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Formulation and Evaluation of Oral Thin Film of Cetirizine Hydrochloride

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Abstract: *The aim of present research was to develop a fast releasing oral polymeric film, with good mechanical properties, instant disintegration and dissolution, producing an acceptable taste when placed on tongue. Solvent casting method was used to prepare oral films. cetirizine hydrochloride an antihistaminic was incorporated to relieve the symptoms of allergic rhinitis. The polymers selected were HPMC 3cps and PVA. glycerin was the plasticizer used. Eight batches of films with drug were prepared using different combinations of polymer concentration. The resultant films were evaluated for weight variation, content uniformity, folding endurance, thickness, surface pH, tensile strength, % elongation, % moisture absorption, %moisture loss in vitro disintegration and in vitro dissolution. The optimized films have disintegrated within 28-60sec. The percentage release was varying with concentration of polymer. The films made with HPMC3cps 200 mg released 98.5% of drug in 2min, which was the best release amongst all.*

Keywords: Oral polymeric film, Cetirizine hydrochloride, plasticizer, solvent casting, Fast releasing.

I. INTRODUCTION

Oral Film:

Oral films are an innovative advancement in oral drug delivery, particularly within the category of fast-dissolving dosage forms. These films are thin, flexible or brittle sheets made from edible and water-soluble polymers, and they come in various shapes and sizes such as rectangles, squares, or discs. Designed to dissolve swiftly upon placement on the tongue, they eliminate the need for water during administration, making them particularly convenient for pediatric, geriatric, and dysphagic patients.

Fast-dissolving films (FDFs) offer a large surface area which promotes rapid disintegration and drug release. They are user-friendly, reduce the risk of choking, and require simple, efficient packaging processes. Despite these advantages, they are limited by low drug-loading capacity and challenges in masking unpleasant tastes. Typically, FDFs are 1–10 mm in thickness and cover an area between 1–20 cm², capable of incorporating up to 30 mg of active pharmaceutical ingredient (API).

The film matrix, usually composed of hydrophilic polymers, ensures rapid hydration and mucoadhesion upon contact with saliva. This helps the film stick to the mucosal site, enabling quick disintegration and subsequent drug release for either buccal absorption or swallowing for systemic action. Film flexibility and mechanical strength are crucial for ease of processing steps like cutting, winding, and packaging.

Cetirizine Hydrochloride:

Cetirizine Hydrochloride is a second-generation antihistamine commonly used to manage allergy symptoms. It works by blocking histamine, a substance in the body responsible for allergic reactions. Cetirizine effectively relieves symptoms such as sneezing, itchy eyes, nasal discharge, and general irritation caused by colds or allergies.

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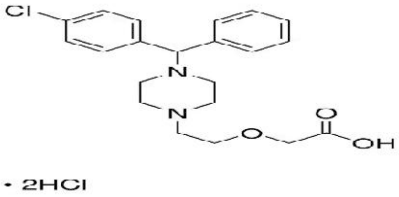
II. DRUG PROFILE

Parameter	Information
Drug Name	cetirizine hydrochloride
Brand Name	Zyrtec
Structure	
Weight	388.89 g/mol
Chemical formula	C21H25ClN2O3.2HCl
IUPAC Name	dihydrogen 2-(2-{4-[(4-chlorophenyl) (phenyl)methyl] piperazin-1-yl}ethoxy)acetic acid dichloride.
BCS Class	Class III
Half life	Approx. 8.3 Hours
Pka 1	2.7
Pka 2	3.6
Log P	1.70
Particle size	50 µm to 500 µm
Hygroscopicity	Slightly hygroscopic in nature.
Polymorphic form	Form A, Form B, and amorphous form.
Solid state Stability	Pantoprazole is not very stable in the solid state
Melting Point	135°C to 140°C
T max	1-2 hours
Solubility	Soluble in Methanol – soluble Soluble in Acetonitrile – soluble Soluble in Water – freely soluble Soluble in 1.1N NaOH – soluble Phosphate Buffer (pH 7.4) – very slightly soluble

III. MATERIAL AND METHODS

Selection of Api Material-

The pharmaceuticals including Cetirizine Hydrochloride was purchased from bora-pharma-pvt-ltd-ahmednagar-maharashtra (India).

