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Original Research Article

Formulation and Evaluation Organogel of Miconazole

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Abstract

Topical administration is applied to deliver a drug instantaneously at the point of application, so enough drugs is depleted into the systemic circulation to cause medicinal effects. To develop an effective drug absorption through an intact skin, several topical preparations are used one of that is "Gels". Gels basically used for the purpose of topical dosage form a lot which is to deliver drug across a localized area of the skin.

Gel formulation contributes for better approach concept and product stability in respect to ointment, paste and cream. Administration of topical gel drug has a limited drug delivery process anywhere in the body system through skin route, vaginal route, rectal route and ophthalmic route as darmal routes. Generally gels used in wide range as applications in food products, cosmetics products, biotechnology. Most of the gels may be designed according to their nature of the liquid phase, for example, Organic solvent containing are organogels (oleogels) and water as solvent phase called hydrogels. Recent research studies have reported many types of gels for topical drug application, like aerogel, bigel and emulgel. Topical dosage forms like Gels are evaluated with following standard parameters such as pH of formulation, homogeneity of preparation, grittiness of active drug content, extrudability and spreadability of formulation, skin irritation studies, in-vitro release and Stability studies.

Keywords: Gel, Stability, Vaginal, Dermal, Organic, Organogel.

Introduction

Topical route of drug delivery is an Effective route for local and systemic treatment. The local delivery of drugs on the skin is known as dermal or topical route of administration for local and dermal diseases. Topical dosage form can penetrate most inner and deeper into the skin and gave better systemic absorption of drug content. The skin is the largest sensitive organ of human body. It covers all the entire body parts and serves as defense line against the external environmental stress and microorganisms. Since the skin is the organ that is the most exposed with the environmental factors and the risk of damage of its mechanism and structural defense line may increase the disease chances.

Topical application has many advantages over the conventional dosage forms. In general, they are deemed more effective less toxic than conventional formulations due to the bilayer composition and structure. In the formulation of topical dosage forms, attempts are being made to utilize drug carriers that ensure adequate

localization or penetration of the drug within or through the skin in order to enhance the local and minimize the systemic effects, or to ensure adequate percutaneous absorption.

CLASSIFICATION OF GELS:

Gels may be classified supported colloidal phases, nature of solvent used, physical nature and rheological properties.

1. Based on nature of solvent

Hydro gels (water based)

Here they contain water as their continuous liquid phase E.g. bentonite, derivatives of cellulose, carpooler, and synthetic poloxamer gel. Example-plastibase (low molecular wt. polyethylene dissolved in oil) Olag (aerosol) gel and dispersion of metallic stearate in oils.

Hydrogel

A Hydrogel, is a semisolid formulation of gel dosage forms, which has an immobilized external apolar phase. The apolar phase is immobilized within spaces of the 3D network structure formed due to the physical interactions amongst all polymers the self-assembling structures of compounds regarded as gelators.3-5

Xerogels

Solid gels with low solvent concentration are called xerogels. These are produced by evaporation of solvent or freeze drying, leaving the gel framework behind on contact with fresh fluid, they swells and may be reconstituted. E.g. Tragacanth ribbons, acacia tear β1-cyclodextrin, dry cellulose and polystyrene.6-8

2. Based on colloidal phases:

They're classified into Inorganic (two phase system) kind of force that's accountable for the linkages determine the structure of the network and therefore the properties of the gel.9-10

Single-phase system these contain large organic molecules existing on the twisted strands dissolved during a continuous phase.

3. Based on rheological properties:

Usually the gels show non-Newtonian flow properties. They're classified into, a) Plastic gels b) Pseudo plastic gels c) Thixotropic gels. (a) Plastic gels E.g. - Bingham bodies, flocculated suspensions of aluminium hydroxide exhibit a plastic flow and also the plot of rheogram gives the yield value of the gels above which the elastic gel distorts and begins to flow. (b) Pseudo-plastic gels E.g. - Liquid tragacanth dispersion, sodium alginate, Na Carboxy methyl cellulose etc. exhibits pseudo-plastic flow.11-12

