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# A RESEARCH ARTICLE ON FORMULATION AND EVALUATION OF POLYMERIC NANOPARTICLES LOADED IN HYDROGEL FOR OPTIMUM ANTIFUNGAL PURPOSE

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**ABSTRACT**
*Miconazole nitrate-loaded chitosan nanoparticles were prepared by the ionotropic gelation method. The nanoparticles were characterized for percentage yield, drug entrapment efficiency, particle size, and zeta potential. The optimized nanoparticles (Formulation F2) were then incorporated into a Carbopol 934 gel base (Formulations GF1, GF2, GF3). The prepared gels were evaluated for pH, spreadability, viscosity, drug content, extrudability, and in vitro drug release kinetics. The percentage yield of the nanoparticle formulations ranged from 63.12±0.14% to 75.65±0.32%. Drug entrapment efficiency was between 63.32% and 73.23% w/w. The optimized nanoparticle formulation F2 exhibited the maximum percentage yield (75.65±0.32%) and entrapment efficiency (73.23±0.45%), with a mean particle size of 85.6 nm and a zeta potential of −36.2 mV. The prepared gels showed acceptable pH values (6.85-7.02). Viscosity was found to be 4568±13 cps for GF1, 4251±11 cps for GF2, and 3978±14 cps for GF3. In vitro drug release from the optimized gel formulation, GF2, was sustained, reaching 98.85% in 12 hours. The drug release followed the Korsemeyer-Peppas kinetic model (R2=0.986). The Miconazole-loaded chitosan nanoparticles were successfully formulated and incorporated into a gel base, resulting in an optimized topical formulation (GF2) with suitable physicochemical properties for skin application. The formulation achieved sustained and controlled drug release, demonstrating its potential as an effective topical preparation for antifungal effects.*
**KEY WORDS:** *Miconazole; Nanoparticle; Gel formulation; Controlled drug release.*

## 1. INTRODUCTION

### 1.1. Transdermal Drug Delivery System (TDDS)

Transdermal drug delivery system (TDDS) showed promising result in comparison to oral drug delivery system as it eliminates gastrointestinal interferences and first pass metabolism of the drug but the main drawback of TDDS is it encounters the barrier properties of the Stratum Corneum i.e. only the lipophilic drugs having molecular weight < 500 Da can pass through it. To improve the permeation of drugs through the skin various mechanisms have been investigated, including use of chemical or physical enhancers, such as iontophoresis, sonophoresis, etc [1].

### 1.2. Fungal Infections

The incidence of superficial fungal infections of skin, hair and nails has been increased in worldwide. It has been estimated that about 40 million people have suffered from fungal infections in developing and under developed nations. The progression offungal infections can be rapid and serious due to compromising with immune function [2-3]. *Dermatophytes* are one of the most frequent causes of *tinea* and o*nchomycosis*. Candidal infections are also among the most widespread superficial cu- taneous fungalinfections [4] even, *candida* can invade deeper tissues as well as the blood which leads to life- threating systemic candidiasis, when the immune system is weakened [5].

### 1.3. Hydrogels

Hydrogels are three-dimensional, hydrophilic, polymericnetworks capable of absorbing large amounts ofwater or biological fluids. Due to their high water content, porosity and soft consistency, they closely simulate natural living tissue, more than any other class of synthetic biomaterials.Hydrogels may be chemically stable or they maydegrade and eventually disintegrate and dissolve [6]. They are prepared from materials such as gelatin, polysaccharides, cross-linked polyacrylamide polymers, polyelectrolyte complexes, and polymers or copolymers derived from methacrylate esters. They are insoluble in water and are available in dry or hydrated sheets or as a hydrated gel in drug delivery systems designed for single use [7].

Furthermore, hydrogels can be formulated in a variety of physical forms, including slabs, microparticles, nanoparticles, coatings, and films. As a result, hydrogels are commonly used in clinical practice and medicine with a wide range of applications, including Tissue Engineering and Regenerative Medicine, Diagnostics, Cellular immobilization, Separation of biomolecules or cells, and barrier

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materials to regulate biological adhesions [8]. These unique physical properties of hydrogels have stimulated particular interest in their use in drug delivery applications. Their highly porous structure can easily be tuned by controlling the density of cross-links in the gel matrix and the affinity of the hydrogels for the aqueous environment in which they are swollen [8]. Their porosity also permits loading of drugs into the gel matrix and subsequent drug release at a rate dependent on the diffusion coefficient of a small molecule or a macromolecule through the gel network [8].

**Classification of Hydrogel Products**

The method of preparation leads to formations of some important classes of hydrogels. These can be exemplified by the following [9]:

**(a) Homopolymeric hydrogels** are referred to polymer network derived from a single species of amonomer, which is a basic structural unit comprising of any polymer network. Homopolymers may have cross-linked skeletal structure depending on the nature of the monomer and polymerization technique.

**(b) Copolymeric hydrogels** are comprised of two or more different monomer species with at least one hydrophilic component, arranged in a random, block or alternating configuration along the chain of the polymer network.

**(c) Multipolymer interpenetrating polymeric hydrogel (IPN),** an important class of hydrogels, is made of two independent cross-linked synthetic and/or natural polymer components, contained in a network form. In a semi-IPN hydrogel, one component is a cross-linked polymer and the other component is a non-cross-linked polymer.

**1.4. Miconazole**

An imidazole antifungal agent that is used topically and by intravenous infusion. In addition to its antifungal and antiparasitic actions, it also has some antibacterial properties. It is marketed in various formulations under various brand names [10].

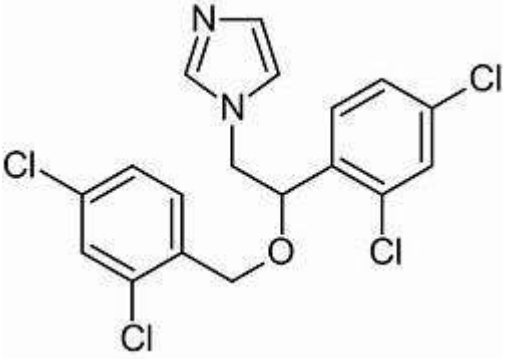


**Figure 1: Structure of Miconazole**

**Molecular weight:** 416.129

**Chemical formula:** $C_{18}H_{14}Cl_4N_2O$

**IUPAC Name:** 1-[2-(2,4-dichlorophenyl)-2-[(2,4-dichlorophenyl)methoxy]ethyl]-1H-imidazole

**Pharmacology**

**Pharmacodynamics:** Miconazole is an anti-fungal medication related to fluconazole (Diflucan), ketoconazole (Nizoral), itraconazole (Sporanox), and clotrimazole (Lotrimin, Mycelex). It is used either on the skin or in the vagina for fungal infections. Miconazole was approved by the FDA in 1974. Miconazole prevents fungal organisms from producing vital substances required for growth and function. This medication is effective only for infections caused by fungal organisms. It will not work for bacterial or viral infections [11].

