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DESIGN, PREPARATION AND CHARACTERIZATION OF ORAL DISINTEGRATING FILMS OF CANDESARTAN CILEXETIL

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ABSTRACT

In the present study, to develop oro dissolving films of candesartan cilexetil with an objective to achieve rapid dissolution/absorption and further improving the bioavailability of the drug. Also, to resolve the swallowing problems in pediatric, geriatric patients by rapid dissolution in saliva and improve the patient compliance. Oral disintegrating films of candesartan cilexetil were formulated using low viscosity grade of hydroxypropyl methylcellulose (HPMC E15) as a film forming polymer and glycerol as a plasticizer by solvent casting method. If higher concentration of HPMC E15 was resulted in sticky film formation. The *in vitro* disintegration time of the optimized batch ODF-2 was found to be 23 seconds. The films exhibited satisfactory thickness, mechanical properties like tensile strength, % elongation and elastic modulus. *In vitro* dissolution studies. The optimized batch was found to be (Formulation ODF-2) exhibited faster disintegration time showing 99.98 % drug release within 15 min.

KEYWORDS

Candesartan cilexetil, HPMC, Solvent casting method, Oral disintegrating films and *In vitro* evaluation.

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INTRODUCTION

In the present scenario mouth dissolving strips have been introduced to towards effective management of immediate attacked diseases. Mouth dissolving strips was developed based on the technology of the transdermal patch[1]. Mouth dissolving strips have attained great importance in the pharmaceutical industry due to their unique properties and advantages[2]. Fast dissolving drug delivery system

have started gaining popularity and acceptance as new drug delivery system, because they are easy to administer and leading to better patient compliance. The delivery systems either dissolve or disintegrate in the mouth rapidly, without requiring any water to aid in swallowing. In these cases oral mucosal drug delivery is most preferred for its wide scope of application for both systemic and local effects of drugs. This novel drug delivery system can also be beneficial for meeting the current needs of the industry are improved solubility/stability, biological half-life and bioavailability enhancement of drug[3].

The oral or buccal mucosa being highly vascularized, drugs can be absorbed directly and can enter the systemic circulation without undergoing first-pass hepatic metabolism. This is one of the added advantage of orodispersible formulation as little quantity of the drug may get absorbed in the buccal cavity, can be exploited in preparing products with improved oral bioavailability of molecules that undergo first pass effect. Availability of larger surface area of the film leads to rapid disintegration in the oral cavity[4, 5].

Candesartan cilexetil is an anti-hypertensive agent, angiotensin II receptor (AT_1) antagonist used in the treatment of hypertension, congestive heart failure and diabetic nephropathy. It has 15% oral bioavailability due to poor aqueous solubility that makes absorption and dissolution rate limited[6].

MATERIAL AND METHOD

Material

Candesartan cilexetil was a Gift sample from Aurobindo Pharma Ltd, Hyderabad. HPMC was a Gift sample from Apex Laboratories Pvt.Ltd, Chennai. All other chemicals and ingredients were used for study are of Analytical grade.

Method[7-8]

Candesartan cilexetil ODFs were prepared using different grades of Hydroxypropyl methyl cellulose like HPMC - 5cp, HPMC - E15, HPMC - 50cp by solvent casting method. The film was carefully removed from the petriplate, checked for the imperfections and cut to the required size to deliver the equivalent dose per strip (3.79 cm^2). Film samples with air bubbles, cuts, or imperfections were excluded from the study (Table No.1).

EVALUATION PARAMETERS

Thickness

The thickness of film is determined by screw gauge or micrometer at different points of the films.

Average Weight

Average Weight is studies by individually weighing 10 randomly selected films and calculating the average weight. The average weight should not deviate significantly from the average weight.

Average weight of films = weight of 10 films /10

Disintegration test

Determined manually by dipping the film in 10 ml of water in beaker with gently shaking when film was dissolved, time was noted.

Drug content

A film of size 2 cm^2 was cut and put 10 ml of volumetric flask which containing solvent. This was then shaken in a mechanical shaker for 2 hrs to get a homogeneous solution and filtered. The drug was determined spectroscopically by appropriate dilution.

