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FORMULATION, EVALUATION AND COMPARATIVE STUDY OF CORTICOSTEROIDAL OINTMENT WITH DEXAMETHASONE AND ALOE VERA

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ABSTRACT

Ointments are a type of semisolid medication that have been used for a variety of skin issues. However, the ointment has been formulated with the three different ointment bases and comparative studies have been done to determine the best formulary for future aspects of in vitro and in vivo studies. Here, the active ingredient is the corticosteroid dexamethasone, which has a good anti-inflammatory effect over the skin and with the help of aloe vera, the aloe vera has been used in the ointment to give out the soothing effect.

KEYWORDS: Dexamethasone, Aloe vera, Ointment Bases, Comparative studies.

INRODUCTION

As a mode of transdermal drug delivery, ointments are widely used as topical medication. Ointments are viscous, unctuous semisolid preparations that contain functional ingredients that are either dissolved or suspended.[4]

Ointment bases are classified into four general groups.

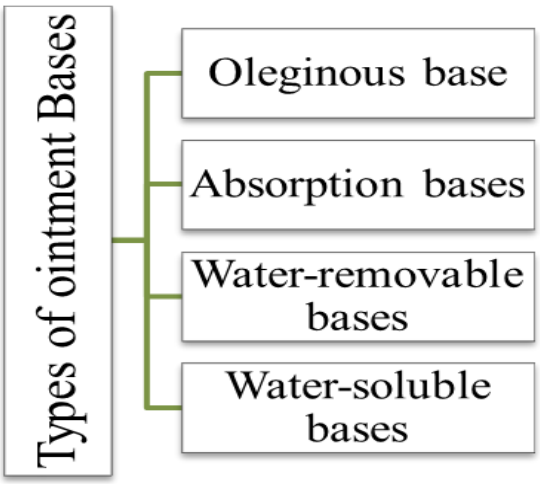

Fig. 1: Types of ointment bases.

Methods of ointment preparation

Ointments can be prepared by various methods as discussed below. Based on the nature of drug and other ingredients ointment preparation method should be carefully selected. Stability, efficacy of the active ingredients and other physico chemical properties of the preparation depends on the type of ointment preparation method.[6]

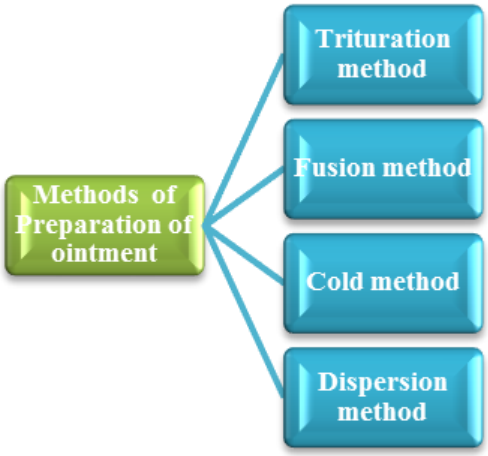

Fig. 2: Methods of ointment preparation.

Packaging

Ointment filling machines are used for filling the ointment tubes with a speed of 60 pack/minutes and filling capacity – 5 Gram to 150 Gram. The ointment is directly fed to the end side of the Ointment tube further the tube is sealed by heating on the end side of the tube and proceeded through the conveyer for secondary packaging, Ointments should be packed and sealed properly so that there are no air spaces. It must be stored in well closed container to avoid contamination.

Advantages of ointment

- It is used externally
- Probability of side effect can be reduced
- First pass gut and hepatic metabolism is avoided
- Convenient for comatose patients or patient having difficulty on oral administration
- Convenient dosage form for bitter drugs
- More stable than liquid dosage form.

Disadvantages of ointment

- There is no dosage accuracy in semi solid dosage forms.
- The base which is used in the semisolid dosage form can be easily oxidized
- May cause staining
- They are bulky to handle
- Application with finger may cause contamination
- Physico - chemically less stable than solid dosage form
- May cause irritation or allergy to some patient.

Dexamethasone - Drug

Dexamethasone belongs to a group of medicines called steroids. It is used in the treatment of various diseases and conditions such as inflammatory and autoimmune conditions. It provides relief from swelling, redness, and pain, by preventing the release of substances that cause inflammation.

Dexamethasone sodium phosphate ointment is an adrenocortical steroid used for steroid responsive inflammatory conditions of the Palpebral and Bulbar conjunctiva, Cornea and Anterior segment of the globe.

Dexamethasone is a synthetic glucocorticoid used in the treatment of inflammatory and immune conditions in children and adults. It is available in forms that can be taken by mouth, through a patch placed on the skin, as a cream, in eye drops, and as an injectable.

Dexamethasone is used to treat a variety of skin conditions, severe allergies, asthma, chronic obstructive pulmonary disease, croup, brain swelling, post-operative eye pain, superior vena cava syndrome (a complication of some types of cancer), and tuberculosis when combined with antibiotics. It may be combined with a mineralocorticoid drug like fludrocortisone to

treat adrenocortical insufficiency. It can be utilized to help the baby's outcomes during premature labour. It can be administered orally, intravenously, intramuscularly, topically as a cream or ointment for the skin, or topically as an ophthalmic solution to the eyes.

Dexamethasone's effects usually appear within a day and last for three days. Extended use of Dexamethasone for a long period may lead to muscle weakness, cataracts, bone loss, thrush, and easy bruising. It should only be used when the benefits are anticipated to outweigh the dangers because it is classified as pregnancy category c in the us. In Australia, oral use falls under category A, indicating that it has been regularly used throughout pregnancy without being determined to have an adverse effect on the unborn child. When nursing, it should not be taken. Both anti-inflammatory and immunosuppressive effects of Dexamethasone are present.

