RESEARCH ARTICLE

Design, Optimization and Characterization of Mouth Dissolving Orodispersible Films of Irbesartan and Triamterene

Abhijeet Motiwale*, Narendra Pratap Singh Sengar

Faculty of Pharmaceutical Sciences, Sanjeev Agrawal Global Educational University, Bhopal, Madhya Pradesh, India

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ABSTRACT

Mouth Dissolving Orodispersible Films (ODFs) **a**re thin, flexible films designed to dissolve quickly in the mouth without the need for water. They are a convenient and patient-friendly drug delivery system, especially useful for pediatric, geriatric, and pediatric patients or those who have difficulty swallowing tablets or capsules. Mouth Dissolving Orodispersible Films represent a promising drug delivery platform that combines convenience, rapid action, and improved compliance, making them increasingly popular in modern pharmaceutical formulations. In the present work Mouth Dissolving Orodispersible Films of Irbesartan and Triamterene was formulated, optimized using design expert software and further characterized.

Keywords: Mouth dissolving film, Oral delivery, Optimization, Diuretic

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INTRODUCTION

Mouth dissolving orodispersible films (ODFs) are innovative drug delivery systems designed to rapidly dissolve and disintegrate in the oral cavity without the need for water. These ultra-thin, flexible films offer a convenient and patient-friendly alternative to traditional tablets and capsules, especially benefiting pediatric, geriatric, and dysphagic patients. Composed of various polymers, plasticizers, sweeteners, and flavoring agents, ODFs provide a pleasant taste and ease of administration. Their quick disintegration enhances bioavailability and ensures rapid onset of action, making them ideal for medications requiring fast relief. Additionally, their portability and discreet nature improve patient compliance and adherence. Despite some challenges related to stability and uniformity, mouth dissolving orodispersible films are gaining popularity as a versatile and effective drug delivery platform in modern pharmaceutical technology. Irbesartan is a potent ARB with remarkable efficacy in the management of hypertension, as a renoprotective agent, and in the prevention of stroke. Its well-established pharmacokinetic profile and numerous studies describing the clinical benefits of irbesartan position it as a valuable drug. Though irbesartan is very well tolerated and has no serious adverse effects, safety considerations must be taken to reduce the overall risk associated with the administration of the drug.[1]

Irbesartan is an Angiotensin II (Ang-II) receptor blocker (ARB) that works by blocking angiotensin II receptor. It is generally prescribed for management of high blood pressure. It is relatively long acting than other ARBs and shows dose-dependent activity. [2] Triamterene belongs to potassium-sparing diuretics class of drugs. The drug also possesses similar properties to dihydrofolate reductase inhibitors. It is an important drug used for management of hypertension and fluid retaining states. It is a valuable diuretic in managing conditions such as hypertension and oedema.[3] The main objective of the present study outlines a systematic approach for design, evaluation and optimization of fast dissolving oral films of some antihypertensive drugs in combination with diuretic drug to enhance the therapeutic efficacy and provide rapid onset of action.

Table 1: Design builds information using Design-Expert®

Parameters	Remarks
Study type	Response Surface
Design type	Central Composite
Design Model	Quadratic
Sub type	Randomized
Runs	13

Table 2: Independent Variables in Experimental Design

S. No.	Independent variables	Level of variation		
		Low	Medium	High
1.	X1- Pullulan (% w/v)	5	7.5	10
2.	X2- PEG-400 (% w/v)	5	10	15

MATERIAL AND METHODS

Formulation of Mouth Dissolving Orodispersible Films (MDODS)

**Author for Correspondence: abhijeet@mcwhealthcare.com*

Table 3: Dependent Variables in Experimental Design

S. No.	Response or dependent variables	Units
1.	R1- % Drug release – Irbesartan/ Triamterene	%
3.	R2-DT	sec
4.	R3- Tensile strength	%

Table 4: Central composite experimental design for mouth dissolving orodispersible films (MDODF)

S. No.	Std. Run	Batch No.	Factor 1 A: Pullulan %	Factor 2 B: PEG-100 %
1.	4	MDODF-1	10	15
2.	13	MDODF-2	7.5	10
3.	12	MDODF-3	7.5	10
4.	2	MDODF-4	10	5
5.	11	MDODF-5	7.5	10
6.	9	MDODF-6	7.5	10
7.	3	MDODF-7	5	15
8.	7	MDODF-8	7.5	2.92893
9.	8	MDODF-9	7.5	17.0711
10.	1	MDODF-10	5	5
11.	6	MDODF-11	11.0355	10
12.	5	MDODF-12	3.96447	10
13.	10	MDODF-13	7.5	10

