FORMULATION AND CHARACTERISATION OF TRIAMCINOLONE ACETONIDE EMULGEL

Reha Chodankar* and Asish Dev

Department of Pharmaceutics, Oriental College of Pharmacy, Sanpada Navi Mumbai.

ABSTRACT

The objective of the study was to increase the solubility and permeability of Triamcinolone acetonide by formulating an oil-in-water emulgel using HLB system for preparation of emulsions. The active moiety was solubilised using oil (Liquid paraffin) and N-Methyl Pyrolidone which acts as a solubliser and also helps in effective permeation. The emulsion was prepared by using HLB system that calculated the optimum quantity of emulsion blend i.e. 30% Span 80 and 70% Tween 80. Further the emulsion ratio was varied (2%, 4%, 6%) and it was found that 6% was stable amongst the three. The prepared emulsion was then incorporated in carbopol 934 as it was low viscous then carbopol 940 that would facilitate effective release of the gel. The oil and gel concentration were varied from 5, 8, 10% and 1, 1.4, 1.8% respectively. The above formulated emulgel was then subjected to evaluation parameters of emulgel like physical properties, spreadability, extrudability, rheological properties, bioadhesive strength measurement, drug content determination, In-vitro release study, drug release kinetics. From In-vitro release study it was concluded that the optimised batch LP-F (Oil-10%, Emulsifiers-6% and Gel-1.4%) showed a sustained release of 96.50% in 7hrs. The Ex vivo studies carried out for the optimised batch showed a maximum release of 108.47 in 6 hrs. Thus, it can be concluded that Triamcinolone acetonide was proven to be a suitable candidate for formulating emulgel for topical delivery to achieve better patient compliance.

KEYWORDS: Emulgel, hydrophobic drug, topical preparation, HLB system.

INTRODUCTION

Psoriasis is a non-contagious chronic inflammatory dermatosis affecting 2% of the world population. It is characterized by recurrent episodes of red and scaly skin plaques that are
sharply demarcated from adjacent normal skin. This disease is to some extent due to a genetic predisposition and other environmental factors. The most frequent type of psoriasis is chronic plaque psoriasis or psoriasis vulgaris. However, the disease can also be classified into 4 different types such as guttate, pustular, erythrodermic, and inverse psoriasis.[1]

The treatment for psoriasis includes topical therapy, systemic therapy and phototherapy. The systemic therapy leads to systemic toxicity as psoriasis requires long term therapy and phototherapy is expensive as well as leads to poor patient compliance. Several conventional topical therapeutic agents like gels, creams, ointments and lotions are used widely in treatment of psoriasis, but these conventional dosage forms have disadvantage of low transdermal penetration which leads to low therapeutic effectiveness.[2]

Triamcinolone Acetonide is a topical corticosteroid used to treat a variety of skin conditions (e.g., eczema, psoriasis, dermatitis, allergies, rash, and mouth ulcers). It is a BCS Class IV drug having low solubility and low permeability. Triamcinolone acetonide when administered orally undergoes extensive first pass metabolism. Triamcinolone acetonide also possesses short half-life of 88 min. Thus from above listed properties of drug and taking into account that psoriasis disease first line of treatment is done by topical route. Topical route is selected for administration of triamcinolone acetonide.[3]

Most widely used topical agents like ointment, cream, lotion have many disadvantages. They are very sticky causing uneasiness to the patient when applied. Moreover they also have lesser spreading coefficient and need to be applied by rubbing. They exhibit the problem of stability also. Due to all these factors within the major group of semisolid preparations, the use of transparent gels has expanded both in cosmetics and in pharmaceutical preparations. A gel is colloid that is typically 99% wt liquid, which is immobilized by surface tension between it and a macromolecular network of fibers built from a small amount of a gelating substance present. In spite of many advantages of gels one of the major limitation is the delivery of hydrophobic drugs, hence to overcome this limitation an emulsion based approach is being used so that even a hydrophobic therapeutic moiety can be successfully incorporated and delivered through gels.