Drug history

Dexamethasone was first synthesized by Philip Showalter Hench in 1957. It was introduced for medical use in 1958. The world health organization has it on their list of mandatory drugs. It received more than 1 million prescriptions in 2020, ranking it as the 272nd most popular pharmaceutical in the country. List of mandatory drugs. It received more than 1 million prescriptions in 2020, ranking it as the 272nd most popular pharmaceutical in the country.

Fig. 3: Philip showalter hench founder of dexamethasone.

Dexamethasone increases the survival rates of hospitalized COVID-19 patients getting oxygen or using a ventilator, according to early data from the Recovery study released on June 16, 2020. Only patients who required respiratory assistance received benefits; those who did not required breathing help had a worse survival rate than the control group, however the

difference might have been a coincidence. The whole dataset was published as a preprint on June 22, 2020, and the demand for dexamethasone increased as a result. On July 18, 2020, the preliminary study was released in the New England Journal of Medicine. In February 2021, the final report was released.[5]

Dexamethasone should only be administered to critically ill patients receiving Covid-19 treatment in a hospital setting, according to the World Health Organization (WHO), and the WHO Director-General stated that "WHO emphasizes that only patients with severe or critical illness should use dexamethasone, and only under close medical supervision. There is no proof that this medication helps people with minor illnesses or as a prophylactic precaution, and it could even be harmful." The WHO announced in July 2020 that they are revising their treatment recommendations to include Dexamethasone or other steroids.

Half life: Dexamethasone is a long-acting corticosteroid with a half-life of 36 to 72 hours.[5]

Contraindications

The most common side effects are sleep problems, mood changes, indigestion and weight gain.[2]

Adverse effects

These adverse effects include ecchymosis, skin thinning and atrophy, acne, mild hirsutism, facial erythema, stria, impaired wound healing, thinning of hair, and perioral dermatitis. Glucocorticoids increase the risk of adverse GI effects, such as gastritis, gastric ulcer formation, and GI bleeding.[2]

Aloe vera

Aloe vera is gel from the leaves of aloe plants. People have used it for thousands of years for healing and softening the skin. Aloe has also long been a folk treatment for many maladies, including constipation and skin disorders.

The modest houseplant is a ‘miracle,’ wonder plant, often hiding in plain sight. Having been around and used as a medicinal herb, it nourishes the body from the inside – it is rich in nutrients, aids in improving digestion and even boost immunity. Aloe vera can be used topically too its gel can be used to enhance one’s skin, especially the face and the hair.[14]

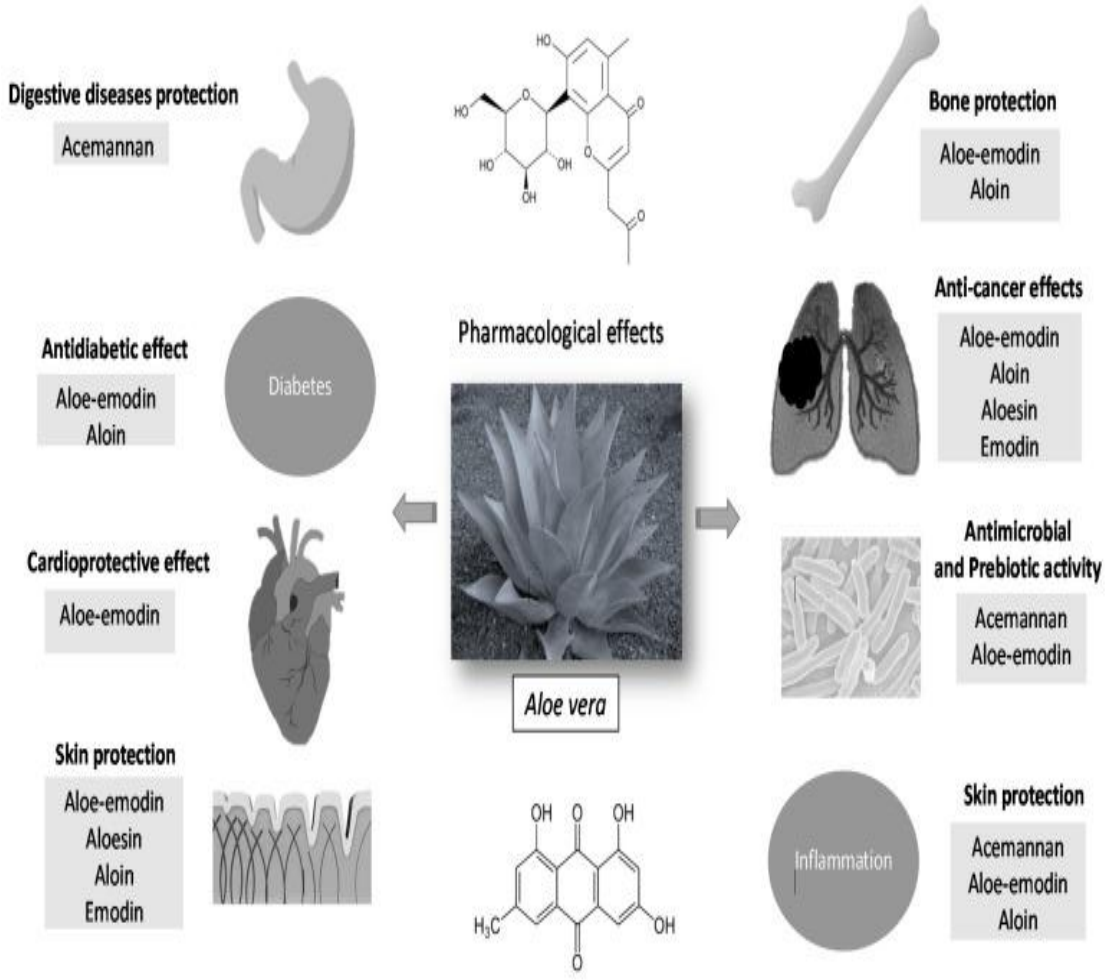

Fig. 4: General pharmacological effects of aloe vera.