The Irbesartan and Triamterene mouth dissolving orodispersible films (MDODF) were formulated by using casting method. The formulation of mouth dissolving orodispersible films by the solvent casting method involves several key steps. First, an appropriate polymer (Pullulan), plasticizer (PEG), taste-masking agents, sweeteners, and other excipients are weighed and dissolved in a suitable solvent, typically water or a mixture of water and alcohol, to prepare the casting solution. The Irbesartan and Triamterene is then uniformly dispersed or dissolved in this solution to ensure even distribution throughout the film. The mixture is thoroughly stirred to achieve homogeneity and free of bubbles. The resulting solution is then cast onto a flat, non-stick surface such as a Petri dish or glass plate, using a casting knife or applicator to spread it evenly. The film is dried at controlled temperature and humidity conditions until it becomes firm and dry. Once dried, the film is carefully peeled off, cut into desired sizes, and packaged in moisture-proof containers to preserve its integrity. [4]

Optimization of Irbesartan and Triamterene loaded Mouth dissolving orodispersible films (MDODF)

Design Expert 13@ Software i.e., CCD was used for the optimization of formulation.

The design builds information is shown in table 1, list of independent variables is shown in table 2, list of response or dependent variables is shown in table 3 and experimental designs for FIM formulation is shown in table 4 The concentration of polymer Pullulan (X1) AND concentration of polymer PEG-400 (X2) were selected as two independent variables and % drug release (R1), disintegration time (R2) and tensile strength (R3) were selected as response variables. Further, statistical validity using ANOVA and 3D-response surface plots were established to find the compositions of optimized formulation.[5]

Characterization of the Irbesartan and Triamterene loaded Mouth dissolving orodispersible films (MDODF)

The prepared and optimized formulation was evaluated for color, smoothness, homogeneity. Thickness was measured by vernier caliper while average weight was determined for every formulated batch. Folding endurance was determined by checking the cracks. Moisture content was determined placing film in the dessicators. By universal testing machine, tensile strength was calculated. pH was determined by pH meter, drug contemt was determined by UV visible spectrophotometer. USP DT apparatus was used to measure the DT and percent release was determined using USP I rotating basket apparatus.[6-7]

RESULTS AND DISCUSSION

Formulation of Mouth Dissolving Orodispersible Films (MDODS)

Irbesartan and Triamterene mouth dissolving orodispersible films (MDODF) were prepared using casting method.

Table 5: Effect of independent variables on response variables

Batch No.	Independent variable		Response variables			
	X1	X2	R1 (%)		R2 (sec)	R3 (%)
	% w/v	% w/v	IBT	TMT		
MDODF-1	10	15	67.22	66.57	12	9.19
MDODF-2	7.5	10	65.44	64.86	10	9.33
MDODF-3	7.5	10	65.44	64.86	10	9.33
MDODF-4	10	5	85.55	84.67	15	9.56
MDODF-5	7.5	10	65.44	64.86	10	9.33
MDODF-6	7.5	10	65.44	64.86	10	9.33
MDODF-7	5	15	70.22	69.32	10	9.67
MDODF-8	7.5	2.92893	87.98	87.12	12	9.43
MDODF-9	7.5	17.0711	72.13	71.89	13	10.02
MDODF-10	5	5	77.23	76.88	13	9.98
MDODF-11	11.0355	10	79.56	78.82	12	9.26
MDODF-12	3.96447	10	62.72	62.05	13	9.55
MDODF-13	7.5	10	65.44	64.86	10	9.33

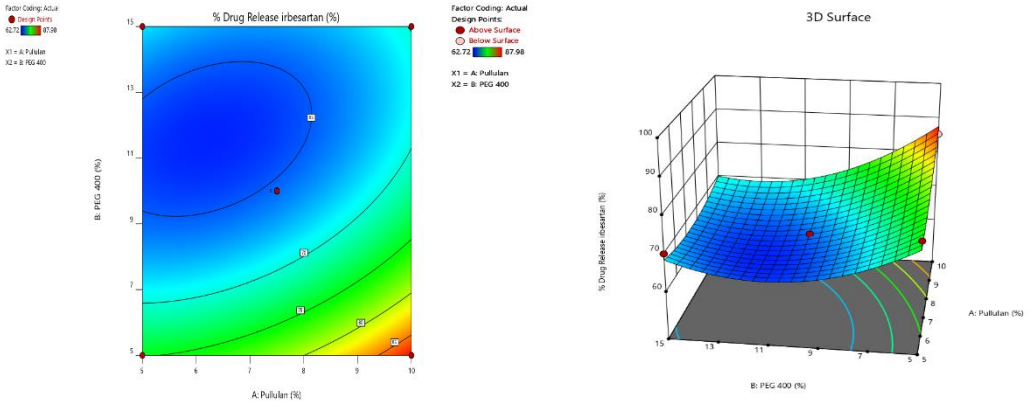

Figure 1: 3D surface plot of Mouth dissolving orodispersible films (MDODF) for % Drug Release Irbesartan