Emulgel are emulsions, either oil-in-water or water-in-oil, which are gelled by mixing with a gelling agent. Emulgel is a most promising vehicle for the delivery of hydrophobic drugs. The Emulgel in other words is a combination of Emulsion and Gel.[4]
Advantages of Emulgel\(^5\)
1. Better stability
2. Hydrophobic drugs can be easily incorporated into gels using d/o/w emulsions
3. Production feasibility and low preparation cost
4. Better loading capacity
5. Controlled release
6. No intensive sonication

Disadvantages of Emulgel\(^6\)
1. Poor permeability of some drugs through skin.
2. Occurrence of bubble during formation of emulgel.
3. Drug of large particle size not easy to absorb through the skin.
4. Skin irritation or allergic reaction on contact dermatitis.

The rationale behind this work was to develop an emulgel of a topical corticosteroid Triamcinolone Acetonide to enhance permeation and to sustain the drug release at the localized area.

Preparation of Emulsion by HLB System
To help save time in emulsifier selection, the HLB (Hydrophile-Lipophile Balance) system was introduced by ICI. Briefly, the HLB System enables you to assign a number to the ingredient or combination of ingredients you want to emulsify, and then to choose an emulsifier or blend of emulsifiers having this same number.

The HLB of an emulsifier is an expression of its Hydrophile-Lipophile Balance, i.e. the balance of the size and strength of the hydrophilic (water-loving or polar) and the lipophilic (oil loving or non-polar) groups of the emulsifier. All emulsifiers consist of a molecule that combines both hydrophilic and lipophilic groups.

An emulsifier that is lipophilic in character is assigned a low HLB number (below 9.0), and one that is hydrophilic is assigned a high HLB number (above 11.0). Those in the range of 9-11 are intermediate.\(^7\)

The HLB system predicts the optimum emulsion stability when the HLB value of the surfactant systems matches the required HLB of the oil/water system. The required HLB is the value at which enhanced emulsion stability will be attained. When two or more
emulsifiers are blended, the resulting HLB of the blend is easily calculated. Optimization of the performance can be achieved by only including surfactant systems with similar HLB values.[8]

MATERIALS AND METHODS
Triamcinolone Acetonide was gifted by Glenmark Generics, Navi Mumbai. Carbopol 934 was purchased from Research Lab, Tween 80 and Liquid Paraffin was procured from Pallav Chemicals, Span 80 was obtained from SD Finechem Ltd, N- Methyl Pyrrolidone and Triethanolamine was purchased from Thomas Baker.

➢ Selection of excipients (solubility studies)[9]

a. Selection of oil phase
An excess amount of Triamcinolone Acetonide was added to each of the oils and was stirred magnetically. After stirring for 24 hours at 37°C, the equilibrated sample was centrifuged for 10 min at 5000rpm (rotations per minute) to remove excess amount of Triamcinolone Acetonide. The supernatant was filtered and properly diluted with methanol. The concentration of Triamcinolone Acetonide was determined by UV spectrophotometry.

b. Selection of emulsifier
An excess amount of Triamcinolone Acetonide was added to each of the emulsifier and was stirred magnetically. After stirring for 24 hours at 37°C, the equilibrated sample was centrifuged for 10 min at 5000 rpm (rotations per minute) to remove excess amount of Triamcinolone Acetonide. The supernatant was filtered and properly diluted with methanol. The concentration of Triamcinolone Acetonide was determined by UV spectrophotometry.

➢ FTIR study of drug- excipients[10]
A Fourier transform instrument determines the absorption spectrum for a compound in the common range of 4000 to 400 cm⁻¹.

Preparation of samples: A base line correction was made using dried potassium bromide. Weighed amount of the drug was mixed thoroughly with potassium bromide (dried at 40° - 50° C) which was then compressed under 10 ton pressure in a hydraulic press to form a pellet which was then scanned from 4000–400 cm⁻¹ using JASCO FTIR.
Preparation of Triamcinolone Acetonide Emulgel

STEP 1: Weighed quantity of Carbopol 934 was dispersed in half quantity of calculated water until completely soaked.

STEP 2: 0.1gm of drug was weighed and dissolved in parts in weighed quantities of Light Liquid Paraffin oil and N-methyl pyrrolidone. Methyl paraben and propyl paraben were dissolved in N-methyl pyrrolidone and then both the solutions were mixed together. Span80 is then dissolved in the above mixture. This makes the oil phase of the emulsion.

STEP 3: For the aqueous phase, take the remaining quantity of calculated amount of water and dissolve weighed quantity of Tween80.