Taxonomy

Aloe perfoliata L. var. vera, Aloe barbadensis Mill, Aloe indica Royle, and Aloe vulgaris Lam. are some of the species' synonyms. Aloe vera with white spots is sometimes referred to as Aloe vera var. chinensis, and the spotted variety of the plant may be conspecific with A. massawana. The species was first described by Carl Linnaeus as Aloe perfoliata var. vera in 1753. It was later described as Aloe vera in 1768 by Nicolaas Laurens Burman in Flora Indica on 6 April and as Aloe barbadensis by Philip Miller in the Gardener's Dictionary around ten days later.

Aloe forbesii, Aloe inermis, Aloe scobinifolia, Aloe sinkatana, and Aloe striata are all said to be close relatives of this plant. All these Aloe species are indigenous to Socotra (Yemen), Somalia, and Sudan with the exception of the South African species A. striata. Several authors have hypothesized that Aloe vera might be a hybrid plant.[14]

METHODOLOGY

Materials used

Table 1: Materials used in the formulation.[25]

S. No	Chemicals	Manufacturer	Use in formulation
01	Emulsifying wax	Indian Research Pharmaceuticals, Chennai.	Binding Agent
02	Bees wax	Indian Research Pharmaceuticals, Chennai.	Solidity to emulsified solution
03	White soft paraffin	Indian Research Pharmaceuticals, Chennai.	Barrier cream by providing a layer of oil on the surface of the skin
04	Liquid paraffin	Nice Chemicals pvt, ltd.	Emollient
05	Benzoic acid	Nice Chemicals pvt, ltd.	Preservative

Instruments used

Table 2: List of equipments used.[30]

S. No	Instruments	Suppliers
01	UV Spectrometer	LABMAN
02	Weighing balance	Scale Tec
03	pH meter	Alpha^{-01} Vision plus
04	Brookfield viscometer	LABMAN LMDV-60
05	HPLC	Shimadzu LC-20AD, Japan
06	FT-IR	Shimadzu, Japan
08	Centrifuge	Remi
09	Waterbath	Hasthas Scientific Instrument, Chennai.
10	Hotplate	Hasthas Scientific Instrument, Chennai.

Development of ointment formulation

Procedure:

Emulsifying wax (F1&F3), Bees wax (F2), Coconut oil (F3), liquid paraffin, White soft paraffin was heated separately in a China dish at 70^0C. Dexamethasone and Benzoic acid were mixed separately. The Ointment base was added drop by drop with constant stirring to the Dexamethasone and Benzoic acid mixture. Then aloe vera was added and triturated well to mix and get smooth texture.[23]

Table 03: Composition of ointment formulation.

Sl. No.	Ingredients	F1	F2	F3
01	Emulsifying wax	15%	-	15%
02	Bees wax	-	15%	-
03	Liquid paraffin	10%	10%	-
04	White soft paraffin	25%	25%	25%
05	Dexamethasone	01%	01%	01%
06	Benzoic acid	02%	02%	02 %

07	Coconut oil	-	-	10%
08	Aloe vera gel	04%	04%	04%

Evaluation of ointment

1. Physical examination

The prepared ointment formulations were inspected visually for their colour, homogeneity, consistency.[26]

2. Determination of pH

2.5gm Ointment sample was taken in 100 ml dry beaker, 50 ml water was added to it. Beaker was heated on water bath maintained at about 60ºC to 70ºC for 10 minutes, cooled to room temperature and then centrifuged at 3000 rpm for 10 minutes. The pH of water extract was measured by using Alpha^{-01} Vision Plus pH meter by dipping the glass electrode into the ointment formulation. The pH measurements were also done by using Litmus pH paper by soaking the paper in the formulation.

3. Centrifugation

It is believed to be a unique tool for the evaluation of accelerated deterioration of ointments. It was determined by using Remi centrifuge in 10 ml-graduated cylinders at 10,000 rpm for 10 min.[31]

4. Spreadability

Spreadability is a term expressed to denote the extent of area to which the ointments readily spread on application to skin or affected part. The spreadability was expressed in terms of times in seconds taken by two slides to slip off from ointment and placed in between the slides under the direction of certain load. Lesser the time taken for separation of two slides, result the better spread ability. Spreadability was calculated by using the formula.[31]

S = (M.L/T)

S = Spreadability

M = Weight tied to upper slide

L = Length of glass slides and

T = Time taken to separate completely from each other.

5. Viscosity

The measurement of viscosity of prepared ointments was carried out with Brookfield Viscometer (model LM-DV 60, spindle NO.3) at different speeds. The values of each ointment formulations were done in triplicate.[26]

6. Micro biological studies

Microbiological studies are done by the cup plate method. For testing the Bacterial growth in the storage period. Nutrient Agar medium is prepared serial dilutions. The sample is inoculated by the help of sterile inoculum loop. The total experiment is only done at Aseptic conditions.