**Mechanism of action:** Miconazole interacts with 14-α demethylase, a cytochrome P-450 enzyme necessary to convert lanosterol to ergosterol. As ergosterol is an essential component of the fungal cell membrane, inhibition of its synthesis results in increased cellular permeability, causing leakage of cellular contents. Miconazole may also inhibit endogenous respiration, interact with membrane phospholipids, inhibit the transformation of yeasts to mycelial forms, inhibit purine uptake, and impair triglyceride and/or phospholipid biosynthesis [12].

**Toxicity:** Oral, mouse: $LD_{50}$ = 3800 mg/kg; Oral, rat: $LD_{50}$ = 3 gm/kg. Ingestion of the amounts of the components contained in a tube of cream are unlikely to produce overdosage and toxic effects [13].

**Routes of administration:** topical, vaginal, sublabial, oral [13].

**Medical Uses**

Miconazole is mainly used externally for the treatment of athlete's foot, ringworm, and jock itch. Internal application is used for oral or vaginal thrush (yeast infection). The oral gel may also be used for the lip disorder, angular cheilitis.

In the UK, miconazole may be used to treat neonatal oral thrush, while the alternative nystatin is only licensed for patients

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over the age of one month. Still, drug interactions are possible [14].

**Side Effect**

Unlike nystatin, some miconazole is absorbed by the intestinal tract when used orally (and possibly if used vaginally; this may lead to drug interactions.

Interactions are possible with anticoagulants, phenytoin, terbinafine, some newer atypical antipsychotics, ciclosporin, and some statins used to treat hypercholesterolemia [15].

## 2. MATERIALS

The following materials that were procured from different sources, some of which were analytical grade and Laboratory Reagent, were used as supplied by the manufacturer without further purification or investigation.

**Table 1: List of materials used**

| Sr. No. | Chemicals | Supplier |
|---|---|---|
| 1. | API | Bioplus Life Science, Bangalore |
| 2. | Disodium Hydrogen Phosphate | S. D. Fine Chem. Ltd., Mumbai |
| 3. | Di potassium Hydrogen Orthophosphate | S. D. Fine Chem. Ltd., Mumbai |
| 4. | Sodium Chloride | S. D. Fine Chem. Ltd., Mumbai |
| 5. | Methanol | Qualigens Fine Chemicals, Mumbai |
| 6. | Ethanol | Qualigens Fine Chemicals, Mumbai |
| 7. | Chloroform | Qualigens Fine Chemicals, Mumbai |
| 8. | Carbopol 934p | S. D. Fine Chem. Ltd., Mumbai |
| 9. | Methyl Paraben | S. D. Fine Chem. Ltd., Mumbai |
| 10. | Propyl Paraben | S. D. Fine Chem. Ltd., Mumbai |
| 11. | Propylene Glycol | S. D. Fine Chem. Ltd., Mumbai |

## 3. PREFORMULATION STUDY

Preformulation studies are an important tool to ensure physical and chemical properties of the drug before performing its formulation development. The physicochemical properties of the drug highly affect the formulation parameters like compatibility, loading efficiency, method of preparation and pharmacokinetic parameters of the formulation. Preformulation studies are essential protocols for improvement of safety, efficacy and stability of dosage form as well. Thus it plays an important role in order to ensure optimum condition for clinically advantageous delivery system.

## 4. RESULTS OF PREFORMULATION STUDY

**Physicochemical properties of miconazole**

It was done by evaluation of sensory characters like taste, appearance, odour, etc.

**Table 2: Organoleptic properties of miconazole**

| | |
|---|---|
| **Color** | White or almost white powder |
| **Odor** | Odorless |
| **Taste** | Slightly unpleasant |

**Results:** It was found to be white or almost white powder, slightly unpleasant in taste.

**Solubility (At Room Temperature)**

**Table 3: Results for solubility studies of miconazole in different solvents**

| S. No. | Solvent Used | Solubility |
|---|---|---|
| 1 | Water | Very Slightly Soluble |
| 2 | Methanol | Freely Soluble |
| 3 | 0.1N HCl | Slightly Soluble |
| 4 | Ethanol | Soluble |
| 5 | Chloroform | Slightly Soluble |
| 6. | 0.1N NaOH | Slightly Soluble |
| 7. | 7.2 phosphate buffer | Soluble |

**Results:** It was found that Miconazole was freely soluble in methanol, ethanol and 7.2 phosphate buffer, slightly soluble in Chloroform, 0.1N NaOH, and 0.1N HCl.

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**Identification test by IR**

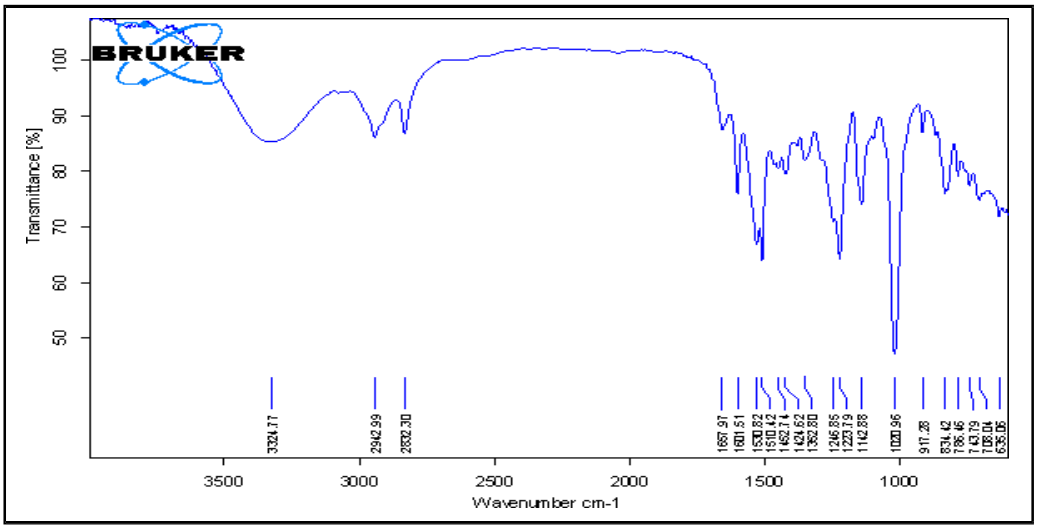


**Figure 2: IR Spectra of Miconazole**

**Table 4: Interpretation of I.R. Spectra**

| Peak | Remark |
|---|---|
| 2929.99 | Aromatic CH stretch |
| 3221.17 | Aliphatic $CH_2$ stretch |
| 2832.30 | Aliphatic CH stretch |
| 1525.32 | C=C aromatic |
| 1510.12 | C=C aromatic |
| 1426.62 | □$CH_2$□ bending |
| 713.19 | C□H bending (aromatic) |

