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Formulation, Development and Evaluation of Posaconazole Oral Dissolving Films For Enhanced Antifungal Therapy

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Abstract

The allure of ODFs lies in their unique properties, making them an attractive. These advantages have been underscored by their utility in serving special populations, including pediatric and geriatric patients and individuals who confront swallowing difficulties. ODFs, with their capacity to mitigate the inherent challenges of other dosage forms, present an exciting avenue for overcoming barriers to drug administration.[3] Absorption from the oral cavity refers to the process by which substances, such as drugs or nutrients, are taken up by the body when they are administered or consumed through the mouth.

Keywords: Allure, Transformative, Drug Delivery System.

Introduction

The allure of ODFs lies in their unique properties, making them an attractive. These advantages have been underscored by their utility in serving special populations, including pediatric and geriatric patients and individuals who confront swallowing difficulties. ODFs, with their capacity to mitigate the inherent challenges of other dosage forms, present an exciting avenue for overcoming barriers to drug administration.[3]

Within the pharmaceutical landscape, the design and application of ODFs have garnered profound attention. ODFs are conceived as a versatile drug delivery system, offering precise dosing, elevated bioavailability, and a route toward improved patient compliance. The ability of ODFs to mask the often bitter taste of certain drugs is of particular relevance, as it addresses a critical issue in the administration of medications to children and the elderly. Moreover, ODFs are enabling the realization of personalized medicine, as they permit the customization of drug delivery profiles and the formulation of multiple APIs within a single strip. [4]

The subject of this thesis is the dynamic world of ODFs. This research seeks to explore, in depth, the evolution and significance of this transformative drug delivery system. By delving into the intricacies of ODF formulation, the nuances of their manufacturing processes, and the subtleties of drug release kinetics, this study endeavors to provide a comprehensive understanding of ODFs. [5]

Absorption from the oral cavity

Absorption from the oral cavity refers to the process by which substances, such as drugs or nutrients, are taken up by the body when they are administered or consumed through the mouth. This absorption can occur through several mechanisms, and the extent of absorption depends on various factors, including the nature of the substance, its formulation, and the physiological characteristics of the oral cavity.[6]

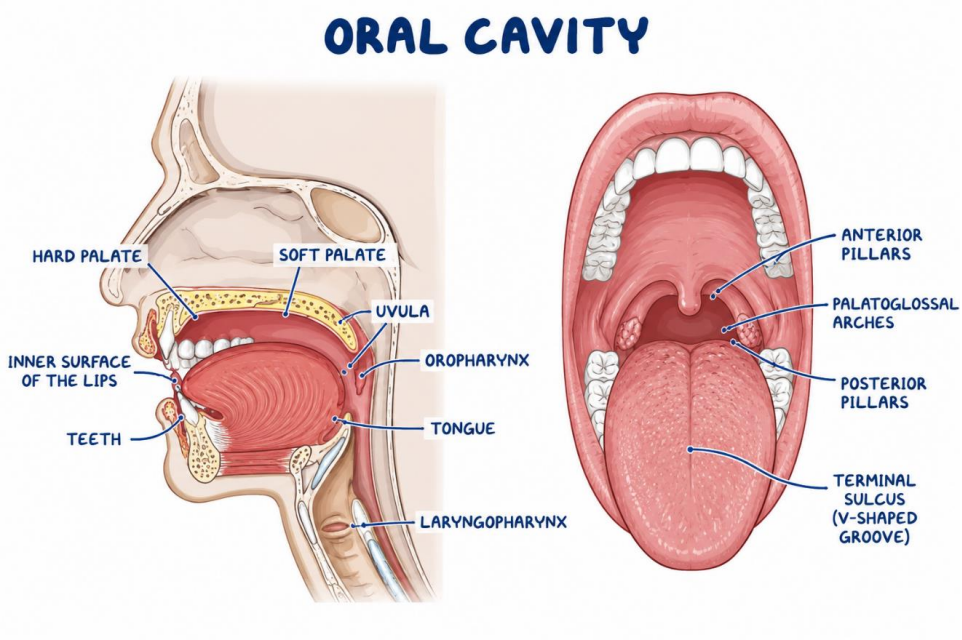

Figure 1: The Oral cavity[7]

