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RESEARCH ARTICLE

Development and Evaluation of Orodispersible Films of Donepezil Hydrochloride Utilizing Banana Powder as a Natural Disintegrant

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Abstract: Alzheimer's disease is a progressive neurodegenerative disorder characterized by a decline in cognitive function and memory, primarily managed through acetylcholinesterase inhibitors such as Donepezil Hydrochloride. A significant challenge in the long-term management of this condition is patient non-compliance, frequently exacerbated by dysphagia in the geriatric population. To address these challenges, this study investigates the formulation and characterization of Orodispersible Films (ODFs) of Donepezil Hydrochloride, designed to disintegrate rapidly in the oral cavity without the need for water. The films were fabricated via the solvent casting method, utilizing Hydroxypropyl Methylcellulose (HPMC E15) as the primary film-forming polymer and varying concentrations of banana powder as a novel, natural disintegrant. Polyethylene Glycol (PEG-400) served as a plasticizer to ensure adequate mechanical flexibility. The formulations were subjected to rigorous physicochemical evaluation, including thickness, folding endurance, surface pH, weight variation, and disintegration time, alongside *in vitro* drug release studies. The results indicated that increasing the concentration of banana powder significantly reduced the disintegration time to less than 40 seconds while maintaining robust mechanical properties. The optimized formulation (F12) exhibited a drug release profile exceeding 99% within 60 minutes. FTIR analysis confirmed the chemical compatibility between the drug and excipients, while DSC analysis suggested a molecular dispersion of the drug within the polymer matrix. This research concludes that banana powder can be used as a potent, biocompatible, and cost-effective alternative to synthetic disintegrants, for enhancing therapeutic adherence in neurodegenerative therapies.

Keywords: Orodispersible films; Donepezil Hydrochloride; Banana powder; Natural disintegrant; Solvent casting.

1. Introduction

The oral route of drug administration remains the most preferred method for therapeutic delivery due to its non-invasive nature, cost-effectiveness, and ease of administration. However, conventional solid dosage forms such as tablets and capsules often present significant challenges for specific patient demographics, particularly pediatric, geriatric, and bedridden patients who suffer from dysphagia or have difficulty swallowing [1]. In the context of neurodegenerative conditions like Alzheimer's disease, where patients may exhibit resistance to medication or reduced motor control, the difficulty in swallowing can lead to poor adherence to prescribed regimens, ultimately compromising therapeutic outcomes [2].

To overcome these limitations, novel drug delivery systems known as Orodispersible Films (ODFs) have gained prominence. These polymeric films are designed to disintegrate or dissolve rapidly upon contact with saliva, releasing the active pharmaceutical ingredient (API) for absorption through the oral mucosa or subsequent gastrointestinal uptake [3]. The large surface area of ODFs facilitates rapid wetting and disintegration, thereby shortening the onset of action and potentially improving bioavailability by bypassing first-pass metabolism to some extent [4].

A critical component in the performance of ODFs is the disintegrating agent. While synthetic superdisintegrants are widely employed, there is a growing interest in natural excipients due to their biocompatibility, non-toxicity, and economic advantages [5]. Banana powder, derived from *Musa paradisiaca*, is rich in starch and pectin, which possess excellent swelling and disintegration properties. Despite its potential, the application of banana powder as a functional excipient in film formulations remains underutilized [6].

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The present research aims to formulate Donepezil Hydrochloride ODFs using the solvent casting technique, incorporating banana powder as a natural disintegrating agent. The study evaluates the impact of varying concentrations of banana powder and film-forming polymers on the physicochemical properties, mechanical strength, and *in vitro* release profiles of the films to establish a stable and effective delivery system for Alzheimer's management.

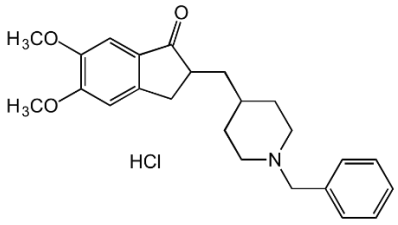

Figure 1. Structure of Donepezil Hydrochloride

ODFs offer several distinct benefits over traditional oral dosage forms and even orally disintegrating tablets (ODTs). Their primary advantage lies in their rapid disintegration and dissolution capabilities, which can enhance the onset of therapeutic action [7]. Furthermore, ODFs exhibit superior flexibility and reduced brittleness compared to ODTs, making them more durable during handling and transport. The precise dosing per strip ensures uniformity, while the convenience of administration requiring no water significantly improves patient compliance in populations with swallowing difficulties or those prone to repeated emesis [8].

