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Determining Anti-Psoriatic Activity of Salicylic Acid and *Wrightia Tinctoria* Herb Using Extemporaneous Formulation

Deepa Singh*[1], Sushama Rawat[1], Neha Riyal[2], Shaneza Aman[1], Preeti Khulbe[1]

1. GyanVihar School of Pharmacy, SGVU
2. Implementation Analyst, Allscripts, Pune

ABSTRACT:
Salicylic acid, a non-steroidal anti-inflammatory drug and *Wrightia tinctoria* herb has been used in the treatment of Psoriasis. This study was conducted to develop and evaluation of gel and beads formulations i.e. extemporaneous formulation for psoriasis by using Carbopol 934 as a gelling agent. The gel formulations were evaluated for physical appearance, drug release and stability. The drug release from carbopol 934 as a gelling agent through a standard cellophane membrane was evaluated using Franz-Diffusion Cell. The gel formulation showed acceptable physical properties concerning color, homogeneity, consistency, spreadability and pH value as well as beads also showed good results with suitable size and no foreign matter is observed. The drug release by polymer Carbopol 934 show high concentration release and Stability studies showed that the formulation remained unchanged upon storage for six months at ambient conditions.

Keywords: Carbopol 934, Franz Diffusion Cell, Psoriasis, *Wrightia tinctoria,* Salicylic acid

INTRODUCTION

Psoriasis is regarded as an autoimmune disease in which genetic and environmental factor has a significant role with a strong genetic predisposition and autoimmune pathogenic traits. The worldwide prevalence is about 2%, but varies according to regions. It shows a lower prevalence in Asian and some African populations, and up to 11% in Caucasian and Scandinavian populations.(1)

Psoriasis is a non-contagious, dry, chronic inflammatory skin disorder; it is a common skin condition which affects men and women of all ages. It occurs classically on the elbows, knees and in the scalp, but can occur on any part of the body on occasion, including the flexures. It can cause the nails to become pitted, discoloured and fragile. While the cause of psoriasis is essentially unknown, it appears to be more common in some families. It has also been associated with various factors in those people who are predisposed to psoriasis, such as trauma to the skin, streptococcal upper respiratory infections, stress, some medications, heavy alcohol intake and smoking.(2)

Patients suffering from psoriasis are mostly at a risk of developing other diseases including psoriatic arthritis, anxiety and depression, lymphoma, metabolic syndrome, cardiovascular disorder, and Crohn's disease. Mild trauma, sunburn or chemical irritants can provoke psoriasis. There are drugs such as non-steroidal anti-inflammatory agents, β-blockers, lithium and antimalarial that can worsen the pre-conditions of the disease. Herbal remedies can be used for the treatment of psoriasis, it can also be helpful to overcome side effect, antagonist effect and bioavailability of the drug.[3,4] *W. tinctoria* (R.Br) has medicinal potentials such as phytochemicals which are of ethno-medico-botanical significance. The phytochemicals like flavonoids, alkaloids, steroids, phenol and tannins and are multi potentially which cures various skin ailments.[5] The oil extracted/prepared from the leaves of *Wrightia tinctoria* is used for the treatment of psoriasis. While salicylic acid acts as a healer by removing the excessive keratin in hyperkeratotic skin disorders.

This work aims to decipher the mechanism of action of the *W. tinctoria* and salicylic acid in the treatment of psoriasis and its comorbidities. The experiment aims to deliver Salicylic acid and *W. tinctoria* through an extemporaneously dosage form prepared using carbopol gel. The extemporaneous formulation would enable the rapid assessment (this causes reduction in cycle time) of formulation with minimal quantity of the active pharmaceutical ingredient needed to demonstrate the desire activity.[6]

MATERIALS AND METHODS

Materials

Salicylic acid, Carbopol 934, Triethanolamine, Propylene Glycol, Calcium Chloride and pectine are obtained from Research Lab Fin Chem, Sodium alginate is obtained from Himedia Lab. Mumbai**,** Acacia Powder is obtained from Burgoyne Burbidges & co.**,** Sodium Hydroxide are gift samples from Loba Chemie.