4. Based on physical nature:

(a) Elastic gels Gels of agar, pectin, guar gum and alginates exhibit an elastic behavior. The fibrous molecules being linked at the purpose of junction by relatively weak bonds like hydrogen bonds and dipole attraction. E.g.: Alginate and Carbapol. (b) Rigid gels this may be formed from macromolecule within which the framework linked by primary valance bond. E.g.: In colloid, silic acid molecules are held by Si-O-Si-O bond to provide a polymer structure possessing a network of pores.13

Preparation of Gels:

Gels are generally prepared at the industrial scale under room temperature. However few of polymers such-Synthetic and Natural need special treatment before processing. Gels are also prepared by following methods.14-15

1. Thermal changes
2. Flocculation
3. Chemical process/ reaction

Materials and Methods

Miconazole was received gift sample from Cipla Ltd, Mumbai, India, Mumbai, India. All Other Chemicals used in the formulation development were of the standard analytical grade. Miconazole formulations organogel were prepared by using penetration enhancer (Coconut Oil and Almond Oil) are dispersed in distilled

water with constant stirring by magnetic stirrer at a medium pace maintaining the temperature at 300C. Gels are packed in a wide mouthed glass jar, and it is covered with screw copped plastic lid after covering with aluminium foil [5,6]. Various preparations of Miconazole topical gel are shown in Table 1. They were kept in the dark and cool place. Evaluation of physicochemical parameters of prepared Miconazole gel Drug-excipients compatibility studies Fourier transfer infrared spectrophotometer (FTIR). The drug, polymer, and excipients interactions are studied using the FTIR method. In general, drug and excipients must be coinciding with each other which produce a stable, safe, and efficacious product. IR spectral analysis of pure drug and polymers carried out [7]. Pure drug that gives peak and patterns were compared with the peaks and patterns with the combination of polymer and drug.

Results and Discussion

Drug-excipients compatibility studies

The IR studies of clear Miconazole formulation comprises greater proportion of the polymers that are conducted to know about the bond between the used polymers and the drug.

The IR spectrum of pure Miconazole and Miconazole gel formulations that used greater proportion of polymer that gives comparable basic patterns and peaks. Outcome status that no notable drug and polymer interactions.

Visual inspection: Visual determination is done to examine the physical properties and color of the developed formulation.

Determination of pH:

The pH value of all developed gel was in the range of 6.5–7.4. This is sufficient for appealing to skin and avoid the chances of irritation with local application.

Spreadability

The study has a few major elements that show the gel character that emerges out from the tube. Spreadability test is carried for all the formulations.

Determination of drug content

The drug content of the formulated gel was estimated. The drug content manifests that the drug was distributed equally throughout the gel.

Percentage yield and viscosity

Percentage yield of a topical gel consisting of Miconazole was in the range of 94.15–98.55%. This was identified that the percentage yield of F5 formulation showed an increase in percentage yield than the other preparation due to use of guar gum polymer.

In vitro drug release

The drug release profile of Miconazole topical gel formulations was accomplished by Franz diffusion cell. As an outcome of the in vitro release studies of all formulations are given in Table 3, and the statistically represented is shown in Figure.