STEP 4: The aqueous phase is stirred at a medium speed using overhead stirrer and gradually oil phase is added into it. Continue stirring it for about 15 minutes until emulsion is formed.

STEP 5: The gel soaked previously is taken and stirred using overhead stirrer until it attains a smooth consistency and then the emulsion is slowly poured into it to get an Emulgel.

STEP 6: While stirring the emulgel triethanolamine is added drop wise to adjust the pH to 6 – 7.

Emulgel Evaluation

- Physical properties\(^\text{[11]}\)
  All the formulated batches were visually checked for the colour and appearance, homogeneity, consistency and pH.

- Rheological study\(^\text{[12]}\)
  A Brookfield digital viscometer (Brookfield eng. Labs inc., U.S.A .Model RVT) with a suitable sample adaptor was used to measure the viscosities of the Carbopol gel in cps. All the measurements were conducted using spindle no. 62 using about 100 ml sample volume at 10RPM and 100 RPM. Direct multiplication of the dial readings with factors given in the Brookfield viscometer catalogue gave the viscosity in centipoises.

- Spreadability\(^\text{[11,13]}\)
  Spreading coefficient (Spreadability) was determined by apparatus which consists of a wooden block, which is attached to a pulley at one end. Spreading coefficient was measured on the basis of ‘Slip’ and ‘Drag’ characteristics of emulgel. A ground glass slide was fixed on the wooden block. An excess of emulgel (about 2 g) under study was placed on this ground slide. The emulgel preparation was then sandwiched between this slide and second glass slide having same dimension as that of the fixed ground slide. The second glass slide is provided
with the hook. Weight of 500 mg was placed on the top of the two slides for 5 min to expel air and to provide a uniform film of the emulgel between the two slides. Measured quantity of weight was placed in the pan attached to the pulley with the help of hook. Time in seconds taken by two slides to slip off from emulgel and placed in between the slides under the direction of certain load. Lesser the time taken for separation of two slides, better the spreadability. It is calculated by using the following formula:

\[ S = \frac{M \times L}{T} \]

Where, \( M \) = wt. tied to upper slide;
\( L \) = length of glass slides;
\( T \) = time taken to separate the slides.

- **Bio adhesive strength measurement**[^14]

The modified method is used for the measurement of bioadhesive strength. The fresh skin is cut into pieces and washed with 0.1N NaOH. Two pieces of skin were tied to the two glass slide separately from that one glass slide is fixed on the wooden piece and other piece is tied with the balance on right hand side. The right and left pans were balanced by adding extra weight on the left-hand pan. 1 gm of topical emulgel is placed between these two slides containing hairless skin pieces, and extra weight from the left pan is removed to sandwich the two pieces of skin and some pressure is applied to remove the presence of air. The balance is kept in this position for 5 minutes. Weight is added slowly to the left-hand pan until the patch detached from the skin surface. The weight (gram force) required to detach the emulgel from the skin surface gave the measure of bioadhesive strength. The Bioadhesive strength is calculated by using following:

\[ \text{Bioadhesive Strength} = \frac{\text{Weight required (in gm)}}{\text{Area (cm}^2)} \]

- **Extrudability**[^14]

The gels were filled into collapsible tubes after formulating them. The extrudability of the formulation has been checked.

Where + average, ++ good, +++ excellent

- **Drug content determination**[^14]

Take 1gm of emulgel. Mix it in 100ml methanol. Filter it to obtain clear solution. Pipette out 1ml from the above solution and further dilute it to 10ml using methanol. Determine its absorbance using UV spectrophotometer. Concentration and drug content was determined by using the same standard plot by putting the value of absorbance in the standard plot equation.
In-vitro release study\textsuperscript{[11, 14]}

The durapore membrane was cut to appropriate size and it was soaked in pH 7.4 phosphate buffer solution for 24 hrs. In-vitro drug release studies were carried out by taking 4-5gms of emulgel on the durapore membrane, which was mounted on the Franz diffusion cell. The receptor medium with pH 7.4 phosphate buffer solution was maintained at constant temperature of 37 °C by circulating water bath. The solution was stirred at 300 rpm and aliquots each of 1ml were withdrawn from the release medium at specified time intervals. The withdrawn samples were replaced by equal volumes of fresh release medium. The samples were assayed spectrophotometrically at λmax 239 nm and the concentration of the drug was determined from the previously constructed calibration curve. Each data point represented the average of three determinations. In vitro release studies were recorded for a 7 hour period.