The maintained parameters for the tests are:

- Temp - 120 ^{0}C
- Time- 20min
- Pressure - 15lb

After solidification of Agar medium and our sample is inoculated and incubated for 48 hours at 37^{0}C ± 2^{0}C temperature.[7]

7. Loss on drying

Take the Petridish and fill it with required quantity of ointment and weigh it. The weighed petridish is put on water bath for drying at 105^{0}C. The formula that can be used for the calculation of loss on drying is given below.[24]

% Loss on Drying = (Weight after heat-Weight before heat) / Weight after heat × 100

8. Adhesion

Test of adhesion have been carried out by weighing 1gm of ointment placed on one surface of glass plate with another plate. Place some weight on it for five minutes, then separate out the two glass plates and then record the stickiness of ointment in sec.[33]

9. Water number test

Water number is the maximum amount of water that can be added to 50 g of base at a given temperature. It was determined by continuously stirring the base with the addition of distilled water. When no more water was absorbed into the base evidenced by droplets of water, remaining in the container was taken as end point.[39]

10. Extrudability test

Extrudability test is the measure of the force required to extrude the material from a collapsible tube when certain amount of force has been applied on it in the form of weight. In the present study the quantity in percentage of ointment extruded from the tube on application of certain load was determined. The extrudability of prepared corticosteroid ointment formulations was calculated by using following formula.[38]

$$\text{Extrudability} = \frac{\text{Amount of ointment extruded from the tube x 100}}{\text{Total amount of ointment filled in the tube}}$$

Identification tests

11. HPLC Analysis

High performance liquid chromatographic system consisting of a pump, an injector, photodiode array (PDA)/UV-Visible detector and suitable data processing software HPLC (Shimadzu LC-20AD, Japan).[35]

Preparation of mobile phase

Buffer (pH 2.6 Solution)

Mix 4 mL of phosphoric acid (concentrated) and 1200 mL of water, adjust the temperature to 20° C and then adjust the pH to 2.6 with sodium hydroxide solution. Filter the solution through a 0.45µm membrane filter.

Mobile phase

Mix 1200 mL of pH 2.6 Buffer, 72 mL of tetrahydrofuran and 728 mL of methanol, sonicate to degas.

Seal wash

Mix water and Methanol in the ratio of 50:50 (v/v) respectively, sonicate to degas.

Needle wash

Mix water and Methanol in the ratio of 10:90 (v/v) respectively, sonicate to degas.

System suitability preparation

Accurately weigh about 2.0 mg of each Dexamethasone phosphate into 100 mL volumetric flask. Add 2 mL of Tetrahydrofuran dissolve, and dilute to volume with diluent and mix. Further dilute 5 mL to 50 mL with diluent and mix.

Reference solution preparation: (Prepare in duplicate)

Accurately weigh and transfer about 30 mg of Dexamethasone sodium phosphate standard into a 50 mL. volumetric flask. Add about 35 mL of diluent to dissolve and make up to the volume with diluent and mix. Further dilute 5 mL of the solution to 50 mL with diluent and mix. (Approximate concentrationis 60 µg/mL).

Sample preparation: (Prepare in duplicate)

Accurately weigh and transfer about 30 mg of substance (sample) into a 50 mL volumetric flask. Add about 35mL of diluent to dissolve and make up to the volume with diluent and mix. Further dilute 5 mL of the solution to 50 mL with diluent and mix. (Approximate concentration is 60 µg/mL).

12. UV standard drug calibration

UV absorbance has been conducted utilizing dissolving techniques. One gram of ointment was dissolved in 100 ml of acetone. then do the dissolve three times, remove the 5 ml of the dissolving sample solution, and place it on a LABMAN double beam UV spectrometer to determine the absorbance.[31]

- ***Calibration standards***

A stock standard solution of Dexamethasone was prepared by dissolving 5 mg of sample in 50 mL of an acetone (50:50 v/v) mixture. Calibration standards (5.0, 10.0, 15.0, 20.0, 25.0, 30.0, 35.0 and 40.0 µg/ mL) were prepared from the stock standard solution by appropriate dilution. All measurements were made in triplicate at 254 nm. The calibration curve was created by plotting the mean response versus the DEX concentration.

13. Drug content

An accurately weighed portion of sample (about 100 mg) is dissolved in 100 mL of suitable solvent in which drug is soluble and then the solution is shaken continuously for 24 h in shaker incubator. The entire solution is then sonicated. Following sonication and subsequent filtration, the drug in solution is spectrophotometrically estimated by appropriate dilution.[42]

The drug content in the samples were measured by using the Beer–Lambert law relates the absorption of light by a solution to the properties of the solution according to the following equation.

A = εbc, where ε is the molar absorptivity of the absorbing species, b is the path length, and c is the concentration of the absorbing species

C= A/εl, where c is concentration ε is extinction coefficient and l path length .

RESULTS AND DISCUSSION

Physical examination

The ointments are tested for organoleptic properties and it provides valuable information about the sensory properties of an ointment and helps to ensure its quality and efficacy.

Table 4: Physical examination tests.

Sl. No.	Formulation code	Colour	Texture	Homogeneity
1.	F1	White	Slightly greasy	Homogenous
2.	F2	White	Smooth	Homogenous
3.	F3	White	Smooth	Homogenous

Inference

- All the Prepared formulation of F1,F2,F3 are white in colour and are free from lumps and no separation of phases are noted and thus it is homogenous in nature
- Among the prepared formulation of F1 is slightly greasy and the F2 and F3 are smooth in texture.