**IR Spectra of a physical mixture**

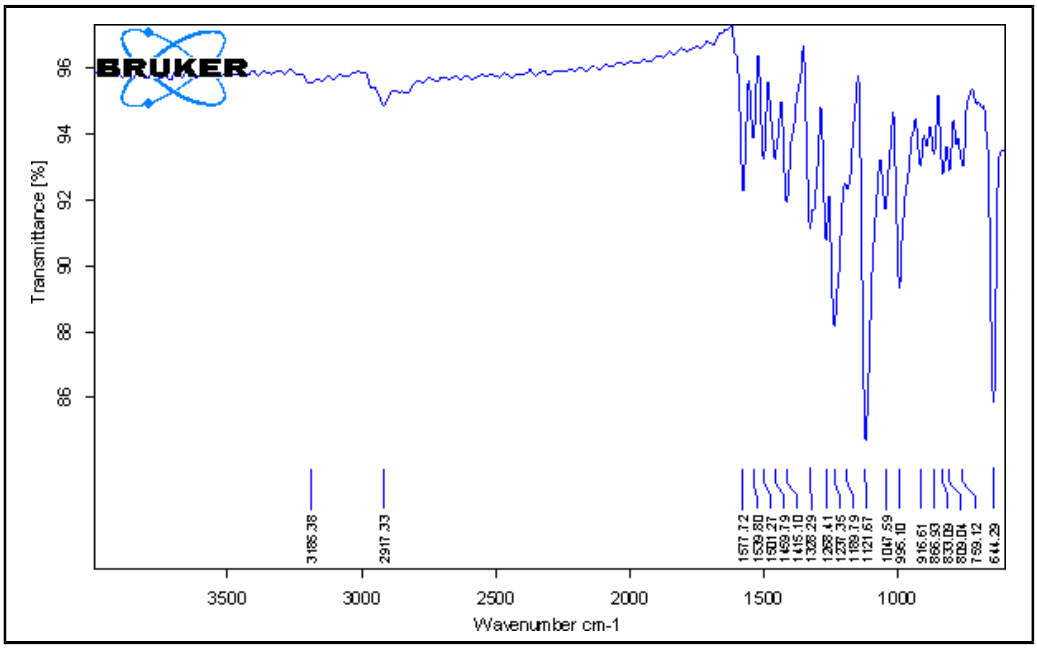


**Figure 3: IR Spectra of Physical mixture**

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**Result of loss on drying:** The percentage of loss on drying of miconazole was found to be 0.45% w/w.

**Table 5: Loss on Drying**

| Drug | % of LOD |
|---|---|
| Miconazole | 0.45% |

**Melting point:**

**Table 6: Melting point range of miconazole**

| S. No. | Melting point | | Result |
|---|---|---|---|
| | Onset | Complete | |
| 1 | 159 | 162 | 159-162 ℃ |
| 2 | 160 | 162 | |
| 3 | 159 | 163 | |

**Result:** Melting point was determined by Melting point apparatus and found 159- 162 ℃.

**Moisture content determination:** The Moisture content of Miconazole was found to be 0.15%

**Determination of $\lambda_{max}$**

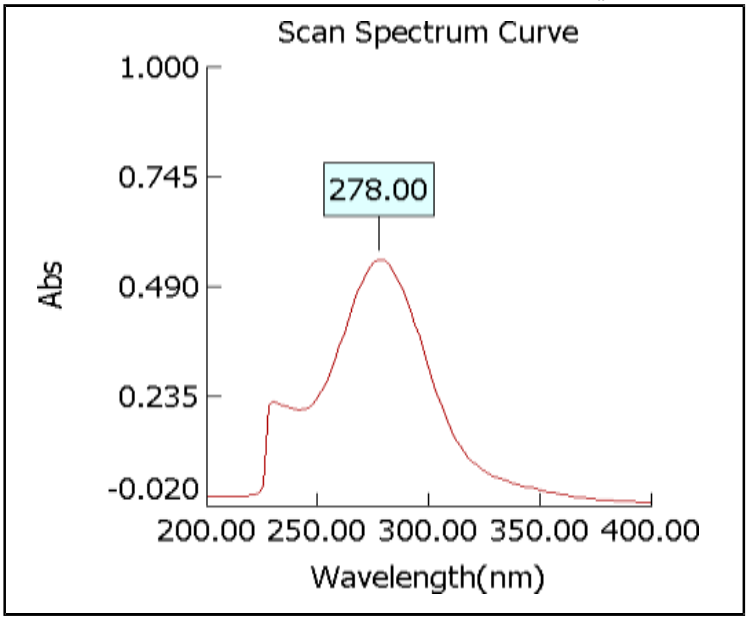


**Figure 4: Determination of λ max of miconazole**

**Calibration curve of Miconazole**

**Table 7: Readings for calibration curve of miconazole**

| Replicate | 5 µg/ml | 10 µg/ml | 15 µg/ml | 20 µg/ml | 25 µg/ml |
|---|---|---|---|---|---|
| **1** | 0.189 | 0.365 | 0.533 | 0.694 | 0.865 |
| **2** | 0.188 | 0.364 | 0.532 | 0.693 | 0.864 |
| **3** | 0.189 | 0.365 | 0.533 | 0.694 | 0.863 |
| **Mean** | 0.189 | 0.365 | 0.533 | 0.694 | 0.864 |
| **SD** | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 |
| **% R.S.D** | 0.306 | 0.158 | 0.108 | 0.083 | 0.116 |

