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Formulation, Development And Evaluation Of Herbal Gel Of Terminalia Chebula Powder For Treatment Of Fungal Infection

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ABSTRACT-

The primary objective of the current study was to develop and evaluate an antifungal herbal gel for the treatment of fungal infection, candidiasis using an extract powder obtained from Terminalia chebula. The main stay of about 75-80% of the world population mainly the developing countries for primary health care because of better cultural acceptability, better compatibility with human body and lesser side effects. The gel was prepared by using synthetic macro molecules polymer bases (Carbopol 940) and various concentration of Methyl paraben as a antimicrobial preservative. The Carbopol 940 and Carrageenan based gels has given better gel formation. The gel was prepared by using Carbopol 940, leaves extract, Polyethylene glycol and required amount of distilled water. Then skin pH (6.8-7) was maintained by with the help of dropwise added triethanolamine. The physiochemical parameters of formulations (pH, viscosity, spreadability, extrudability etc.) were determined. The results showed the Carbopol 940 has better gel properties than the marketed formulation with significant anti-fungal activity. Formulation B6 shows approximately equal anti-fungal activity. Hence, there is no need to used roots for the preparation of medicines for anti-fungal action. From the present study, it was concluded that the prepared herbal gel formulation showed significant antifungal activity and found to possess better fungal activity.

Keywords- Fungal Infection, Herbal Preparation, Carbopol 940, Methyl Paraben, skin irritation.

Introduction-

In developing nations, herbal medications are currently much sought-after for basic health care due to their low cost, higher cultural acceptability, improved bodily compatibility, and fewer side effects. These days, fungus-induced skin infections rank among the most prevalent dermatological issues [(1)]. There are numerous reports on the inhibitory effects of various plant extracts on the growth of many bacteria and fungi in culture. For example, ethanol extracts of Cassia alata L. leave sex hibited high antimicrobial activities against various species of dermatophytic fungi. [(2)] The skin is the body's largest organ. It covers the entire body. It serves as a protective shield against heat, light, injury, and infection. The skin also:

1. Regulates body temperature
2. Stores water and fat Is a sensory organ
3. Prevents water loss
4. Prevents entry of bacteria. [(2)]

In human being, skin is the most susceptible part for entering of various pathogens, microorganisms and spreading of diseases. In general, acne vulgaris originates at puberty stage due to hormonal changes which ultimately results in changes in pathophysiologic factors. [(8)] World Health Organization (WHO) has defined herbal medicines are finished, labeled medicinal products that contain active ingredients, aerial or underground parts of the plants or other plant material or combination. Herbal formulations have reached widespread acceptability as therapeutic agents like anti-microbial, anti-diabetic, anti-ageing, anti- arthritic, anti-depressant, anti-anxiety, anti-inflammatory, anti-HIV, treatment of cirrhosis, asthma, migraine, Alzheimer's disease and memory enhancing activities. [(4)] Gelling agent which are used in formulation of gel are synthetic macro molecules like Carbopol 940, triethanolamine. herbal gel is used on topical. [(5)]

Topical Drug Delivery System: -

The goal of any drug delivery system is to provide a therapeutic amount of drug to the proper site in the body to promptly achieve and then maintain the desired drug concentrations. The route of administration has a significant impact on the therapeutic outcome of a drug. Skin is one of the most readily accessible organs on human body for topical administration and is main route of topical drug delivery system. Topical delivery can be defined as the application of a drug containing formulation to the skin to directly treat cutaneous disorders (e.g. acne) or the cutaneous manifestations of a general disease (e.g. psoriasis) with the intent of containing the pharmacological or other effect of the drug to the surface of the skin or within the skin. [(4)]

Advantages of Topical Drug Delivery System: -

- •Avoidance of first pass metabolism.
- •Convenient and easy to apply.
- •Achievement of efficacy with lower total daily dosage of drug by continuous drug input.
- •Avoids fluctuation in drug levels, inter- and intrapatient variations.
- •Ability to easily terminate the medications, when needed.
- •A relatively large area of application in comparison with buccal or nasal cavity
- •Ability to deliver drug more selectively to a specific site.
- •Providing utilization of drugs with short biological half-life,
- •Improving physiological and pharmacological response. [4]

Disadvantages of Topical Drug Delivery System: -

- •Skin irritation of contact dermatitis may occur due to the drug and/or excipients.
- •Poor permeability of some drugs through the skin.
- •Possibility of allergenic reactions.
- •Can be used only for drugs which require very small plasma concentration for action
- •Enzyme in epidermis may denature the drugs
- •Drugs of larger particle size not easy to absorb through the skin. [4]

