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RESEARCH ARTICLE OPEN ACCESS

FORMULATION AND EVALUATION OF MUCOADHESIVE TABLET OF MICONAZOLE NITRATE BY USING LIQUISOLID TECHNIQUE

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ABSTRACT

Liquisolid technology is an effective technique for enhancing the solubility and dissolution properties of poorly water-soluble drugs. Miconazole, a broad-spectrum antifungal agent, is classified as a BCS Class II drug due to its limited water solubility and high lipophilicity, resulting in low oral bioavailability (approximately 25-30%) and an elimination half-life of 24 hours. This study aimed to improve the solubility and dissolution rate of miconazole using liquisolid technology and develop a mucoadhesive tablet formulation for buccal administration. The formulations were designed using Design Expert software (version 13, Stat-Ease), with PEG-400 as the solvent, MCC PH-102 and Aerosil 200 as the carrier and coating materials, respectively, and Carbopol 934 as the mucoadhesive agent along with Mannitol to enhance the drug release. Mucoadhesive liquisolid tablets were prepared using direct compression. FTIR studies confirmed no drug-excipient interactions. The prepared formulations were evaluated for precompression and post-compression parameters. The optimized formulation, F5, exhibited 87% drug release at 4 hours and a swelling index of 68%. This study demonstrated the effectiveness of liquisolid technology in improving the solubility and dissolution properties of poorly water-soluble drugs like Miconazole nitrate.

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INTRODUCTION

The goal of any drug delivery system is to provide a therapeutic amount of drug to target site and then maintain desired drug concentration. A well-designed drug delivery system can overcome some of problems of conventional therapy and enhance the therapeutic efficacy of given drug. Solubility and dissolution rate of Biopharmaceutical Classification System Class II (BCS II) drugs are often limited, which impaired their bioavailability from the gastrointestinal tract. Nevertheless, most of the drugs within these classes are highly lipophilic and present in a low water solubility form. Consequently, improving the bioavailabilities of these poorly water-soluble drugs by enhancing their solubility and dissolution is a problem that many pharmaceutical scientists are interested in.[1] Several formulation strategies have been described to improve the solubility of poorly water-soluble compounds. The most common pharmaceutical strategy to increase the solubility of a drug in current use appears to be via micronization, which increases surface area, although micronized hydrophobic drugs often agglomerate readily and this can negate the enhanced surface area as a means to surmount solubility problems when these drugs are formulated into tablets or capsules.[2] Although solid dispersion for enhancing drug dissolution has been investigated extensively during the last decades, its commercialization is very limited and only few products. This is due largely to its very poor storage stability and an incomplete understanding of its state structure. Another popular method is formulating soft gelatin capsules, which is expensive and requires sophisticated technologies. Though other methodologies such as inclusion complexation, microencapsulation and preparation of nanosuspension, self-nano-emulsions (SNE), solid lipid nanoparticles (SLN) have been studied for improving dissolution of poorly water-soluble drugs. However, these methods requiresophisticated machinery and advanced preparation techniques, which result in high production costs.[3, 4, 5] The recently created and so phisticated liquidsolid technology for dissolution improvement can get past several of the obstacles stated above.[6] Liquisolid systems are designed to hold liquid medications (liquid drugs, drug solutions, or suspensions) in powdered form and distribute the drug in a manner akin to that of soft gelatin capsules that contain liquids.The process of turning liquid pharmaceuticals into seemingly dry, non-adherent, free-flowing, and compressible powder mixtures by mixing them with appropriate excipientsgenerally referred to as carriers and coating materialsis known as the liquidsolid technique.First, the liquid drug is absorbed into the carrier's internal structure. A liquid layer forms on the carrier surface, once the interior of the carrier is saturated with liquid medication, and the fine coating materials immediately absorb this layer.[7] As a result, a liquisolid system may have a higher

dissolving rate because of its improved wetting qualities, greater dissolution area, or improved water solubility. In addition to improving dissolve, the liquisolid approach has lately been studied as a means of improving medication photostability, reducing the impact of pH change on the dissolution profile, and delaying drug release[8, 9, 10].

METHODOLOGY

Determination of Melting Point [11]: The melting point was determined by capillary method, a small amountof pure drug was transferred into a capillary tube. Then the capillary tube was placed in melting point apparatus and the temperature at which the melting of drug started was noted by using the thermometer placed in the apparatus.

Drug- Excipient Compatibility *[12, 13]*: Fourier Transform Infrared Spectroscopy (FTIR) analysis was carried out on pure substances and their physical mixtures. FTIR spectra of pure drug, excipients and their physical mixtures were taken by direct method between 400-4000 cm-1. The peaks of pure drug, excipients and physical mixtures were compared for incompatibility.

