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Formulation and Evaluation of Multipurpose Antibacterial Cream of Gentamicin Sulphate

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Abstract

A cream is preparation usually for application skin. Gentamicin sulphate is commonly used for treating bone and soft tissue infection. Topical gentamicin is often used in the treatment of impetigo, infected bed sores, burns, nasal staphylococcal carrier state, pyodermata, in infections of the external eye and adenexa. Topical absorption of gentamicin sulphate for wound care in a concentration of 0.1% in water miscible bases with the advantages of painless application, good penetration and low incidence of toxicity of the used dose. Upon the topical application of gentamicin sulphate formulated as a 0.1 % (w/w) cream. In this formulation we studied antibacterial activity of formulation to know its in vitro antimicrobial activity. In this formulation there is use of low cost ingredient. The formulation was made in triplicate by changing minute quantity of chemicals and observe effect. The variability in cream thickness, and hence applied dose, is likely to be even greater. It increase dose of medication is applied where it is needed. It avoids low risk of systemic adverse effect and interaction at low cost. It provides easy administration to a young child. This formulation Work better on larger area of skin because of their spredability factor as compared to ointment. This work represents formulation of antibacterial cream and testing of antimicrobial activity. By making changes in ingredient which show minor fluctuation in its viscosity good applicable properties.

Introduction

Topical use of antibiotic drugs has occupied a large area of the pharmaceutical field and markets. The majority of these agents exist in markets as ointments and creams. Gentamicin sulphate is an amino glycoside antibiotic which is used topically in the control of gram positive and gram negative bacterial infections especially in burns and wounds. Gentamicin sulphate is a mixture of such salt of antibiotic subsatance produced by Micromonospora purpurea. Gentamicin sulphate has potency not less than 590

micro gram of gentamicin per milligram,calculated on dried basis. It is white powder and hygroscopic, as per Indian pharmacopoeia. Gentamicin sulphate is commonly used for treating bone and soft tissue infection. Topical gentamicin is often used in the treatment of impetigo, infected bed sores, burns, nasal staphylococcal carrier state, pyodermata, in infections of the external eye and adenexa.

The topical absorption of gentamicin sulphate for wound care in a concentration of 0.1% in water miscible bases induces defective protein synthesis with the advantages of painless application, good penetration and low incidence of toxicity of the used dosage form. Whereas, amino glycosides are bactericidal while most other antibiotics which interfere with protein synthesis are bacteriostatic.

Upon the topical application of gentamicin sulphate formulated as a 0.1 % (w/w) cream. The variability in cream thickness, and hence applied dose, is likely to be even greater.

Formula for cream

Parameter	C1	C2	C3
Stearic acid	2.5%	3.0%	2.5%
White bees wax	2.0%	_	_
Cetyl alcohol	6.5%	6.0%	6.5%
Propylene glycol	5.0%	5.0%	_
Isopropyl myristate	_	5.0%	5.0%
Benzoic acid	0.01%	0.01%	0.01%
Citric acid	0.04%	0.04%	0.04%
Emulcifying wax	_	2.0%	2.5%
Polysorbate 20	1.0%	2.0%	1.5%
GS (AOI)	0.1%	0.1%	0.1%
Purified water	Up to 100%	Up to 100%	Up to 100%

Material and Method

The main ingredient Gentamicin Sulphate is obtained by Shree chemical Pune, Mharashtra, India. Other ingredients are obtain from college lab of K T Patil college of Pharmacy, Osmanabad, MH. India.

Preparation of cream

- Oil in water emulsion based cream formula.
- Stearic acid (emulsifier), cetyl alcohol, white bees wax melt together=phase1.
- Gentamicin Sulphate , preservatives , propylene glycol mix with p. water=phase2
- Mix both phases with heating and stirring.

Formulation of Gentamicin Sulphate Cream

Evaluation of the cream:

The cream was then evaluated for the following physical parameters

Formulation Properties:

The formulation properties of the cream were studied by visual appearance and characteristics.

Presence of foreign particles/grittiness:

A small amount of cream was taken and spread on a glass slide and it was observed against diffused light to check for presence of foreign particles.

pH of the cream:

The pH of this formulation was determined by using digital pH meter. About 1 g of the cream was weighed and dissolved in 100 ml of distilled water and stored for two hours. The measurement of pH of each formulation was done in three times and average values were calculated.
It was also tested by using p H paper.

Viscosity:

Viscosity of the formulation was determined by Brookfield Viscometer II + model using spindle no S – 64 at 20 rpm at a temperature of 26^{o}C and the determinations were carried out in three times and the average of three readings was recorded.

Determination of type of emulsion Dilution test:

In this test the sample of formulation was diluted with water. After dilution with water, the sample remains stable then it shows it is oil in water emulsion. When the sample or emulsion breaks after dilution with water then it shows water in oil type but it remains stable after dilution with oil.

Dye solubility test:

The formulated sample was mixed with scarlet dye. Then a small drop of this mixture was taken and place on microscopic slide, covers this slide by cover slip and examines it under microscope. In case the disperse globules appears in red color and the ground or continuous phase is colorless, it shows the sample is oil in water. If the reverse condition occurs which is globules are colorless and ground or continuous phase in red color.