Despite their benefits, ODFs have specific limitations. They are generally unsuitable for carrying high drug loads due to the thin nature of the film. Consequently, they are restricted to potent APIs with low dose requirements [9]. Additionally, taste masking is a critical formulation challenge, as the drug is released directly into the oral cavity. Drugs that are unstable at buccal pH or those that cause irritation to the oral mucosa are not suitable candidates for this delivery system. Moreover, ODFs require specialized packaging to protect them from humidity and maintain structural integrity [10].

2. Materials and Methods

2.1. Materials

Donepezil Hydrochloride was obtained as a gift sample. The film-forming polymer, Hydroxypropyl Methylcellulose (HPMC E15), and the natural disintegrant, banana powder, were procured from Brew Lab Food and Beverage Pvt. Ltd., Delhi. Plasticizers and surfactants, including Polyethylene Glycol (PEG-400) and Sodium Lauryl Sulphate (SLS), were sourced from standard chemical suppliers (Bangalore Fine Chemicals and Qualikems Pvt. Ltd., respectively). Sweetening and flavoring agents, specifically Sodium Saccharin, were utilized to improve palatability. All other solvents and reagents, including methanol and citric acid, were of analytical grade.

2.2. Preparation of Orodispersible Films

The ODFs of Donepezil Hydrochloride were fabricated using the solvent casting method.

Table 1. Formulation of Donepezil HCl (All weights in mg)

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Donepezil HCl (mg)	10	10	10	10	10	10	10	10	10	10	10	10
HPMC E15 (mg)	100	120	140	160	100	120	140	160	100	120	140	160
Banana Powder (mg)	20	20	20	20	25	25	25	25	30	30	30	30
Sodium Saccharin (mg)	2	2	2	2	2	2	2	2	2	2	2	2
Sodium Lauryl Sulphate (mg)	1	1	1	1	1.5	1.5	1.5	1.5	2	2	2	2
Citric Acid (mg)	2	2	2	2	2	2	2	2	2	2	2	2
Polyethylene Glycol-400 (mg)	20	20	20	20	30	30	30	30	40	40	40	40
Tween-80 (mg)	1	1	1	1	1	1	1	1	1	1	1	1
Methanol (mL)	5	5	5	5	5	5	5	5	5	5	5	5
Distilled Water (mL)	10	10	10	10	10	10	10	10	10	10	10	10

A polymeric solution was first prepared by dissolving a weighed quantity of HPMC E15 in distilled water under continuous stirring until a clear solution was obtained. To this solution, Polyethylene Glycol (PEG-400) was added as a plasticizer to impart flexibility to the films.

Separately, ripe bananas were processed by drying, grinding, and sieving to produce a fine powder. This banana powder was then dispersed into the polymeric solution alongside the active drug, Donepezil HCl. To ensure uniform distribution and enhance the formulation's organoleptic properties, Sodium Saccharin (sweetener), Citric Acid (saliva stimulant), and Tween-80 (surfactant) were incorporated into the mixture. The resulting homogenate was degassed to remove entrapped air bubbles and cast onto leveled Petri dishes. The films were dried in a hot air oven at 40–50°C until the solvent was completely evaporated. The dried films were carefully peeled from the substrate, cut into 2×2 cm^2 strips containing 10 mg of Donepezil HCl, and stored in varying environmental conditions for further evaluation. The composition of the twelve formulations (F1–F12) is detailed in the appended table.

2.3. Evaluation of Orodispersible Films

The prepared films were subjected to various physicochemical characterization tests to ensure their quality and performance.

2.3.1. Thickness and Weight Variation

The thickness of the films was measured using a calibrated screw gauge at five different locations (center and four corners), and the average thickness was recorded. For weight variation, individual films were weighed using a digital analytical balance, and the average weight was calculated to determine uniformity across the batch [11].

2.3.2. Folding Endurance

Folding endurance was determined to assess the mechanical strength and flexibility of the films. This was performed by repeatedly folding a specific area of the film at the same place until it broke. The number of times the film could be folded without rupture was recorded as the folding endurance value [12].

2.3.3. Surface pH

The surface pH of the films was measured to evaluate the potential for mucosal irritation. The films were slightly wetted with distilled water, and a pH electrode was brought into contact with the surface. The readings were taken in triplicate to ensure accuracy.

2.3.4. Disintegration Time

The disintegration time was measured by placing the film in a beaker containing simulated salivary fluid or phosphate buffer (pH 6.8). The time required for the film to break into small fragments was noted. A limit of less than 60 seconds is generally considered acceptable for ODFs [13].

2.3.5. Drug Content Uniformity

To determine the drug content, a film of known dimensions was dissolved in a specific volume of phosphate buffer (pH 6.8). The solution was filtered and analyzed spectrophotometrically at the maximum absorbance wavelength (λmax) of Donepezil HCl. The drug content was calculated using a standard calibration curve.