Solubility Studies*[13,]*:Solubility of Miconazole nitrate was observed in different solvents such as distilled water, methanol, PEG-400 and Phosphate buffer (pH-6.8).

material (Q) in the liquisolid system, is another crucial liquisolid system parameter.

$$L_f = \frac{W}{Q}$$

The liquid loading factor for the production of a liquisolid system with acceptable flowability can be determined by:

$$L_f = \emptyset_{carrier} + \emptyset_{coating} \times \frac{1}{R}$$

Where ∅ values correspond to the flowable liquid retention potential of the carrier and coating material. Correspondingly, the flowable liquid retention potential of a liquisolid system can be determined by:

$$\emptyset = \frac{Weight\ of\ solvent}{Weight\ of\ carrier\ or\ coating\ material}$$

Method of Preparation of Mucoadhesive Liquisolid Tablet*[16]*: Accurately weighed quantities of the drug and PEG-400 were mixed in a beaker. Then, weighed quantities of microcrystalline cellulose (as the carrier) and Aerosil 200 (as the coating material) were added to the beaker and mixed thoroughly to ensure even distribution of the liquid medication within the powder. The liquid/powder admixture was evenly spread as a uniform layer on the surface of a mortar and left standing for approximately 10-20 min to allow the drug solution

Table 1. Formulation table for mucoadhesive liquisolid tablet

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	F13
Miconazole nitrate (mg)	50	50	50	50	50	50	50	50	50	50	50	50	50
Peg-400 (ml)	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02
MCC-PH 102 (mg)	281.95	317.1	281.95	317.1	281.95	317.1	307.6	307.6	307.6	307.6	307.6	307.6	307.6
Aerosil 200 (mg)	56.39	21.14	56.39	21.14	56.39	21.14	30.76	30.76	30.76	30.76	30.76	30.76	30.76
Carbopol (mg)	10	10	30	30	20	20	10	30	20	20	20	20	20
Mannitol (mg)	25.06	25.16	5.06	5.56	15.06	15.16	25.04	5.04	15.04	15.04	15.04	15.04	15.04
Magnesium stearate (mg)	4	4	4	4	4	4	4	4	4	4	4	4	4

Precompression Parameters of Liquisolid Powder: The powder blend was analyzed for bulk density, tapped density, Carr's index, Hausner's ratio, angle of repose, and liquid retention potential.

Preparation of Mucoadhesive Liquisolid Tablet

Mathematical Application*[7]*: Two essential characteristics of a powder, the flowable liquid retention potential (Φ value) and the compressible liquid retention potential (Ψ value)form the basis of the concept. The maximum amount of liquid vehicle that may be kept in the powder bulk without sacrificing flowability and compressibility is indicated by the Φ and Ψ values of a powder excipient. Preferably, the angle of repose of the created liquid-powder admixture is measured in order to determine the Φ value. The following is the definition of the excipients ratio (R), commonly referred to as the carrier/coating ratio:

$$R = \frac{q}{Q}$$

As a result, R is the weight ratio of coating material (q) to carrier (Q). Higher amounts of the carrier and lesser amounts of the coating material will result from an increase in the R value. The liquisolid system's flowability, compressibility, disintegration, and dissolution rate are all correlated with the R value. The liquid loading factor (L_f), which is the weight ratio of the liquid drug (W) to the carrier

to be absorbed inside powder particles. The powder was scraped off the mortar surface using a spatula and remaining ingredients were added producing the final powder which was compressed using a tablet compression machine.

Evaluation of Mucoadhesive Liquisolid Tablet

Thickness[17]: Thickness of tablets was measured by using micrometer.

Hardness[17]: The tablet to be tested was held between a fixed and a moving jaw of Monsanto Hardness Tester.

Friability[17]: The test was performed using friability test apparatus. The friabilator consists of a plastic chamber divided into two parts and revolves at 25 rpm. Six tablets were weighed and placed in the tumbling chamber and rotated for four minutes at 100 revolutions. After 100 revolutions the tablets were again weighed.

Weight Variation[17]: 20 Tablets were randomly selected and individually weighed and calculated the average weight and compared the individual tablet's weight to the average weight.

Drug Content[15]: Twenty tablets were taken, powdered and the powder equivalent to one dose each was transferred to a 100 mL volumetric flask and phosphate buffer (pH-6.8) was added. The volume was then made up to the mark with phosphate buffer. The solution was filtered and diluted suitably and drug content in the samples was estimated using UV- Visible spectrophotometer at 272 nm.