Materials

The chemicals and solvents used in the present investigation are listed in Table below:

Table 1: List of Ingredients

Sn	Name	Supplier / Manufacturer
1	Posaconazole	Gift sample from IPCA Labs PVT. LTD.,Mumbai
2	Sodium starchGlycolate	Central Drug House (P) Ltd., New Delhi
3	Sodium Alginate	Central Drug House (P) Ltd., New Delhi
4	Pullulan	Nagase India PVT. LTD.
5	Eudragit	Central Drug House (P) Ltd., New Delhi
6	Gycerol	Central Drug House (P) Ltd., New Delhi
7	HPMC	Rajasthan Drug House (P) Ltd., Jaipur
8	PEG-400	Rajasthan Drug House (P) Ltd., Jaipur
9	Citric Acid	Rajasthan Drug House (P) Ltd., Jaipur
10	Aspartame	Triveni Chemicals India, Gujrat

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Instruments/Equipment

The equipment and instruments used in the present investigation are listed in Table

Table 2: List of Instruments and Equipments

Sn	Name	Manufacturer WithModel
01	Melting Point Apparatus	Sunbim, India
02	Digital Weighing Balance	Fisher brand, PS-200
03	Double beam UV Spectrophotometer	Systronics 2203
04	Differential Scanning Calorimeter(DSC)	Perkin Elmer, Pyris-1, DSC, USA
05	Infra-Red Spectrophotometer	Shimadzu FTIR-5300
06	Incubator	Instrument India, Mumbai
07	Micrometer	Instrument India, Mumbai
08	Disintegrator	Lab India DT 1000
09	Six Basket Dissolution RateApparatus (USP 24)	Lab India DS 8000
10	Magnetic stirrer	Instrument India, Mumbai
11	Heating mantle	Instrument India, Mumbai

Identification of Drug

The FTIR spectrum of pure Posaconazole showed characteristic absorption peaks corresponding to the functional groups present in the drug molecule. The obtained peaks were found to be in agreement with reported standard values, confirming the identity and purity of Posaconazole. The characteristic peaks are summarized in Table 6.1 and represented in Figure 6.1.

Table 3: FTIR Spectrum of Posaconazole

Functional Group Present	Standard Wave Number Range (cm^{-1})	Observed Peak (cm^{-1})
O–H Stretching	3600 – 3200	3392.14
C–H Stretching (Aliphatic)	3000 – 2850	2941.28
C=O Stretching	1750 – 1650	1698.42
C=N Stretching	1650 – 1550	1604.75
C=C Aromatic Stretching	1600 – 1450	1508.31
C–O Stretching	1300 – 1000	1105.63
C–Cl Stretching	850 – 600	748.22

Melting Point Determination

The melting point of Posaconazole was determined by capillary fusion method. The observed melting point was found to be close to the reported literature value, indicating purity of the drug sample.

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Table 4: Melting Point of Posaconazole

Sn	Method	Literature Melting Point	Observed Melting Point
1	Capillary Fusion Method	170°C – 172°C	171°C

Drug-Excipient Compatibility Study

a) Physical Compatibility Study

The compatibility study of Posaconazole with selected excipients was carried out by storing samples under open (O), closed (Cl), and controlled (Co) conditions at accelerated stability conditions (40°C/75% RH). The samples were visually observed periodically for any change in color, appearance, liquefaction, or physical instability for four weeks.

Table 5: Drug-Excipient Physical Compatibility Study

Combination (1:1 Ratio)	**After I Week**			**After II Week**			**After III Week**			**After IV Week**		
	Co.	Cl.	O	Co.	Cl.	O	Co.	Cl.	O	Co.	Cl.	O
HPMC E5	W	W	W	NC	NC	NC	NC	NC	NC	NC	NC	NC
PEG 400	Clr	Clr	Clr	NC	NC	NC	NC	NC	NC	NC	NC	NC
Citric Acid	W	W	W	NC	NC	NC	NC	NC	NC	NC	NC	NC
Aspartame	OW	OW	OW	NC	NC	NC	NC	NC	NC	NC	NC	NC
HPMC E5 + Posaconazole	W	W	W	NC	NC	NC	NC	NC	NC	NC	NC	NC
PEG 400 + Posaconazole	W	W	W	NC	NC	NC	NC	NC	NC	NC	NC	NC
Citric Acid + Posaconazole	W	W	W	NC	NC	NC	NC	NC	NC	NC	NC	NC
Aspartame + Posaconazole	OW	OW	OW	NC	NC	NC	NC	NC	NC	NC	NC	NC