Topical drug administration is a localized drug delivery system anywhere in the body through ophthalmic, rectal, vaginal and skin as topical routes. Skin is one of the most readily accessible organs on human body for topical administration. For the topical treatment of dermatological diseases as well as skin care, a wide variety of vehicle ranging from solids to semisolids and liquid preparation is available to clinician and patients. Within the major group of semisolid preparations, the use of transdermal gels has expanded both in cosmetics and in pharmaceutical preparations. Transdermal application of gels at pathological sites offers great advantage in a faster release of drug directly to the site of action, independent of water solubility of drug as compared to creams and ointments. [9]

Among the skin care formulations, single-phase gel is extensively used for cosmetic products due to its aesthetic appearance. Moreover, organic macromolecules are uniformly distributed throughout a liquid in such a manner that no apparent boundaries exist between the dispersed macromolecules and the liquid. Terminalia chebula Retz., plants are found to possess antifungal activity Keeping this in view, we planned to bring it our as semisolid external preparation (Terminalia chebula extract) and to screen its efficacy for topical antifungal activity by gel formulation. More over literature survey revealed that there is no scientific validation for this formulation and stability studies. So, an attempt was made to formulate the gel of aqueous extract of the leaves of Terminalia chebula, and their stability studies. [10]

Material and Methods: -

Collection of Sample: -

Plant Materials: -

Collection, identification and authentication of raw Terminalia chebula, was done. Fresh leaves of Terminalia chebula, were collected in a street in Local market in Jalgaon district, Maharashtra, India.

Chemicals: -

Polyethylene glycol, Sodium CMC, Carbopol 940, Methyl paraben, Sodium Benzoate, Triethanolamine, were obtained from Shri Sureshdada Jain Institute of Pharmaceutical Education and Research Jamner, 424206. Maharashtra, India.

Carbopol: -

Is used as a thickener.

It is also used to stabilize, suspend, and control the release of pharmaceutical product.

Methyl paraben:

To prevent the growth of mould and other harmful bacteria.

Triethanolamine:

Is used as a neutralizer and the pH of the gels.

Formulation of Gel: -

While another beaker contained the weighed and necessary amount of terminalia chebula extracted drug powder, which was dissolved in polyethylene glycol and sonicated for 15 minutes, different ratios of Sodium CMC and Carbopol 940 were distributed in distilled water with constant stirring with the aid of a mechanical stirrer. Following 15 minutes of sterilized, this mixture was added to the first solution, which included a combination of carbopol-

940 and sodium CMC, while stirring continuously. The necessary amount of sodium benzoate, on the other hand, was dissolved by boiling 5 ml of distilled water in a water bath. Polyethylene glycol was added and mixed with the previously mentioned solution once the solution had cooled. In order to get the desired consistency for the gel, all components were finally thoroughly combined with the carbopol-940 while being stirred continuously. Using this technique, six herbal gel formulations were produced, each batch containing 0.5 %, 1.5 %, 1.5 %, 1 %, 1 %, 2.5 % of terminalia chebula extracted drug powder were used respectively.

Table 1 Formulation Table: -

Sr. No.	Ingredients	B1	B2	B3	B4	B5	B6
1.	Extracted Powder (gm)	1	3	3	2	2	5
2.	Polyethylene glycol (ml)	2	1.5	1	2	1	2
3.	Sodium carboxy methylcellulose (gm)	1	1	0.5	0.5	1	0.5
4.	Carbopol 940 (gm)	4	5	5	4	4	4.5
5.	Methyl Paraben(ml)	-	0.2	0.1	-	0.1	0.2
6.	Sodium benzoate (gm)	0.30	-	0.10	0.30	-	0.15
7.	Triethanolamine(ml)	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.
8.	Distilled water(ml)	100	100	100	100	100	100

Evaluation and characterization of prepared gel: -

Physical appearance: -

Visual inspection was done to assess the produced gel formulation's color, homogeneity and grittiness. [1,2,6,8]

pH: -

The produced gel formulation's pH is measured using a digital pH meter. After dissolving 1 g of gel in 100 ml of distilled water, it was kept for 2 hours. In order to prevent any kind of skin irritation, the pH of the topical gel formulations was determined in the range of 6.8–7.1, which is close to the natural pH of the skin. [1,2,3,8,9]

Grittiness: -

A microscopical analysis was performed to determine if the generated gel formulation included fine particles. [1,2]

Homogeneity: -

Visual examination was used to assess the homogeneity of produced gel formulations once the gel had solidified in the container. It was recognized by the way the aggregates in the gel formulations looked and felt. [1,3,6,7]

Viscosity: -

The Brookfield viscometer was used to measure the viscosity of the gel. Spindle number 64 was used to rotate the gels at 10 rpm, and the dial reading was recorded. [1,2,3,6,9,10]