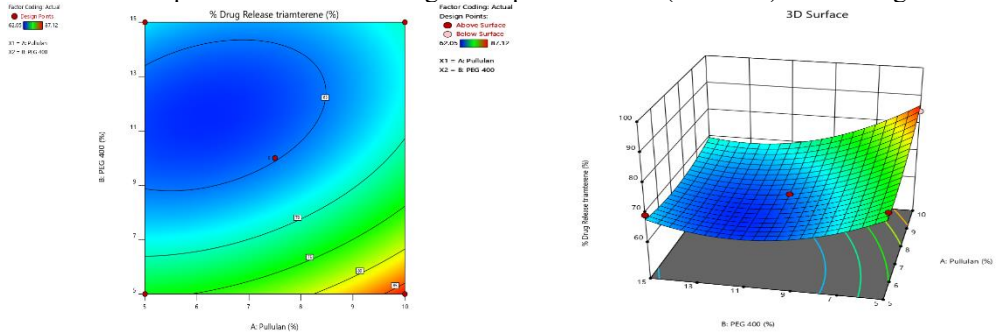

Figure 2: 3D surface plot of Mouth dissolving orodispersible films (MDODF) for % Drug Release Triamterene

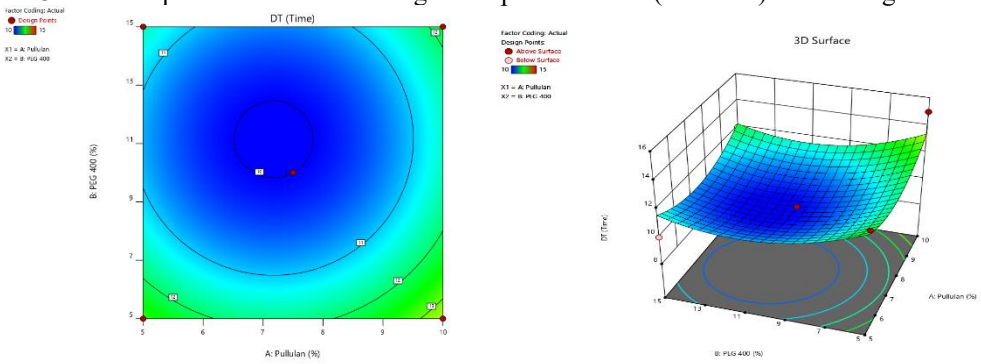

Figure 3: 3D surface plot of Mouth dissolving orodispersible films (MDODF) for Disintegration Time

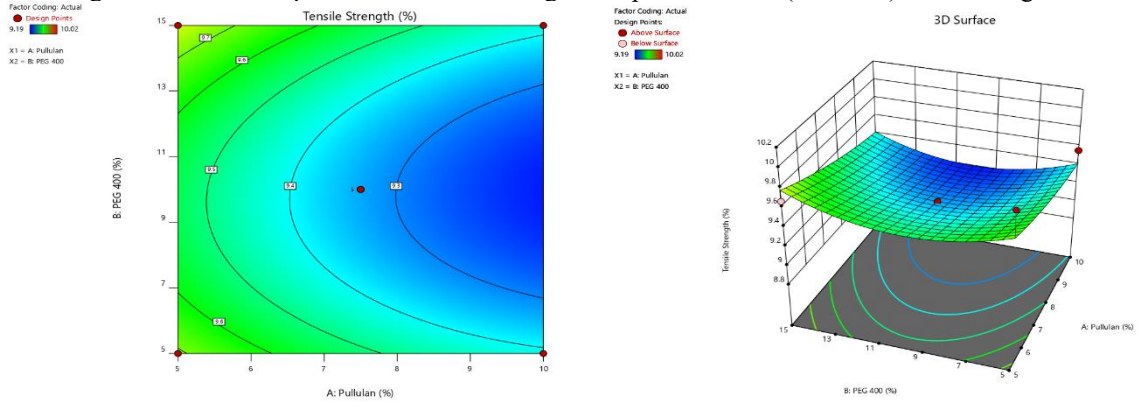

Figure 4: 3D surface plot of Mouth dissolving orodispersible films (MDODF) for Tensile Strength

Optimization of Irbesartan and Triamterene loaded Mouth dissolving orodispersible films (MDODF)

Total 13 runs were done in experimental design and effects of independent variable were investigated. Table 5 showed effect of independent variable responses. Figure 1, 2 ,3 and 4 represent the 3D surface plot for % drug release of Irbesartan, % drug release of Triamterene, DT and tensile strength respectively. Table 6 represents validated values of both the variables. Results were found to be very close to the batch selected from solutions given by software

Characterization of the Irbesartan and Triamterene loaded Mouth dissolving orodispersible films (MDODF)