Ex-vivo studies\textsuperscript{[15]}

Ex- Vivo skin permeation was performed by Franz Diffusion cell with effective skin diffusion area of 3.56 cm\textsuperscript{2}. The excised sample of rat skin (Dorsal side) was clamped between donor and receptor compartment of Franz diffusion cell with stratum corneum facing the donor compartment. Than fixed quantity of emulgel containing 0.1% triamcinolone acetonide was applied on donor compartment. The receptor compartment was filled with phosphate buffer pH 7.4 was maintained at temperature 37°C with stirring at 100rpm. At predetermined intervals 1hr, 1ml was withdrawn and same volume of same medium was added immediately into receptor compartment. Procedure was repeated upto 6hrs. The samples were analyzed by UV spectrophotometer at 239 nm using blank as phosphate buffer pH 7.4.

Stability Study\textsuperscript{[16,17]}

The prepared emulgel were packed in aluminium collapsible tubes (5 g) and subjected to stability studies at 25°C± 2°C/ 60% RH± 5% RH, 30°C± 2°C/65% RH± 5% RH, and 40°C± 2°C/75% RH± 5% RH for a period of 3 months.

RESULTS AND DISCUSSIONS

Selection of excipients (saturated solubility)

Selection of oil phase
1. Lemon oil : 1.8 mg/ml
2. Eucalyptus oil : 1.2 mg/ml
3. Liquid paraffin : 0.7 mg/ml
4. Isopropyl myristate: 0.6 mg/ml

b. Selection of emulsifier

1. Tween 80: 3.1 mg/ml
2. Tween 20: 2.2 mg/ml
3. Span 80: 0.9 mg/ml

Hence, lemon oil was selected as the oil phase but after carrying out the In-vitro release study it was seen that the drug was released within an hour so the remaining batches were prepared using liquid paraffin as the oil phase.

➢ FTIR study of drug-excipients

<table>
<thead>
<tr>
<th>Peak</th>
<th>Functional group</th>
</tr>
</thead>
<tbody>
<tr>
<td>3385</td>
<td>-OH stretching</td>
</tr>
<tr>
<td>1707</td>
<td>-C=O stretching</td>
</tr>
<tr>
<td>1666</td>
<td>Carbonyl groups of aliphatic esters and ketone</td>
</tr>
<tr>
<td>1614</td>
<td>-CH stretching</td>
</tr>
<tr>
<td>1176</td>
<td>-CF stretching</td>
</tr>
</tbody>
</table>

The IR spectrum of drug was found to be similar to the standard IR spectrum of TACA which indicates that the sample obtained was pure.

➢ Preparation of Triamcinolone Acetonide Emulgel

The batches were formulated (Table no.1) by varying the oil concentrations (5, 8, 10%) and carbopol 934 (1, 1.4, 1.8%).
Table 1: Formulation batches.

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>LP-A</th>
<th>LP-B</th>
<th>LP-C</th>
<th>LP-D</th>
<th>LP-E</th>
<th>LP-F</th>
<th>LP-G</th>
<th>LP-H</th>
<th>LP-I</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug</td>
<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>Carbopol 934</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1.4</td>
<td>1.4</td>
<td>1.4</td>
<td>1.8</td>
<td>1.8</td>
<td>1.8</td>
</tr>
<tr>
<td>Liq Paraffin</td>
<td>5</td>
<td>8</td>
<td>10</td>
<td>5</td>
<td>8</td>
<td>10</td>
<td>5</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>Tween-80</td>
<td>4.2</td>
<td>4.2</td>
<td>4.2</td>
<td>4.2</td>
<td>4.2</td>
<td>4.2</td>
<td>4.2</td>
<td>4.2</td>
<td>4.2</td>
</tr>
<tr>
<td>Span-80</td>
<td>1.8</td>
<td>1.8</td>
<td>1.8</td>
<td>1.8</td>
<td>1.8</td>
<td>1.8</td>
<td>1.8</td>
<td>1.8</td>
<td>1.8</td>
</tr>
<tr>
<td>NMP</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Methyl paraben</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
</tr>
<tr>
<td>Propyl paraben</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
</tr>
<tr>
<td>Triethanolamine</td>
<td>Q.S</td>
<td>Q.S</td>
<td>Q.S</td>
<td>Q.S</td>
<td>Q.S</td>
<td>Q.S</td>
<td>Q.S</td>
<td>Q.S</td>
<td>Q.S</td>
</tr>
</tbody>
</table>
Emulgel Evaluation