In vitro drug release

Dissolution testing can be performed using the standard basket or paddle apparatus described in any of the pharmacopoeia. The dissolution medium will essentially be selected as per the sink conditions and highest dose of the API. Many times the dissolution test can be difficult due to tendency of the strip to float onto the dissolution medium when the paddle apparatus is employed.

RESULTS AND DISCUSSION

ODF-2 formulations resulted in less transparent and highly brittle films compared with the ODF-1, ODF-3 formulations which are transparent and separated easily. Thus ODF-1, ODF-2 and ODF-3 formulations were further evaluated for various parameters. Various tests performed are weight variation test, thickness measurement, Assay, *in vitro*

disintegration time (Table No.2, Figure No.1) and in *vitro* dissolution test (Table No.3, Figure No.2).

Table No.1: Preparation of Oral Disintegrating Films of Candesartan Cilexetil

S.No	Formulation code	Drug (mg)	HPMC 5CP (mg)	HPMC E15 (mg)	HPMC 50CP (mg)
1	ODF-1	8	8	-	-
2	ODF-2	8	-	8	-
3	ODF-3	8	-	-	8

Table No.2: Evaluation of Candesartan cilexetil ODF formulations

S.No	Formulation code	Thickness[a] (mm)	Average weight[a] (mg)	Disintegration time[a] (sec)	Drug content[b] (%)
1	**ODF-1**	0.47±0.04	12.85±0.1	13.80±1.05	104.19±0.71
2	**ODF-2**	0.79±0.05	13.49±0.07	10.00±0.08	99.40±0.74
3	**ODF-3**	0.52±0.06	12.9±0.08	29.71±0.95	101.82±0.16

a: Mean ± S.D., n=6 films , b: Mean ± S.D., n=5

Table No.3: Cumulative percent release of Candesartan cilexetil ODF formulations

S.No	Cumulative percent (±S.D) drug release			
	Time (min)	ODF-1	ODF-2	ODF-3
1	2	33.35±1.12	34.25±0.50	28.13±0.14
2	4	46.15±0.75	52.75±0.66	35.76±0.65
3	6	58.25±0.65	65.38±1.25	42.18±0.40
4	8	78.45±0.23	73.89±0.13	68.95±0.24
5	10	92.16±0.92	95±0.92	82.75±0.45
6	15	98.6±0.40	99.98±0.19	97.85±0.50

