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Research Article

Formulation and Evaluation of Oral Thin Film of Betahistine Dihydrochloride

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Abstract:
Oral route of medication, many substitutes have reliably been presented by including progressing novel headways for paediatrics, geriatrics, nauseous and resistance patients. Bio adhesive mucosal estimation structures including tablets, gels and fixes are after effects of mechanical new development. Orally disintegrating films (ODF) has one of the most famous types of medication administration because of its superb patient comfort and consistence. It very well may be put on the tongue without the need of water. Contrasted with ordinary oral measurements structures, ODFs typically bring about improved bioavailability with quicker onset of activity. Oral strip innovation gives a backup way to go to drugs with first pass digestion. This survey gives subtleties of materials utilized in ODF, fabricating perspectives, advances, and assessment tests.
Keywords: Oral disintegrating films, Bioavailability, Disintegration, conventional oral dosage forms, first pass metabolism.

Introduction

Oral route of drug administration has been one of the utmost expedients and acknowledged route of drug delivery and amongst it the intraoral route is the most ideal due to its ease and rapid onset of action. [1] The majority of the intraoral dose structures are expected to disintegrate, dissolve or release the drug in the oral cavity where it has an open door to be privately assimilated, partially or whole and afterward again may be swallowed and thusly assimilated along the gastro-digestive system (GIT).[2]

Rapidly dissolving films mostly dissolve within seconds to release the active agents but can be adapted to release the drug more slowly depending upon film thickness and assortment of the polymer matrix. A film or strip can be distinct as a dose structure that utilizes a water dissolving polymer which allows the measurement structure to rapidly hydrate, stick and break up when put on the tongue or in the oral hole to offer rapidly or fundamental medication conveyance. [3-6]

Betahistine is an antivertigo drug (BCS Class I) as often as possible utilized in balance problems or to mitigate vertigo side effects related with Meniere sickness. Betahistine is an exceptionally hygroscopic particle and acidic in nature. The object is to plan stable mouth dissolving films of Betahistine. Consequently, an endeavour will be made to figure out and assess the quick delivering oral slight films of Betahistine for disintegration and assimilation of medication, which might create the fast acting activity in the treatment of vertigo. [7]

In the current situation mouth dissolving strips have been presented towards effective management of immediate attacked sicknesses. This research includes the plan enhancement of settled Betahistine mouth dissolving strips that will be ingested straight forwardly and can enter the fundamental course without going through first-pass hepatic digestion.

Materials and Methods:: Betahistine dihydrochloride was a gift sample from Intas pharma. Hypromellose (HPMC 15 cps) was purchased from Balaji drugs and Polyvinyl Alcohol was purchased from Nippon Gohsei. All other excipients were in house.

Table 1: Composition of ODF Betahistine dihydrochloride

INGREDIENTS	FUNCTION	F1	F2	F3	F4
Betahistine dihydrochloride	Anti- vertigo	10	10	10	10
HPMC 15CPS	Film forming agent	15	15	18	18
Polyethylene Glycol	Plasticizer	20	20	20	20
Glycerine	Plasticizer	5	5	5	5
Polyvinyl Alcohol	Film forming agent	2	2	2	2
Sodium Benzoate	Preservative	0.1	0.1	0.1	0.1
Citric Acid	pH adjusting agent	6	6	6	6
Sucralose	Sweetener	1	1	1	1
Aspartame	Sweetener	1	1	1	1
Beta cyclodextrin	Complexing agent	0.1	0.1	0.1	0.1
Croscarmellose Sodium	Super disintegrant	1	1	1	1
Purified water	Vehicle	Q. S	Q. S	Q. S	Q. S

Methods:

Formulation ingredients with their limits were as listed in table-1. Oral disintegrating films of Betahistine dihydrochloride were prepared by solvent casting method. Take purified water and added preservatives Sodium benzoate in it. Then added HPMC 15 cps and homogenous polymeric solution was prepared by continuous stirring. Then added Beta cyclodextrin in it. Added sweetener Sucralose, Aspartame in it and mixed well. Betahistine dihydrochloride was dissolved in small amount of solution. Both the solution was combined by using high shear method. In a separate container took polyethylene glycol, Polyvinyl alcohol and Glycerine mixed well and added in above step. The solution formed was then cast as a film and pour. The solution in a glass mould and allow the solution to dry in oven at 45 – 50˚C. Then cut in to pieces of desired size.

Evaluation:

1. Uniformity of Weight:

Each film was individually weighed on electronic balance (Effem (OHAUS)) and average weight of 3 films was found. A large difference in weight denotes the nonuniform distribution of drug in the film. (n=3)

2. Thickness of Film:

The thickness of the different films was measured using a calibrated dial gauge (Baker Precision Measuring Instruments) with an accuracy of 0.001 mm.