Physical properties

Table 2: Physical properties of formulated batches.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>LP-A</th>
<th>LP-B</th>
<th>LP-C</th>
<th>LP-D</th>
<th>LP-E</th>
<th>LP-F</th>
<th>LP-G</th>
<th>LP-H</th>
<th>LP-I</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour &amp; Appearance</td>
<td>White fluidy</td>
<td>White creamy</td>
<td>White creamy</td>
<td>White creamy</td>
<td>White creamy</td>
<td>White creamy</td>
<td>White creamy</td>
<td>White creamy</td>
<td>White creamy</td>
</tr>
<tr>
<td>Homogeneity</td>
<td>Good</td>
<td>Good</td>
<td>Good</td>
<td>Good</td>
<td>Good</td>
<td>Excellent</td>
<td>Excellent</td>
<td>Excellent</td>
<td>Excellent</td>
</tr>
<tr>
<td>Phase separation</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>pH</td>
<td>6.43±0.32</td>
<td>6.75±0.62</td>
<td>6.36±0.55</td>
<td>6.12±1.2</td>
<td>6.59±0.65</td>
<td>6.60±0.76</td>
<td>6.04±0.36</td>
<td>6.39±0.63</td>
<td>6.12±0.04</td>
</tr>
</tbody>
</table>

All the prepared formulations were white in appearance and they showed good homogeneity and no separation was observed. The pH of all the formulation was found to be ranging from 6.04 to 6.75 as shown in Table no. 2 which were found to be acceptable to avoid any skin irritation.

Rheological study

Table 3: Rheological study of formulated batches.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>LP-A</th>
<th>LP-B</th>
<th>LP-C</th>
<th>LP-D</th>
<th>LP-E</th>
<th>LP-F</th>
<th>LP-G</th>
<th>LP-H</th>
<th>LP-I</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viscosity (cps) 10 RPM</td>
<td>48649±2.0</td>
<td>50862±1.1</td>
<td>51748±1.1</td>
<td>49617±1.2</td>
<td>52190±2.0</td>
<td>54625±1.1</td>
<td>53891±0.5</td>
<td>56928±1.0</td>
<td>59684±1.1</td>
</tr>
<tr>
<td>100 RPM</td>
<td>5039 ±1.1</td>
<td>5196 ±1.15</td>
<td>5348±1.1</td>
<td>5257 ±2.1</td>
<td>5568±1.2</td>
<td>5796±1.5</td>
<td>5481±2.0</td>
<td>5712 ±1.0</td>
<td>5879±2.0</td>
</tr>
</tbody>
</table>

The viscosities of all nine formulations at 10 rpm and 100 rpm are shown in Table no.3. It is observed that as the concentrations of polymer increases the viscosity of formulation also increases.
Spreadability

Table 4: Spreadability of formulated batches.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>LP-A</th>
<th>LP-B</th>
<th>LP-C</th>
<th>LP-D</th>
<th>LP-E</th>
<th>LP-F</th>
<th>LP-G</th>
<th>LP-H</th>
<th>LP-I</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spreadability (g/s)</td>
<td>14.98</td>
<td>17.45</td>
<td>24.06</td>
<td>20.45</td>
<td>22.78</td>
<td>25.64</td>
<td>25.08</td>
<td>27.43</td>
<td>31.09</td>
</tr>
</tbody>
</table>

Spreadability is the term expressed to denote the extent of area to which the emulgel spreads on application to skin or affected part. The therapeutic efficacy of formulation depends upon its spreading value. The spreadability value ranged from 14.98 to 31.09 as shown in Table no. 4. The spreadability is dependent on the viscosity of formulation. With an increase in the gelling agent concentration in the formulation, the spreadability of formulation decreases.

