



COMPARATIVE STUDY OF SUSPENDING AGENTS PRESENT IN CALAMINE LOTION

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Abstract

Lotions are liquid suspensions, solution or emulsion for external application of the body. Calamine lotion is a mixture of calamine, zinc oxide, glycerin and methyl cellulose. Methyl cellulose is a suspending agent used in the calamine lotion. Methylcellulose is derived from the cellulose and it's used as a thickener and emulsifier in various food and cosmetic products. Methyl cellulose is a non toxic, non allergen also used in treating constipation. In this research work three formulations containing different synthetic suspending agents were used. The F1 formulation containing bentonite as thickener, F2 formulation containing methyl cellulose as thickener and finally F3 formulation containing hydroxypropylmethylcellulose as thickener. The prepared lotion is evaluated for thermal stability, patch test, pH, viscosity and stability.

Key Words: Calamine, Bentonite, Methylcellulose, Hydroxypropylmethylcellulose, viscosity

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Introduction

Calamine lotion is used as an antipruritic to reduce itching caused by sun burns, insects and rashes. Zinc oxide is used as an antiseptic and astringent so it's used in healing process. Liquid phenol was used as a topical disinfectant. Glycerin used in the formulation as a moisturizing agent. The stability of the suspension can be improved by the addition of suspending agents. Suspending agents may also increase the viscosity of the formulations. Suspending agents form film around the particle and decrease inter particle attraction. The suspending agents used in this research work are bentonite, methylcellulose and hydroxypropylmethylcellulose. The suspending

agents increase the viscosity and prevent the sedimentation of the suspended particles. The ingredients uses are shown in table no 1.

Table no 1 Description of Chemicals used in Calamine Lotion

S.no	Ingredients	Company	Category
1	Calamine	Nice Chemicals	Astringent
2	Zinc oxide	Nice Chemicals	Protective
3	Tri sodium citrate	Nice chemicals	Chelating agents
4	Liquefied Phenol	Chen chems	Antiseptic and preservative
5	Glycerin	Nice Chemicals	Moisturizing agents

Table no 2 Suspending Agent's Properties and Uses

S.no	Suspending agents	Properties	Uses
1	Bentonite	Swelling property	Lubricant, suspending agents
2	Methylcellulose	More soluble in cool water than hot water.	Thickener, emulsifier, lubricant and in treating constipation
3	Hydroxypropylmethyl cellulose	Soluble in organic solvent than in water.	As a film former, tablet binder, viscosity increasing agent

Method of preparation

Calamine lotion was prepared by using mortar and pestle by trituration method.

Step 1: Required quantity of calamine, zinc oxide and suspending agents (Bentonite, methyl cellulose, hydroxypropylmethylcellulose) with solution of tri sodium citrate in about 70% of water was triturated

Step 2: Liquefied phenol along with a glycerin (humectant) was added to the above mixture with sufficient purified water to produce 100ml of lotion. The quantity required is shown in table no 3

Table no 3: Formulation Table

S.No	Ingredients	F1	F2	F3
1	Calamine	15 gm	15 gm	15 gm
2	Zinc oxide	5 gm	5 gm	5 gm
3	Methyl cellulose	-	3 gm	-
4	Bentonite	3 gm	-	-
5	Hydroxypropylmethyl Cellulose	-	-	3 gm
6	Tri sodium citrate	0.5 gm	0.5 gm	0.5 gm
7	Liquefied Phenol	0.5 gm	0.5 gm	0.5 gm
8	Glycerin	5ml	5ml	5ml
9	Purified water	100ml(q.s)	100ml(q.s)	100ml(q.s)

Evaluation

Determination of pH

5 gms of lotion was weighed and transferred to 100ml beaker.45ml of water was added to the lotion and allowed to disperse it. The pH meter was used to determine the pH. The electrode of pH meter was dipped in a beaker containing diluted lotion, and then pH was recorded digitally in a pH meter. ⁽⁴⁾