***In-vitro* Dissolution Studies**[14, 15]: The *in-vitro* drug release study was performed for the single unit tablets using USP Type II dissolution apparatus (Paddle type). Tablet was placed in the dissolution apparatus containing 900 ml of phosphate buffers pH 6.8 and the paddle was rotated at 50 rpm at a temperature of 37±0.5°C. Samples of 5 ml were collected at different time intervals up to 4hours and analysed by spectrophotometer at 272nm. Then the cumulative amount of drug release from the prepared tablets at different time intervals was calculated, the average of triplicate measurement was used as the final value and dissolution profile was plotted.

Surface pH[22]: The formulated tablet was kept in contact with 1 ml of phosphate buffer for 2 hours at room temperature. The surface of the tablet was placed in contact with a glass electrode, and the pH was measured after allowing it to equilibrate for 1 minute.

Swelling Index[22, 23]*:* The buccal tablet was placed on a cover slide, weighed precisely and placed in a petri dish containing 15 ml of phosphate buffer (pH 6.8) solution. The tablet together with the cover slide was taken from the petri dish, and extra surface water was dried cautiously using the filter paper at regular intervals and reweighed.

Formulation Optimization via DOE[20]*:* A computer-aided optimization approach employing a statistical design of experiments was used to identify critical factors, their interactions, and the optimal process conditions necessary to achieve the targeted results. Design Expert Stat Ease Software was utilized to determine the optimal formulation. The optimization process utilized a central composite design, excipient ratio andCarbopol934 were selected as the two variables, while *in-vitro* drug release and swelling index were considered as the two response variables. As a result, thirteen experimental trials were performed. Contour plots were created, and the optimal formulation was chosen based on the established optimization criteria.

RESULT AND DISCUSSION

Determination of Melting Point: Melting point was determined by capillary rise method and was found to be 184.33 ± 0.47°C (n=3).

Drug–Excipient Compatibility: Compatibility study was done by performing FTIR studies. During FTIR studies, the peaks of Miconazole nitrate was obtained at637 cm^{-1}(C-Clstretching), 1473cm^{-1}(C=Cstretching), 1086cm^{-1}(C-Ostretching), 1326cm^{-1}(C-Nstretching), 3104cm^{-1}(Ar C-H stretching), 1738cm^{-1}(C=Ostretching). There was no significance change in the peak of pure drug and physical mixture. This indicates that the drug and excipients are compatible.

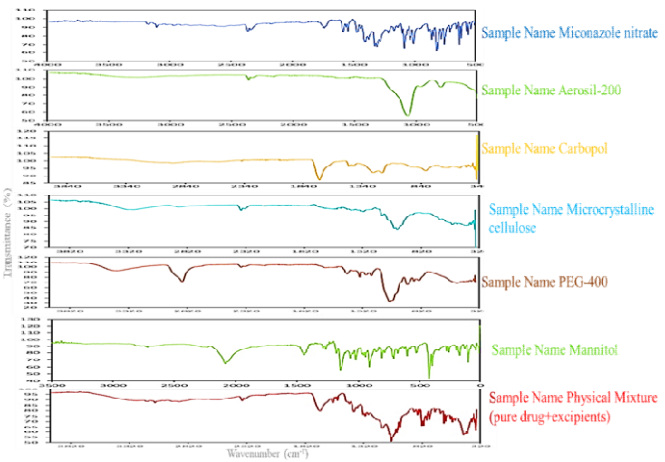


Figure 1. FTIR spectrum of Miconazole nitrate, microcrystalline cellulose, aerosol-200, Carbopol 934, mannitol, physical mixture (Miconazole nitrate+microcrystalline cellulose+ aerosol-200+Carbopol 934+mannitol)

The λ_{max} was found to be 272nm, so the standard calibration curve of Miconazole nitrate was developed at this wavelength. The curve was found to be linear and obeys Beer- Lambert's law in the range of 1-10 µg/ml with regression co-efficient 0.999. The absorbance values are tabulated in the Table 2.

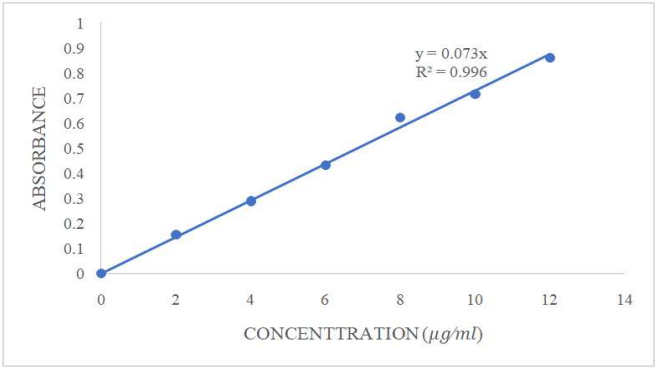
Table 2. Absorbance values for Miconazole nitrate

