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Formulation and characterization of Carbopol based caffeine hydrogel transdermal film

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Abstract

A transdermal patch containing caffeine was developed using Carbopol-940 as the hydrogel matrix. Caffeine transdermal films were made utilizing the solvent casting method with the lipophilic PEG-1500 and hydrophilic carbopol-940. As a plasticizer, propylene glycol (PG) was employed. The drug content, thickness, tensile strength, folding durability, and in vitro drug release—which was investigated using Franz diffusion cells—were all assessed for these films.

The purpose of the study was to publish physicochemical data, including in vitro drug release, and the film-forming capabilities of the polymers utilized.

PEG-1500, carbopol-940, and PG as a plasticizer were found to have good film-forming qualities. According to the results, the formulation of caffeine made solely with Carbopol-940 and 20% PG was the most flexible and had the best folding endurance of the two polymers employed. Subsequent research on the drug release of PEG 1500 and caffeine has revealed 88.32% and 87.28% release via the rat skin, respectively.

Keywords: Caffeine; Hydrogel; Ethanol; PEG-1500; Carbopol-940; Transdermal Film; Topical Formulation

1. Introduction

1.1. History

The 1st Transdermal Patch: 1981

Reason:- To prevent Nausea, Vomiting & Motion sickness.

Up to 2003, the FDA has authorized over 13 different transdermal patch devices.

In 2001, the transdermal market in the US was close to $1.2 billion. GTN, fentanyl, estradiol, ethylestradiol, norethisterone acetate, testosterone, clonidine, nicotine, lidocaine, primocaine, and scopamine were the eleven drug molecules on which it was built.

When applied to intact skin, a Transdermal Drug Delivery System (TDDS) is a self-contained, discrete dosage form that delivers the medication to the systemic circulation at a regulated rate through the skin. The creation of TDDS involves the usage of polymeric materials as a rate-controlling membrane, TDDS creates a thin polymeric film that delivers the medication from the drug reservoir over an extended period of time.

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The properties of the polymer, the casting solvent, and the plasticizer all affect how well drugs penetrate polymeric films.
The selection of medications determines whether TDDS is successful. Drugs should not cause allergic reactions; they should be non-irritating; and they should have therapeutic benefits.

2. Methodology

2.1. Solvent Casting Technique

Solvent Casting Technique is used to form a thin film/coating by dissolving a material in a solvent, then evaporating the solvent to form a solid layer.

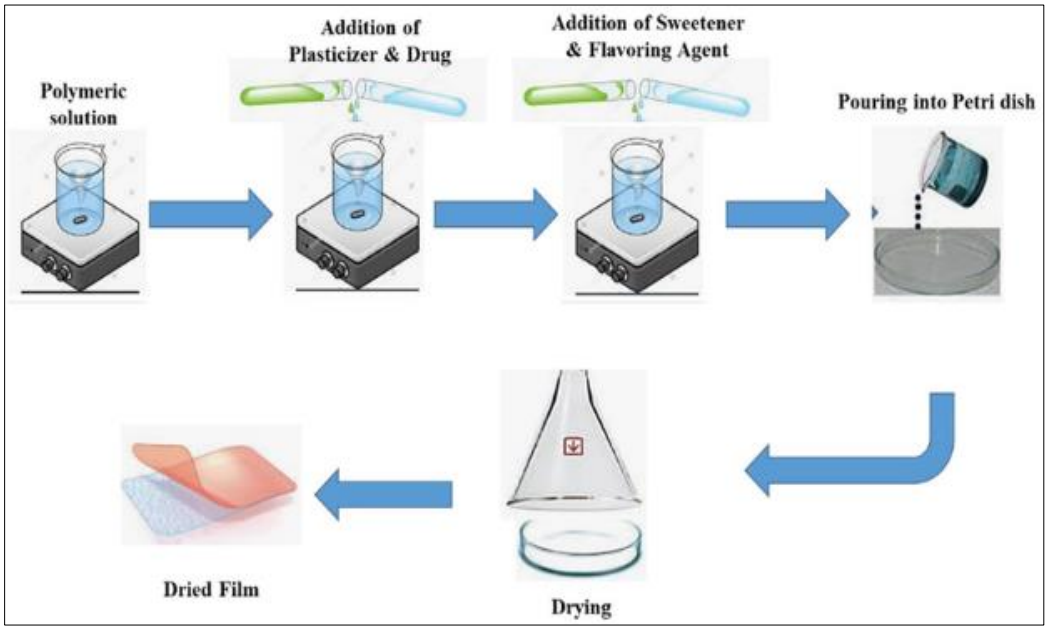

Figure 1 Steps involved in solvent casting technique

2.2. Method and Materials

Table 1 Materials required for formulation and their exact amount

Chemicals	Amount
Carbopol-940	1 g
Ethanol	25 ml
Caffeine	0.25 g
PEG 1500	0.33 g
Propylene Glycol	0.3 ml
Triethanolamine	Dropwise
Methyl Paraben	0.2-0.25 g

2.3. Pre-formulation

Table 2 Organoleptic study of Caffeine

Organoleptic properties	Nature
Physical State	Powder
Odour	Acetic odour
Color	White
pH Range	2.5-3.0
Solubility	Soluble in Water, Alcohol
	& Glycerin

2.4. Procedure

- Weigh Carbopol-940 about 1 g and put it into 50% alcohol (Ethanol) in 1st Beaker.
- Place 1st Beaker on the Magnetic stirrer at 800rpm for 30 minutes which may dissolve the polymer homogeneously.
- Again weigh 0.25g Caffeine and 0.33g PEG-1500.
- Put Caffeine and PEG-1500 into 50% alcohol (Ethanol) in the 2nd Beaker.
- Again place the 2nd Beaker on the Magnetic stirrer at 800rpm for 30 minutes which may dissolve the powder sample homogeneously.
- Then, Mix about 0.3ml Propylene glycol (PG) into 1st Beaker of Polymer solution & Place on the magnetic stirrer for 30 minutes.
- Now, Mix the 2nd Beaker solution into the 1st Beaker solution and place on the magnetic stirrer for 30 minutes also.
- Check pH of the Solution. If it shows acidic then, Add Triethanolamine (TEA) for pH adjustment.
- Also add Methyl paraben (0.25g) as a Preservative.
- Pour the prepared solution into Petri dish & dried at the Room temperature for 48 hours.
- Cover the Petri dish by Inverted funnel to avoid rapid evaporation of the solvent.