Patch Test

2 to 3 gms of lotion was weighed and applied to the skin of 1 sq mt The site of patches were examined after 24 hrs. The site was examined for redness, swelling, irritation etc. If there is no hypersensitivity reaction then the formulation passes the test. ^(5, 6)

Visual Appearance

The visual appearance of the formulation was noted. The color of the lotion was compared with the marketed product (calamine lotion) ⁽⁷⁾

Viscosity test

The viscosity of the prepared formulation was determined using Brookfield viscometer. The viscosity was measured every 10 secs for the duration of 5 mins. Many readings were taken. Finally the average value was calculated. ⁽⁸⁾

Microbial contamination test

Weigh accurately 1 gm of material and aseptically transfer in to conical flask which contains 50ml of dilute phosphate buffer at pH 7.2, then pipette out 1 ml portion into three sterile plates. Pour the melted soya bean casein digest medium at 45°C and cool. The plates are properly mixed by rotating and finally the plates are incubated at 30-40°C for 74 hrs.

Stability studies

The shelf life of the product was fixed by performing stability studies for the prepared formulation. Accelerated stability studies was conducted for the prepared formulation by storing the containers at 40±2°C temperature and 75±5%RH and studied for one month.

Results and Discussion

pH test:

The pH values are recorded for all the three formulations. The F2 formulation shows 7.53pH which was nearer to the skin pH. The results are shown in table no 4.

Table no 4 .Table showing pH results of the prepared formulation

S.No	Formulation code	pH
1	F1	8.12±1.2
2	F2	7.53±0.5
3	F3	7.13±0.6

All the values are expressed as mean ±SD, n=3

Patch Test

The patch test was performed on the human skin by applying the formulation gently on the human skin. After 24 hrs the skin shows no hypersensitivity reactions. So the prepared formulation shows no hypersensitivity reactions.

Viscosity test

The viscosity test was performed using Brookfield viscometer. The F2 formulation containing methylcellulose as suspending agent shows better viscosity than other formulations. The results are shown in table no 5

Table no 5 Table showing viscosity of the prepared formulations

S.No	Formulation code	Viscosity
1	F1	24.4±0.8
2	F2	57.0±0.5
3	F3	34.1±0.1

All the values are expressed as mean ±SD, n=3

From the viscosity studies it was concluded that F2 formulation shows more viscous than other formulations, so it has ability to retain in the skin for a long time.

Microbial contamination test ^(9, 10)

After 74 hrs, the incubated plates show no turbidity, which confirms the absence of microbes in the lotion.

Stability Studies

The stability study was conducted for the selected formulation F2 as per ICH guidelines for a period of 1 month. The stability results are shown in table no 6

Table no 6 Table showing stability studies reports

S.no	Parameters	Initial	Final			
			1 st week	2 nd Week	3 rd Week	4 th week
1	Color	Pink	Pink	Pink	Pink	Pink
2	pH	7.53±0.5	7.54±0.3	7.55±0.1	7.56±0.2	7.60±0.4
3	Viscosity	57.0±0.5	58.5±1.2	58.9±1.3	59.1±1.4	59.3±1.2
4	Skin sensitivity	Does not cause any allergies and rashes.				
5	Patch test	No hypersensitivity reaction				

All the values are expressed as mean ±SD, n=3

From the results it was found that the prepared formulation F2 was found to be stable. There was no significant changes from initial readings to final results after I month.

Conclusion

The lotion was prepared by trituration method. F2 formulation was found to be best when compared to other formulations F1 and F3. The pH was found to be 7.53 which are nearer to skin pH and viscosity was found to be 57.0. The patch test indicates there was no allergic reaction after 74 hrs of observation. From the stability studies it was confirmed that the prepared formulation F2 was found to be stable. So the formulation F2 containing methyl cellulose as suspending agents was effective in all the aspects.

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