CONCENTRATION (µg⁄ml)	ABSORBANCE
0	0
2	0.155 ± 0.0007
4	0.289 ± 0.018
8	0.432 ± 0.0007
6	0.623 ± 0.002
10	0.718 ± 0.0016

All values are expressed as mean ± SD, n=3

Flow Properties of Liquisolid Powder

Liquisolid Retention Potential



All values are expressed as mean ± SD, n=3

Figure 2. Standard calibration curve for Miconazole nitrate in phosphate buffer (pH 6.8)

The liquid retention potential of microcrystalline cellulose (MCC) and Aerosil 200 was evaluated based on their ability to absorb and retain liquid medication within a powder mixture while maintaining good flow and compressibility. The liquid retention potentials were determined to be 0.18 and 0.56 for microcrystalline cellulose and Aerosil 200, respectively.

Precompression parameters of liquisolid powder: The precompression parameters of the formulations are shown in the table no.4. All the formulations exhibited excellent flow properties of powder blend. The bulk and tapped density had shown good density values, which indicates that the powder blend was not too bulky and had good packing characteristics. The Carr's index and Hausner's ratio values lies in the range of 9.6% to 23.4 and 1.11 to 1.40 which indicates good flow properties of powder blend.

Evaluation of Mucoadhesive Liquisolid Tablet

Post Compression Parameters of Liquisolid Tablet

Thickness & Hardness: All the formulations showed uniform thickness of 3.48 to 3.68mm & the hardness of the tablets ranged from 4.89 to 5.46 kg/cm^2.

Friability: The percentage friability of the tablets ranged from 0.26 to 0.38 indicating that the tablets were mechanically stable.

Drug Content: Drug content was found to be uniform among different batches of the tabletsand ranged from 96.89 to 98.11.

Weight Variation: All the formulated tablets passed weight variation test as the % weight variation was within the pharmacopeial limits of 5 % of the weight. The weights of all the tablets were found to be uniform with low standard deviation values.

Table 5. Post compression parameters of liquisolid tablet of different batches of formulations

FORMULATON	HARDNESS (kg/cm^2)	THICKNESS (mm)	FRIABILITY (%)	DRUG CONTENT (%)	WEIGHT VARIATION (mg)	SURFACE pH
F1	5.34±0.83	3.58±0.02	0.34±0.23	98.01±0.25	450.03±0.10	6.6±0.01
F2	5.46±0.63	3.53±0.069	0.26±0.33	97.56±0.15	446.21±0.03	6.5±0.013
F3	4.89±0.77	3.47±0.034	0.38±0.19	96.89±0.12	449.18±0.01	6.9±0.002
F4	4.93±0.93	3.68±0.08	0.36±0.37	97.36±0.35	450.11±0.02	6.6±0.024
F5	5.5±0.38	3.48±0.05	0.26±0.42	98.11±0.02	445.53±0.013	6.7±0.068
F6	4.97±0.82	3.56±0.03	0.35±0.58	97.56±0.16	446.64±.0.04	6.2±0.025
F7	5.11±0.12	3.67±0.07	0.31±0.95	97.78±0.34	451.02±0.08	6.7±0.030
F8	4.86±0.17	3.53±0.34	0.38±0.64	96.87±0.22	447.03±0.022	6.6±0.014
F9	5.12±0.92	3.54±0.91	0.29±0.65	97.22±0.31	444.03±0.022	6.9±0.026
F10	5.11±0.24	3.56±0.27	0.28±0.51	97.18±0.43	444.05±0.025	6.9±0.024
F11	5.12±0.89	3.56±0.55	0.29±0.47	97.15±0.27	443.13±0.047	6.8±0.024
F12	5.16±0.77	3.55±0.21	0.29±0.64	97.26±0.18	444.21±0.032	6.9±0.021
F13	5.14±0.14	3.54±0.15	0.28±0.75	97.25±0.66	444.14±0.025	6.9±0.027