***Clr = Clear, W = White, OW = Off White, NC = No Change**

b) Chemical Compatibility Study

The chemical compatibility study of Posaconazole with selected excipients was performed using FTIR and DSC analysis prior to formulation development. The FTIR spectra of pure drug and physical mixtures showed all characteristic peaks of Posaconazole without significant shifting, disappearance, or appearance of additional peaks. DSC thermograms also showed the characteristic endothermic peak of Posaconazole with no significant alteration in melting behavior.

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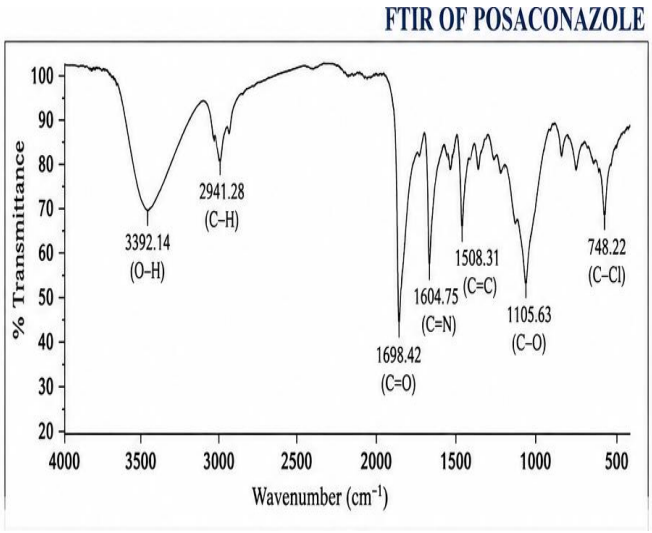

Functional Group	Standard Range (cm^{-1})	Observed Peak (cm^{-1})
O–H Stretching	3600 – 3200	3392.14
C–H Stretching (Aliphatic)	3000 – 2850	2941.28
C=O Stretching	1750 – 1650	1698.42
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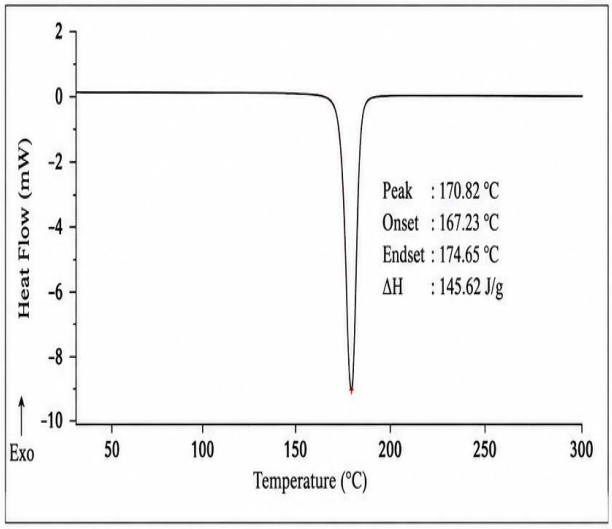
C=C Aromatic Stretching	1600 – 1450	1508.31
C–O Stretching	1300 – 1000	1105.63
C–Cl Stretching	850 – 600	748.22

Figure 2: FTIR Spectrum of Posaconazole



Parameter	Observation
Nature of Peak	Sharp Endothermic Peak
Melting Temperature (T_m)	170–172 °C
Onset Temperature	167.23 °C
Endset Temperature	174.65 °C
Enthalpy (ΔH)	145.62 J/g
Interpretation	Confirms crystalline nature and purity of Posaconazole
Compatibility Observation	No significant shift in peak in physical mixture