Preparation of gel

Appropriate quantity of salicylic acid was dissolved in a co-solvent (a mixture of water and propylene glycol). Then drug solution was mixed with Carbopol 934 in a beaker. The resulting mixtures were stirred slowly until homogenous solution formed. After this triethanolamine was added to drop wise until gel was formed.[7]

Table 1: **Composition of gel formulation**

Ingredients	Concentration (%)
Salicylic acid	3.0
Carbopol 934	3.0
Propylene glycol	46
Water	q.s

Preparation of beads

The Extracted oil, Acacia powder and pectine were mixed in mortar pestle. The Sodium alginate dissolved in water then above solution was added and suspended in the polymer solution. This polymeric solution was dropped through a syringe nozzle into ion solution. After this polymeric solution was dispersed in a Calcium chloride solution, by magnet stirring, and the polymeric solution was added drop wise through a needle syringe into this dispersion.[8]

Table 2: Composition of beads formulation

Ingredients	Concentration (%)
Sodium alginate	2
Oil	2
Acacia powder	2
Pectine	2
Water	q.s

Calcium chloride solution- 30gm in 100ml water.

Evaluation of Gel

Organoleptic properties

The prepared gel formulations were inspected visually for their colour, homogeneity, consistency, grittiness and phase separation.[9]

Measurement of pH

The pH of gel formulations was determined by using digital pH meter. One gram of gel was dissolved in 100 ml of distilled water and it was placed for two hours. The measurement of pH of each formulation was done in triplicate and average values were calculated.[10]

Rheological Study

The viscosity of the formulation was determined using a Brookfield Viscometer with spindle 07. The formulation whose viscosity was to be determined was added to the beaker and was allowed to settle down for 30 min at the assay temperature (25±1ºC) before the measurement was taken. Spindle was lowered perpendicular in to the center of gel taking care that spindle does not touch bottom of the jar and rotated at a speed of 50 rpm for 10 min. The viscosity reading was noted.[9]

Spreadability

The spreadability of the gel formulation was determined by, measuring diameter of 1 g of gel between horizontal plates after 2 min. The standardized weight tied on the upper plate was 100 gm. The spreadability was calculated by using the formula.[11]

$$S = ml \div t$$

Where, S= spreadability
m= weight tied to upper plate
l= length of glass slide
t= time taken

Drug content determination

Take 10 g of gel formulation and dissolved it in mixture of 20 ml of ethanol and 20ml of ether. Then titrate this with 0.1 M sodium hydroxide using phenol red solution as an indicator.[12]

1 ml of 0.1 M sodium hydroxide equivalent to 0.01381 g of $C_7H_6O_5$

In Vitro Drug Release Study

The in vitro drug release studies were carried out using a modified Franz diffusion (FD) cell. The formulation was applied on dialysis membrane which was placed between donor and receptor compartment. Phosphate buffer pH 7.2 was used as a dissolution media. The temperature of the cell was maintained at 37°C. This whole assembly was kept on a magnetic stirrer and the solution was stirred continuously using a magnetic bead. Sample (1 ml) was withdrawn at suitable time intervals and replaced with equal amounts of fresh dissolution media. Samples were analyzed spectrophotometrically at 231.6 nm and the cumulative % drug release was calculated.[(9)]

Stability study

The formulated gel were filled in the collapsible tubes and stored at room temperatures for a period of six months. Samples were withdrawn at time intervals, studied for pH and spreadability.[(13)]

Evaluation of beads

Particle size

Mean particle size of beads was determined using Digital Vernier Caliper.[(14)]

Feel of foreign matter

It was performed by applying the sample on the skin, on the portion of forearm and the feeling of foreign matter was overall subjected to an organoleptic test. The evaluation was divided in the following manner.[(14)]

a. No feeling of foreign matter
b. Slight feeling of foreign matter
c. Extreme feeling of foreign matter

Escape of beads

It was performed by applying the sample on the skin, on the portion of forearm, the escape of beads when rubbed with the palm of hands, reputability, smoothness during application were evaluated overall according to an organoleptic test. The evaluation was divided in four rankings.[14]

a. Very good
b. Good
c. Average
d. Poor

RESULT AND DISCUSSION

Evaluation parameters of Gel

The evaluating parameters of the prepared gel using salicylic acid and carbopol 934 used as gelling agents in the formulation. The pH, Viscosity, Color, Spreadibility, Drug content uniformity and In vitro drug release study were evaluated.

Organoleptic properties

The organoleptic properties of the prepared gel were studied and result shown in table 3. The Color, Homogenecity, Consistency, Grittiness and Phase separation of the gel were observed.