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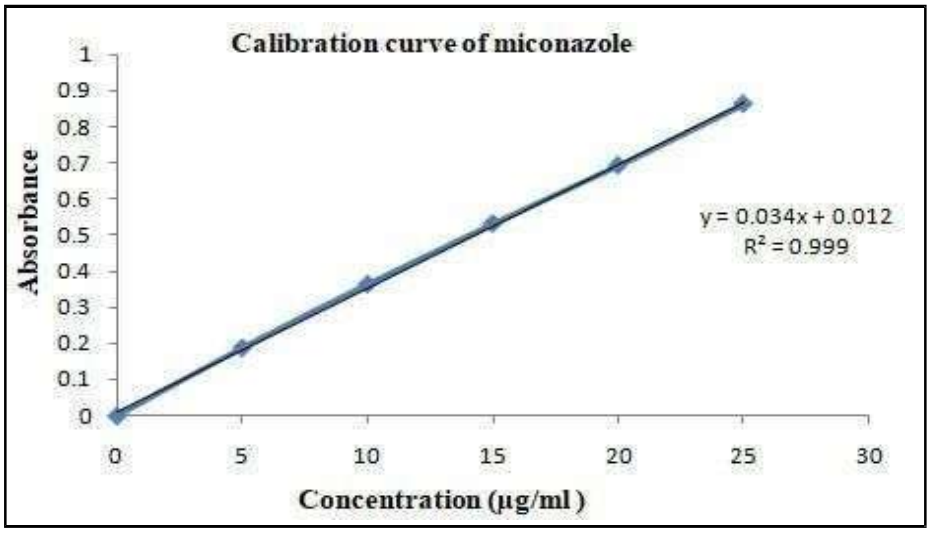


**Figure 5: Calibration curve of miconazole**

**Table 8: Statistical data for linearity**

| S. No. | Parameter | Remark |
|---|---|---|
| 1 | Linearity Range | 5-25 µg/ml |
| 2 | Regression Equation | 0.034x+0.012 |
| 3 | Correlation Coefficient | 0.999 |

## 5. METHODOLOGY

**Preparation of chitosan nanoparticles of Miconazole:** Chitosan nanoparticles were prepared by the ionotropic gelation method.

**Preparation I:** Chitosan stock solution (0.25 to 0.75% w/v) was prepared by dissolving chitosan in acetic acid (1% v/v) at room temperature.

**Preparation II:** The drug (10 mg) was dissolved in chitosan solution.

**Preparation III:** 1% Sodium tripolyphosphate solution was prepared in water.

**Preparation IV:** Sodium tripolyphosphate solution was added dropwise with a syringe to chitosan solution while stirring. The solution was magnetically stirred for half an hour, followed by filtration and rinsing with distilled water. Nanoparticles were obtained, which was air dried for twenty-four hours, followed by oven drying for six hours at 40˚C [41].

**Table No. 9: Formulations of chitosan nanoparticles prepared**

| Sr. No | Formulation Code | Miconazole (mg) | Chitosan (mg) | STPP (mg) |
|---|---|---|---|---|
| **1.** | **F1** | 10 | 250 | 100 |
| **2.** | **F2** | 10 | 250 | 100 |
| **3.** | **F3** | 10 | 250 | 100 |
| **4.** | **F4** | 10 | 500 | 100 |
| **5.** | **F5** | 10 | 500 | 100 |
| **6.** | **F6** | 10 | 500 | 100 |
| **7** | **F7** | 10 | 750 | 100 |
| **8** | **F8** | 10 | 750 | 100 |
| **9** | **F9** | 10 | 750 | 100 |

**Table 10: Formulation of Miconazole-loaded nanoparticles gel**

| S. No. | Formulation Code | Drug % (Equivalent to transfersomes) | Carbopol 934 (gm) | Water |
|---|---|---|---|---|
| 1. | GF1 | 2 | 1 | 100 |
| 2. | GF2 | 2 | 2 | 100 |
| 3. | GF3 | 2 | 3 | 100 |

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## 6. EVALUATION

**Evaluation of nanoparticles of Miconazole Percentage Yield**

**Table No. 11: Percentage Yield for Different Formulations**

| Formulation | Percentage Yield* (%) |
|---|---|
| F1 | 65.56±0.45 |
| F2 | 75.65±0.32 |
| F3 | 69.98±0.65 |
| F4 | 65.45±0.85 |
| F5 | 63.12±0.14 |
| F6 | 65.78±0.25 |
| F7 | 63.56±0.36 |
| F8 | 68.89±0.78 |
| F9 | 71.23±0.54 |

*Average of three determinations (n=3)

**Figure 6: Percentage Yield for different formulations**

**Entrapment Efficiency**

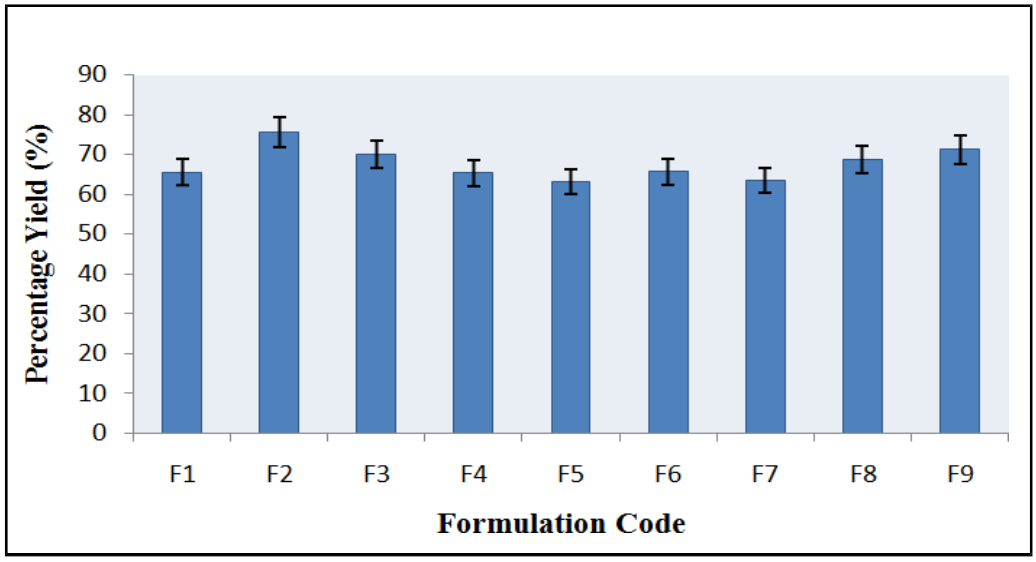


**Table No. 12: Entrapment Efficiency for Different Formulations**

| Formulation | Entrapment Efficiency of prepared nanoparticles* |
|---|---|
| F1 | 65.56±0.32 |
| F2 | 73.23±0.45 |
| F3 | 70.12±0.45 |
| F4 | 68.85±0.65 |
| F5 | 65.45±0.56 |
| F6 | 65.56±0.41 |
| F7 | 63.32±0.45 |
| F8 | 65.85±0.36 |
| F9 | 68.89±0.25 |

*Average of three determinations (n=3)

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**Figure 7: Entrapment Efficiency for Different Formulation**