Determination of pH

The pH of the formulations of F1, F2 , and F3 are measured using 2 methods.

a) Vision Plus Digital pH meter and

b) pH strips.

Table 5: pH of formulated ointments.

Sl. No	Formulation Code	pH
1.	F1	5.84
2.	F2	5.90
3.	F3	6

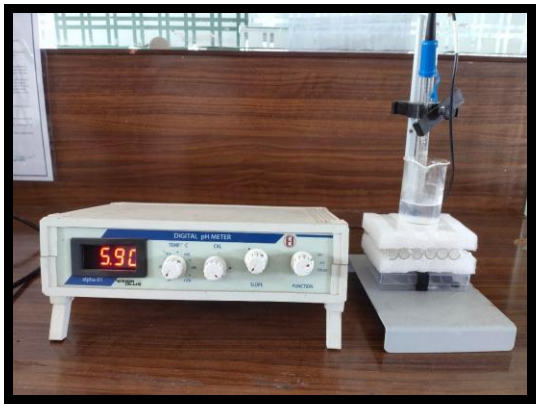

Fig. 5: a. Digital pH Meter.

Fig. 5: b. pH strips.

Inference

- The pH of all the formulation was found to be satisfactory in the range of 5.84- 6 as depicted in table – 7.2 so it does not cause any irritation to skin.

Centrifuge test

Samples of the prepared formulations F1, F2, and F 3 are tested using Remi Centrifuge machine.

Table 6: centrifuge test of formulated ointment.

Sl. No	Formulation code	Inference
1.	F1	Not Separated
2.	F2	Not Separated
3.	F3	Not Separated

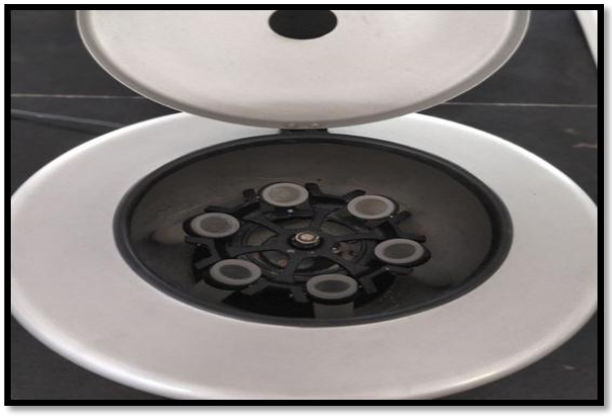

Fig. 6: Instrument of centrifuge.

Inference

- There is no evidence of separation in all the 3 formulations and the ointment remains homogenous. Therefore, the results of centrifuge test ensured that the product is of consistent quality and it will remain stable over time.

Spreadability test / Dispersion test

The spreadability test was done by using multimer to study the spreadability of formulations.

Table 7: Spreadability of formulated ointments.

Sl. No	Formulation Code	Spreadability (time)
1.	F1	3.20 Sec
2.	F2	3.6 Sec
3.	F3	2.42 Sec

Fig. 7: Spreadability test.

Inference

- The test shows that all the formulations of F1, F2, and F3 meet the necessary standard for consistency and it spread uniformly on surface with ease.

Viscosity test

Viscosity of the formulations are tested by using LABMAN Scientific Instrument Viscometer at different speeds 6 rpm, 12 rpm, and 30 rpm and the results are displayed in the table.

Table 8: Viscosity measurements at different rpms.

S. no.	Formulation code	Viscosity		
		6rpm	12rpm	30rpm
1.	F1	21439mpa	10702mpa	4198mpa
2.	F2	21445mpa	10701mpa	4280mpa
3.	F3	21352mpa	10511mpa	4283mpa

Fig. 8: Labman viscometer.

Inference

- The viscosity test provides Information about the flow properties of an ointment, which is important for ensuring its usability and effectiveness in delivering the active ingredients into the skin and it is found that all the formulations are viscous enough to retain in semisolid form.

Microbiological test

The microbiological test of the sample Formulations F1, F2, and F3 are done by using Agar medium to check the sterility of the product and to confirm whether its free from microbes.

Table 9: Microbiological test.

Sl. no.	Formulation code	Microbial test
1.	F1	No Microbial
2.	F2	No Microbial
3.	F3	No Microbial

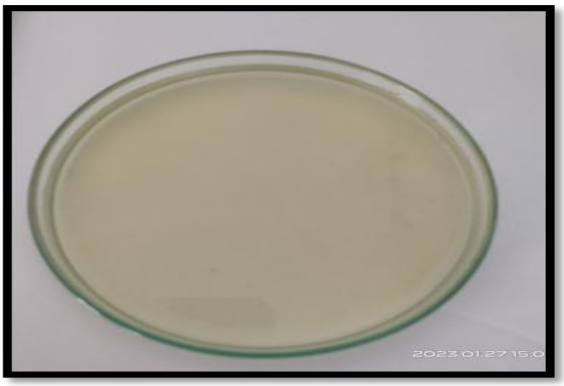

Fig. 9: Microbiological test using agar medium.

Inference

- All the Prepared formulations F1, F 2, and F 3. are observed for microbial growth and it is confirmed that there is no microbial growth. So, the ointments are safe enough for human use.

