

# “Formulation and Evaluation of Hydrogel Containing Clotrimazole”

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Submitted: 02-10-2022

Accepted: 12-10-2022

**ABSTRACT:** The skin is one of the most extensive and readily accessible organs of the human body. The skin of an average adult body covers a surface area of approximately 3000 inch<sup>2</sup> and receives about one third of the blood circulating through the body. The different type of route of administration are available but topical are vary preferred hydrogel containing Clotrimazole was prepared and evaluated for efficacy treatment of fungal infection. There are following four types of fungus infection on the basis of site. They are Athlete’s foot, Yeast infection, Ringworm and Jock itch.

After prepare the hydrogel using different composition of Carbopol, gellangum, ascorbic acid, polyethylene glycol was prepared and evaluated.

Hydrogel the optimization formulation was characterised for appearance, viscosity, pH, spreadibility, homogeneity drug content, content uniformity, in vitro drug release. Based on the results are obtained the formulation F1 showed the best result.

**Keywords-:** fungal infection, hydrogel, Clotrimazole, homogeneity

## I. INTRODUCTION

The skin is one of the most extensive and readily accessible organs of the human body. The skin of an average adult body covers a surface area of approximately 3000 inch<sup>2</sup> and receives about one third of the blood circulating through the body. It is elastic, rugged and under normal physiological conditions, self-regenerating with a thickness of a fewer mm (2.±0.28mm)

### 1.1 NOVEL DRUG DELIVERY SYSTEM

Many substances are applied as cosmetics and therapeutics agents on human skin from their beginning of life on the earth however the skin has becomes the routes for long terms delivery on twentieth century.

Transdermal drug delivery provides a means to sustain drug release as well as reduce the intensity of action and thus reduce the side effects associated with its oral therapy .the choice of drug delivered transdermally clinical needs ,and the drug pharmacokinetics are some of the important consideration in the development of TDDS.

Transdermal drug delivery system are dosage forms involves drug transport to viable epidermal and or dermal tissue of the skin for local therapeutics effect while a very major fraction of drug is transported into the systemic blood circulation.

### 1.2 STRUCTURE OF SKIN

The skin is considered to have 3 layers

□ Epidermis □ Dermis □ Subcutaneous connective tissue

#### 1. EPIDREMIS:

The epidermis is the outermost of the three layers that make up the skin, the inner layers being the dermis and hypodermis the outermost layer of skin, provides a water proof barrier and creates our skin tone. The epidermis is composed of four main strata, or layers. The outermost layer is called the stratum corneum, which is Latin for "horny layer". The layers of the epidermis include the stratum basale (the deepest portion of the epidermis), stratum spinosum, stratum granulosum, stratum lucidum, and stratum corneum (the most superficial portion of the epidermis)..

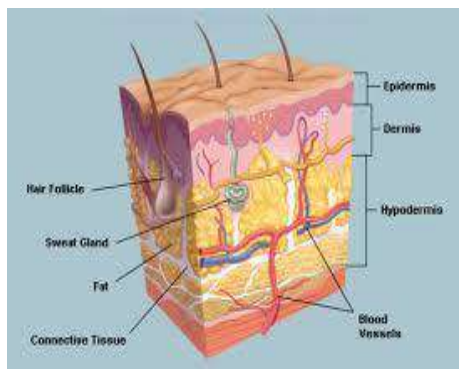
#### 2. DERMIS

The dermis is held together by a protein called collagen. This layer gives skin flexibility and strength. The dermis also contains pain and touch receptors.

#### 3. HYPODERMIS

The subcutaneous tissue or hypodermis is not actually considered a true part of the structured

connective tissue. It is composed of loose textured, white, fibrous connective tissue containing blood and lymph vessels, secretory pores of the sweat gland and cutaneous nerves.



**Fig. 1 The anatomy of human skin:**  
(wikieducator.org, 11/09/20)

### Clotrimazole

Clotrimazole commercially available in several dosage forms for oral and topical administration. Clotrimazole topical is an antifungal medication that fights infection caused by fungus. It is topically used to treat skin infections such as athlete's foot, jock itch, ringworm, and yeast infection.

Name: Clotrimazole, Clotrimazol  
Clotrimazolium

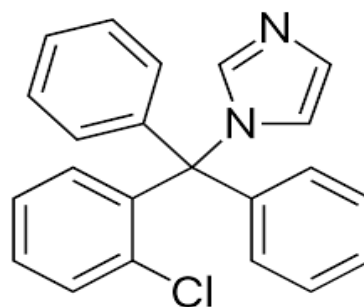
Preformulation may be described as the process of optimizing a drug through determination and identification of those physical and chemical properties considered important in the formulation of a stable effective and safe dosage form.

Preformulation involved in the late 1950s and early 1960s as a result of a shift in emphasis in industrial pharmaceutical product development. It was improvement in analytical methods that spurred the first programs that might bear the name "Preformulation". The overall objective of preformulation testing is to generate information useful to the formulator in developing stable and bioavailable dosage forms which can be mass-produced.

During the early development of a new drug substance, the synthetic chemist, alone or in co-operation with specialists in other disciplines including preformulation, may record some data which can be appropriately considered as preformulation data.