3. Results and Discussion

3.1. Drug-Excipient Compatibility Studies (FTIR)

Fourier Transform Infrared Spectroscopy (FTIR) was employed to determine potential chemical interactions between Donepezil Hydrochloride and the excipients used in the formulation. The FTIR spectrum of pure Donepezil HCl exhibited a characteristic broad band around 3433 cm^{-1}, corresponding to the protonated amine, and distinct peaks between 1100–1650 cm^{-1} attributed to aromatic C=C stretching and C–N/C–O vibrations.

The FTIR spectrum of the optimized formulation (F12) displayed all the major characteristic peaks of the pure drug with no significant shifts or disappearance of functional group bands. This indicates that the chemical structure of Donepezil HCl remained

intact within the polymeric matrix and that there were no adverse chemical interactions between the drug and the banana powder or HPMC E15.

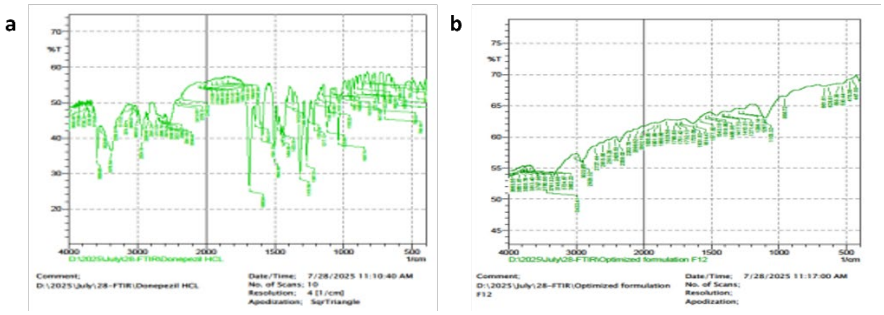

Figure 2. FTIR Spectra of a. Pure Donepezil HCl and b. Optimized Formulation F-12

3.2. Thermal Analysis (DSC)

Differential Scanning Calorimetry (DSC) was conducted to examine the physical state of the drug within the film. The thermogram of pure Donepezil HCl showed a sharp endothermic peak at 227.8 °C, corresponding to its melting point, indicating its crystalline nature.

In the thermogram of the optimized formulation (F12), the characteristic sharp melting peak of the drug was absent. Instead, a broad endotherm was observed between 33 °C and 78 °C. The disappearance of the drug's melting peak suggests that Donepezil HCl was either converted into an amorphous state or molecularly dispersed within the polymer matrix [14]. This transformation is advantageous as the amorphous form typically possesses higher solubility and dissolution rates compared to the crystalline form, supporting the rapid drug release observed in the dissolution studies.

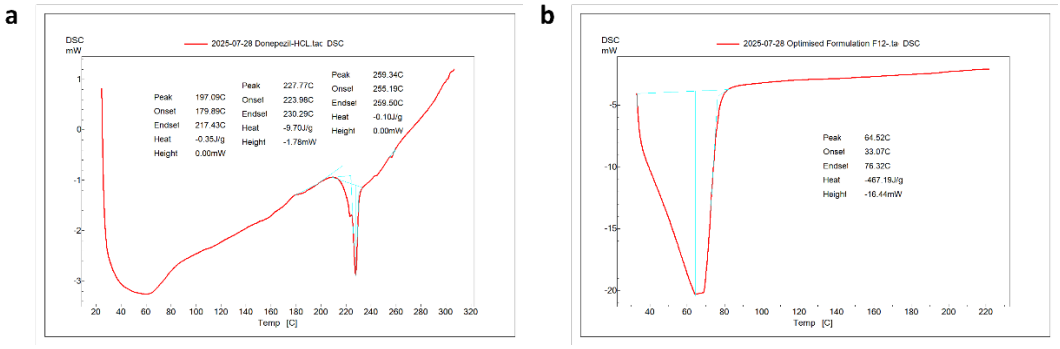

Figure 3. DSC Thermograms of a. Pure Drug and b. Optimised formulation F-12

3.3. Physicochemical Characterization

The formulated Orodispersible Films (ODFs) of Donepezil Hydrochloride were evaluated for their physicochemical properties, as shown in Table 2. Visually, the films appeared smooth, transparent to translucent, and free from air bubbles, indicating the efficacy of the solvent casting method and the degassing process.

3.3.1. Thickness and Weight Variation

The thickness of the prepared films ranged from 0.24 mm to 0.32 mm. A direct correlation was observed between the concentration of the polymer (HPMC E15) and film thickness; formulations containing higher polymer concentrations (F4, F8, F12) exhibited greater thickness values. Uniformity in thickness is critical for ensuring dose accuracy. Similarly, the weight variation data indicated that all formulations were within acceptable limits, suggesting a homogeneous distribution of the drug and excipients within the polymeric matrix.