**Particle Size Analysis**

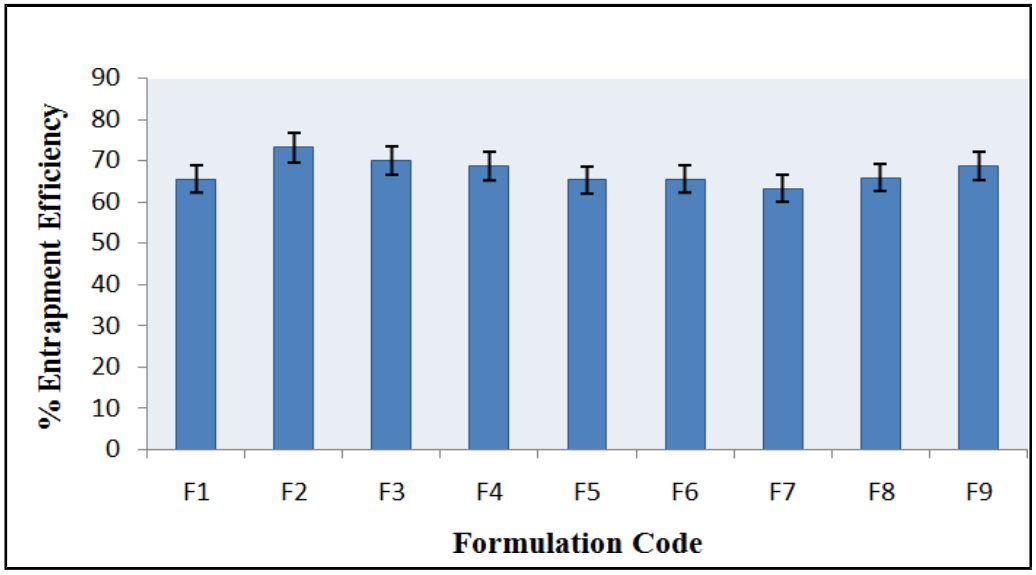


**Table 13: Results of gel formulations**

| Code | pH | Spreadability* (gm.cm/sec.) | Viscosity* (cps) | Drug Content* (%) | Extrudability* (gm) |
|---|---|---|---|---|---|
| **GF1** | 6.85±0.02 | 12.23±0.45 | 4568±13 | 98.45±0.25 | 145±4 |
| **GF2** | 7.02±0.04 | 11.56±0.98 | 4251±11 | 99.25±0.12 | 165±2 |
| **GF3** | 6.95±0.02 | 10.32±0.65 | 3978±14 | 97.25±0.25 | 125±3 |

***Average of three determinations (n=3)**

**Figure 8: Graph of pH of formulation GF1, GF2 and GF3**

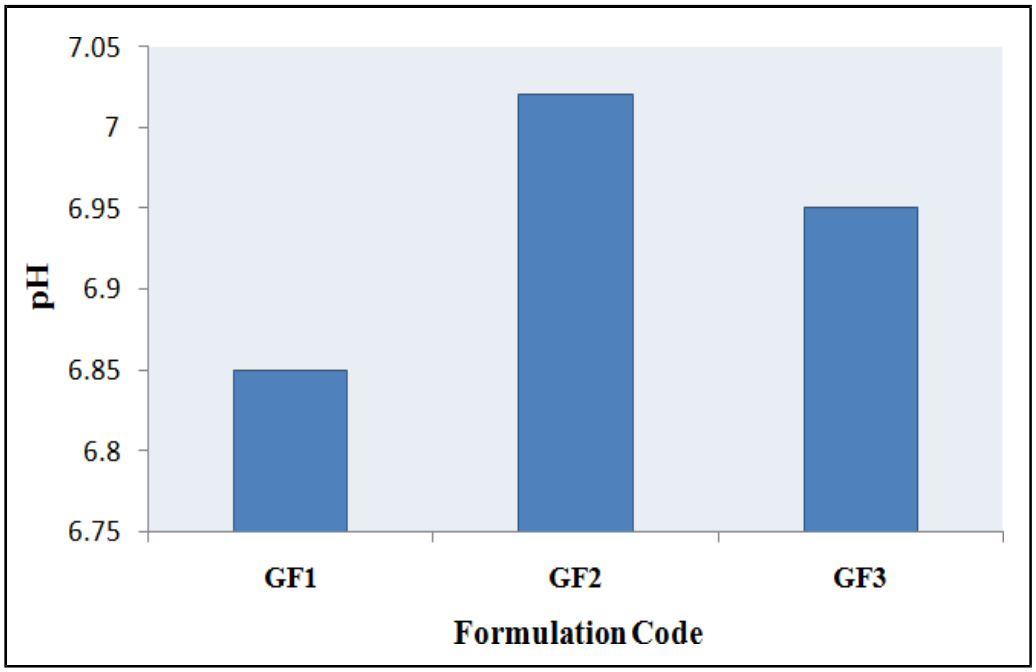

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Figure 9: Graph of the Spreadability of formulation GF1, GF2 and GF3