All values are expressed as mean ± SD, n=3

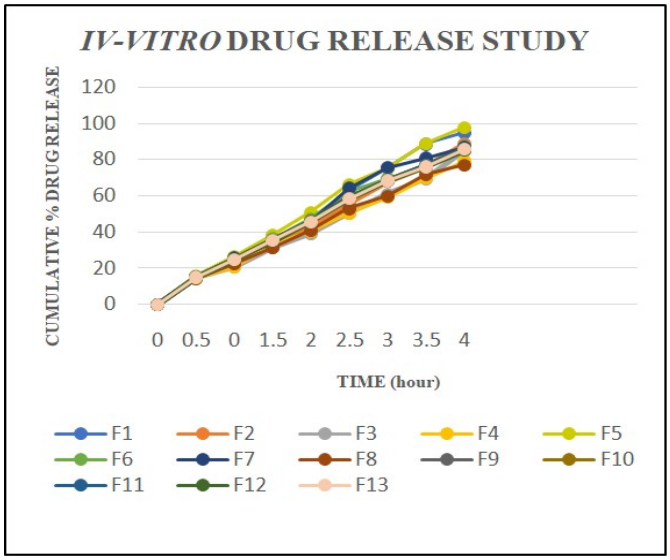


Figure 3. *In-vitro* drug release ofdifferent batches of formulations

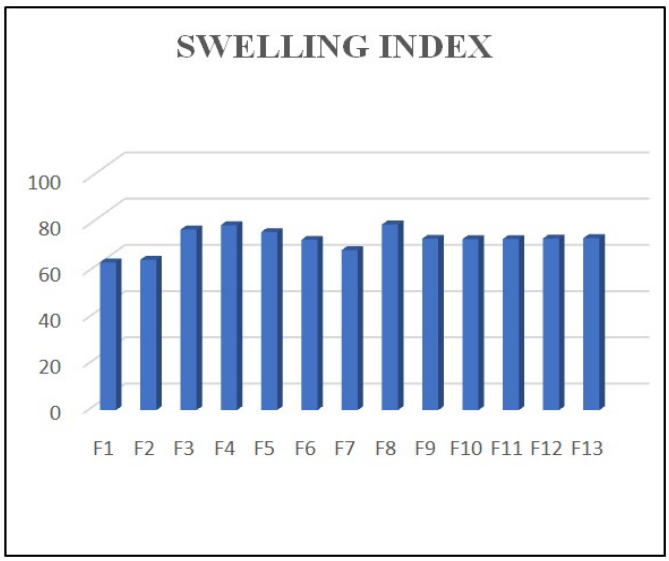


Figure 4. Graphical representation of swelling index in different batches of formulations

Table 6. Numerical test results of model adequacy checking for influence of independent variables on response variables

Response	Model	Sequencial p value	R^2	Adjusted R^2	Predicted R^2	Adequate precision	CV %
Drug release	Quadratic	<0.0001	0.9710	0.9565	0.8840	27.8407	1.31
Swelling index	Quadratic	<0.0001	0.9791	0.9642	0.8185	25.1847	1.43

Surface pH: The surface pH values of all the formulation were found to be not more than 7 and not less than 5.5 as shown in table no.27. This indicates that the all formulations are suitable for mucosal delivery.

In-vitro Dissolution Studies: The in-vitro drug release of all 13 formulations was determined using a USP II paddle apparatus with phosphate buffer (pH 6.8). F5 exhibited the highest drug release (97.78%) at the end of 4 hours, likely due to its low aerosil and microcrystalline cellulose content, which increased porosity and facilitated rapid penetration of the dissolution medium. In contrast, high Carbopol concentrations in formulations F3, F4, and F8 led to decreased drug release, possibly due to increased viscosity and the formation of a thick gel layer around the tablets. Formulations with moderate Carbopol levels and an excipient ratio of 5 demonstrated more favourable drug release profiles**.**

Swelling Index: Swelling study was performed on all the batches for 4hrs.From the results it was concluded that swelling increases as the time passes because of gradual absorption of water due to hydrophilicity of polymer.The hydrophilic polymer hydrates and swells, forming a gel barrier on the outer surface. As the gelatinous layer gradually dissolves, the hydration and swelling process continues, exposing new surfaces while maintaining the dosage form's integrity.The swelling index and mucoadhesion are interrelated, with higher swelling indices generally resulting in stronger mucoadhesive properties.

Optimization by Design Expert Software: Optimization was done byDesign Expert software (Version13.0.7.0, Stat-Ease). 2 factors were selected for optimizing the formulation i.e., excipient ratio, and Carbopol. To determine the best formulation2 responses i.e., *in-vitro* drug release and swelling index were considered. 13 formulations were suggested by the software and Central composite design was used to investigate the effect of the two independent variables and their potential interaction. On the basis of the fit summary, Quadratic model was chosen to be the best fit for *in-vitro* drug release and swelling index as suggested by the software.The outcomes of ANOVA indicated that the selected models were significant ($p < 0.05$) and the lack of fit (LOF) were not significant (p-values >0.05) indicating the reliability of the models.

The numerical optimization tool provided 13 sets of optimal solutions among which 19.105mg and excipient ratio 5 was selected by the software as optimized concentration with desirability of 0.905.The observed values of responsevariables were close to the values

predicted (error <5%), indicating the reliability of developed mathematical models.