Figure 3: DSC of Posaconazole

Table 6: FTIR Compatibility Study of Posaconazole with Different Polymers

Combination (Drug + Polymer)	IR Peaks (cm^{-1})	Liquefaction	Compatibility
Posaconazole	3392, 2941, 1698, 1604, 1508, 748	No	Compatible
Posaconazole + Pullulan	3390, 2938, 1695, 1602, 1505, 745	No	Compatible
Posaconazole + HPMC E5	3388, 2940, 1697, 1605, 1507, 749	No	Compatible
Posaconazole + Sodium Alginate	3395, 2935, 1692, 1601, 1503, 742	No	Compatible
Posaconazole + PVA	3387, 2942, 1696, 1603, 1509, 747	No	Compatible
Posaconazole + PEG 400	3391, 2937, 1694, 1604, 1506, 746	No	Compatible
Posaconazole + Citric Acid	3385, 2939, 1691, 1600, 1502, 744	No	Compatible
Posaconazole + All Excipients	3390, 2940, 1695, 1604, 1507, 748	No	Compatible

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Development of Calibration Curve of Posaconazole

Table 7: Mean Absorbance Values and Statistical Data of Calibration Curve of Posaconazole

Sn	Concentration (µg/ml)	Mean Absorbance* ± S.D
1	2	0.118 ± 0.002
2	4	0.236 ± 0.003
3	6	0.351 ± 0.004
4	8	0.469 ± 0.002
5	10	0.587 ± 0.003
6	12	0.704 ± 0.004

*Mean of three determinations

Evaluation of Placebo Oral Dissolving Films

Table 8: Evaluation Parameters of Placebo Oral Dissolving Films

Parameters	F1	F2	F3	F4	F5	F6	F7	F8	F9
Weight variation (mg)	20.15±0.12	21.45±0.18	22.10±0.15	23.08±0.11	21.88±0.14	20.75±0.10	22.50±0.09	21.60±0.16	23.15±0.13
Thickness (mm)	0.041±0.002	0.044±0.003	0.046±0.002	0.048±0.001	0.045±0.002	0.043±0.003	0.047±0.002	0.044±0.001	0.049±0.003
Surface Ph	6.21	6.35	6.44	6.58	6.70	6.52	6.33	6.61	6.82
Folding endurance	185	198	210	225	240	232	238	246	255

a) Appearance

Films prepared using pullulan and HPMC E5 appeared transparent and smooth with good flexibility. Films containing sodium alginate showed slightly opaque appearance. Pullulan-based films demonstrated better texture and uniformity compared to other polymeric formulations.

b) Weight of Film

Films of 4 cm² area were weighed using electronic balance and average weight was determined. The weight variation of placebo films ranged from 20.15–24.20 mg.

c) Thickness of Film

Thickness was measured using Vernier caliper and found to range between 0.041–0.050 mm, indicating uniform film casting.

d) Surface pH of Film

The surface pH of films was found in the range of 6.21–6.82, which is close to salivary pH and suitable for oral mucosal application without causing irritation.

e) Folding Endurance

Folding endurance values ranged from 185–268, indicating good flexibility and mechanical strength of the films.

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Evaluation of Posaconazole Oral Dissolving Films

Table 9: Physical Characterization of Posaconazole Oral Dissolving Films

Parameters	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Weight variation (mg)	21.32±0.25	22.54± 0.31	23.15± 0.29	24.08± 0.42	25.12± 0.35	21.88± 0.26	22.96± 0.18	23.44± 0.32	24.15± 0.24	25.42± 0.28
Thickness (mm)	0.042±0.002	0.045± 0.003	0.048± 0.001	0.050± 0.002	0.052± 0.003	0.044± 0.002	0.047± 0.002	0.049± 0.001	0.051± 0.002	0.053± 0.003
Surface pH	6.42	6.55	6.61	6.74	6.82	6.48	6.67	6.79	6.88	6.91
Folding endurance	205	218	230	242	258	224	236	245	259	272
Tensile strength (kg/mm²)	0.845±0.05	0.964± 0.04	1.152± 0.03	1.425± 0.06	1.862± 0.08	1.284± 0.05	1.518± 0.04	1.662± 0.06	1.745± 0.05	1.958± 0.07
Percent elongation (%)	2.35	2.42	2.48	2.56	2.64	2.45	2.53	2.58	2.62	2.70
Disintegration time (sec)	34±0.32	28±0.24	21±0.15	18±0.21	12±0.18	30±0.25	24±0.19	20±0.16	16±0.12	10±0.14
Drug content (%)	96.45±0.42	97.18± 0.38	98.02± 0.31	98.74± 0.27	99.56± 0.25	97.25± 0.36	98.14± 0.29	98.88± 0.34	99.15± 0.28	99.72± 0.22

