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DEVELOPMENT AND EVALUATION OF HAIR GEL FOR THE TREATMENT OF DANDRUFF

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ABSTRACT

Dandruff is a very serious problem today; various treatments are available in the market but show temporary effect. An attempt has been made to formulate an antidandruff hair gel of carbopol 940 containing ketoconazole (Antidandruff drug) and *Aloe vera* (Natural antifungal agent), which are effective for number of hours as compared to other marketed hair oils. Hair gel increases the retaining time of drug and improve the effectiveness of antifungal agents. *Aloe vera* keep your hair moisturized, prevent from damage and drying. *Aloe vera* is used in formulation to reduce the dose of ketoconazole and also reduces the adverse and side effect of same.

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INTRODUCTION:

Fungal infections are common throughout the world. In humans, fungal infections occur when an invading fungus takes over an area of the body and is too much for the immune system to handle. Fungi can live in the air, soil, water, and plants[1].Ketoconazole is a synthetic imidazole antifungal drug used primarily to treat fungal infections such as in creams (used to treat tinea; coetaneous Candidiasis, including candidal paronychia; and pityriasisversicolor) and in shampoos (used primarily to treat dandruff-seborrhoeic dermatitis of the scalp)[1]. *Aloe vera* has antibacterial as well as antifungal activity against the various types of bacteria and fungus[5]. Hair gel can hold moisture and protect the hair and are perfect for most hair types and can be applied to wet or dry hair[4].

MATERIAL AND METHODS:

Ketoconazole was obtained as gift sample from Alkem pharmaceuticals, Mumbai. Carbopol 940, Triethanolamine, polyethylene glycol, glycerin and ethanol etc. All excipients were of laboratory reagent grade.

Preformulation Studies

The preformulation studies were carried out in term of test for identification (physical appearance, melting point, partion coefficient, solubility profile and qualitative estimation of drug.

Determination of organoleptic properties/description of drug

The organoleptic studies like general appearance like nature, color, odor and state etc. were performed by visual observation[2].

Determination of partition coefficient

Partition coefficient was determined by taking excess amount of ketoconazole in10 ml mixture of n-octanol and water (1:1) in a separating funnel, shaken intermittently for 30 minute and kept undisturbed for overnight to achieve equilibrium. Then the two phases were separated and centrifuge at 10000 rpm for 15minutes. After centrifugation, the concentration of ketoconazole in both phases was determined by measuring the absorbance at 226 nm on UV-Visible spectrophotometer[2].

Preparation of calibration curve of ketoconazole

Preparation of calibration graph

Varying standard dilutions of 2, 4, 6, 8 and 10 µg/ml of drug in methanol was prepared and absorbance of each solution was measured at 226 nm against methanol blank. A standard graph was prepared by plotting the concentration against the absorbance values.

Preparation of hair gel

Measured quantity of methylparabenes, glycerin and polyethylene glycol, were dissolved in about 35 ml of water in beaker and were stirred at high speed using mechanical stirrer. Then carbopol 940 was added slowly to the beaker containing above the liquid while stirring .In another beaker , ketoconazole drug was dissolve in ethanol and added to the above solution by stirring,

neutralized the solution by slowly adding triethanolamine solution with constant stirring until the gel was formed. Then measured quantity of *Aloe vera* extract was added[3].

Table 1: Formulation of Ketoconazole and *Aloe vera* Hair Gel

Ingredients	HG-1	HG-2	HG-3	HG-4	HG-5
Ketoconazole	1%	1%	1%	1%	%
Alovera	2%	2%	2%	2%	2%
Carbopol 940	1%	2%	3%	4%	5%
Polyethylene glycol 400	5%	5%	5%	5%	5%
Methylparabene	0.01%	0.01%	0.01%	0.01%	0.01%
Triethanolamine	Q.S	Q.S	Q.S	Q.S	Q.S
Glycerin	5%	5%	5%	5%	55
Distilled water (q.s.)	100	100	100	100	100

Evaluation of Anti -dandruff Hair Gels

Psychorheological characteristic- The psychorheological chracterististic was checked for hair gel formulation (colour, clogging, homogenicity and texture)[2].

Washability- Formulations were applied on the skin and then ease and extent of washing with water checked manually[2].

Extrudability study-The hair gel formulations were filled into collapsible metal tubes. The tubes were pressed to extrude the material and the extrudability of the formulation was checked[2].

Spreadability- A sample of 0.5 g of each formula was pressed between two slides (divided into squares of mm sides) and left for about 5 minutes where no more spreading was expected. Diameters of spreaded circles were measured in cm and were taken as comparative values for Spreadability. The results obtained are average of three determinations[2].

Determination of pH- The pH of hair gels was determined by digital pH meter. One gram of gel was dissolved in 25 ML of distilled water and the electrode was then dipped into gel formulation for 30 minute until the constant reading obtained. And constant reading was noted. The measurements of pH of each formulation were replicated two times[2].

Viscosity- The measurement of viscosity of the prepared gel was done using Brookfield digital viscometer. The viscosity was measured using spindle no.6 at 10 rpm and 25°C.The sufficient quantity of gel was filled in appropriate wide mouth container. The gel was filled in the wide mouth container in such way that it should sufficiently allow to dip the spindle of the viscometer. Samples of the gels were allowed to settle over 30 min at the constant temperature (25±1°C) before the measurements[3].