Bio adhesive strength measurement

Table 5: Bioadhesive strength of formulated batches.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>LP-A</th>
<th>LP-B</th>
<th>LP-C</th>
<th>LP-D</th>
<th>LP-E</th>
<th>LP-F</th>
<th>LP-G</th>
<th>LP-H</th>
<th>LP-I</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength (gm/cm²)</td>
<td>4.58</td>
<td>3.73</td>
<td>4.26</td>
<td>5.8</td>
<td>5.86</td>
<td>5.33</td>
<td>6.4</td>
<td>5.8</td>
<td>5.6</td>
</tr>
</tbody>
</table>

Table no. 5 shows the bioadhesive strength measurement of all nine formulations. Bioadhesive strength for the nine formulation varies from 3.73 to 6.4 gm/cm². The bioadhesive strength depends on the concentrations of gelling agent. As the gelling agent concentration increases the strength required to separate the skin increases.

Extrudability

Table 6: Extrudability of formulated batches.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>LP-A</th>
<th>LP-B</th>
<th>LP-C</th>
<th>LP-D</th>
<th>LP-E</th>
<th>LP-F</th>
<th>LP-G</th>
<th>LP-H</th>
<th>LP-I</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extrudability</td>
<td>+++</td>
<td>+++</td>
<td>++</td>
<td>+++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

+++ indicates excellent
++ indicates good
+ indicates poor

The extrudability gives the extent to which a semisolid formulation is extruded out from the tube. The extrudability (Table no. 6) depends on the viscosity and consistency of formulation. The less the viscosity the more the extent to which the formulation is extruded out.
Drug content determination

Table 7: Rheological study of formulated batches.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>LP-A</th>
<th>LP-B</th>
<th>LP-C</th>
<th>LP-D</th>
<th>LP-E</th>
<th>LP-F</th>
<th>LP-G</th>
<th>LP-H</th>
<th>LP-I</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug content (%)</td>
<td>92.3±0.37</td>
<td>100.7±0.51</td>
<td>93.2±0.62</td>
<td>100.8±0.62</td>
<td>90.4±1.16</td>
<td>99.5±0.32</td>
<td>100.3±0.36</td>
<td>95.9±0.55</td>
<td>99.6±0.81</td>
</tr>
</tbody>
</table>

The percentage drug content of all the nine formulations of Triamcinolone Acetonide was determined and the percentage of drug present was reported in the Table no.7. The drug content varied from 90.4 to 100.8%.

In-vitro release study

Table 8: In-vitro release study of formulated batches.