Extrudability: -

10 grams of gel compositions were placed into either a metal or aluminum collapsible tube. The gel was extruded from the collapsible aluminum tube by pressing the tube with the finger. a higher extrusion volume of gel guarantees improved extrudability. By quantifying the quantity of gel extruded from an aluminum collapsible tube, the extrudability of the formulations was examined. [1,3,4,7,9,10]

Spreadability: -

Spreadability was determined by the apparatus which consists of a wooden block, which was provided by a pulley at one end. By this method spreadability was measured on the basis of slip and drag characteristics of gels. An excess of gel (about 2g) under study was placed on this ground slide. The gel was then sandwiched between this slide and another glass slide having the dimension of fixed ground slide and provided with the hook. A. one kg weighted was placed on the top of the two slides for 5 minutes to expel air and to provide a uniform film of the gel between the slides. Excess of the gel was scrapped off from the edges. The top plate was then subjected to pull of 80 gm. With the help of string attached to the hook and the time (in seconds) required by the top slide to cover a distance of 7.5 cm be noted. A shorter interval Indicate better spreadability. Spreadability was calculated using the following formula: - [1,2,3,4,6 ,8,10]

$S = M \times L / T$

Where,

S = Spreadability,

M= Weight in the pan (tied to the upper slide)

L = Length moved by the glass slide

T = Time (in sec.) taken to separate the slide completely each other.

Result and Discussion: -

Formulation and Development Six trial batches were formulated and evaluated for pH, viscosity, appearance. Batch B6 selected as best batch because they have very high spreading coefficient.

Table 2 Formulation table of gel

Sr. No.	Ingredients	B6
1.	Terminalia chebula extracted drug powder (gm)	5
2.	Polyethylene glycol (ml)	2
3.	Sodium carboxy methylcellulose (gm)	0.5
4.	Carbopol 940 (gm)	4.5
5.	Methyl Paraben	0.2
6.	Sodium benzoate (gm)	0.25
7.	Triethanolamine(ml)	Q.S.
8.	Distilled water(ml)	100

Based on the preceding data, we may conclude that the B6 batch has a satisfactory pH, extrudability as a result, it was chosen as the best batch for further development of antifungal gel for the treatment of fungal infection.

Evaluation of antifungal gel: -

Homogeneity and grittiness: -

There was no grittiness and good homogeneity in any of the developed gel compositions.

Appearance: -

The developed gel compositions had a smooth look, an aromatic scent, a brown color, and a slightly thick consistency.

pH: -

Gel formulations were found to have pH values between 5.9 and 6.9, which is within the pH range of normal skin. (Table 3).

Extrudability: -

All gel formulations were determined to have acceptable extrudability.

Table 3 Colour pH, homogeneity of gel formulations: -

Batches	Colour	Ph	Homogeneity	Grittiness
B1	Dark Brown	5.9	Homogeneous	No
B2	Dark Brown	6.4	Homogeneous	No
B3	Dark Brown	6.6	Homogeneous	No
B4	Dark Brown	6.8	Homogeneous	No
B5	Dark Brown	6.3	Homogeneous	No
B6	Dark Brown	6.1	Homogeneous	No

Viscosity: -

Table 4 displays the viscosities of several antifungal gel formulations. There is a range of viscosity from 2528 to 3149 cps. The findings indicate a greater viscosity in the B6 formulation. The B1 formulation was found to have a low viscosity.

Table 4 Viscosity, spreadability, extrudability of gel formulations: -

Batches	Viscosity (cp.)	Speadability (%)	extrudability
B1	2528	2.7	Good
B2	2756	2.9	Average
B3	2829	3.5	Good
B4	2889	4.0	Excellent
B5	3120	4.2	Good
B6	3149	4.5	Excellent

Spreadability: -

The spreadability of a gel refers to how easily it covers a certain area after being applied. Spreadability is dependent on the gel's viscosity; as viscosity rises, spreadability falls. Good adhesiveness, adhesive power, and hardness (firmness) were demonstrated using B6 fomulation. Gel hardness and compressed gel structural strength are correlated. Gel has a thicker consistency the higher its hardness value. The polymer's concentration and viscosity determine how spreadable it is. Good spreadability (4.5) was seen in the B6 gel.

Conclusion: -

Terminalia chebula extracted drug powder are therapeutic plants that contain numerous phytoconstituents. Herbal formulations are becoming increasingly popular in the global market. A topical gel containing terminalia chebula extracted drug powder, with Carbopol 940 as a gelling agent (4.5 gm), was effectively made and tested for fungal infection as a candidiasis therapy. In the antifungal investigation, there are two types of preservatives was used such as Methyl paraben and Sodium benzoate in various concentration in batch B6 the high concentration of extracted drug powder and preservative was used. The antifungal action of terminalia chebula extracted drug powder is due to phytoconstituents and phytochemicals. As a result, it can be stated that a topical gel it gives the better result.

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