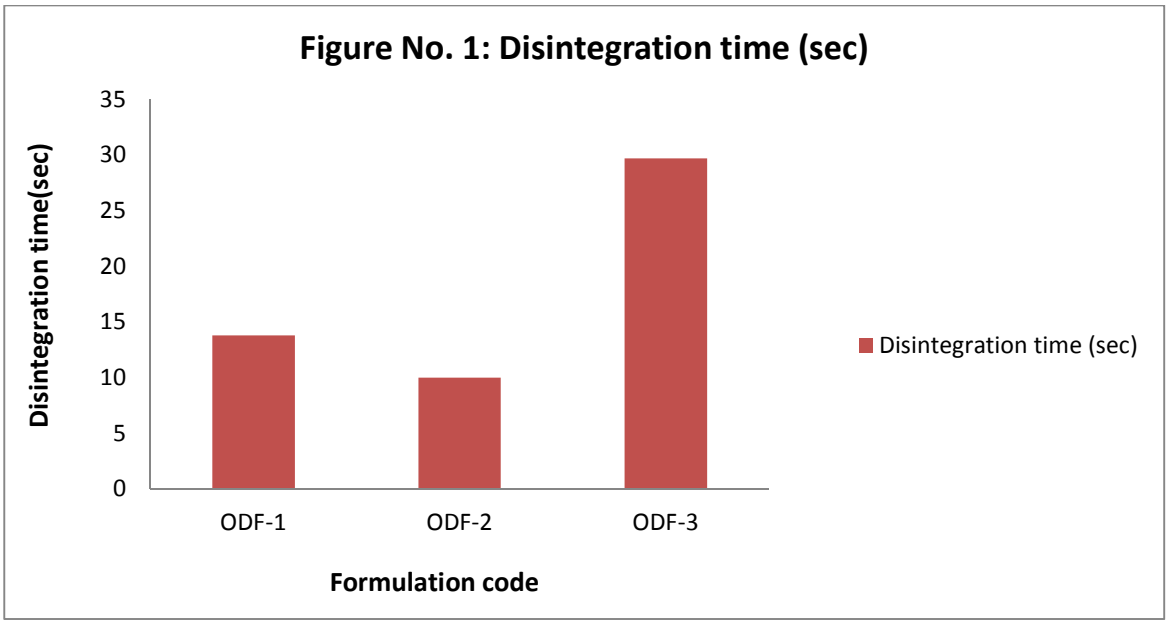

Figure No.1: Graphical representation disintegration times of Candesartan cilexetil oro dissolving films

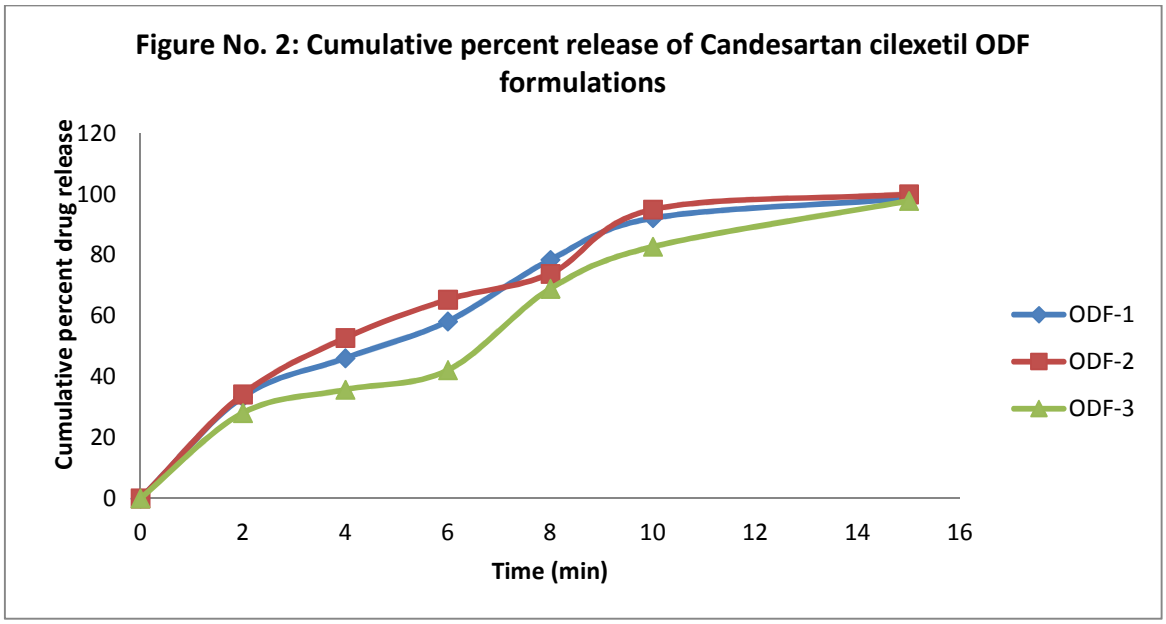

Figure No.2: Graphical representation of cumulative % release of Candesaran cilexetil - ODF formulations

CONCLUSION

Candesartan cilexetil Oro Dissolving Films were prepared by solvent casting method using different grades of Hydroxypropyl methylcellulose like HPMC - 5cps (ODF-1), HPMC – E15 (ODF-2) and HPMC - 50cps (ODF-3). Formulation ODF-2 exhibited faster disintegration time showing 99.98 drug release within 15 min. Oro Dissolving Films of candesartan cilexetil were found to improve the versatility, convenience, patient compliance leading to an enhanced approach for the administration of drug to the pediatrics and geriatrics.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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