<table>
<thead>
<tr>
<th>Time</th>
<th>LP-A (%)</th>
<th>LP-B (%)</th>
<th>LP-C (%)</th>
<th>LP-D (%)</th>
<th>LP-E (%)</th>
<th>LP-F (%)</th>
<th>LP-G (%)</th>
<th>LP-H (%)</th>
<th>LP-I (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15 mins</td>
<td>27.40±0.14</td>
<td>25.70±0.09</td>
<td>19.90±0.47</td>
<td>16.80±1.10</td>
<td>16.80±0.05</td>
<td>14.64±0.19</td>
<td>3.20±0.39</td>
<td>2.66±0.73</td>
<td>1.36±0.06</td>
</tr>
<tr>
<td>30mins</td>
<td>34.72±0.05</td>
<td>37.65±0.67</td>
<td>24.06±0.67</td>
<td>26.24±0.34</td>
<td>24.16±0.47</td>
<td>21.14±0.60</td>
<td>7.88±0.05</td>
<td>6.42±0.10</td>
<td>5.69±0.15</td>
</tr>
<tr>
<td>45mins</td>
<td>45.46±0.15</td>
<td>49.58±0.44</td>
<td>37.08±0.15</td>
<td>36.35±0.69</td>
<td>30.84±0.44</td>
<td>27.24±0.16</td>
<td>9.17±0.08</td>
<td>7.85±1.09</td>
<td>6.17±0.47</td>
</tr>
<tr>
<td>60 mins</td>
<td>69.19±0.16</td>
<td>61.54±0.04</td>
<td>55.67±0.89</td>
<td>55.53±0.47</td>
<td>33.65±0.15</td>
<td>34.19±0.09</td>
<td>11.18±0.10</td>
<td>9.31±0.37</td>
<td>8.46±0.76</td>
</tr>
<tr>
<td>120mins</td>
<td>74.89±0.10</td>
<td>75.31±0.15</td>
<td>70.12±0.06</td>
<td>52.91±0.15</td>
<td>42.28±0.34</td>
<td>42.86±0.10</td>
<td>29.44±0.04</td>
<td>27.76±1.16</td>
<td>25.40±0.38</td>
</tr>
<tr>
<td>180 mins</td>
<td>86.45±0.56</td>
<td>85.67±0.46</td>
<td>78.88±0.10</td>
<td>65.82±0.43</td>
<td>53.64±0.56</td>
<td>54.22±0.16</td>
<td>43.36±0.01</td>
<td>39.22±0.69</td>
<td>35.33±0.10</td>
</tr>
<tr>
<td>240 mins</td>
<td>88.95±0.50</td>
<td>93.02±0.65</td>
<td>85.47±0.45</td>
<td>87.07±0.47</td>
<td>64.81±0.05</td>
<td>64.84±0.65</td>
<td>52.73±0.15</td>
<td>47.49±0.10</td>
<td>42.83±0.15</td>
</tr>
<tr>
<td>300 mins</td>
<td>90.45±0.74</td>
<td>98.65±0.47</td>
<td>89.00±0.10</td>
<td>94.25±0.21</td>
<td>76.64±0.15</td>
<td>79.04±0.31</td>
<td>59.18±0.10</td>
<td>51.74±0.09</td>
<td>49.16±0.06</td>
</tr>
<tr>
<td>360 mins</td>
<td>96.36±0.09</td>
<td>102.12±1.15</td>
<td>88.76±0.9</td>
<td>87.22±0.12</td>
<td>62.38±0.09</td>
<td>56.97±0.24</td>
<td>53.33±0.72</td>
<td>58.09±0.10</td>
<td></td>
</tr>
<tr>
<td>420 mins</td>
<td>96.50±0.25</td>
<td>69.63±0.43</td>
<td>61.90±0.46</td>
<td>96.00±0.25</td>
<td>69.63±0.43</td>
<td>61.90±0.46</td>
<td>58.09±0.10</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The percentage cumulative drug release of all the prepared emulgel formulations using liquid paraffin ranged from 58.09 to 102.12% at the end of 7hrs. The percent cumulative drug release of the emulgel formulations are shown in Table no. 8 and represented graphically in the fig 2 to 4. Maximum drug release was observed in formulation LP-F after 7hrs. The reason attributed for a higher release is the lower concentration of gelling agent i.e. 1.4% of Carbopol 934.
Fig 2: In-vitro release profile of batches (LP-A, LP-B, LP-C) of Liquid paraffin.

Fig 3: In-vitro release profile of batches (LP-D, LP-E, LP-F) of liquid paraffin.

Fig 4: In-vitro release profile of batches (LP-G, LP-H, LP-I) of liquid paraffin.

Ex-vivo studies

Table 9: In-vitro release study of formulated batches.

<table>
<thead>
<tr>
<th></th>
<th>1hr</th>
<th>2hr</th>
<th>3hr</th>
<th>4hr</th>
<th>5hr</th>
<th>6hr</th>
</tr>
</thead>
<tbody>
<tr>
<td>LP-F (%)</td>
<td>10.66</td>
<td>14.65</td>
<td>35.06</td>
<td>56.48</td>
<td>80.17</td>
<td>108.47</td>
</tr>
</tbody>
</table>
Fig 5: Ex-vivo release profile of batches (LP-G, LP-H, LP-I) of liquid paraffin.

The percentage cumulative drug release of the batch LP-F was observed as 108.47% at the end of 6hrs. The percent cumulative drug release of the batch LP-F is shown in Table no. 9 and represented graphically in the fig 5.

- Stability Study

The optimised batch LP-F was subjected to all the evaluation parameters and the results obtained were within acceptable limits which showed that formulations were stable over the period of 3 months.

CONCLUSION

The present study involved formulation of topical emulgel of Triamcinolone Acetonide. The emulsion was formulated by HLB method using liquid paraffin as oil phase, blend of Tween 80 and Span 80 as emulsifier, N-Methyl Pyrrolidone as a permeation enhancer and Carbopol 934 as a gelling agent. On the basis of evaluation parameters, it can be concluded that the prepared emulgel was stable throughout the stability study and showed sustained release for 6hrs hence, proving it a suitable formulation to achieve patient compliance for treatment of psoriasis.

REFERENCE


7. The HLB System A time saving guide to emulsifier selection; Edited and reprinted from CHEMMUNIQUE, publication of ICI Americas Inc.