Drug Formulation:

Innovator	Qty / batch (mg)	Role
Cetirizine hydrochloride	40mg	Active ingredient
Polyvinyl Alcohol (PVA)	50mg	Film-forming agent
HPMC 3cps	500mg	Film-forming agent
Glycerine	300mg	Plasticizer
Aspartame	55mg	Sweetener
Distilled Water	15ml	Solvent for dissolving the film-forming agents

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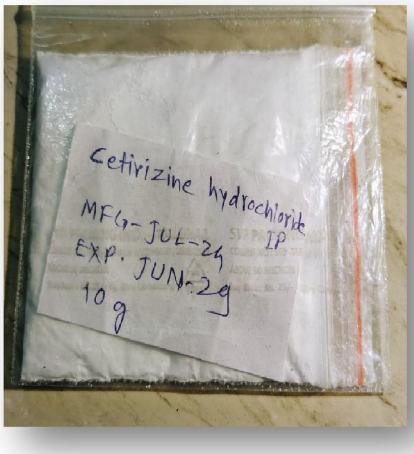

Formulation table Batches:

Ingredient (mg)	F1	F2	F3	F4
Cetirizine hydrochloride	25mg	25mg	25mg	25mg
HPMC	100mg	-	-	125mg
Sorbitol	100mg	100mg	100mg	15mg
Citric Acid	100mg	8mg	100mg	15mg
Sodium lauryl sulphate	7mg	10mg	10mg	15mg
Glycerin	4ml	2ml	3ml	2ml
Vanillin	10mg	10mg	10mg	10mg
Distilled water	q.s	q.s	q.s	q.s

Procedure-

- Accurately weigh all ingredients.
- Prepare oral thin films of Cetirizine Hydrochloride using the solvent casting evaporation method.
- Use **HPMC** as the polymer (influences film strength).
- Add **glycerin** as plasticizer (improves flexibility, reduces brittleness).
- Include **citric acid** as a saliva-stimulating agent (aids disintegration).
- Add **sodium lauryl sulfate** as a surfactant (enhances solubility), and **sorbitol** as a sweetener.
- Dissolve HPMC in 10 ml hot distilled water; add glycerin → stir for 30 mins → *1st solution*.
- Dissolve drug, surfactant, saliva stimulant, sweetener, and flavor in 3–4 ml distilled water → *2nd solution.*
- Mix *2nd solution* into *1st solution* → let stand for 2 hrs to remove air bubbles.
- Pour final mixture into a clean Petri dish → dry at room temperature for 24 hrs.
- Cut dried film into 2 × 2 cm² pieces → wrap in butter paper → store in aluminium foil inside desiccator.
- Evaluate selected films for: Thickness, Folding endurance, Swelling index, Weight variation, Surface pH, Drug content uniformity, Disintegration time, Dissolution rate.

Solvent Casting method:

Ingredients that are water soluble are dissolved in water.

↓

Drug and other ingredients are dissolved in a suitable solvent to form a clear viscous solution.

↓

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Both solutions are mixed.

↓

degass under vaccume

↓

The resulting solution casted as a film.