Viscosity measurement of the cream:

The viscosity at different rpm was measured using Brookfield viscometer. The flow property of the formulation was studied by taking 80 g of the cream in the beaker. The rate of shear was 20 rpm check the corresponding reading of respective three formulations of antibacterial cream.

Partition coefficient of cream:

The partition coefficient is determined by using mixture of equal volume of n-hexane and phosphate buffer solution (1:1) taken with small sample of cream in separating funnel.

It was placed on a water bath for 24 h. The solution was shaken occasionally. Then the both of them were separated and filtered through a 2 µ filter and take the filtrate for amount solubilized in each phase was determined by measuring the absorbance using UV spectrophotometer. Hexane has polarity zero. Hence it is chosen for the study of partition coefficient.

Stability studies:

Phase separation:

Take the small quantity of formulated cream and it was kept intact in a closed container at 25 – 80^{o} C not exposed to light. This test observed every 24 hrs for 20-25 days.

Moisture absorption studies:

Take the small amount of sample of formulated cream was on a watch glass. A beaker was taken with full of water and it was kept in a desiccators without adsorbents and allowed to get saturated. Watch glass with cream was introduced into the desiccators. It was left for 24 hrs.

Extrude ability

Extrude means the force which is required to remove cream from the tube. The tube was placed between two glass slides & was clamped. A 500gm was placed over glass slide and cap was opened. The amount of cream extruded were collected and weighed. The percent of cream extruded was calculated grad were allotted (Excellent, Good, Fair, Poor)

Spread ability

Spread ability denotes extent of area to which formulation readily spread on skin. The spread ability of formulated cream expressed in terms of time in one minute by two slides to slip off from

cream, placed in between these two slides, under certain load. The time in which upper glass moves over lover plate to cover distance is noted.

Antibacterial activity tested against bacteria of Pseudomonas & Klebsiella

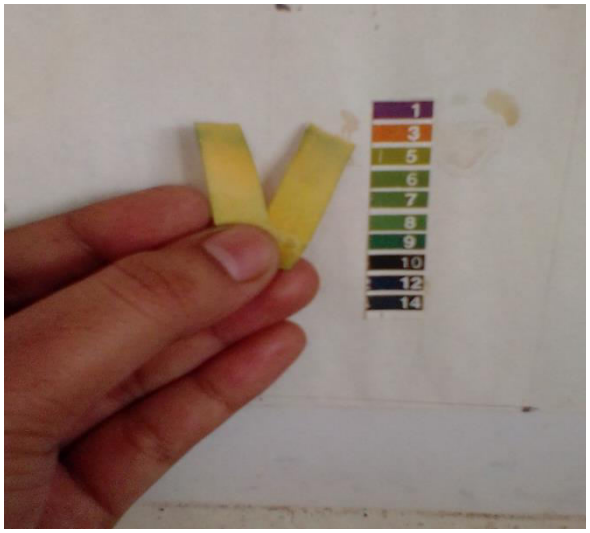
In Vitro antibacterial activity

1) **Preparation of nutrient broth**
Take the sufficient amount of nutrient agar which is dissolve in quantity sufficient of water by heating. Transfer this nutrient broth solution to autoclave for 15 minutes.

2) **Prepare inoculums of Gram positive bacteria (Pseudomonas) and Gram negative bacteria (Klebsiella).**
Take the sufficient amount of agar and dissolve it in quantity sufficient of water along with heating and stirring .Incubate this solution in to autoclave for 20 minutes. Transfer this solution in to test tube and insert microorganism which are subculture previously to ensure these microorganisms are their log phase of growth. These microorganisms (bacteria) insert in to test tube inoculating loop and this suspension kept in incubator up to 24 hrs.

3) **Preparation of bacterial plate**
Dissolved solution of nutrient agar allow for autoclave up to 20 minutes, transferred to petri plate and allow for solidify. The sterile cotton swab soaked in bacterial suspension and streakedover the solidified petri plate. Incubate this plate for 24 hrs.

4) **Assay**
By using sterile cork borer make the holes in incubated nutrient agar plate in sterile media. Allow transferring the antibacterial formulated cream sample to these holes and kept it for incubation for 18 hrs. Observe the zone of inhibition.



Test of p H by using p H paper

Sample C1

Activity against Klebsiella

Zone of inhibition is 4.3

Sample C1

Zone of inhibition is 4.2

Activity against Pseudomonas

Sample C1

Evaluation of antibacterial cream formulation

Parameters	C1	C2	C3
Colour	Light White	Light White	Light White
Appearance	Smooth & Consistent	Smooth & Cosistent	Smooth & Consistent
Forign particles	Free from forign particles	Free from forign particles	Free from forign particles
Odour	Characteristic	Characteristic	Characteristic
pH	5.0	4.8	4.8
Viscosity(cps)	46075	46073	46071
Extrudability	Good	Good	Good
Spreadability	Easily spreadable	Easily spreadable	Easily spreadable
Antimicrobial Tast	Pass	Pass	Pass

Result

The characteristics of cream in terms of appearance, pH, viscosity, spreadability, extrudability were analyzed by reported methods. The cream formulations prepared was found to be of a light White. The results proved that the prepared formulations are also having the acceptable property. The pH of cream formulations was found 4.8 to 5. It was found that the cream was homogenous, smooth, non – greasy film on the skin surface and consistent in nature and the cream was easily spreadable and moisturizes the skin surface of human volunteer.