Kinetic Studies: Thedata obtained from *in-vitro* drug release studies of formulation F5 was fitted into various kinetic model zero order,

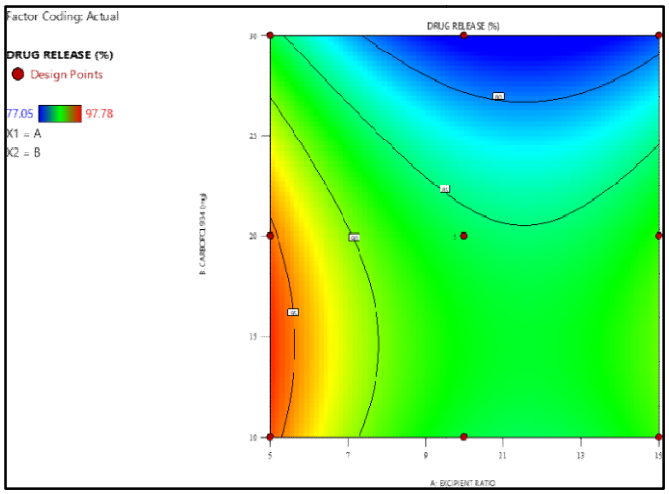


Figure 5. Contour plot showing the effect of excipient ratio and Carbopol on *in-vitro* drug release

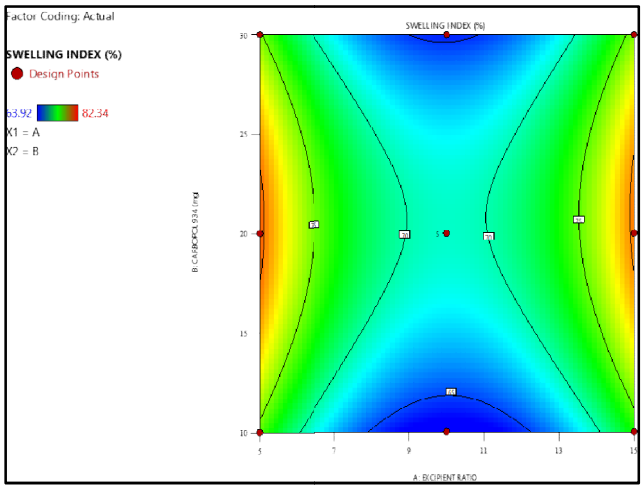


Figure 6. Contour plot showing the effect of excipient ratio and Carbopol on swelling index

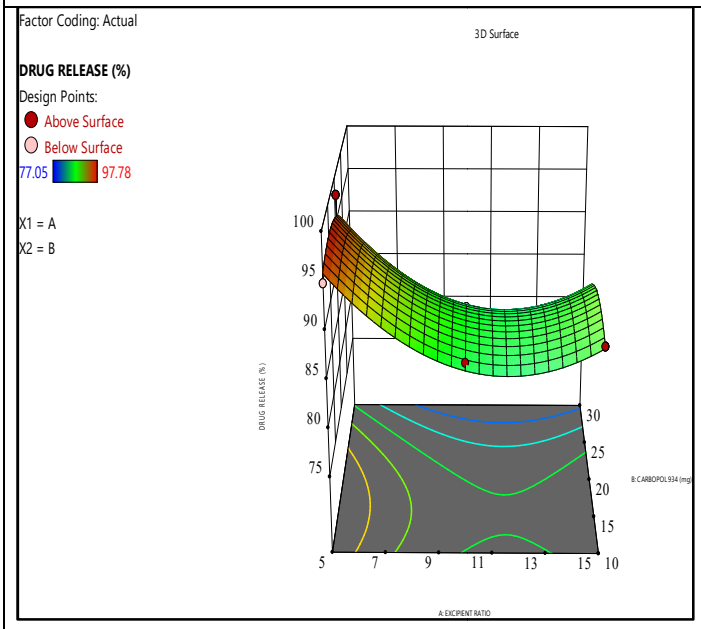


Figure 7. 3-D response surface plot for effect of excipient ratio and Carbopol on *in-vitro* drug release