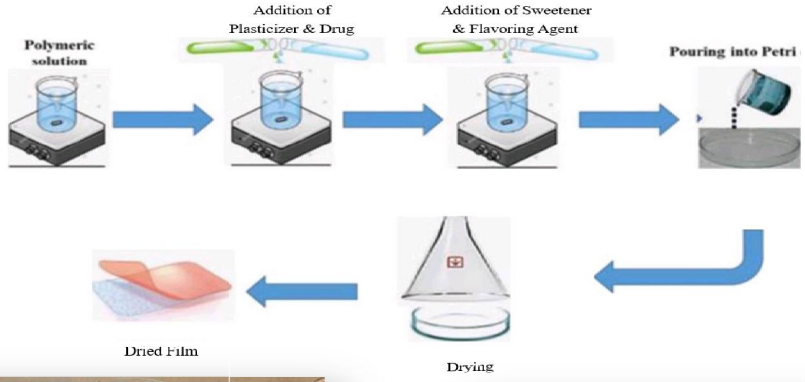

Fig 5: Excipients

Fig 6: Cetirizine Hydrochloride Oral Film

Evaluation:

Pre-Formulation Study

Pre-formulation studies help guide the formulation process by examining the physicochemical properties of Cetirizine Hydrochloride. These include solubility, physical appearance, powder flow characteristics such as angle of repose, compressibility index, and bulk/tapped densities.

1. Solubility Study:

The solubility of Cetirizine Hydrochloride was assessed in water and alcohol. It was found to be soluble in water, forming an acidic aqueous solution.

2. FTIR Spectroscopy:

Drug-polymer compatibility was analyzed using Fourier Transform Infrared (FTIR) spectroscopy. The sample was blended with potassium bromide and pressed into pellets, then scanned in the range of 4000–400 cm^{-1} to identify characteristic functional groups and check for interactions.

Physical appearance and surface texture:

These parameters were checked simply with visual inspection of films and by feel or touch. The observation reveals that the films are having smooth surface and they are elegant in appearance.

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Thickness:

Thickness of the film was measured using a screw gauge with a least count of 0.01mm at different spots of the film. The thickness was measured at three different spots of the film and the average was taken by using the following formula.

Least count = pitch/Total number of division of the circular scale

=1 mm/ 100

= 0.01 mm

Weight Variation of oral films:

The weight of the films was determined using digital balance and the average weight of all films.

Drug content uniformity of oral films:

Cetirizine hydrochloride oral films prepared with various polymers were subjected to the valuation for uniform dispersion of drug throughout the patch. In each case films were used and the average drug content was calculated

Folding endurance of oral films:

The folding endurance gives the idea of flexible nature of films. The folding endurance was measured manually, films were folded repeatedly till it broke, and it was considered as the end point. The folding endurance was found optimum and the films exhibited good physical and mechanical properties and the average folding endurance of all films

Swelling index:

The swelling index in the oral films ranged from 14.16 to 15.07%

In- vitro disintegration test:

Formulation containing surfactant show better disintegration time F4 batch show better disintegration compare to F3 and F2.

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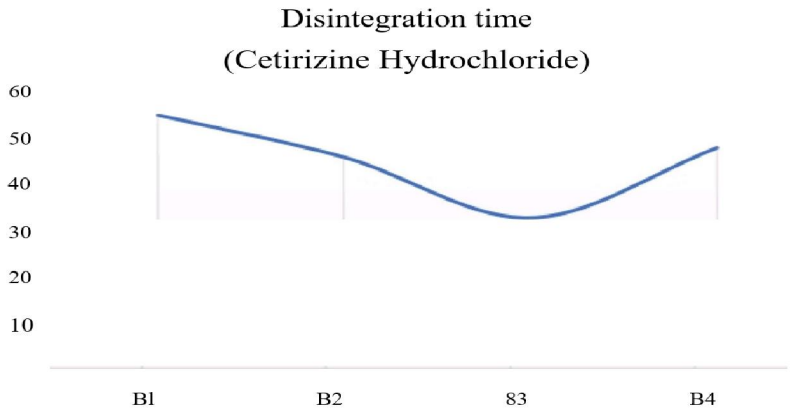

In vitro dissolution studies:

Formulation containing Sodium lauryl sulphate showed maximum drug release within 120 sec the release was found to be 98.8%. The release of F4 is less than F3 this can be attributed due to less concentration of surfactant. F2 shows less percentage release than F4. F5 shows still lesser due to less surfactant concentration. The formulation without surfactant shows the following order of release. The other formulation released almost appropriately same amount of drug. The least percentage drug
release was found to be F7

Table 5: - In vitro dissolution studies

Sr. No	Time (sec)	F1%	F2%	F3%	F4%
1.	0	0	0	0	0
2.	15	10.81	12.98	25.42	16.43
3.	30	25.92	30.12	43.67	31.15
4.	45	46.78	49.67	57.87	50.42
5.	60	54.78	56.76	65.78	72.35
6.	90	67.54	68.25	78.12	88.67
7.	120	78.87	76.59	82.23	92.22
8.	180	84.43	88.98	88.45	95.67
9.	240	92.4	90.14	91.12	98.75

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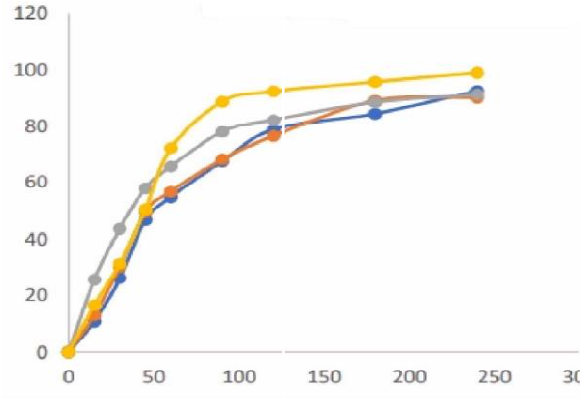
Cetirizine Hydrochloride



Evaluation test for oral thin film:

Table 6: Evaluation test

Parameter	F1	F2	F3	F4
Average Weight(mg)	42.12	44.78	43.24	47.88
Thickness (mm)	0.26	0.28	0.25	0.24
Swelling index	14.43	13.42	15.22	14.64
Folding endurance	72	77	74	78
Drug content (%)	88.55	90.14	91.82	93.54
Disintegration dine	35	46	39	28

IV. RESULTS

Pre-formulation studies confirmed that Cetirizine HCl is freely soluble in water and ethanol but only sparingly soluble in organic solvents. Flow property assessments indicated good powder flowability. FTIR studies showed no significant drug-polymer interactions, confirming compatibility.

Physical evaluation showed that the films were smooth, transparent, and uniform in appearance. Thickness and weight variation across all formulations were within acceptable limits, ensuring uniformity in dosage. **Folding endurance** results confirmed that the films were flexible and mechanically stable, showing good durability upon repeated folding.

Drug content was found to be uniformly distributed across the films, with satisfactory drug loading efficiency. **Swelling index** values indicated moderate water uptake, supporting rapid disintegration.

Disintegration tests revealed that formulations containing surfactants, especially F4, disintegrated more rapidly than others, suggesting enhanced saliva interaction.

In vitro dissolution studies showed that the presence of sodium lauryl sulfate significantly improved drug release. The F4 formulation demonstrated a maximum release (~98.8% within 120 seconds), whereas formulations with lower or no surfactant showed comparatively slower release.

V. CONCLUSION

The study confirmed that release-modifying polymers can effectively produce Cetirizine Hydrochloride oral films with desirable drug release and permeability. FTIR analysis showed no incompatibility between the drug and excipients. Evaluated films demonstrated acceptable physical and mechanical properties, including weight and thickness uniformity, folding endurance, and pH balance. Among all formulations, F4 showed optimal performance, releasing over 90% of the drug within 120 seconds and fully disintegrating in 30 seconds. Its low-viscosity polymer improved

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solubility and film quality. Overall, the films may offer faster onset and better bioavailability. Further clinical studies are recommended to confirm therapeutic effectiveness and safety.

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