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Research Article
International Journal of Pharmacy and Engineering (IJPE)
ISSN 2320-849X

A Comparative Study of Gel and Gel-Based Transdermal Patch of Riboflavin on Skin Permeation Evaluation

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ABSTRACT

In the revolutionize era, pharmaceutical sector also going on the path of advancement. Traditional drug delivery system is replacing with novel drug delivery system. In this article, developed formulation are traditional gel and gel based transdermal patch with its evaluation. This work has two prospective which is to compare the traditional and novel formulation based on permeability and stability of the formulations. The used method in the transdermal patch formulations is solvent casting method. This method is widely used all over world. After the preparation of these formulation the evaluation take placed which is based on some parameters. The parameters are measurement of pH, homogeneity, viscosity and in vitro permeation study for the gel along with thickness, weight variation, folding endurance, percentage moisture absorption, percentage moisture loss and final one is the in vitro drug permeation study for the gel based transdermal patch. After performing this evaluation, the gel has better permeation ability but it is for the short period of time which is a drawback for whole treatment process. This issue is solved by the gel based transdermal patch. The gel based transdermal patch has not only better permeation ability ,but also it can use for long duration of time than gel with the sustainable released of drug. It has better stability than gel formulation.

Keywords- Traditional drug delivery system, novel drug delivery system, evaluation, gel, gel based transdermal patch.

INTRODUCTION

Conventional drug delivery methods including oral tablets, capsules, and injectables have long been used to provide therapeutic substances. Despite their decades-long widespread use, these techniques have inherent drawbacks. Due to hepatic first-pass metabolism, variable gastrointestinal absorption, and variations in plasma drug concentrations, oral administration—the most popular route—often has low bioavailability [5]. The necessity for frequent dosage, greater side effects, and less than ideal therapeutic outcomes might result from these variations. Although injectable formulations effectively circumvent these restrictions, patient compliance is hampered by discomfort, infection risk, and the need for qualified medical staff [1].

Topical drug delivery methods have been extensively studied as a non-invasive option for systemic and localized medication administration in order to solve these issues. Because of their high drug solubility, improved skin permeability, and simplicity of administration, topical formulations—especially gels—are often utilized [2]. They have benefits include preventing hepatic metabolism and minimizing systemic adverse effects. However, conventional topical gels require frequent reapplication due to their short retention period, quick medication elimination, and uneven absorption [3]. Furthermore, their efficacy in long-term treatment is restricted by their low skin penetration and burst drug release [4].

To overcome these limitations, a state-of-the-art technique called Transdermal Drug Delivery Systems (TDDS) was created, which allows for controlled and extended drug release through the skin. Gel-based transdermal patches have emerged as a promising alternative for TDDS by fusing the benefits of gels with the controlled medication release of transdermal patches [5]. By resolving the drawbacks of both standard gels and systemic medicines, these patches guarantee consistent medication absorption, extended retention, and enhanced patient compliance. Gel-based transdermal patches, as opposed to standalone gels, stick firmly to the skin to stop medication loss from evaporation or outside influences [1].

The medications which have short half-lives or high first-pass metabolism, these systems are notably helpful in the administration of antibiotics, hormone therapy, pain control, and anti-inflammatory therapies (Benson, 2005). Developments in nanotechnology, bio-adhesive polymers, and penetration enhancers continue to improve their efficacy in spite of obstacles including restricted permeability and possible skin irritation [4]. The use of gel-based transdermal patches is a significant breakthrough in drug delivery, providing sedatives that are safer, more efficient, and more appealing than traditional topical and systemic treatments.

Hence, I have developed conventional transdermal gels and gel based transdermal patches to evaluate their effectiveness

MATERIAL AND METHODS

Materials

The API is Riboflavin, Guar-Gum, sodium meta bisulphate, propylene glycol (PG) and Distilled Water.