Evaluation of Posaconazole Oral Dissolving Films

a) Organoleptic and Physical Evaluation

Films prepared using pullulan and HPMC E5 exhibited smooth texture, flexibility, and transparency. Sodium alginate-containing films were slightly opaque but showed acceptable appearance and handling properties.

b) Weight Variation

The weight of films ranged from 21.32–25.42 mg, indicating uniform distribution of ingredients within the film matrix.

c) Thickness of Film

Film thickness ranged from 0.042–0.053 mm, confirming uniform casting and controlled film preparation.

d) Surface pH

Surface pH values ranged from 6.42–6.91, indicating compatibility with oral mucosa and minimizing chances of irritation.

e) Folding Endurance

The folding endurance of films ranged between 205–272, demonstrating excellent flexibility and mechanical stability.

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f) Tensile Strength

Tensile strength values ranged from 0.845–1.958 kg/mm², indicating adequate mechanical strength for handling and packaging.

g) Percent Elongation

Percent elongation values ranged from 2.35–2.70%, suggesting good elasticity and flexibility of oral films.

h) Disintegration Time

The disintegration time of films ranged from 10–34 seconds, demonstrating rapid dissolution suitable for oral candidiasis therapy.

i) Drug Content

Drug content was found between 96.45–99.72%, indicating uniform distribution of Posaconazole in all formulations.

j) In-vitro Drug Release Study

The in-vitro dissolution study of Posaconazole oral dissolving films was carried out using USP dissolution apparatus in simulated salivary fluid (pH 6.8 phosphate buffer) maintained at 37±0.5°C and stirred at 50 rpm. Samples were withdrawn at predetermined intervals of 1, 2, 4, 6, 8, and 10 minutes and analyzed spectrophotometrically at 262 nm.

The optimized formulation exhibited rapid and maximum drug release due to the hydrophilic nature of polymers and rapid disintegration characteristics of oral films. The cumulative drug release of optimized formulation reached approximately 98% within 10 minutes.

The release data were fitted into kinetic models such as:

- Zero-order kinetic model (Cumulative % drug release vs time)
- First-order kinetic model (Log cumulative % drug remaining vs time)
- Higuchi diffusion model
- Korsmeyer-Peppas model

Table 10: Dissolution Parameters for Formulations

S.No	Formulation code	t25% (min)	t50% (min)	t70% (min)	t90% (min)	Cumulative % drug release in 10 minutes
1.	F1	2.47	5.47	8.13	>10	82.94
2.	F2	2.74	6.10	8.46	>10	87.36
3.	F3	2.00	4.00	6.00	>9	97.21
4.	F4	1.35	3.00	4.22	>8	97.52
5.	F5	1.00	2.00	2.10	>6	98.57
6.	F6	2.98	6.00	8.23	>10	79.87
7.	F7	3.00	5.47	8.12	>10	82.48
8.	F8	2.13	4.47	7.10	>10	89.36
9.	F9	2.00	4.00	6.01	>10	95.58
10.	F10	1.48	2.49	4.47	>10	98.01

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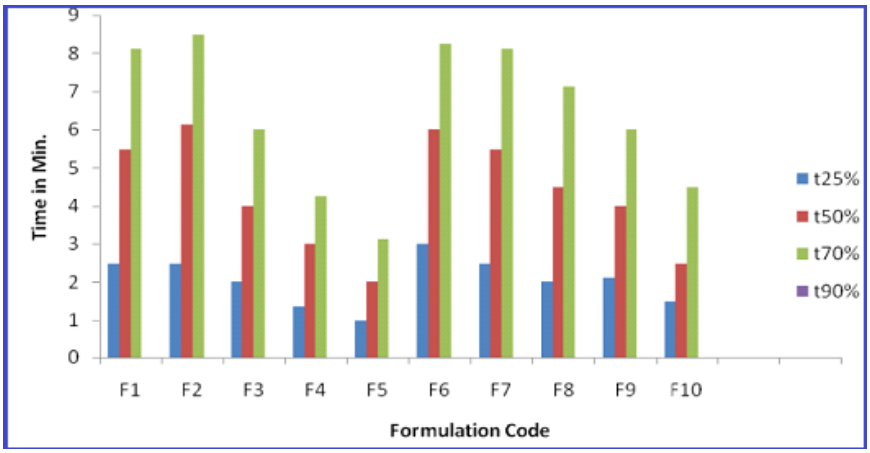