After observation it was found that cream did not leave greasy substances on skin surface after application. The viscosity of three cream formulations prepared was 46075, 46073, and 46071 centipoise (cps) for C1, C2, and C3 cream formulations respectively.

Discussion

In present work formulation and evaluation of multipurpose anti bacterial cream was aimed to formulate a cream using gentamicine sulphate as an antibacterial agent. The antibacterial activity of formulated cream is also determined. Gentamicin Sulphate is an aminoglyciside antibiotic used topically in the control of gram positive & gram negative infections commonly used to treat bone & soft tissue infection. This formulation was making in triplicate that is C1, C2, and C3 by changing quantity of some ingredient to check the effect. Evaluation test of cream passes all test, appearance, grittiness, viscosity 46075, 46073, 46071. pH5.0, 4.8, 4.8.Extrudability is good, spread ability is easily spreadable.

Conclusion

The advantages of cream include its ease of use, patient compliance, sustained drug delivery, local application & safety. The Gentamicin Sulphate active against infection caused by staphylococci, pseudomonas, klebsiella, enterobacter, serratia. This formulation of Gentamicin Sulphate cream is tested for bacteria of pseudomonas and klebsiella which results Gentamicin Sulphate active against these bacteria. Gentamicin Sulphate is a aminoglycoside antibiotic. The formulation C1 has greater viscosity.

Reference

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Tax Invoice

Shree Chemicals (2017-18) Shop No:2, Al-Shafi Society, 381, Bhavani Peth,Harka Nagar Near Vimay High School. Pune 411042 FSSAI License No:11514033000372 Proprietor :Mr Vinayak J Kulkarni IEC Code:3110007632 Pollex No:PUNE/POLSON/02/2016-16 GSTIN/UIN: 27ACDPK9319F1ZK State Name : Maharashtra, Code : 27 E-Mail : info@shreeshemicalspune.com	Invoice No. 2187 Dated 31-Jan-2018 Delivery Note Mode/Terms of Payment Supplier's Ref. 2187 Other Reference(s) Buyer's Order No. Dated Despatch Document No. Delivery Note Date Despatched through Destination Terms of Delivery
Buyer **Shaikh Nazma Khamroddin** K.T. Patil College of Pharmacy Siddharth Nagar, Barshi Road, Osmanabad-413501 PAN/IT No : State Name : Maharashtra, Code : 27	

Sl No.	Description of Goods	HSN/SAC	GST Rate	Part No.	Quantity	Rate	per	Disc. %	Amount
1	Gentamicin Sulphate (GM) 5gm SRL	29419040	18 %	37636-5gm	1 Pcs	2,148.00	Pcs		2,148.00
	Output CGST@9%					9	%		193.32
	Output SGST@9%					9	%		193.32
	Round Off								0.36
	Total				1 Pcs				2,535.00

Amount Chargeable (in words) *E. & O.E*

INR Two Thousand Five Hundred Thirty Five Only

HSN/SAC	Taxable Value	Central Tax		State Tax		Total Tax Amount
		Rate	Amount	Rate	Amount	
29419040	2,148.00	9%	193.32	9%	193.32	386.64
Total	2,148.00		193.32		193.32	386.64

Tax Amount (in words) : **INR Three Hundred Eighty Six and Sixty Four paise Only**

Date & Time : **31-Jan-2018 at 15:58**

Company's Bank Details
Bank Name : **Dena Bank 061013001058**
A/c No. : **061013001058**
Branch & IFS Code : **Bhavani Peth & BKDN0610610**

Company's PAN : **ACDPK9319F**

Customer's Seal and Signature

for Shree Chemicals (2017-18)

Authorised Signatory

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Certificate of Analysis

Product	37636 - Gentamicin Sulphate - [1405-41-0]
Batch No	1443532
Analysis Date	18-Jun-2016
Date of Manufacture	June 2016
Expiry Date/Re-Test Date	June 2021
Molecular Formula	C21H43N5O7 H2SO4
Molecular Weight	575.67

Test Parameters	Standards	Actual Results
Appearance (Colour)	White to almost white	Almost white
Appearance (Form)	Powder	Powder
Assay	min. 590 µg/mg	635 µg/mg
pH (5% aq. solution)	3.5 - 5.5	3.9
Specific rotation [a]	+107° to +121° (C=10 , Water)	113°
Loss on drying	max. 15%	4.9%
IR Identification Test	Passes test	Passes
Not for medicinal use		

FRM/62/11/4/37636 Rev No. 1 Date 01/11/2015

Prepared by Sakshee

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