Drug content- The drug content was determined by taking 1 g of gel (equivalent to 10 mg of ketoconazole) in 10 ml volumetric flask diluted with methanol. The above solution was suitably diluted and determined using UV-Vis spectrophotometer at 226 nm[2].

***In vitro* Drug release study-** *In vitro* drug release of ketoconazole from hair gel was carried out by dialysis test tube method. The donor medium phosphate buffer (pH 7.4) was taken in 250 ml beaker. Then the beaker contain a donor medium placed on magnetic stirrer and stirred at 50 rpm at 37°C± 0.5°C and hair gel solution was kept in the test tube with egg membrane and sample of 5 ml was withdrawn in each 5 min from donor medium and maintain sink condition .Then these sample were analyzed in UV visible spectroscopy at 226 nm and phosphate buffer ph 7.4 using as blank[3].

Stability Study-The selected formulation were stored at refrigerator (0-8°C), room temperature (25-30°C) and accelerated temperature (45°C) for 4 weeks and observed for any changes in their physical characteristics and drug content[2].

RESULT AND DISCUSSION:

Preformulation Study- ketoconazole is white odorless powder having absorption maximum at 226 nm.

Partition Coefficient- Partition coefficient value of ketoconazole was observed as 0.055 which showed that ketoconazole islipophilic in nature.

Calibration curve for ketoconazole in Methanol- The absorption of 2 to10 µg/ml of standard ketaconazole solution in methanol were recorded at absorption maximum (226 nm).

Table 2: Psychorheological characteristic

Form	Colour	Clogging	Homogeneity	Texture
HG1	Transparent	Absent	++	Smooth
HG2	Transparent	Absent	+++	Smooth
HG3	Transparent	Absent	++	Smooth
HG4	Transparent	Absent	+	Smooth
HG5	Transparent	Absent	+	Smooth

Excellent (+++) Good: (++) Average: (+) Poor (-)

Evaluation of formulation- All the formulation except HG-4 & HG-5 show good psychorheological characteristic. The Carbopol quantity 2% affects the psychorheological characteristic such as presence of clogging and decrease of homogeneity.

Table 3: Washability, Extrudability, Spreadabilty, pH and Viscosity of Hair gel

Formulation	Washability	Extrudability	Spreadabilty (gcm/sec)	pH	Viscosity (cps)	% drug content
HG1	+++	++	9.5	6.9	3500	98
HG2	+++	++	8.5	7.0	5300	99
HG3	+++	+++	7.3	7.1	8000	99
HG4	++	+	7	7.1	8500	98
HG5	+	+	6.8	7.4	9000	98

Excellent (+++) Good: (++) Average: (+) Poor (-)

All the formulation except HG-4 &HG-5 showed good wash ability, formulation (HG-1 to HG-5) showed good satisfactory Extrudability. The spreadabilty of formulated gel was decreased as the concentration of gelling agent increased. Formulation HG-1 to HG-3 shows satisfactory spreadibility, pH of all gel formulation was found between 6.9 to 7.4, all formulation showed in increased viscosity as the concentration of the gelling agent was increased. The prepared gel formulation showed uniformity in drug contents. The In-vitro drug release of drug from gel was in the order of decreasing as the concentration of gelling agent was increased. The decrease in vitro –release of drug may be due to the increased viscosity of the gels.

Stability study of optimized formulation: The hair gel formulation HG-2 was subjected to stability performance as it was exhibited good drug release and other evaluation parameters.

Table 4: Stability study of optimized formulation HG-2

Temperature	Refrigerator temperature room (0-8^{0}C)	Room temperature (25-30^{0}C)	Accelerated Temperature (45^{0}C)
Period	28 days	28 days	28 days
Viscosity	5300	5280	5130
pH	7.0	7.0	6.9
Spreadability (gcm/sec)	8.5	8.3	8.1
Drug content (%)	99	98	98

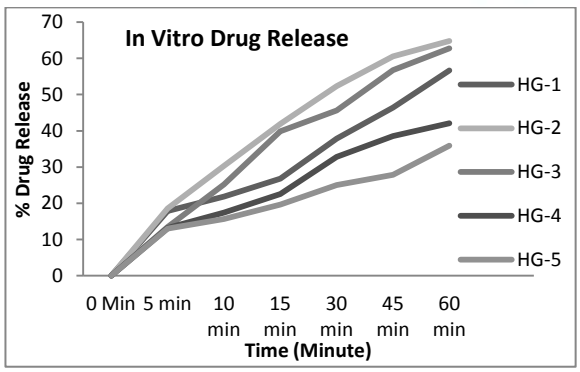

Figure 1: Comparative drug release profile data of all formulation

CONCLUSION:

Hair gel of ketoconazole and *Aloe vera* were formulated and evaluated for the drug content, viscosity, Spreadability, wash ability, in vitro drug release and stability. Formulation HG-2 was better compare to other. The release rate of drug from HG-2 formulation is best compare to other.The most satisfactory formulation HG-2 did not show any significant change in drug content, viscosity, pH, and spreadability after stability studies at 25-30 °C, 0-8°C and 45^{0}C for 4 weeks. Thus, the objective of the work of formulation and evaluation of ketoconazole and alovera topical gel has been achieved with success.

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