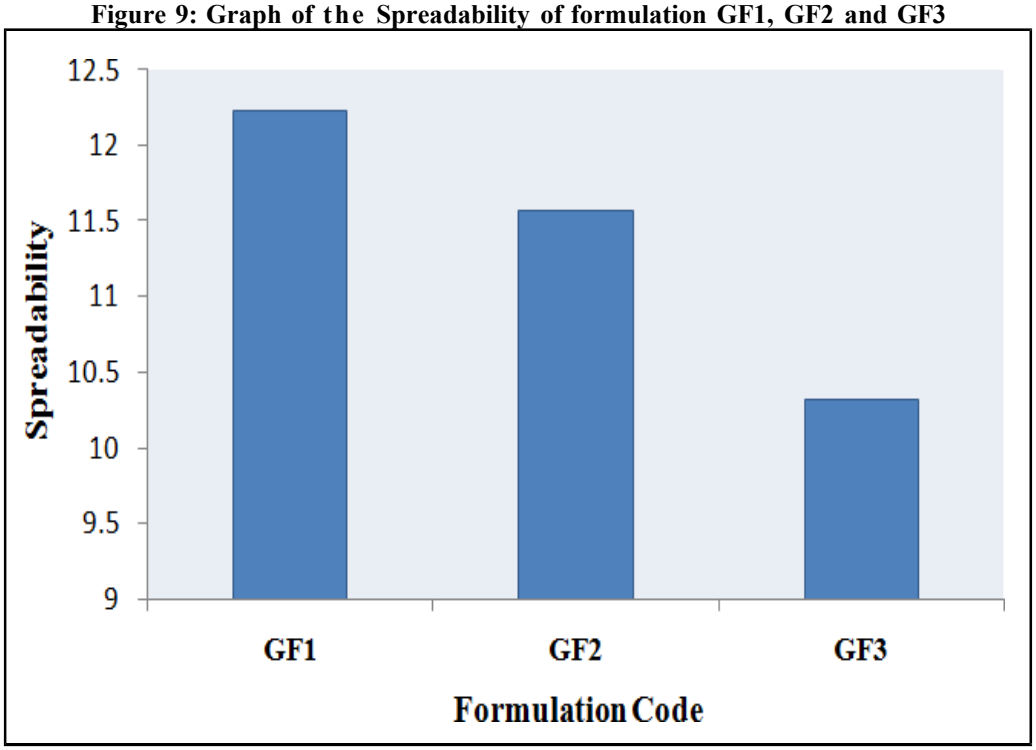


Figure 10: Graph of viscosity of formulation GF1, GF2 and GF3

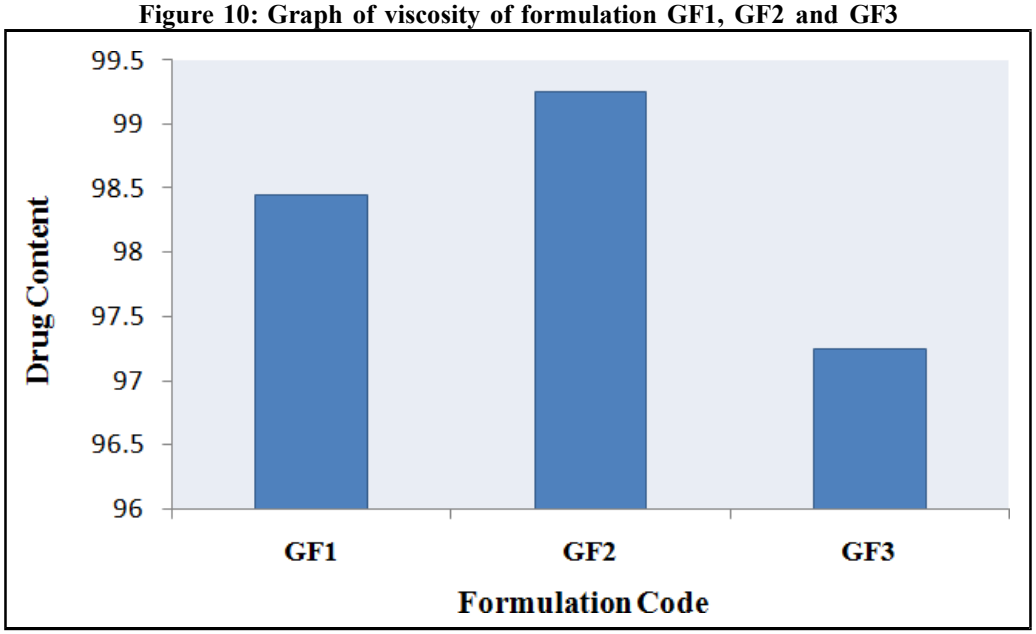

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**Figure 11: Graph of drug content of formulation GF1, GF2 and GF3**

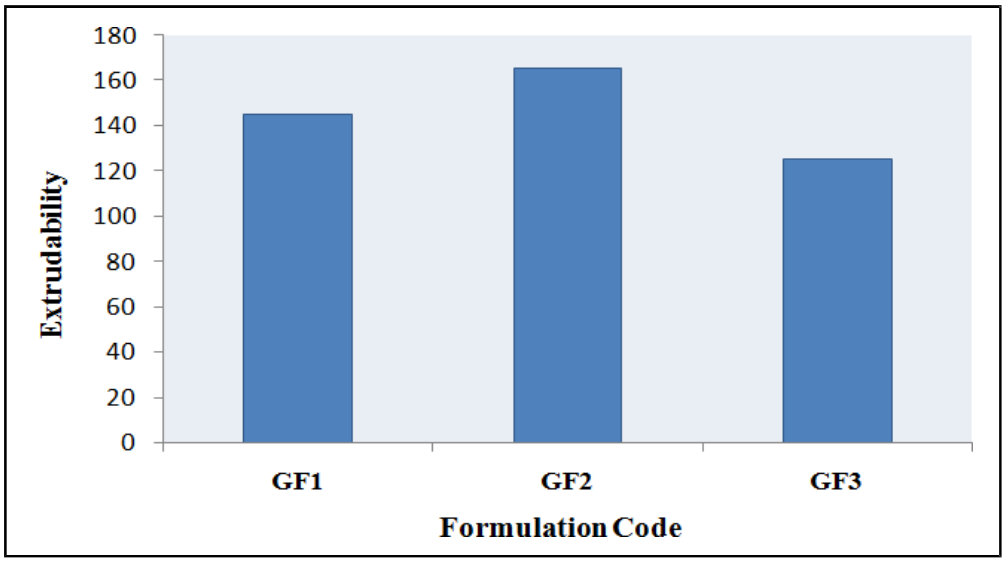


**Figure 8.9: Graph of extrudability of formulation GF1, GF2 and GF3**

***In vitro* drug release study of the prepared gel formulation**

**Table 14: *In vitro* drug release study of prepared gel formulation**

| S. No. | Time (hr) | % Cumulative Drug Release | | |
|---|---|---|---|---|
| | | GF1 | GF2 | GF3 |
| **1** | 0.5 | 12.32±0.25 | 11.32±0.32 | 9.85±0.36 |
| **2** | 1 | 18.89±0.32 | 19.98±0.45 | 11.32±0.25 |
| **3** | 2 | 23.32±0.14 | 35.65±0.65 | 15.56±0.14 |
| **4** | 3 | 26.65±0.65 | 40.23±0.74 | 18.89±023 |
| **5** | 4 | 43.32±0.47 | 45.65±0.65 | 22.32±0.14 |
| **6** | 5 | 53.45±0.32 | 65.58±0.32 | 26.69±0.23 |
| **7** | 6 | 59.98±0.74 | 73.32±0.14 | 38.89±0.14 |
| **8** | 8 | 63.32±0.23 | 81.14±0.65 | 45.56±0.74 |
| **9** | 10 | 65.45±0.25 | 91.45±0.32 | 55.56±0.36 |
| **10** | 12 | 66.68±0.21 | 98.85±0.74 | 63.32±0.25 |