Methods

Preparation of gel

The measured amount of guar gum was taken then it was mixed with hot water and leaved it for 30 mins to formation of a gel base. In another beaker riboflavin was taken and diluted with water and it mixed with the gum solution. Then sodium meta bisulphate and propylene glycol (PG) was mixed with the guar gum solution under continuous stirring at moderate speed until a homogeneous gel is obtained. Transfer into airtight containers and store at room temperature.

Formulation of gel

The composition of the formula used for preparation of the gel delivery system is revealed in table 1

Table 1: Composition of Gel (for 100 mL Solution)

Ingredients	Quantity	Function
Riboflavin (Vitamin B2)	2 g	API (Antioxidant, Wound Healing, UV Protection)
Guar gum (1.5% w/v)	1.5 g	Natural Gelling Agent (Provides viscosity & stability)
sodium meta bisulphate	0.2 g	Preservatives, antioxidant
propylene glycol (PG)	5 ml	stabilizer
Distilled Water	q.s. to 100 mL	Vehicle

Preparation of gel based transdermal patch

The measured amount of guar gum was taken then it was mixed with hot water and leaved it for 30 mins to formation of a gel base. In another beaker riboflavin was taken and diluted with water and after the sonication it mixed with the gum solution. Then Incorporate Dibutyl phthalate and HPMC to improve penetration, stability and hydration in the guar gum and riboflavin solution under continuous stirring at moderate speed until a homogeneous solution is obtained. At the last it placed on petri dish which was incorporated with aluminium foils for the backing layer of the patch and leaved it for 24 hours.

Formulation of gel based transdermal patch

The composition of the formula used for preparation of the gel based transdermal patch is revealed in table 1

Table 1 : Composition of Gel based transdermal patch (for 100ml)

Ingredients	Quantity	Function
Riboflavin (Vitamin B2)	2g	API (Antioxidant, Wound Healing, UV Protection)
Guar-Gum (1% w/v)	1 g	Natural Gelling Agent (Provides viscosity & stability)
HPMC (Hydroxypropyl Methylcellulose, 3% w/v)	3 g	Film-forming agent (Controls drug release)
Dibutyl phthalate (1% w/v)	1 g	Plasticizer (Provides flexibility)
Distilled Water + Ethanol (70:30 v/v)	q.s. to 100 mL	Solvent

EVALUATIONS

Evaluation of Gel [6,7]

Measurement of pH

The pH of gel formulation was determined by using digital pH meter (Systronics India).

Homogeneity

It was determined by visual inspection for the appearance of gel and presence of any aggregates/lumps.

Viscosity

The Brookfield digital viscometer with spindle S64 was used to measure the formulation's viscosity. After allowing the gel formulations to settle for five minutes in the viscometer's sample container, the viscosity was measured at room temperature (between 25 and 27-degree C) while rotating at a speed of 50 rpm.

In vitro drug permeation of gel

Preparation of Egg membrane: - I bought an egg from a local department shop carefully the skin was taken off the eggs outer layer and separated from the membrane underneath the eggs outer skin was painstakingly removed the membrane could now be used for additional experiments studies on in vitro permeability.

In vitro permeation study. The eggshell membrane was used for in vitro permeation studies. the eggshell membrane the franz diffusion cell is a frequently used piece of equipment for in vitro permeation investigations the integrity of the reservoir patch is lost because larger surface area patches cannot be placed into the donor chamber of the cell without cutting. At first Franz diffusion cell apparatus was placed properly. The eggshell membrane was attached on the top of the Franz diffusion cell apparatus after filling it with the buffer solution. The sample gel was placed on the eggshell membrane. The temperature was maintained at 37 ± 0.2˚C and the rotation of apparatus was adjusted at 300 rpm. This study performed in the duration of 2hr and the sample was collected 10 mins of interval from starting to end of the experiment. Total 12 sample were collected by using micropipette. These sample was evaluated though UV-spectrometry at 375 nm [8,9].

Evaluation of patches [10-11]

The patches were evaluated for the following physicochemical properties:

Patches were evaluated for thickness, weight variation.

