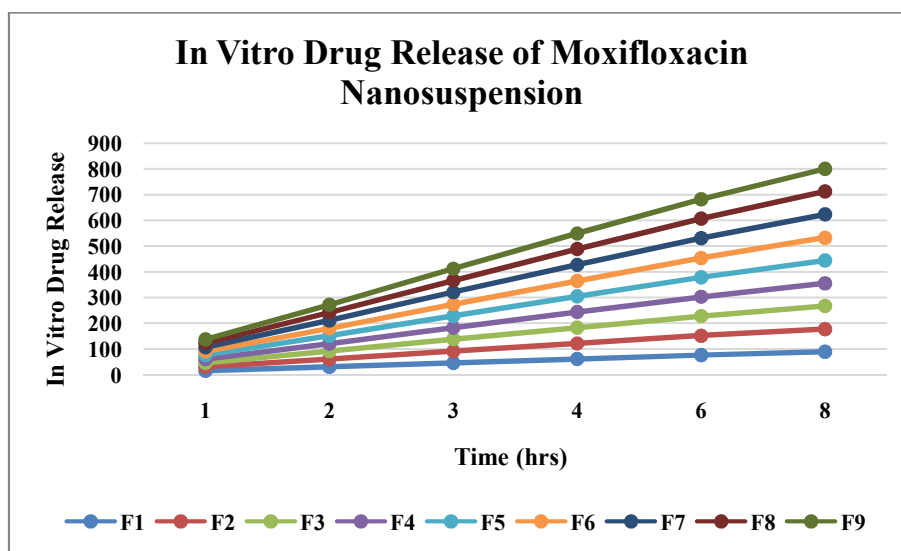


Fig 2: In Vitro Drug Release of Moxifloxacin Nanosuspension

IV. CONCLUSION

The study successfully designed and optimized a Moxifloxacin nanosuspension using the solvent diffusion method, achieving nanosized, stable formulations with high drug content and desirable physicochemical characteristics. Among the tested batches, formulation F7 demonstrated optimal properties, including high encapsulation efficiency, appropriate viscosity, and sustained drug release, indicating its potential to enhance the bioavailability and therapeutic performance of Moxifloxacin. The stability study further validated the robustness of the formulation under various storage conditions, highlighting its suitability for future pharmaceutical applications. This nanosuspension system thus offers a promising approach for the effective delivery of Moxifloxacin in the treatment of bacterial infections.

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