Before starting the preformulation studies we should know the properties of the drug, potency relative to the competitive products and the dosage form, literature search providing stability and decay

data, the proposed route of drug administration, literature search regarding the formulation approaches, bioavailability and pharmacokinetics of chemically related drugs.



**fig- Clotrimazole**

### EXPERIMENTATION-

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#### Identification of Drug

The drug (Clotrimazole) was purchased from Central Drug House India and was identified from its physical appearance, melting point, uv absorption maxima and IR spectra.

#### Physical Appearance

The procured drug sample was observed visually and was found to be white, amorphous and odorless powder. It was noted in visually observation.

#### Melting Point

A capillary melting point apparatus was used for determine the melting point.

#### Determination of the Wavelength Maxima

Accurately weighed 10mg of clotrimazole was dissolved in small quantity of ethanol and the volume was made up to 10ml of ethanol in a 100ml volumetric flask. then 1ml of the stock solution was pipette out in a 10ml volumetric flask and volume was made up to 10ml with ethanol. The sample solution was then scanned between 200-400nm using UV-visible spectrophotometer (Shimadzu 1700, Japan) to determine the absorption maxima.

#### Infrared Spectroscopy

The infrared spectrum of any compound or drug gives information about the functional groups. it was done by making pellets of the drug in Kbr. IR spectra was taken by FTIR spectrophotometer. The obtained IR Spectrum with various peaks was interpreted for different functional groups present in compound against reference IR of Clotrimazole.

S.No	Wave No.(cm-1)	Groups
1	878.93	Chlorine
2	1256.45	Aromatic ring
3	1390.87	C=O

Table : Imported band frequencies in IR spectra of Clotrimazole

#### Solubility

The solubility is the maximum quality of solute that can be dissolved in certain quantity of solvent or quantity of solution at a specified temperature.the solubility of the drug was determined in different polar and non-polar solvents.

Drug (10mg) was added separately to a series of solvents (2ml) in capped test tubes at room temperature. These test tubes were shaken mechanically on wrist action shaker for 6hrs.the test tubes were then observed visually

DEFINITION	PARTS OF SOLVENT REQUIRED FOR 1 PART OF SOLUTE
Very soluble	< 1
Freely soluble	1 – 10
Soluble	10 – 30

Sparingly soluble	30 – 100
Slightly soluble	100 – 1000
Very slightly soluble	1000– 10,000
Insoluble	>10,00

**Table: According to Indian pharmacopeia provides general terms to describe a different solubility ranges.**

## II. RESULT AND DISCUSSION

Clotrimazole drug was purchased from central drug house Pvt. Ltd. The obtained drug sample was first authenticated for purity by performing the Preformulation studies. Drug was matching with standard in I.P. and U.S.P. preformulation studies which were performed are physical appearance, melting point, solubility study, partition coefficient, IR, analysis absorption maxima determination.

The drug sample was observed and found white colour, amorphous powder, and smooth texture.

Stability study of prepared Hydrogels was carried out at different temperatures and % relative humidity for 90 days at regular interval of 15 days and effect on % residual drug content was determined and observation are recorded in table. From the observation table. It was concluded that at temperature  $4 \pm 2$ , negligible or no change was observed on % drug content. In case of temperature  $25 \pm 2 / 60\%RH \pm 5\%RH$  there was minimum change that was observed in % drug content but that change doesn't disturb or interfere with the stability of product.

## III. CONCLUSION

Fungal infection of the skin generally named "Tinea". Many of these infection affect the skin. Most people are unaware that is whole set of disorders related to fungi. Infection are found in the top of the layer mucous membranes, skin, the hair, and the nails. Some example of infection as a jock itch, athlete foot, ringworm and prevention of superficial and systemic fungal infection.

"Preformulation is the study of the physical and chemical properties of the drug prior to compounding process". It commences when a newly synthesized drug shows sufficient pharmacologic promise in animal models to warrant evaluation in man.

Clotrimazole drug was procured from central drug house Pvt. Ltd. India. The obtained drug sample was first authenticated for purity by performing the preformulation studies.

Preformulation studies which were performed are physical appearance, melting point, solubility study, partition coefficient, IR analysis and absorption maxima determination. Later calibration curve and drug excipient interaction study was also performed.

Partition coefficient is an important parameter used to determine lipophilicity of a drug. Partition coefficient of drug was found to be in n-octanol and aqueous base PBS 7.4 suggesting this drug is to be lipophilic in nature (1.4917) (table 4.4).

Standard curve of Clotrimazole was prepared in different fluid ethanol  $R^2$  values are 0.893, 0.909 and a straight line was obtained in both the cases the range is 2-20  $\mu\text{g/ml}$ . This confirms that the Beer-Lambert's Law was followed in UV spectroscopy. The formulation were evaluated for their **physical appearance** this prepared formulation were viscous, smooth and transparent homogeneous appearance, **pH** were found in 6.0-6.3 by the pH strips and digital pH meter apparatus. Which was near the pH value of the skin, so it does not give any adverse effect. The pH value of formulation was found to be suitable for topical delivery.

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