Folding Endurance

A piece of film was taken and folded repeatedly till it broke. Folding endurance is precisely determined by how many times the film can be folded in the same spot without breaking.

Percentage Moisture Absorption

A desiccator filled with a saturated solution of aluminum chloride (79.5% RH) was used to hold precisely weighed films for three days in order to test their physical stability under high humidity conditions. The formula was used to determine the films' percentage moisture absorption after they had been reweighed.

$$\text{Percentage moisture absorption} = \frac{\text{Final weight} - \text{initial weight} \times 100}{\text{Initial weight}}$$

Percentage Moisture Loss

A desiccator filled with fused anhydrous calcium chloride was used to hold precisely weighed films for 72 hours in order to measure the amount of moisture loss from freshly made film. Following a 72-hour period, the films were reweighed, and the following formula was used to determine the percentage moisture loss:

$$\text{Percentage moisture loss} = \frac{\text{Initial weight} - \text{Final weight} \times 100}{\text{Initial weight}}$$

In vitro drug permeation of gel based transdermal patch

Preparation of Egg membrane: - I bought an egg from a local department shop carefully the skin was taken off the eggs outer layer and separated from the membrane underneath the eggs outer skin was painstakingly removed the membrane could now be used for additional experiments studies on in vitro permeability [12].

In vitro permeation study. The eggshell membrane was used for in vitro permeation studies. the eggshell membrane the franz diffusion cell is a frequently used piece of equipment for in vitro permeation investigations the integrity of the reservoir patch is lost because larger surface area patches cannot be placed into the donor chamber of the cell without cutting. At first Franz diffusion cell apparatus was placed properly. The eggshell membrane was attached on the top of the Franz diffusion cell apparatus after filling it with the buffer solution. The sample patch was placed on the eggshell membrane. The temperature was maintained at 37 ± 0.2˚C and the rotation of apparatus was adjusted at 300 rpm. This study performed in the duration of 2hr and the sample was collected 10 mins of interval from starting to end of the experiment. Total 12 sample were collected by using micropipette. These sample was evaluated though UV-spectrometry at 375 nm [8,9]