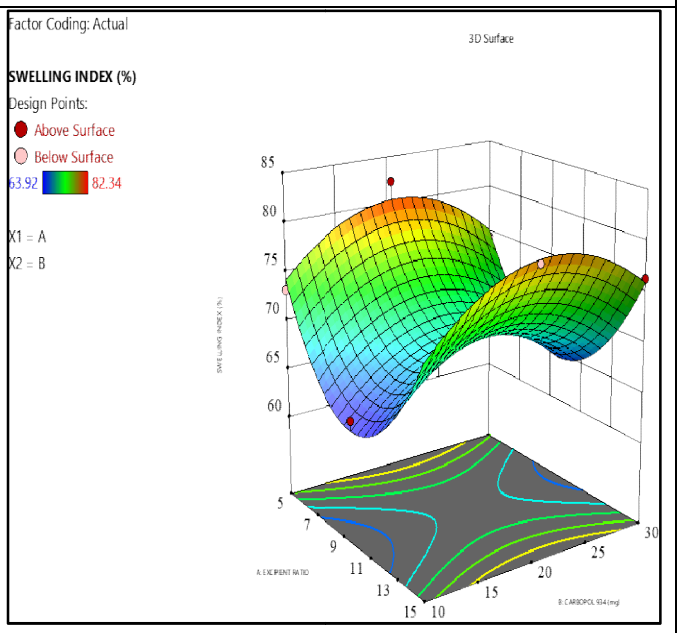


Figure 8. 3-D response surface plot for effect of excipient ratio and Carbopol on swelling index

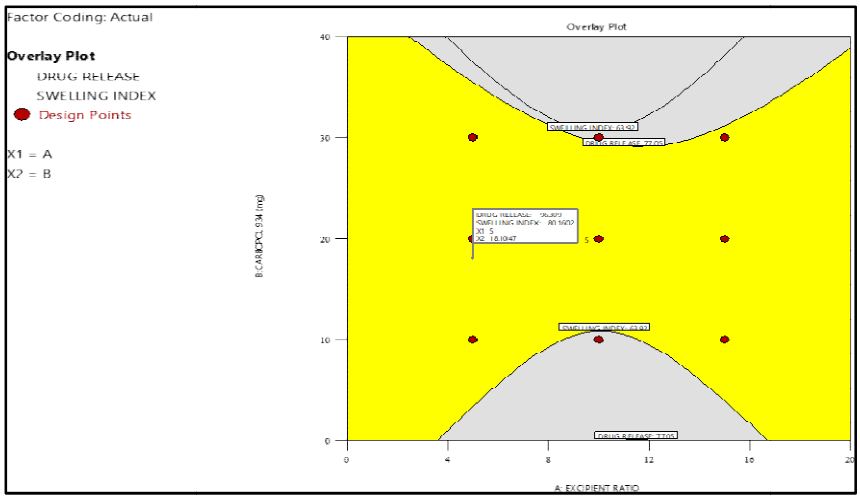


Figure 9. Overlay plot of optimized formulation of Miconazole nitrate liquisolid tablet

first order, Higuchi and Korsmeyer-Peppa's models. The correlation coefficients for zero order kinetics (0.9984), first order kinetics (0.9648), Higuchi model (0.99707) and Korsmeyer-Peppa's model (0.9863) were determined. As indicated by the R^2 values, first order kinetics best describes the drug release mechanism from the liquisolid tablets, indicating a immediate drug release.

The n value of 0.87 indicates anomalous (non-Fickian) diffusion, suggesting a combination of diffusion and erosion-controlled release mechanisms.

Stability Studies: The optimized formulation was subjected for stability studies as per ICH Guidelines for 3 months.

Table 7. Response values of predicted, experimental and percentage error obtained at optimal levels of the factors

Response	Predicted	Experimental	%Error
Drug release	96.3089	97.01	0.72
Swelling index	80.1602	80.84	0.84