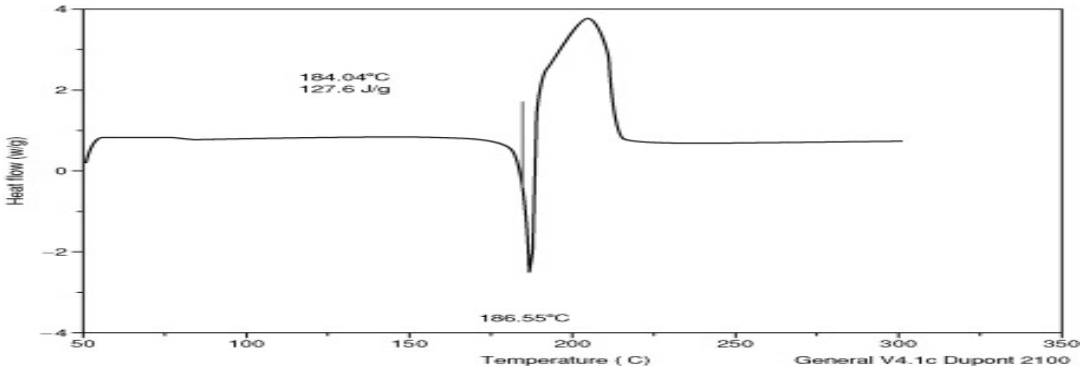

Figure 1: DSC Miconazole

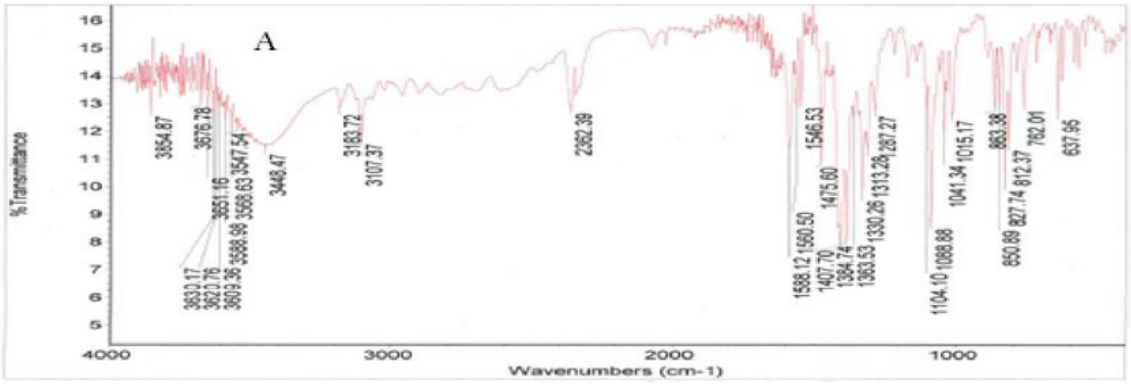

Figure 2: IR Spectra Miconazole

Table 1: Calibration Curve Data of Miconazole

Concentration	Absorbance (290 nm)
0.0	0
2.0	0.176
4.0	0.306
6.0	0.498
8.0	0.639
10.0	0.809
12.0	0.920
14.0	0.998

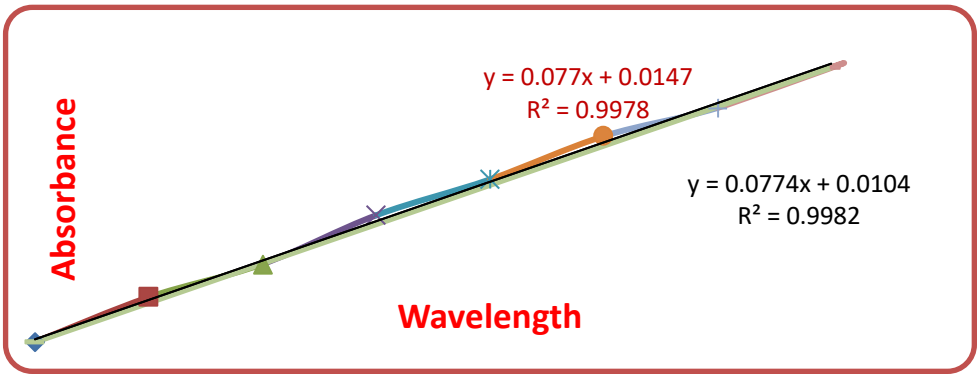

Figure 3: Calibration Curve of Miconazole

Table 2: Solubility Profile of Miconazole

S.No.	Solvents	Solubility
1.	Distilled water	+
2.	0.1N Hydrochloric acid	+++
3.	Ethanol	++++
4.	Ethyl ether	++
5.	Dichloro methane	++
6.	chloroform	++
7.	DMSO	+++

Practically insoluble + Slightly soluble ++ Soluble ++++

Table 3: Characterization of formulation of Miconazole Gel

Charact erization	Formulation code								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
pH	7.2	7.1	7.3	7.1	7.1	6.9	7.0	7.3	7.1
Viscosity	70	96	132	157	173	169	196	232	266
Gelling capacity	++	++	++	++++	++++	++++	+++	++++	++++
Content uniform	96.09 ±0.38	97.54 ±0.70	96.17 ±0.81	98.51 ±0.34	99.03 ±0.21	98.97 ±0.54	96.63 ±0.87	98.68 ±0.21	97.74 ±0.18