Figure 4: Comparison of Dissolution Parameters (T25%, T50%, T70%, T90%) Of oral Dissolving Films of Posaconazole

Table 11: Kinetic value obtained from in vitro release

Formulation Code	Zero order		First order	
	Ko (mg/h)	R^2	K1 (hr^{-1})	R^2
F1	7.497	0.567	0.487	0.957
F2	7.537	0.482	0.489	0.977
F3	7.597	0.457	0.487	0.969
F4	7.447	0.460	0.402	0.970
F5	8.517	0.628	0.478	0.995
F6	8.123	0.541	0.458	0.832
F7	7.737	0.529	0.263	0.991
F8	6.487	0.466	0.289	0.943
F9	7.861	0.601	0.378	0.907
F10	8.154	0.643	0.432	0.898

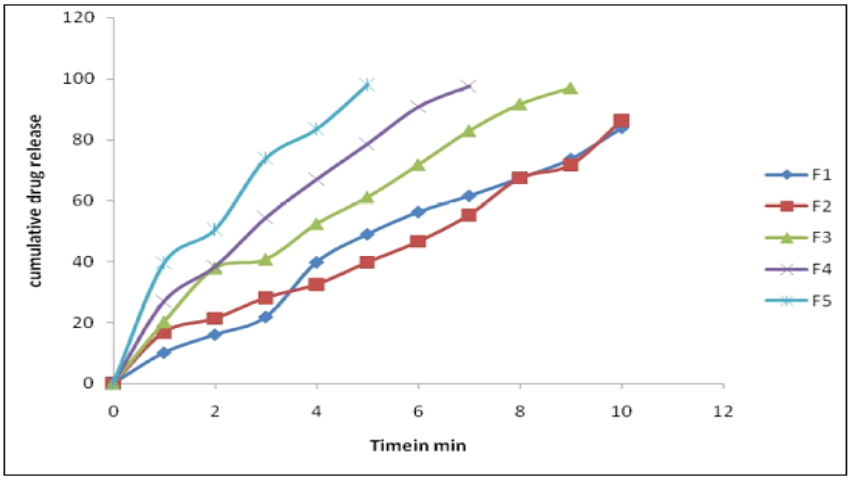

Figure 5: Cumulative Percent Drug Released Vs Time Plots (Zero Order) Of Formulations F1, F2, F3, F4 and F5 in pH 6.8 Phosphate Buffer

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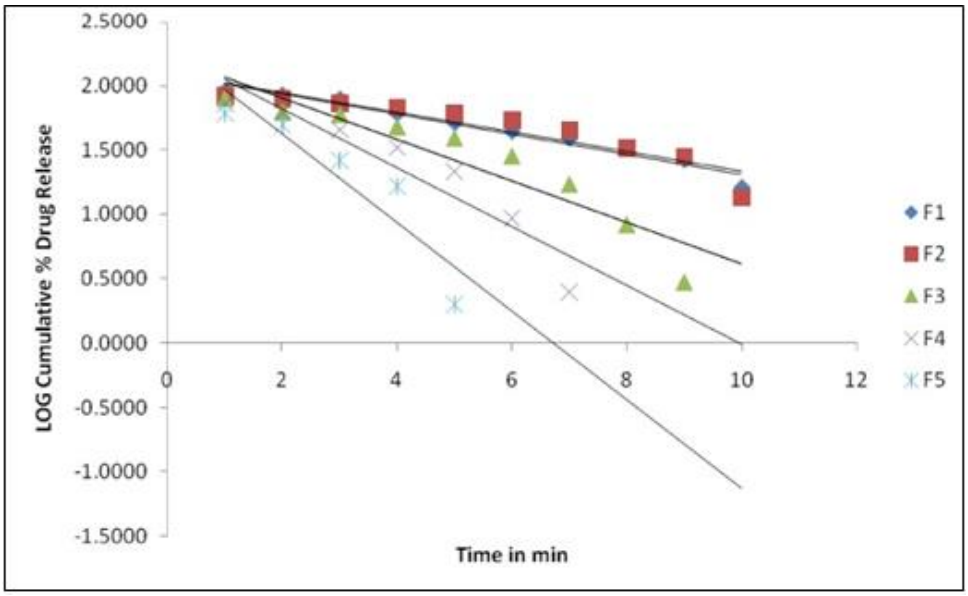

