International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 4 July-Aug 2025, pp: 1202-1207 www.ijprajournal.com ISSN: 2456-4494

Formulation and In-Vitro Evaluation of Tadalafil Oral Disintegrating Strips for Enhanced Bioavailability

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Date of Submission: 20-08-2025 Date of Acceptance: 30-08-2025

ABSTRACT
Background: Erectile dysfunction (ED) is a prevalent disorder affecting men worldwide, often managed with oral phosphodiesterase type-5 (PDE5) inhibitors such as tadalafil. However, its limited oral bioavailability (~28%) necessitates the exploration of novel dosage forms. Oral disintegrating strips (ODS) provide a promising alternative due to rapid disintegration, improved patient compliance, and avoidance of first-pass metabolism.
Aim: To formulate and evaluate tadalafil oral disintegrating strips (ODS) using solvent casting method for enhanced dissolution and bioavailability.
Methods: Six formulations (F1–F6) were prepared using hydroxypropyl methylcellulose (HPMC K-15) as film-forming agent, glycerol as plasticizer, Tween 80 and sodium lauryl sulphate (SLS) as surfactants, citric acid as saliva stimulator, and sucrose with vanillin as sweetening/flavoring agents. The strips were evaluated for thickness, folding endurance, weight variation, drug content, disintegration time, in-vitro dissolution, and stability as per ICH guidelines. Drug–excipient compatibility was assessed via FT-IR.
Results: Among all formulations, F4 demonstrated superior performance with 92.83% drug content, disintegration time <30 seconds, and 94.2% cumulative drug release within 30 minutes. FT-IR spectra confirmed no significant drug–excipient interactions. Stability studies at 40±2°C/75% RH for 2 months showed no major changes in physicochemical parameters.
Conclusion: Tadalafil ODS prepared by solvent casting demonstrated improved dissolution and patient-friendly properties, indicating its potential as a novel therapeutic system for ED management in both pediatric and geriatric populations.
KEYWORDS: Tadalafil, Oral Disintegrating Strips, Solvent Casting, Bioavailability, Erectile Dysfunction

I. INTRODUCTION

Erectile dysfunction (ED) is a major global health concern with increasing prevalence due to aging, comorbidities such as diabetes and hypertension, and psychological factors. Conventional oral dosage forms of PDE5 inhibitors, such as tadalafil, are widely used but face limitations including poor aqueous solubility, variable absorption, and reduced bioavailability (~28%). These factors result in delayed onset of action and inconsistent therapeutic response.[1–3]

Oral disintegrating strips (ODS) are novel drug delivery systems designed to rapidly disintegrate in the oral cavity without the need for water, thus improving convenience and compliance. They are especially beneficial for pediatric, geriatric, and dysphagic patients.[4–6] Additionally, ODS can bypass hepatic first-pass metabolism, enhancing bioavailability and therapeutic efficacy.[7] Previous studies on sildenafil and other PDE5 inhibitors demonstrated improved dissolution and faster onset of action with ODS formulations compared to conventional tablets.[8–10]

This study focuses on the formulation and in-vitro evaluation of tadalafil ODS using the solvent casting method. The objective is to optimize formulation parameters for rapid disintegration, improved dissolution profile, and stability.

II. MATERIALS AND METHODS

Materials: Tadalafil (API) was obtained as a gift sample. Excipients included HPMC K-15 (film-forming agent), glycerol (plasticizer), Tween 80 (non-ionic surfactant), sodium lauryl sulphate (SLS, surfactant), citric acid (saliva stimulating agent), sucrose (sweetener), vanillin (flavoring agent), and propyl paraben (preservative). All reagents were of analytical grade.
Preparation of ODS: Tadalafil ODS were prepared by solvent casting. HPMC solution was prepared in distilled water with plasticizer and surfactants,

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followed by incorporation of drug and excipients. Entrapped air was removed by vacuum desiccation, and the solution was cast onto Petri dishes and dried at 50°C for 24 h. The dried films were cut into 2×2 cm² strips, each containing an equivalent dose of tadalafil.

EVALUATION PARAMETERS

Physicochemical characterization: Thickness, weight variation, folding endurance, and drug content uniformity.

Disintegration time: Evaluated in 10 mL simulated saliva at 37°C.