Table 3: **Organoleptic study**

Test	Color	Homogenecity	Consistency	Grittiness	Phase separation
Result	Yellowish transparent	Homogenous	Thin	No	No

pH

The gel formulation was found in normal range of skin pH. The pH value of the gel formulation was 6.8, which lies in the normal range of skin pH which is considered acceptable to avoid the risk of irritation after its application on the skin.

Viscosity

The viscosity of salicylic acid gel was found to be 26,523cps.

Spreadability

The spreadability indicates that the gel is easily spreadable by small amount of shear. Spreadability of the gel decreases with the increase in the concentration of the polymer. The spreadability is very much important as it shows the behavior of gel when it comes out from the tube, the spreadability of the formulation was found to be 4.5gm.cm/sec.

Drug content

The drug content of the formulated gel was estimated spectrophotometrically at 231.6nm and it was found to be 95.67%.

Table 4: **Other evaluation study of gel**

Test	pH	Viscosity	Spreadability	Drug content(%)
Result	95.67%	26,523 cps	4.5 gm.cm/sec	95.67 ± 0.35

In Vitro Drug Release study

The in vitro drug release prepared gel formulations are shown in table 5. The maximum drug release was observed after 3hrs was 67.06%.

Table 5: **In vitro drug release study**

Time (Min.)	%Cumulative Release
0	0
15	1.45
30	2.54
45	5.28
60	9.44
75	13.31
90	18.24
105	25.09
120	31.2
135	40.09
150	48.11
165	57.17
180	67.06

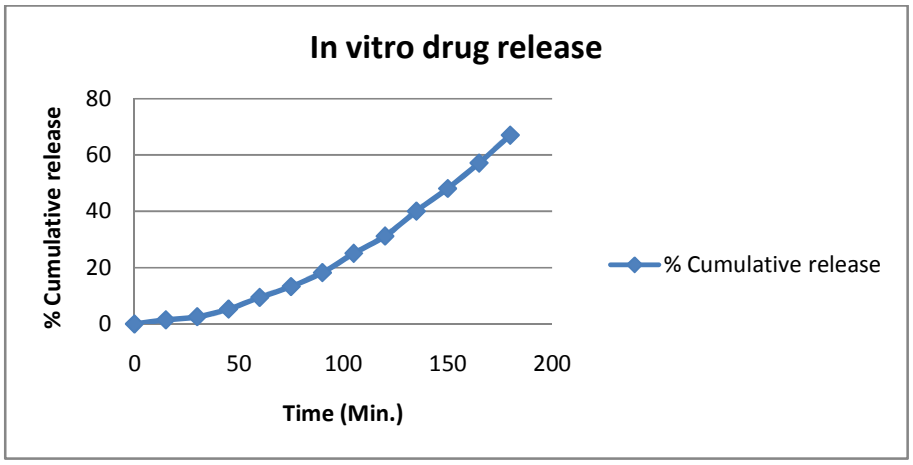

Figure 1: **In vitro drug release study**

Stability study

The prepared gel formulation was found to be stable upon storing them for six months. Minor changes were observed after six months.

Table 6: **Stability study**

Time (Months)	pH	Spreadability (gm.cm/sec)
0	6.8	4.5
1	6.9	4.5
3	7.0	4.8
6	7.0	4.9

Evaluation parameters of Beads

As a need of the present formulation, beads enclosing oil extract must break down completely and leave no residue as a result of gentle rubbing on skin and are stable on storage. As revealed in the table 7 the beads of formulation break down upon rubbing onto the skin to release. Also these beads stable to storage conditions.

Table 7: **Characterization of beads**

Test	Result
Particle size analysis (mm)	1.96 ± 0.05
Feel of foreign matter	B
Escape of beads	Y

α- Very Good	A -No feeling
β- Good	B- Slight feeling
Ϋ- Average	C- Extreme feeling
δ - Poor	

CONCLUSION

From above results, we can conclude that Salicylic acid gel formulation prepared with carbopol 934 as a gelling showed acceptable physical properties and In vitro drug release study. The prepared gel showed acceptable physical properties concerning color, homogeneity, consistency, spreadability and pH value. It has showed better release i.e 67.06% in 180 minutes. The beads formulation containing oil of *Wrightia tinctoria* herb also show good result when rub on the skin and no foreign matter is observed during applied. Hence it can be concluded that this extemporaneous formulation can be used for various topical formulations for external application for psoriasis. For future studies work will be continued to check the anti – psoriasis effect of Salicylic acid and herb *Wrightia tinctoria*, using animal model.

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