Figure 6: Log Cumulative Drug Remaining Vs Time Plots (First Order) Of Formulations F1, F2, F3, F4 and F5 in pH 6.8 Phosphate Buffer

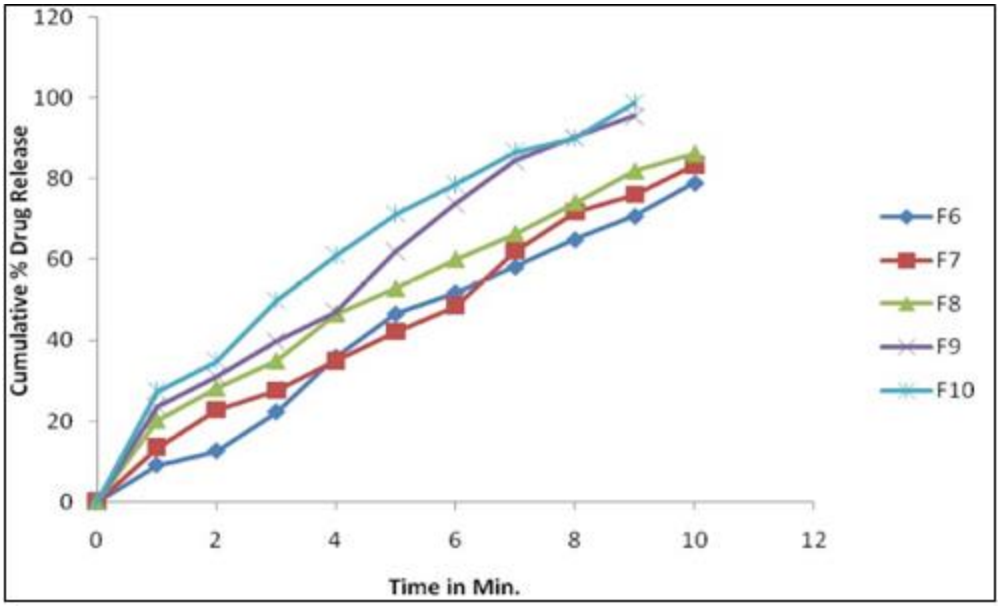

Figure 7: Cumulative Percent Drug Released Vs Time Plots (Zero Order) OfFormulations F6, F7, F8, F9 and F10 in pH 6.8 Phosphate Buffer