Table 8. Drug release kinetics of optimized formulation

FORMULATION	ZERO ORDER	FIRST ORDER	HIGUCHI	KORSMEYER-PEPPAS	
	R^2	R^2	R^2	R^2	n
F5	0.9851	0.9928	0.9707	0.9863	0.8782

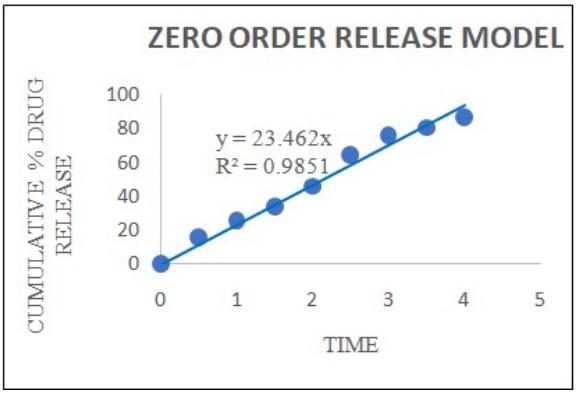


Figure 11. First order release model

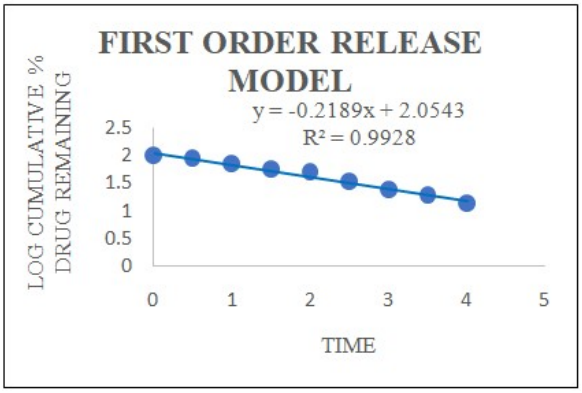
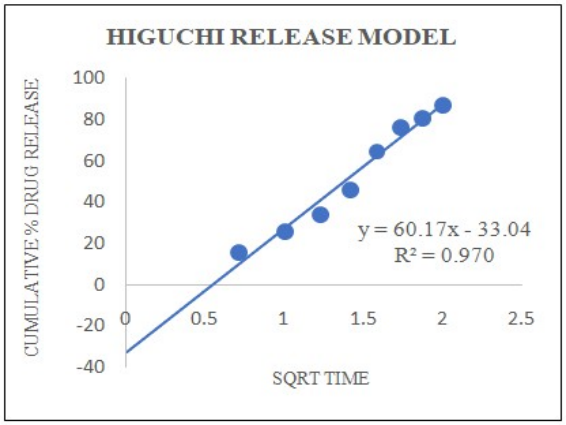


Figure 12. Higuchi release model



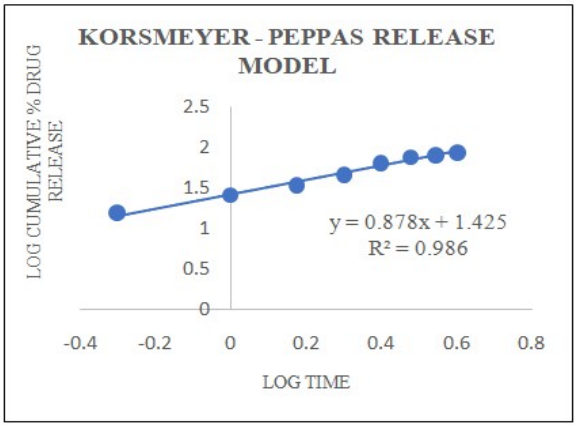


Figure 13. Korsmeyer-Peppas release model

STORAGE CONDITION	SAMPLING INTERVAL	HARDNESS kg/cm^2	FRIABILITY (%)	DRUG CONTENT (%)	SWELLING INDEX (%)	*IN-VITRO* DRUG RELEASE (%)
40°C ± 2°C at 75% ± 5% RH	Initial study	5.5±0.24	0.26±0.34	97.99±0.21	80.84±0.27	97.01±0.37
	30 days	5.5±0.38	0.26±0.27	97.27±0.39	80.51±0.54	97.27±0.53
	90 days	5.5±0.11	0.26±0.51	97.13±0.28	8025±0.37	96.88±0.41
25°C ± 2°C at 60% ± 5% RH	Initial study	5.5±0.24	0.26±0.34	97.99±0.21	80.84±0.27	97.01±0.37
	30 days	5.5±0.22	0.26±0.54	97.74±0.41	81.73±0.74	97.15±0.46
	90 days	5.5±0.38	0.26±0.16	97.41±0.41	80.54±0.24	97.03±0.38
5°C ± 3°C	Initial study	5.5±0.24	0.26±0.34	97.99±0.21	80.84±0.27	97.01±0.37
	30 days	5.4±0.38	0.26±0.62	97.25±0.53	80.31±0.68	97.57±0.34
	90 days	5.5±0.44	0.27±0.31	97.12±0.33	80.11±0.31	96.94±0.28

All values are expressed as mean ± SD, n=3

It showed that formulated tablets were stable at conditions as per ICH guidelines with not much significant changes in hardness, friability, drug content, swelling index and *in-vitro* drug release.

CONCLUSION

This study successfully developed and optimized mucoadhesive liquisolid tablets of Miconazole nitrate using microcrystalline cellulose (carrier) and Aerosil-200(coating material). The optimized formulation, which comprised 19.105 mg of Carbopol and an excipient ratio of 5, demonstrated a desirable drug release profile with a high desirability value of 0.905. The formulation followed first-order kinetics with a non-Fickian release pattern and remained stable under storage conditions. In conclusion, Miconazole, was formulated into liquisolid mucoadhesive tablets to enhance drug release, thereby improving absorption and therapeutic response. Better drug release was achieved by maintaining a low excipient ratio and incorporating a moderate amount of bioadhesive agent. The liquisolid system increased the drug's solubility and improved the bioavailability at site of action.

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