Loss on drying

The loss of drying of the ointment is performed to measure the amount of moisture or volatile compounds lost during drying and its one of the essential parameters which determine the stability of the ointment.

Table 10: Loss on drying.

Sl. No.	Formulation code	Loss on drying
1.	F1	0.181 gm
2.	F2	0.184 gm
3.	F3	0.181 gm

Inference

- It ensures that all the 3 formulations meet the necessary standards for LOD and thus ensures the stability of the ointment.

Adhesion test

The adhesion test of the ointment was performed to measure the stickiness of the ointment on skin surface.

Table 11: Adhesion test.

Sl. No.	Formulation Code	Adhesion (time)
1.	F1	4.36 sec
2.	F2	4.45sec
3.	F3	3.45sec

Inference

- In this test, the adhesion properties of an ointment are measured, which is important for ensure its efficacy in delivering the active ingredients to the intended site of application and it is confirmed that the ointment adheres on the skin.

Water number test

The water number test has done to determine the amount of water absorptivity in 50 gm of ointment base.

Table 12: Water number test.

Sl. No	Formulation Code	Water number (%)
1.	F1 – (white soft paraffin)	20%
2.	F2-(bees wax)	23.5%
3.	F3-(coconut oil)	18%

Inference

- The drug loaded formulations ointment satisfies the water number test, so it is easy to apply and thus helps in the diffusion of drug through skin.

Extrudability test

Extrudability test is the measure of the force required to extrude the material from a collapsible tube when certain amount of force has been applied on it.

Table 13: Extrudability.

Sl. No	Formulation Code	Extrudability (gm)
1.	F1	0.4 gm
2.	F2	0.56 gm
3.	F3	0.42 gm

Fig. 10: Extrudability test.

Inference

- The extrudability of prepared of corticosteroid ointment was determined for the formulations of F1 F2 and F3 and it is found that the ointment is easy to extrude through ointment tubes

High Performance Liquid Chromatography (HPLC)

The Chromatograms were studied for the presence of drug in the formulation

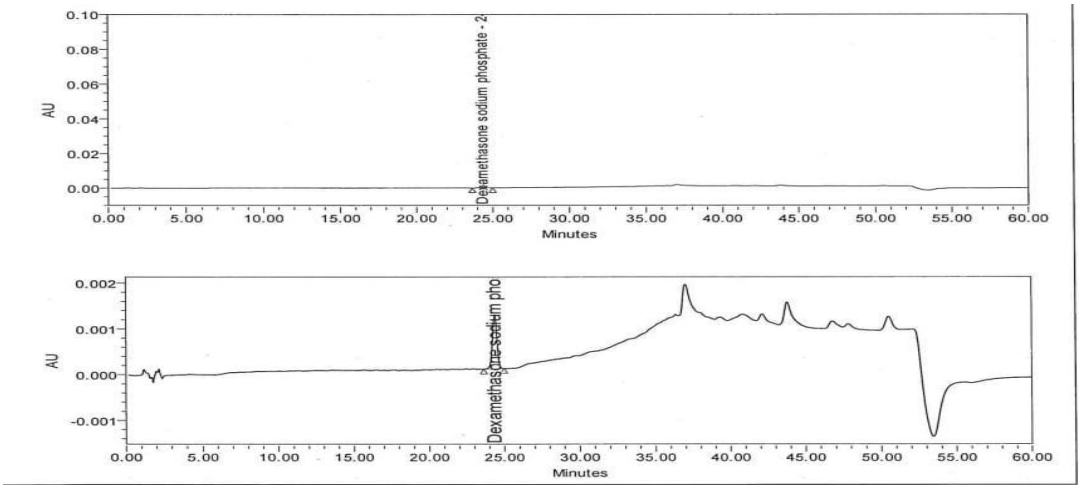

Fig. 11: HPLC graph of an standard drug.

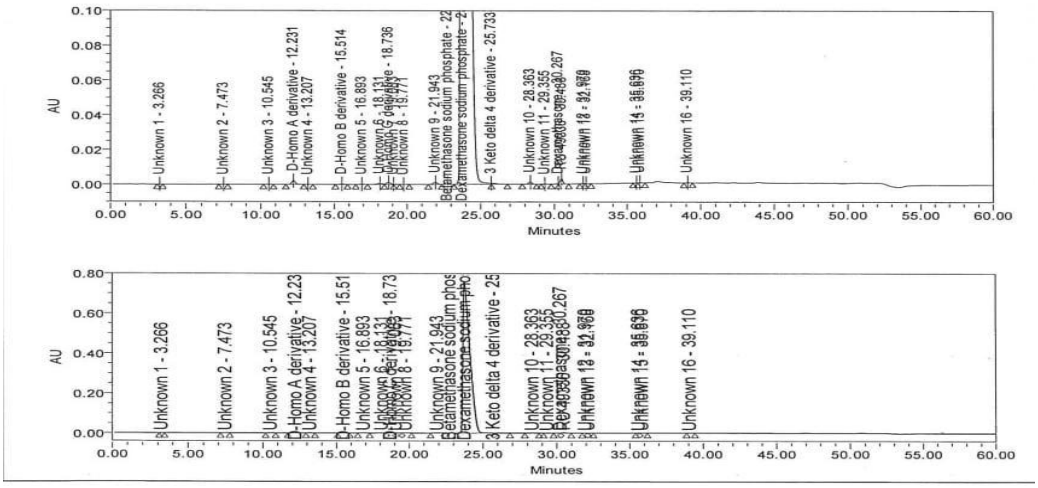

Fig. 12: HPLC sample information and Chromatogram

Inference

The chromatographic parameters determined under optimal conditions for the sample formulation and standard drug were satisfactory.