3. Surface pH

Surface pH of the film, the film was placed in a Petri dish and was moistened with 0.5 mL of distilled water and kept for 30 sec. The surface pH was measured by means of pH digital meter (Lab India) placed on the surface of the swollen films. The average of 3 determinations for each formulation was found out. (n=3)

4. Folding Endurance

Folding endurance was measured manually for the prepared films. A 7.07 cm^2 ODF was repeatedly folded at 180°C angle of the plane at the same place until it breaks. The number of times the film could be folded at the same place without breaking was noted for 3 films of same batch.[10]

5. HPLC Analysis

A HPLC method was used in determination of drug content of films and analysis of samples in drug release studies using HPLC. The mobile phase was a mixture of two in the proportion 60: 40: the first one was the buffer of pH 2.5 prepared with 0.1% Di basic sodium phosphate, 0.1% ammonium acetate, and 0.1% sodium pentane sulfonate filtered through 0.45 micron filter and the second one was acetonitrile and methanol mixed in the proportion of 20 : 20, sonicated, and degassed for 10 minutes by using sonicator. [11,12]

6. Drug Content and Uniformity of Dosage Units

A film was taken in a 100 mL volumetric flask and sonicated with 70 mL of methanol for 5 minutes after which the volume was made up to 100 mL with methanol. Then 1.0 mL of this solution was diluted to 100 mL with 0.1 N hydrochloric acid which was filtered through 0.45-micron filter and diluted as required and the drug content was found out by HPLC analysis.

7. In Vitro Drug Dissolution Study

The dissolution studies were performed in 900 mL of simulated salivary fluid as well as 0.1 N hydrochloric acid using Lab India DS8000 dissolution (paddle) apparatus (Lab India Instruments Pvt. Ltd., India) with autosampler at °C with paddle rotation speed at 50 rpm. The samples were collected through built-in 10 µ filter which were diluted previous to HPLC analysis.[13]

Results and Discussion:

Appearance, Weight, and Thickness

The ODFs were homogenous, smooth, and rough surface. The weight variation was found to be minimum as indicated by a small standard deviation of ±1.66 mg. The thickness shows a narrow range of 124.26 to

129.63 µm further substantiating the above inference.

Surface pH

The ODFs were pH having 7.03 to 7.08.

Table 2: Evaluation of ODFs

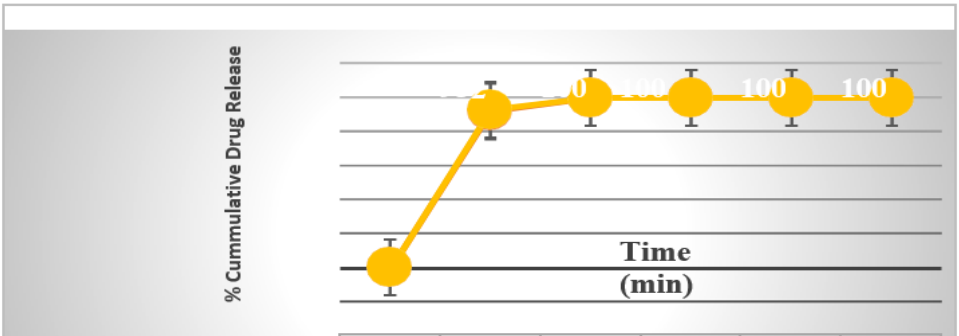
Formulation	Appearance	Weight	Thickness	pH
F1	Transparent	90.4 ± 1.36	126.26 ± 3.32	6.83±0.2
F2	Transparent	91.2 ± 1.62	124.26 ± 3.12	7.08±1.2
F3	Transparent	91.2 ± 0.96	128.26 ± 3.08	7.11±0.2
F5	Transparent	92.6 ± 1.16	126.26 ± 2.18	6.92±0.1

Table 3: Folding Endurance

Formulation	Folding Endurance
F1	4±1
F2	4±1
F3	5±1
F5	5±1

In-vitro Dispersion & Disintegration Time – As per the FDA recommendation the dispersion time of mouth dissolving films is less than 30s or less based on ODT's Disintegration test. Disintegration time of Betahistine dihydrochloride is 12sec.

In-Vitro Drug Release Study: In-vitro release study of oral dissolving films carried out in simulated saliva fluid & 0.1N HCL for 30 minutes. Betahistine Dihydrochloride oral dissolving films show rapid release in both media that correlated the disintegration time & in-vitro dispersion.



	0	1	5	10	15	30
Simulated Salivary Fluid	0	92	100	100	100	100
Dissolution 0.1N HCL	0	93	100	100	100	100

Figure 1: In-vitro release study

Taste Evaluation

Table 4: Results of Disintegration & Palatability

In-Vivo Disintegration Time (sec)	**Average rating by 10 Human Volunteers**			
	Initial Observation			
8.6 ± 0.5 sec	Sweetness	Mouth Feel	Bitterness	Flavor
	4.8	4.4	3.8	4.8
	After 5 minutes			
	4.2	4.4	4.2	4.4

Conclusion:

ODFs have a couple of positive perspectives differentiated and the other oral dosing structure. They offer negligible cost treatment with additional created bioavailability, sufficiency, and patient consistence.

To accomplish, the created Betahistine Dihydrochloride ODF with both improved disintegration and acceptable taste concealing was accomplished by framing consideration with HPMC 15CPS film shaping specialist, Beta Cyclodextrin, sucralose and aspartame. Formulation procedure F3 and F4 accomplished improved outcome than F1 and F2. The arrangement had straight forward in variety and practically impartial in pH, having collapsing perseverance close around 5±1 and break down with in 8.6 ± 0.5 sec. This formulation likewise gave a positive taste and thus could be considered as a promising ODF formulation.

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