***Average of Six Determinations (n=6)**

***In-vitro* drug release study of GF1, GF2 and GF2**

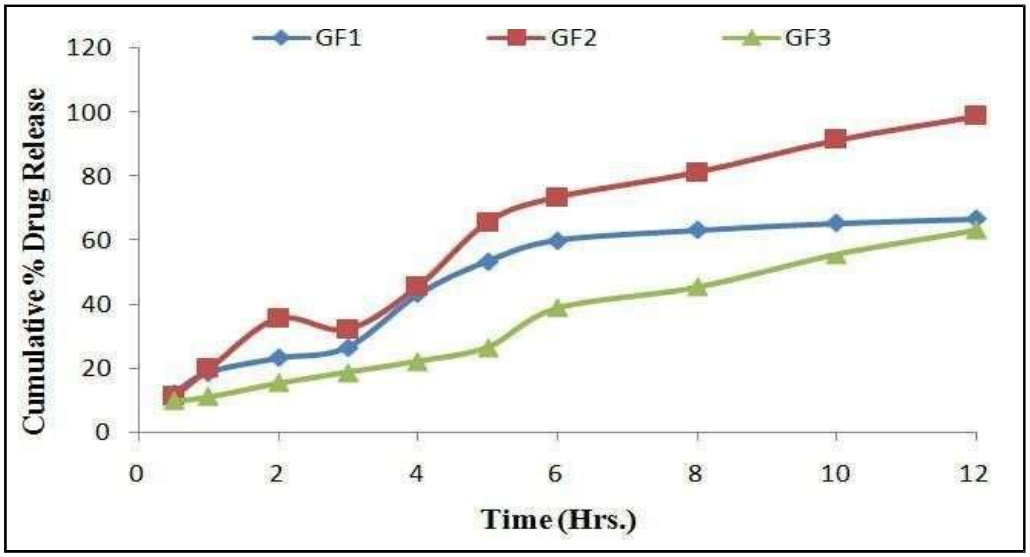


**Figure 12: Graph of GF1, GF2 and GF3 Release Kinetics of gel GF2**

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Table 15: *In-vitro* drug release data for gel GF2

| Time (h) | Square Root of Time(h) 1/2 | Log Time | Cumulative % Drug Release | Log Cumulative % Drug Release | Cumulative % Drug Remaining | Log Cumulative % Drug Remaining |
|---|---|---|---|---|---|---|
| **1** | 0.5 | -0.301 | 11.32 | 1.054 | 88.68 | 1.948 |
| **2** | 1 | 0.000 | 19.98 | 1.301 | 80.02 | 1.903 |
| **3** | 2 | 0.301 | 35.65 | 1.552 | 64.35 | 1.809 |
| **4** | 3 | 0.477 | 40.23 | 1.605 | 59.77 | 1.776 |
| **5** | 4 | 0.602 | 45.65 | 1.659 | 54.35 | 1.735 |
| **6** | 5 | 0.699 | 65.58 | 1.817 | 34.42 | 1.537 |
| **7** | 6 | 0.778 | 73.32 | 1.865 | 26.68 | 1.426 |
| **8** | 8 | 0.903 | 81.14 | 1.909 | 18.86 | 1.276 |
| **9** | 10 | 1.000 | 91.45 | 1.961 | 8.55 | 0.932 |
| **10** | 12 | 1.079 | 98.85 | 1.995 | 1.15 | 0.061 |

**Zero order Release Kinetics of optimized gel GF2**

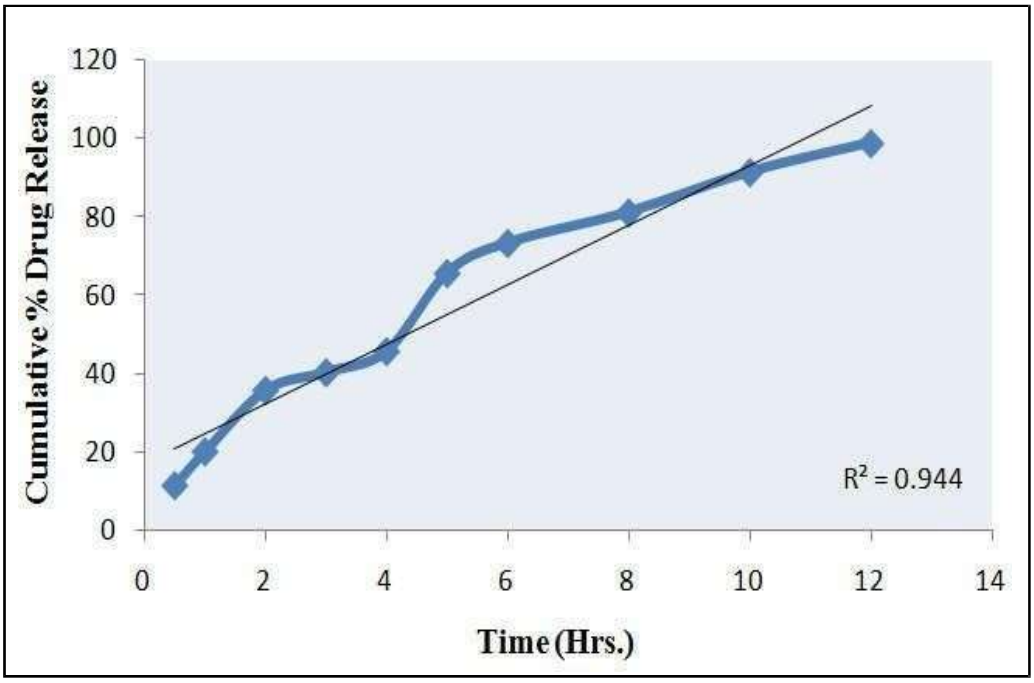


**Figure 13: Graph of Zero order Release Kinetics of optimized gel GF2 (Cumulative % drug released Vs Time)**

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**First order Release Kinetics of optimized gel GF2**