UV- Standard calibration graph of dexamethasone

Dexamethasone was analysed using the UV/Vis spectrophotometric method. The drug's absorbance was measured at a wavelength of 254nm.

Table 14: Data of standard calibration curve.

Concentration (mcg/ml)	Absorbance
0	0.2
5	0.4
10	0.6
15	0.8
20	1
25	1.2
30	1.5
35	1.6
40	1.8

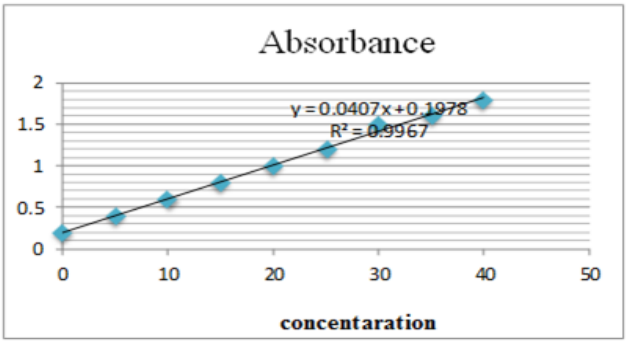

Fig. 13: Calibration curve of dexamethasone.

Inference

- The samples of Dexamethasone were found to be linear.
- It follows Beer-Lambert's Law

Drug content

Drug content is one of the most important evaluation parameters for any type of dosage form. The percentage of active ingredient in the formulation is shown in the table.

Table 15: Drug content of formulated ointments.

Sl. No.	Formulation Code	UV absorbance	Drug content %
1.	F1	0.917	92%
2.	F2	0.920	96%
3.	F3	0.919	95%

Inference

- In this test, it provides information about the amount of drug present in the ointments for diffusion.
- The drug content of all formulations was 91%-96% indicating uniform drug distribution in all formulations.
- This test shows that F2 contains highest % of drug content.

Comparative studies

All the data are collected from prepared ointment formulations and are compared to find the best formulation.

Table 16: Comparative study of F1, F2, F3.

Evaluation parameters	Formulation 1	Formulation 2	Formulation 3
pH	5.8	5.90	6
Spreadability	3.20 sec	3.6 sec	2.42 sec
Viscosity	**6rpm**-21439 mpa **12rpm**-0702mpa **30rpm**-4198mpa	**6rpm**-21445mpa **12rpm**-0701mpa **30rpm**-4280mpa	**6rpm**-21352mpa **12rpm**-0511mpa **30rpm**-4283mpa
Microbiological test	No microbial growth	No microbial growth	No microbial growth
Centrifuge	Not separated	Not separated	Not separated
Physical evaluation	Colour :white	Colour :white	Colour :white
	Texture: slightly greasy	Texture: smooth	Texture :smooth
	Homogeneity : homogenous	Homogeneity : homogenous	Homogeneity : homogenous

Adhesion	4.36 sec	4.45 sec	3.45 sec
Loss of drying	0.181 gm	0.184 gm	0.181 gm
Drug content	96%	91%	94%
Extrudability test	0.4 gm	0.56 gm	0.42 gm
Water number	20%	23.5%	18%

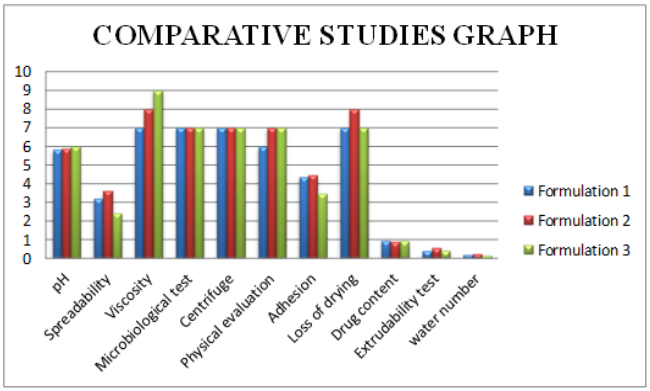

Fig. 14: Comparative study graph of 3 formulations.

SUMMARY

Corticosteroids-Dexamethasone is mainly used topically for its Anti-inflammatory activity. The prepared formulations F1, F2, F3 are further checked for its formulated properties like colour, PH, viscosity, melting point, spreadability, extrudability, centrifugation, microbiological studies, loss on drying, Adhesion, water number test, analytical studies etc.,

Some of the noted side effects of Dexamethasone ointments are flushing or redness of the skin redness, blistering, peeling, or loosening of the skin. So, in order to reduce its side effects, we have used a plant extract Aloe Vera gel, which soothes the skin and prevent or reduce the side effects of Dexamethasone.

All the formulation had good physical appearance, at room temperature. The drug content of all formulations was 92%-96% indicating uniform drug distribution in all formulations and it is found that formulation F2 contains highest % of drug content. The analytical reports of IR, HPLC suggests that the drug is present in sufficient quantity in the samples. The overall results indicate that formulation of corticosteroids- Dexamethasone ointments with Aloe Vera gel is stable enough and there is no notable interaction between the added ingredients.

A comparison table is prepared to show the difference between each formulations and the result shows there is no significant difference between F1, F2, F3 and all the formulations are stable.

CONCLUSION

The current research work yields useful information for future studies aimed at developing products for large-scale production. By avoiding systemic side effects and reducing the frequency of drug administration, the topical delivery approach design of Dexamethasone is more advantageous than the available conventional dosage form.