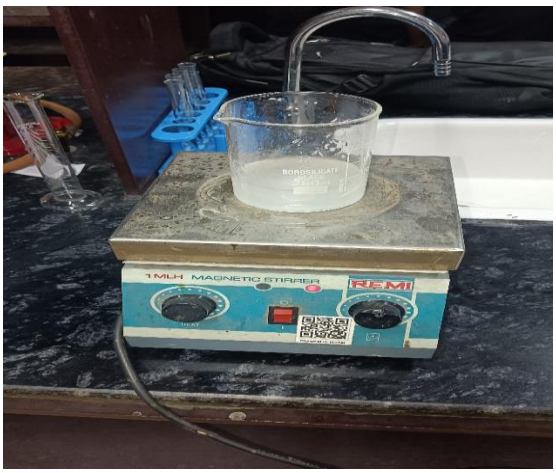

Figure 2 Preparation of gelling base

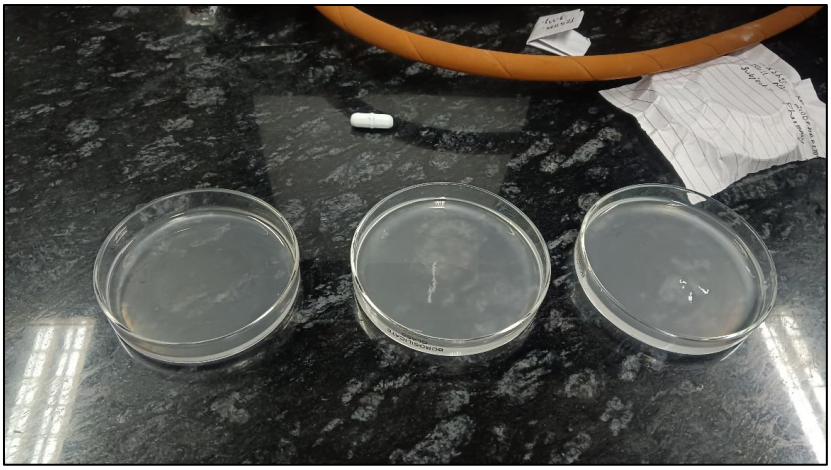

Figure 3 Image of Transdermal Patches

Table 3 Composition of Formulation

Polymer Conc. Carbopol-940	Plasticizer Conc. PEG-1500	Propylene Glycol(PG)	Drug Sample Caffeine	Physical appearance
1g(4%)	0.33g	0.3ml	0.25g(1%)	Uniform
1g(4%)	0.33g	0.3ml	0.50g(2%)	Uniform
0.75g(3%)	0.25g	0.3ml	0.75g(3%)	Uniform
0.50g(2%)	0.16g	0.3ml	1g(4%)	Uniform
0.50g(2%)	0.16g	0.3ml	1.25g(5%)	Uniform

3. Results and discussion

3.1. Evaluation parameter

3.1.1. Physicochemical evaluation

The produced films were assessed for their in vitro release studies over the rat skin, drug content, tensile strength, folding durability, uniformity of thickness, weight variation, and physical attractiveness.

3.1.2. Weight variation

A digital balance was used to weigh a uniformly sliced 2 cm2 film.

3.1.3. Thickness of the film

To measure the films' thickness, a screw gauge was employed. By sandwiching the film between two glass slides of known thickness, it was positioned in three different ways, and the average thickness was determined.

3.1.4. Folding endurance [11]

By hand, the folding endurance was measured. A 2 cm2 strip of film was cut uniformly, then folded repeatedly at the same spot until it snapped or cracked. The precise value of folding endurance is determined by how many times the film could be folded in the same spot without cracking or breaking.

3.1.5. Tensile strength [12]

An analytical two-pan balance was used to assess the tensile strength. On one side, a 20 mm wide by 50 mm long patch was cut and secured between two clamps. Until the patch cracked, weights were placed to the opposite side of the pan. The tensile strength of the patch was determined by measuring the weight needed to break it.

3.2. Evaluation Table

Table 4 Evaluation results of Carbopol in accordance with evaluation parameters

Carbopol	Thickness(mm)	Weight(mg)	Tensile strength(gm/10^2cm)	Folding endurance
4%	0.2	5.23	48.1	191
4%	0.2	5.21	47.97	190
3%	0.19	5.03	46.69	209
2%	0.17	4.73	43.11	206
2%	0.16	4.69	42.89	190

4. Conclusion

The prepared films were translucent, smooth, thin, and bendable. The films were satisfactorily prepared using the solvent casting technique. It is clear from the films' physicochemical evaluation data that while they were kept at room temperature, there were no physical changes to their look, color, or flexibility. The films made with 2% w/v polymers by themselves and in conjunction with 20% PG were determined to have the least thickness.

The study clearly shows that the films made with PEG-1500: carbopol-940 (1:3) have good folding durability, tensile strength, and % elongation. In every instance, the drug release was expected to decrease as the polymer concentration rose to 3% and 4%; therefore, the ratio of additives and film composition was chosen to achieve the best release over an extended length of time.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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