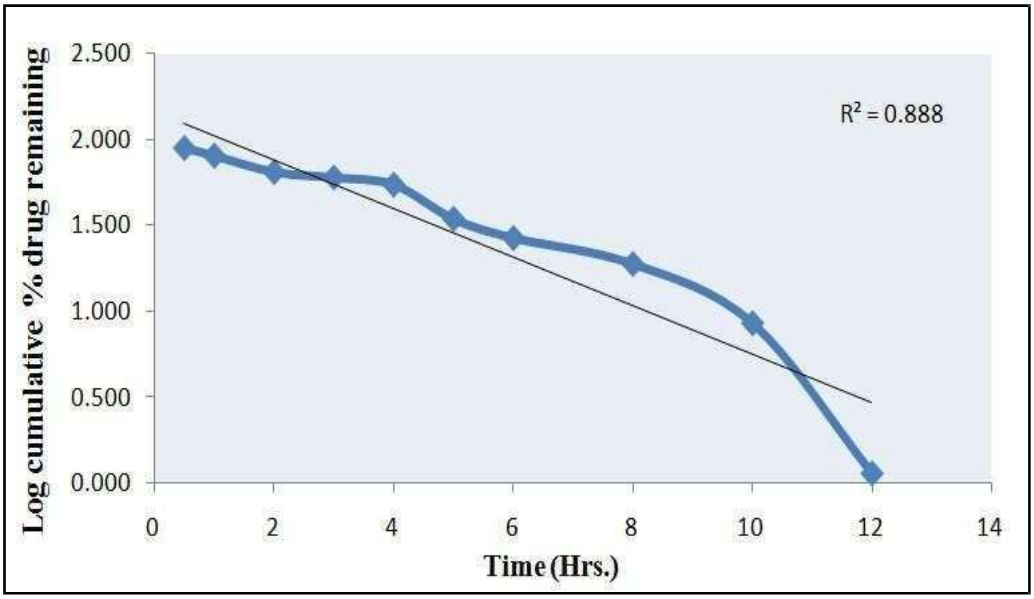


**Figure 14: Graph of first order Release Kinetics of optimized gel GF2 (Log cumulative % drug remaining Vs Time)**

**Higuchi Release Kinetics of optimized gel GF2**

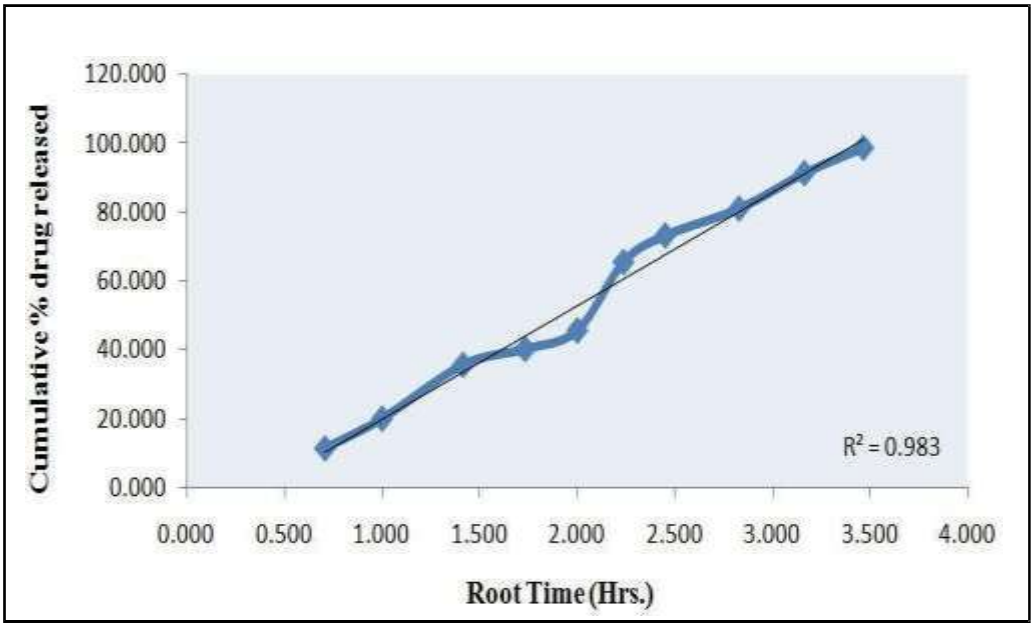


**Figure 15: Higuchi release Kinetics (Cumulative % drug released Vs Root Time)**

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**Korsmeyer-Peppas Release Kinetics of optimized gel GF2**

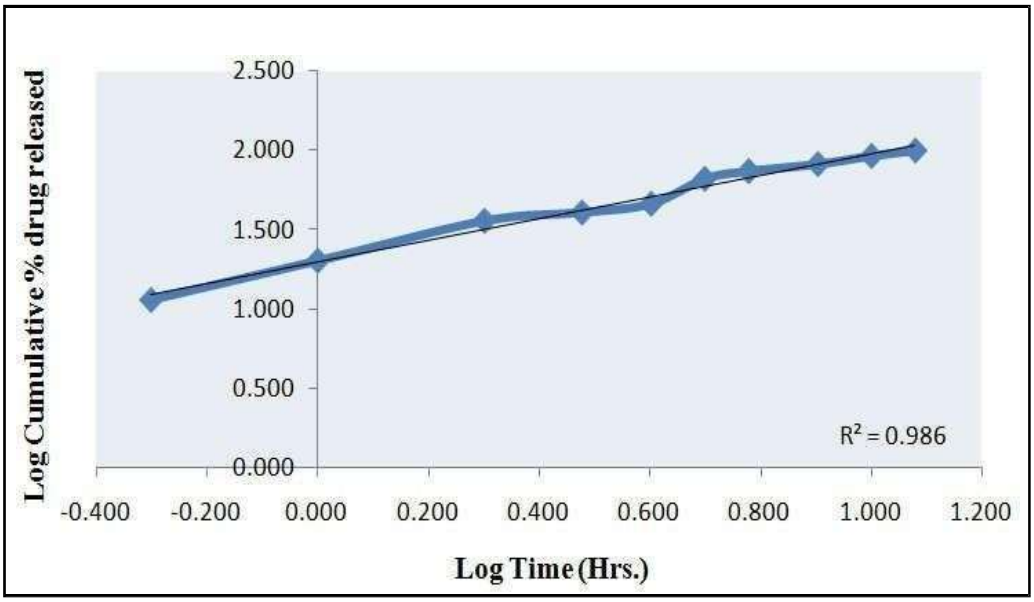


**Figure 16: Korsmeyer-Peppas release Kinetics (Log Cumulative % drug release Vs Log Time)**

**Release Kinetics Regression values of formulation GF2**

**Table 16: Release Kinetics Regression values of formulation GF2**

| Formulation code | Zero order | First order | Higuchi | Korsmeyer-Peppas |
|---|---|---|---|---|
| GF2 | 0.944 | 0.888 | 0.983 | 0.986 |

## 7. CONCLUSION

The conclusion is that the prepared chitosan nanoparticles of Miconazole, which were optimized (Formulation F2: 85.6 nm particle size, −36.2 mV zeta potential, and maximum yield/entrapment), were successfully incorporated into a gel base and optimized for topical delivery. The optimized gel (likely GF2 based on subsequent text mentioning TF2 and optimal viscosity/pH) demonstrated suitable skin application properties (pH 6.99−7.02, optimal viscosity, and spreadability) and provided a sustained and controlled drug release of up to 98.85% over 12 hours (following Korsemeyer-Peppas kinetics), making it a promising topical preparation for antifungal effect.

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