Table 7: Physical appearance, Thickness and Average weight of Irbesartan and Triamterene loaded Mouth dissolving orodispersible films (MDODF)

Batch No.	Physical appearance	Thickness (mm)	Average weight (mg)	Folding endurance (%)	Moisture content (%)	Surface pH
MDODF-1	Transparent	0.24±0.09	67.3±1.13	139±1.15	1.19±0.043	6.5±0.11
MDODF-2	Transparent	0.28±0.02	50.2±1.18	122±2.20	0.97±0.320	6.2±0.05
MDODF-3	Transparent	0.32±0.03	54.7±1.20	127±1.18	1.80±0.012	6.4±0.06
MDODF-4	Transparent	0.48±0.06	50.2±2.11	132±3.20	2.22±0.006	6.1±0.03
MDODF-5	Transparent	0.12±0.03	59.6±3.16	134±1.11	2.53±0.732	6.7±0.01
MDODF-6	Transparent	0.22±0.09	55.9±1.12	128±2.10	2.60±0.044	6.5±.02
MDODF-7	Transparent	0.51±0.08	59.8±1.16	130±1.17	2.65±0.035	6.6±0.11
MDODF-8	Transparent	0.39±0.01	68.4±1.86	116±3.18	2.10±0.063	6.8±0.10
MDODF-9	Transparent	0.41±0.07	63.7±1.29	114±2.22	1.90±0.082	6.6±0.06
MDODF-10	Transparent	0.62±0.02	62.6±1.18	122±1.48	1.87±0.007	6.7±0.12
MDODF-11	Transparent	0.57±0.02	56.2±1.10	130±1.12	1.08±001	6.9±0.46
MDODF-12	Transparent	0.29±0.03	60.3±2.10	132±1.10	0.90±0.030	6.2±0.18
MDODF-13	Transparent	0.39±0.05	54.3±1.10	119±0.97	0.93±0.480	6.5±0.03
Optimized	Transparent	0.58±0.04	70.6±1.15	110±2.45	0.98±0.028	6.7±0.04

Table 8: Tensile strength, drug content and disintegration time of Irbesartan and Triamterene loaded Mouth dissolving orodispersible films (MDODF)

Batch No.	Tensile strength (%)	Drug content (%)		Disintegration time (sec)	Drug release (%)	
		IBT	TMT		IBT	TMT
MDODF-1	9.19	94.32	93.11	12	67.22	66.57
MDODF-2	9.33	90.29	92.86	10	65.44	64.86
MDODF-3	9.33	93.28	90.11	10	65.44	64.86
MDODF-4	9.56	93.29	96.27	15	85.55	84.67
MDODF-5	9.33	90.48	90.37	10	65.44	64.86
MDODF-6	9.33	93.12	93.28	10	65.44	64.86
MDODF-7	9.67	94.28	95.48	10	70.22	69.32
MDODF-8	9.43	94.25	94.16	12	87.98	87.12
MDODF-9	10.02	95.10	96.28	13	72.13	71.89
MDODF-10	9.98	93.24	90.39	13	77.23	76.88
MDODF-11	9.26	90.10	94.19	12	79.56	78.82
MDODF-12	9.55	90.49	93.20	13	62.72	62.05
MDODF-13	9.33	93.28	90.21	10	65.44	64.86
Optimized	9.433	98.26	99.10	12.714	84.698	83.829

Table 6: Validated Reading of Variables

Type of Variable	Variables	Optimized Value	Validated Value (n=3)
Independent	X1	9.312	9.312
	X2	5	5
Response or Dependent	R1 (IBT)	84.698	84.698
	R1 (TMT)	83.829	83.820
	R2	12.714	12.710
	R3	9.433	9.421

The mouth dissolving orodispersible films (MDODF) were transparent, smooth with no bubbles and cracks. The results pf physical appearance thickness, average weight, folding endurance, moisture content and pH was reported in table 7. The tensile strength of mouth dissolving orodispersible films (MDODF) ranges from 9.19 to 10.02.

The drug content of Irbesartan and Triamterene loaded Mouth dissolving orodispersible films (MDODF) were determined and were found in between 90.10 to 98.26 % fot IBT & 90.11 to 99.10 for TMT. The *in vitro* disintegration time of Irbesartan and Triamterene loaded Mouth dissolving orodispersible films (MDODF) were determined and were found in between 10 to 15 sec. The percentage drug release of Irbesartan and Triamterene loaded Mouth dissolving orodispersible films (MDODF) were determined and were found in between 62.72 to 87.98 % for IBT & 62.05 to 87.12% for TMT. The results were given in table 8.

CONCLUSION

This study demonstrates the successful development of Mouth Dissolving Orodispersible Films of Irbesartan and Triamterene

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