Result

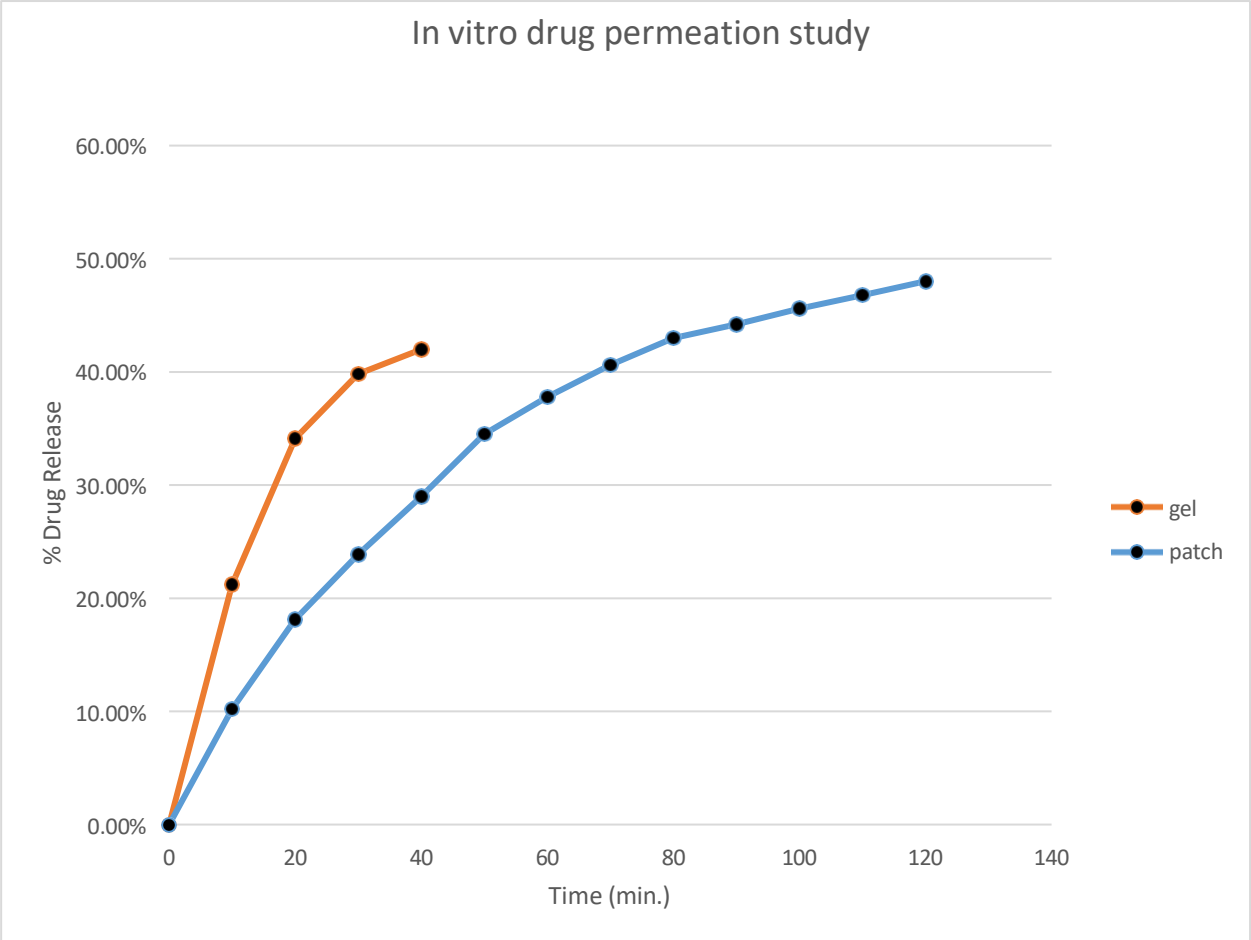
The evaluation of gel and gel based transdermal patch were done. The evaluation was mainly based on the comparisons in the aspects of permeation between a traditional topical formulation which was gel and a novel formulation which was the gel based transdermal patch. The results of the evaluation of gel and transdermal patch was given on the table 3 and table 4 respectively.

Table 3 – Evaluations results of Gel Based Transdermal Patch

Evaluation parameters	Sample 1	Sample 2	Sample 3	Average± S.D.
Thickness	0.0198 cm.	0.0201 cm.	0.0200 cm.	0.019967 ± 0.000153
Weight variation	5g	5g	6g	5.333333 ± 0.57735
Folding Endurance	41	43	39	41 ± 2
Percentage Moisture Absorption	9.78	10.03	8.97	9.593333 ± 0.554106
Percentage Moisture Loss	7.56	8.31	10.29	8.72 ± 1.410425

Table 4 – Evaluations results of gel

Evaluation parameters	Sample 1	Sample 2	Sample 3	Average± S.D.
pH	6.94	6.91	6.93	6.926667 ± 0.015275
Homogeneity	Good	Good	Good	
Viscosity	3287	3301	3293	3293.667 ± 7.023769



Discussion

The present study has been developed the traditional formulation gel and novel formulation gel based transdermal patch with the riboflavin which is work as API and others are Guar-Gum, sodium meta bisulphate, propylene glycol (PG) and Distilled Water. The evaluation of that formulation has been performed. In the evaluation, measurement of pH, homogeneity, viscosity and in vitro permeation study for the gel along with thickness, weight variation, folding endurance, percentage moisture absorption, percentage moisture loss and final one is the in vitro drug permeation study for the gel based transdermal patch has been done. As per the evaluation of gel based transdermal patch found better. The further modification also can be done by using nanotechnology which is also a novel approach[13].

Acknowledgment: I am very thankful the Guru Nanak institute of pharmaceutical science and technology for their valuable support.

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Received: February 10th 2025, Accepted: February 19th February 2025