Table 4: In-vitro release data of Miconazole Gel

Time (Hrs)	% cumulative drug release from various batches				
	F1	F2	F3	F4	F5
0	0	0	0	0	0
1	16.50	17.40	21.40	12.24	21.32
2	25.30	24.20	20.42	12.46	22.31
3	44.25	46.13	43.16	26.21	33.45
4	64.23	60.41	62.12	38.29	46.56
5	72.27	77.46	76.33	40.09	60.01
6	87.42	85.03	83.14	53.46	69.21
7	92.02	92.46	93.33	75.63	74.91
8	97.98	98.72	98.04	89.32	84.12
9	16.50	17.40	21.40	12.24	21.32
10	25.30	24.20	20.42	12.46	22.31
11	44.25	46.13	43.16	26.21	33.45
12	64.23	60.41	62.12	38.29	46.56

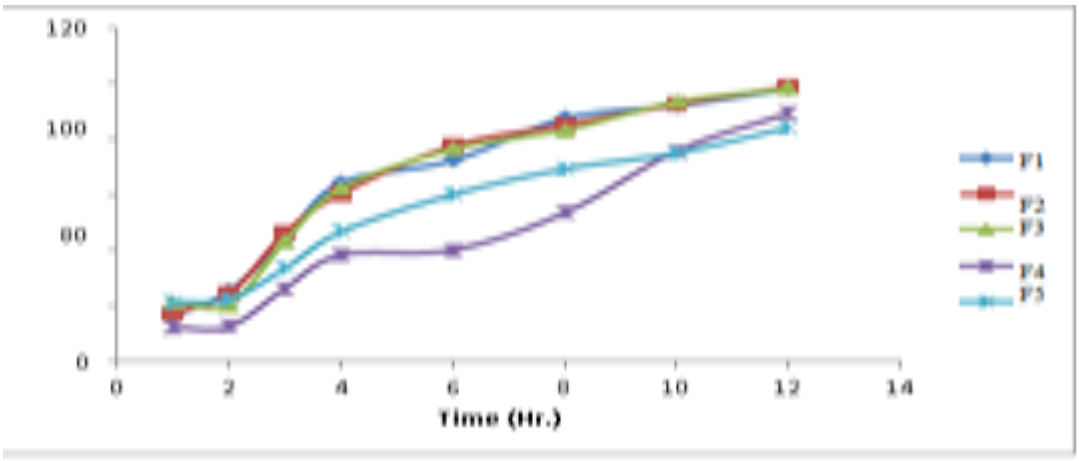

Figure 3: In vitro release curve of Micona

Table 5: In-vitro release data of Miconazole Gel

Time (Hrs.)	% cumulative drug release from various batches			
	F6	F7	F8	F9
0	0.00	0.00	0.00	0.00
1	18.40	28.42	22.37	25.13
2	28.17	37.72	27.08	32.26
3	30.46	43.27	42.36	35.52
4	49.81	49.60	51.18	49.09
6	61.21	57.12	55.19	56.72
8	70.15	66.61	61.68	58.40
10	74.96	63.32	72.84	63.61
12	83.28	79.10	77.37	74.12

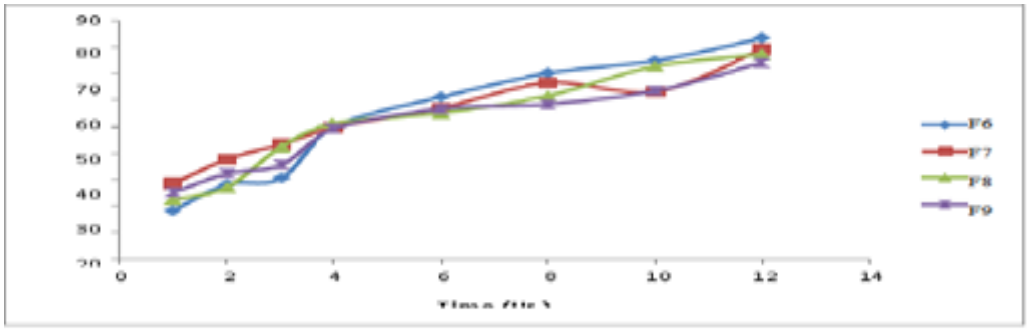

Figure 4: In Vitro release curve of Miconazole

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