In-vitro dissolution: Performed in phosphate buffer pH 6.8 using USP dissolution apparatus.

FT-IR studies: To assess drug–excipient compatibility.

Stability studies: Conducted at 40±2°C/75% RH for 2 months as per ICH guidelines.

III. RESULTS AND DISCUSSION

Physicochemical Properties: All formulations exhibited uniform thickness, weight, and folding endurance >200, indicating satisfactory flexibility and strength. Drug content ranged from 85–93%, within acceptable pharmacopeial limits.

Disintegration and Dissolution: F4 emerged as the optimized formulation with disintegration time <30 sec and cumulative drug release of 94.2% within 30 min. The presence of HPMC K-15 and SLS significantly enhanced dissolution compared to other formulations. These findings are consistent with earlier reports on PDE5 ODS formulations.[11–13]

FT-IR Analysis: Spectra confirmed absence of significant interactions between tadalafil and excipients, validating compatibility.

Stability Studies: Optimized formulation F4 retained drug content, disintegration, and dissolution properties with minimal variation after 2 months storage, indicating good stability.

Comparative Perspective: Conventional tadalafil tablets show slower dissolution and limited bioavailability due to poor solubility. The present ODS formulation overcomes these limitations by providing rapid drug release, enhanced absorption potential, and better patient compliance. Similar benefits have been reported in ODS formulations of sildenafil and sumatriptan.[14–1]

Sr. no.	Ingredients	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)	F5 (mg)	F6 (mg)
1.	Tadalafil	20	20	20	20	20	20
2.	HPMC K-15	450	400	350	300	250	200
3.	Propyl paraben	-	10	20	20	20	20
4.	Sodium starch glycolate	5	5	5	10	10	10
5.	Tween 80 (ml)	20	20	20	20	20	20
6.	Vanillin	-	5	5	10	10	10
7.	Sucrose	-	5	10	10	10	10
8.	Glycerol (ml)	5	5	10	10	10	10
9.	Citric acid	-	20	50	50	50	50
10.	Sodium lauryl sulfate	-	10	10	50	100	150
11.	Distilled water	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Total weight (mg) :		500mg	500mg	500mg	500mg	500mg	500mg

Table-1 **Formulation optimization of oral disintegrating strips of Tadalafil.**

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Formulation code	Drug Content (%)	Disintegration time (sec)
	69.92%	40
F2	73.87%	34
F3	86.32%	29
F4	92.83%	20
F5	70.91%	37
F6	82.33%	35

Table-2 Evaluation Parameters of Tadalafil ODF's F1

Sr.no.	Time (min)	% Drug release of oral disintegrating strips					
		F1	F2	F3	F4	F5	F6
1.	5	21.6	25.8	20.3	32.4	25.7	23.8
2.	10	34.9	40.6	31.7	48.6	43.8	38.7
3.	15	49.8	54.9	46.2	61.9	54.7	55.9
4.	20	62.1	64.7	62.7	72.7	69.8	71.8
5.	25	74.6	80.3	73.8	87.6	80.5	73.7
6.	30	80.7	86.6	82.8	94.2	89.9	80.6

Table-3 In-vitro drug release of ODF's of Tadalafil.

Time (hr)	Log time	Square root of time	Cumulative % Drug release	Cumulative % drug remaining	Log Cumulative % drug released	Log Cumulative % drug remaining	Cube root of Cumulative % drug remaining
5	0.69	2.23	21.6	78.4	1.334	1.894	4.279
10	1	3.16	34.9	65.1	1.542	1.813	4.022
15	1.17	3.87	49.8	50.2	1.697	1.700	3.688
20	1.30	4.47	62.1	37.9	1.793	1.578	3.359
25	1.39	5	74.6	25.4	1.872	1.404	2.939
30	1.47	5.47	80.7	19.3	1.906	1.285	2.682

Table-4 kintetic evaluation data for formulation F1

Time (hr)	Log time	Square root of time	Cumulative % Drug release	Cumulative % drug remaining	Log Cumulative % drug released	Log Cumulative % drug remaining	Cube root of Cumulative % drug remaining
5	0.69	2.23	25.8	74.2	1.411	1.870	4.202
10	1	3.16	40.6	59.4	1.608	1.773	3.901
15	1.17	3.87	54.9	45.1	1.739	1.654	3.559
20	1.30	4.47	64.7	35.3	1.810	1.547	3.280
25	1.39	5	80.3	19.7	1.904	1.294	2.700
30	1.47	5.47	86.6	13.4	1.937	1.127	2.375