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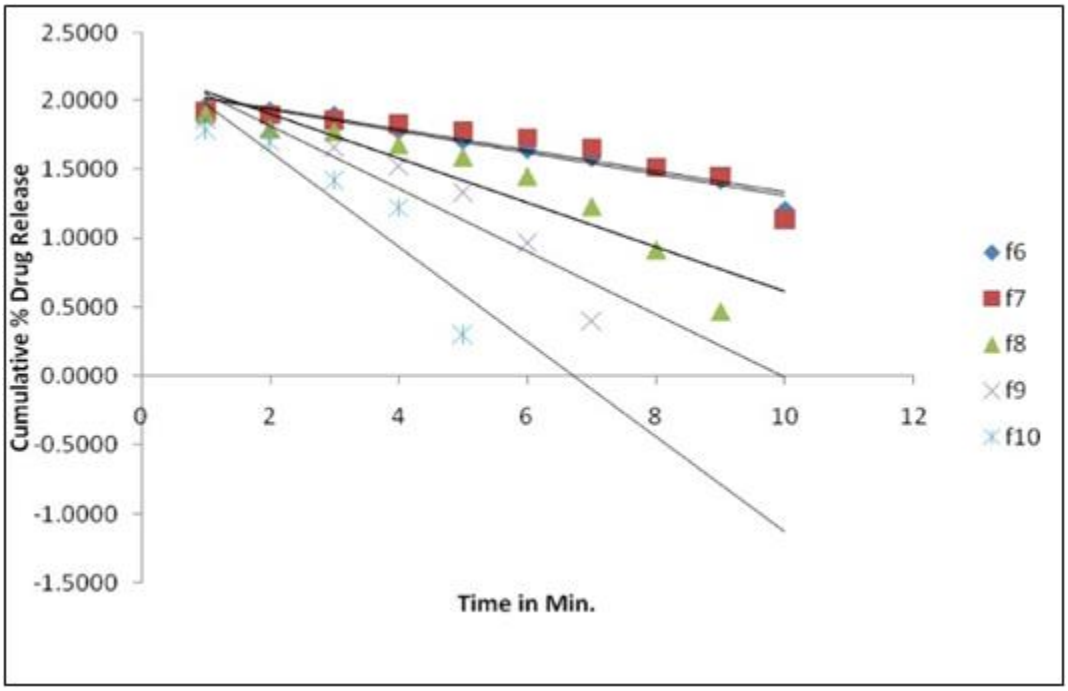

Figure 8: Log Cumulative Drug Remaining Vs Time Plots (First Order) Of Formulations F6, F7, F8, F9 and F10 in pH 6.8 Phosphate Buffer

Stability Studies

Stability Studies for Optimized Formulation F10

Stability studies of the optimized Posaconazole oral dissolving film formulation (F10) were carried out according to ICH stability guidelines. The prepared films were stored at refrigerated temperature (4±2°C), room temperature (25±2°C), and accelerated stability conditions (40±2°C/75% RH) for a period of three months.

The films were evaluated periodically for physical appearance, surface pH, tensile strength, percent elongation, folding endurance, and drug content. The formulation remained physically stable throughout the study period without any significant change in appearance, flexibility, or mechanical properties.

Table 12: Physical Stability Study of Optimized Formulation F10

Parameters	Initial	Room Temperature (25±2°C)	40±2°C / 75% RH	4±2°C
Appearance	Transparent, Smooth	No Significant Change	Slight Increase in Brittleness	No Significant Change
Surface Ph	6.91	6.88	6.84	6.90
Tensile Strength (kg/mm²)	1.958	1.942	1.915	1.950
Percent Elongation (%)	2.70	2.66	2.60	2.68
Folding Endurance	272	268	261	270
Disintegration Time (sec)	10	11	13	10

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Chemical Stability Evaluation

The chemical stability of the optimized formulation was evaluated by estimating drug content over a storage period of three months under different storage conditions. The formulation showed minimal reduction in drug content, indicating good chemical stability of Posaconazole within the oral dissolving film matrix.

Table 13: Drug Content of Optimized Formulation F10 During Stability Study

Storage Condition	0 Month	1 Month	2 Months	3 Months
4±2°C	99.72	99.10	98.64	98.15
Room Temperature (25±2°C)	99.72	98.88	98.32	97.94
40±2°C / 75% RH	99.72	98.45	97.82	97.20

Conclusion

From the overall experimental findings, it can be concluded that:

- Pullulan and HPMC E5 were found to be suitable film-forming polymers for the preparation of transparent, smooth, and flexible Posaconazole oral dissolving films.
- The developed oral dissolving films demonstrated satisfactory physicochemical and mechanical properties including uniform thickness, acceptable surface pH, high folding endurance, good tensile strength, and rapid disintegration.
- The optimized formulation showed excellent drug content uniformity and rapid in-vitro drug release, making it suitable for localized oral candidiasis therapy.
- The rapid dissolution and localized delivery of Posaconazole through oral dissolving films may enhance antifungal efficacy while minimizing systemic side effects.
- Stability studies confirmed that the optimized formulation remained physically and chemically stable under different storage conditions.
- The developed Posaconazole oral dissolving film system represents a promising alternative to conventional antifungal dosage forms due to its convenience, improved patient compliance, rapid onset of action, and effective localized therapy.

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