3.3.2. Folding Endurance

Folding endurance serves as an indicator of the film's mechanical integrity and flexibility, which are essential for handling and transport. The values obtained ranged from 160 to 195 folds. Formulations with higher concentrations of HPMC E15 and plasticizer (PEG-400), specifically F4, F8, and F12, demonstrated superior folding endurance. This suggests that the plasticizer effectively reduced the glass transition temperature of the polymer, imparting sufficient flexibility to withstand mechanical stress without rupturing.

3.3.3. Surface pH

The surface pH of the films was found to be in the range of 6.65 to 6.78, which is close to the neutral pH of saliva (6.8). This neutrality is crucial for patient comfort, as acidic or alkaline formulations can cause irritation to the oral mucosa. The results confirm that the selected excipients and the drug are compatible with the oral environment.

3.3.4. Disintegration Time

Rapid disintegration is the defining characteristic of ODFs. The disintegration times for the formulations ranged from 33 to 48 seconds. It was observed that the incorporation of banana powder significantly influenced disintegration behavior. Formulations containing higher amounts of banana powder (30 mg), such as F11 and F12, exhibited faster disintegration times (33–35 seconds) compared to those with lower concentrations. This can be attributed to the high starch and pectin content in banana powder, which acts as a wick, facilitating rapid water uptake and swelling, thereby accelerating the breakdown of the polymeric matrix [15].

Table 2. Physico-chemical Characterization of Oro dispersible Films

Formulation	Thickness(mm)	Wt. Variation(mg)	Folding endurance (no .of folds)	Surface values	Disintegration time(sec)	Drug content (%)
F1	0.24	15.6	180	6.72±0.05	42	97.8%
F2	0.26	17.6	185	6.70±0.04	38	98.1%
F3	0.28	19.6	190	6.68±0.05	33	98.3%
F4	0.30	21.3	195	6.65±0.05	45	98.5%
F5	0.25	16.1	170	6.67±0.05	41	97.6%
F6	0.27	18.1	175	6.73±0.05	36	98.2%
F7	0.29	20.1	180	6.69±0.05	34	98.6%
F8	0.31	22.1	185	6.78±0.05	48	98.9%
F9	0.26	16.6	160	6.76±0.05	43	97.5%
F11	0.30	20.6	170	6.73±0.05	33	98.4%
F12	0.32	22.6	175	6.70±0.06	35	98.7%

3.4. *In vitro* Dissolution Studies

The drug release profiles of the twelve formulations were analyzed to determine the efficiency of the delivery system. The cumulative percentage drug release data is presented in Table 3.

Table 3. *In-Vitro* Dissolution Studies with percentage (%) Drug Release from original document]

Time (min)	Drug release in Percentage (%)											
	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
0	0	0	0	0	0	0	0	0	0	0	0	0
5	18	20	23	25	22	26	28	31	27	30	34	38
10	31	36	36	44	39	45	49	52	47	53	58	61
15	43	49	49	60	54	61	66	70	68	72	77	81
30	61	68	68	78	76	80	84	88	87	91	94	97
45	75	80	80	89	88	92	94	96	96	97	98	99
60	85	89	89	94	93	96	97	98	98	99	99.5	99.8

The dissolution study revealed that the release rate was influenced by both the polymer concentration and the amount of banana powder. Formulation F12, which contained an optimized ratio of HPMC E15 and the highest concentration of banana powder (30

mg), demonstrated the most favorable release profile, with 99.8% of Donepezil HCl released within 60 minutes. In contrast, formulations with lower concentrations of disintegrant showed slower release kinetics. The rapid initial release observed in F10–F12 suggests that the porous nature created by the natural disintegrant enhances solvent penetration, leading to faster dissolution of the drug.

4. Conclusion

Orodispersible Films of Donepezil Hydrochloride were successfully formulated and evaluated using the solvent casting method. This research highlighted the potential of banana powder as an effective, natural disintegrating agent. The physicochemical evaluation indicated that the films possessed adequate mechanical strength, uniform drug content, and a neutral surface pH suitable for oral administration. Among the formulations tested, F12 emerged as the optimized candidate, exhibiting a rapid disintegration time of 35 seconds and a cumulative drug release of 99.8% within 60 minutes. The compatibility studies using FTIR confirmed the stability of the drug in the formulation, while DSC analysis suggested the formation of a solid dispersion or amorphous state, which likely contributed to the enhanced dissolution profile. The use of natural excipients like banana powder offers a biocompatible and cost-effective alternative to synthetic superdisintegrants. These results suggest that the developed ODFs of Donepezil Hydrochloride represent a viable therapeutic strategy for improving compliance in Alzheimer's patients, particularly those suffering from dysphagia.

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