Future plans

- In-vivo studies and In vitro- In vivo correlation studies.
- Bioequivalence studies with marketed formulation.

BIBLOGRAPHY

1. L.H. Block, “Medicated Applications,” in Remington: The Science and Practice of Pharmacy, A.R. Gennaro, Ed. (Mack Publishing Company, Easton, Pennsylvania, 1995; 577–1597.
2. J.L. Zatz and G.P. Kushla, “Gels,” in Pharmaceutical Dosage Forms: Disperse Systems, H.A. Liebermann, M.M. Rieger, and G.S. Banker, Eds. (Marcel Dekker, Inc., New York, NY, 4. USP 24–NF 19, (United States Pharmacopeial Convention, Inc., Rockville, MD, 1999, 1996; 399–421.
3. B. Anand et al., “Applications of Organogels in Pharmaceuticals,” J. Sci. Ind. Res, 2001; 60(4): 311–318.
4. “Structure, Function, Diseases, and Topical Treatment of Human Skin,” in Dermatological Formulations — Percutaneous Absorption, B.W. Barry, Ed. (Marcel Dekker, Inc., New York, NY, 1983; 1–48.
5. G.L. Flynn, “Topical Drug Absorption and Topical Pharmaceutical Systems,” in Modern Pharmaceutics, G.S. Banker and C.T. Rhodes, Eds. (Marcel Dekker, Inc., New York, NY, 1990; 263–325.
6. R. Panchagnula, “Transdermal Delivery of Drugs,” Ind. J. Pharmacol, 1997; 29(3): 140–156.
7. “Transdermal Drug Delivery,” in Novel Drug Delivery Systems, Y.W. Chien, Ed. (Marcel Dekker, New York, NY, 1982; 200–213.
8. "Dexamethasone sodium phosphate solution/ drops". DailyMed, 2022; 27: 31.
9. "Dexycu- dexamethasone injection, suspension". DailyMed, 2022; 27: 20.
10. "Ozurdex EPAR". European Medicines Agency (EMA), 2020; 24.
11. "Neofordex EPAR". European Medicines Agency (EMA). Retrieved, 2020; 24.

12. Dogra P, Vijayashankar NP (14 September 2020). "Dexamethasone Suppression Test". StatPearls, 2020; 4. PMID 31194457.
13. Jobe AH, Milad MA, Peppard T, Jusko WJ (March). "Pharmacokinetics and Pharmacodynamics of Intramuscular and Oral Betamethasone and Dexamethasone in Reproductive Age Women in India". Clinical and Translational Science, 2020; 13(2): 391–99. doi:10.1111/cts.12724. PMC 7070803. PMID 31808984.
14. "Dexamethasone". The American Society of Health-System Pharmacists. Archived from the original on, 2017; 31: 29.
15. Hirvikoski T, Nordenström A, Lindholm T, Lindblad F, Ritzén EM, Wedell A, Lajic S (February). "Cognitive functions in children at risk for congenital adrenal hyperplasia treated prenatally with dexamethasone". The Journal of Clinical Endocrinology and Metabolism, 2007; 92(2): 542–48. doi:10.1210/jc.2006-1340. PMID 17148562.
16. ^ Lajic S, Nordenström A, Hirvikoski T. "Long-term outcome of prenatal dexamethasone treatment of 21-hydroxylase deficiency". Endocrine Development, 2011; 20: 96–105. doi:10.1159/000321228. ISBN 978-3-8055-9643-5. PMID 211642
17. Harper, Douglas (2021). "Aloe". Online Etymology Dictionary, 2021; 1.
18. Curwin, David (16 March 2008). "aloe". Balashon - Hebrew Language Detective, 2022; 16.
19. Lewis, Charlton T.; Short, Charles "vērus". A Latin Dictionary. Perseus Digital Library, 1879.
20. Liao Z, Chen M, Tan F, Sun X, Tang K. "Microprogagation of endangered Chinese aloe". Plant Cell, Tissue and Organ Culture, 2004.
21. Rawlings AV, Harding CR. Moisturization and skin barrier function. Dermatol Ther, 2004; 17, 1: 43-8.
22. Marty JP. NMF and cosmetology of cutaneous hydration. Ann Dermatol Venereol, 2002; 129: 131-6.
23. Cravello B, Ferri A. Relationships between skin properties and environmental parameters. Skin Res Technol, 2008; 14: 180-6.
24. Cancalon P. Chemical composition of sunflower seed hulls. J Am Oil Chem Soc, 1971; 486: 29-32, 12.
25. Morrison WH. Variation in the wax content of sunflower seeds with location and hybrids. J Am Oil Chem Soc, 1983; 60: 1013-5.
26. Ayerbe R. A study on the recovery of byproducts from the dewaxing of sunflower oils of national production. Grasas Aceites, 1985; 36: 1-4.

27. Wannee J. Review of nutraceutical uses of an antioxidant sunflower sprouts. Asian J Pharm Clin Res, 2016; 9: 21-3.
28. Mariani C. Minor components of vegetable oils: Non-glyceridic esters. Riv Ital Sostanze Grasse, 1989; 66: 397-401.
29. Carelli AA. Wax composition of sunflower seed oils. J Am Oil Chem Soc, 2002; 79: 763-8.
30. Sharma PP. Cosmetics-formulation, Manufacturing and Quality Control, Delhi, India: Vandana Publications, 2014; 7, 5: 181-91.