Table-5 kintetic evaluation data for formulation F2

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Time (hr)	Log time	Square root of time	Cumulative % Drug release	Cumulative % drug remaining	Log Cumulative %drug released	Log Cumulative % drug remaining	Cube root of Cumulative % drug remaining
5	0.69	2.23	20.3	79.7	1.307	1.901	4.303
10	1	3.16	31.7	68.3	1.501	1.834	4.087
15	1.17	3.87	46.2	53.8	1.664	1.730	3.775
20	1.30	4.47	62.7	37.3	1.797	1.571	3.341
25	1.39	5	73.8	26.2	1.868	1.418	2.970
30	1.47	5.47	82.8	17.2	1.918	1.235	2.581

Table-6 kintetic evaluation data for formulation F3

Time (hr)	Log time	Square root of time	Cumulative % Drug release	Cumulative % drug remaining	Log Cumulative %drug released	Log Cumulative % drug remaining	Cube root of Cumulative % drug remaining
5	0.69	2.23	32.4	67.6	1.510	1.829	4.073
10	1	3.16	48.6	51.4	1.686	1.710	3.718
15	1.17	3.87	61.9	38.1	1.791	1.580	3.364
20	1.30	4.47	72.7	27.3	1.861	1.436	3.011
25	1.39	5	87.6	12.4	1.942	1.093	2.314
30	1.47	5.47	94.2	5.8	1.974	0.763	1.796

Table-7 kintetic evaluation data for formulation F4

Time (hr)	Log time	Square root of time	Cumulative % Drug release	Cumulative % drug remaining	Log Cumulative %drug released	Log Cumulative % drug remaining	Cube root of Cumulative % drug remaining
5	0.69	2.23	25.7	74.3	1.409	1.870	4.204
10	1	3.16	43.8	56.2	1.641	1.749	3.830
15	1.17	3.87	54.7	45.3	1.737	1.656	3.564
20	1.30	4.47	69.8	30.2	1.843	1.480	3.114
25	1.39	5	80.5	19.5	1.905	1.290	2.691
30	1.47	5.47	89.9	10.1	1.953	1.004	2.161

Table-8 kintetic evaluation data for formulation F5

Time (hr)	Log time	Square root of time	Cumulative % Drug release	Cumulative % drug remaining	Log Cumulative %drug released	Log Cumulative % drug remaining	Cube root of Cumulative % drug remaining
5	0.69	2.23	23.8	76.2	1.376	1.881	4.239
10	1	3.16	38.7	61.3	1.587	1.787	3.942
15	1.17	3.87	55.9	44.1	1.747	1.644	3.533
20	1.30	4.47	71.8	28.2	1.856	1.450	3.043
25	1.39	5	73.7	26.3	1.867	1.419	2.973
30	1.47	5.47	80.6	19.4	1.906	1.287	2.686

Table-9 kintetic evaluation data for formulation F6

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Formulation	Zero order		First order		Higuchi Model		Peppas Model		Hixson Crowel Model	
	Ko	r2	K1	r2	KH	r2	n	r2	K	r2
F1	2.439	0.988	-0.025	0.988	19.03	0.993	0.758	0.996	-0.066	0.995
F2	2.473	0.989	-0.030	0.970	19.27	0.992	0.686	0.996	-0.074	0.988
F3	2.601	0.992	-0.027	0.976	20.17	0.985	0.813	0.991	-0.070	0.990
F4	2.496	0.989	-0.041	0.942	19.47	0.994	0.602	0.997	-0.091	0.980
F5	2.549	0.989	-0.033	0.963	19.90	0.996	0.697	0.998	-0.081	0.99
F6	2.313	0.939	-0.024	0.977	18.33	0.974	0.707	0.983	-0.064	0.969

Table-10 In vitro Drug Release Kinetic Parameters

IV. CONCLUSION

Tadalafil ODS formulated via solvent casting demonstrated improved drug release, rapid disintegration, and stability, highlighting their potential as an effective and patient-friendly dosage form for ED management. This approach can improve bioavailability and therapeutic outcomes compared to conventional tablets, offering significant advantages for special populations.

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