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Formulation and Evaluation of Amoxicillin-Containing Cream to Treat Bacterial Infection (Gonorrhea)

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ABSTRACT

Gonorrhea is the disease of sexually transmitted disease caused by the Neisseria Gonorrheae. Most commonly but not exclusively in women, such as endometritis, pelvic inflammatory disease, infertility, and/or life-threatening morbidity via ectopic pregnancy. It is treated by some bacterial drugs like amoxicillin and clavulanic acid, cephalosporin, etc.ream is the best choice for the treatment of gonorrhea. *N. gonorrhoeae* infection's diagnosis is made by direct detection of the gonococcal pathogen in urogenital, anorectal, pharyngeal, or conjunctival swab specimens or first-catch urine. WHO gives so many guidelines for the cure of this disease? The present study aimed to formulate topical creams containing Amoxicillin to treat Bacterial Infection.

INTRODUCTION -

Gonorrhea is a bacterial infection. *Neisseria gonorrhoeae*, an obligate human pathogen, is a sexually transmitted disease that causes consequential worldwide morbidity both in resource-abundant and resource-limited nations, and its diagnosis and treatment require costly expenditures annually. The obligate pathogen *N. gonorrhoeae* infects only humans in nature and most commonly manifests as urethritis in men and cervicitis in women. Obligate pathogens refer to bacteria that must manifest disease to facilitate transmission from one host to another. To survive, these bacteria must infect a host and cannot survive outside of a host. Undiagnosed and/or untreated gonorrheal urogenital infections can ascend through the upper urogenital tract and cause many severe reproductive complications, most commonly but not exclusively in women, such as endometritis, pelvic inflammatory disease, infertility, and/or life-threatening morbidity via ectopic pregnancy.

EPIDEMIOLOGY-

A major public health concern, *N. gonorrhoeae*, is currently the second most common cause of bacterial sexually transmitted infections worldwide. The World Health Organization (WHO) estimates that 106 million new gonorrhea cases are documented among adults annually worldwide; many more infections go unreported. With more than 500,000 cases noted annually in the United States, *N. gonorrhoeae* is the second most commonly reported sexually transmitted disease in the United States.

Gonorrhea infection has a slight male prevalence secondary to the increased likelihood that males will manifest urogenital symptoms and also due to increased diagnoses among men who have sex with men. Over the last decade, the incidence of gonorrheal STIs has increased as a result of the rising number of antibiotic-resistant strains.

PATHOPHYSIOLOGY

N. gonorrhoeae infection starts with the adhesion of gonococci to epithelial cells, followed by local cellular invasion. Gonorrhea has multiple surface proteins that facilitate adhesion. *N. gonorrhoeae* utilize pili to initiate adhesion to epithelial cells. Hair-like appendages and pili cover the bacterial surface. Their ability to lengthen and retract allows the bacteria to attach from a distance and move closer to the epithelial cells, promoting cellular invasion. Pili also provide motility and protection. Other surface proteins involved in cellular attachment

include Opa, opacity-associated proteins, and LOS, lipooligosaccharide. LOS attaches to sperm cells and likely leads to transmission from males to uninfected sexual partners.

Invasion of cervical epithelium involves bacterial cells interacting with host cell complement receptors type 3 (CR3). This communication is initiated by the binding of pili to the CR3. This causes extensive rearrangement of the host cell actin, resulting in large projections called ruffles. Ruffling then allows gonococci to enter host cells in large vacuoles called macropinosomes and subsequently multiply within infected cells.

Neisseria gonorrhoeae induces localized infection at the anatomic site of inoculation, typically the urethra, cervix, pharynx, or anus in adults and the eye conjunctiva or the pharynx of newborns, but dissemination can occur. Gonococci are classified as either serum-sensitive or serum-resistant based upon their sensitivity to killing by complement activation; serum-resistant strains have the potential to cause disseminated infection. *N. gonorrhoeae* has evolved multiple mechanisms to combat the innate and adaptive immunity systems of their host organisms' immune defenses.

DIAGNOSIS-

Diagnostic laboratory assays are essential to confirm the clinical suspicion of gonorrhea. Laboratory confirmation of *N. gonorrhoeae* infection's diagnosis is made by direct detection of the gonococcal pathogen in urogenital, anorectal, pharyngeal, or conjunctival swab specimens or first-catch urine.

DRUG PROFILE

Amoxicillin is a prescription medicine used to treat the symptoms of many different types of bacterial infections such as Tonsillitis, Bronchitis, Pneumonia, and infections of the ear, nose, throat, skin, or urinary tract. Amoxil may be used alone or with other medications. Amoxil belongs to a class of drugs called Penicillins, Amino.

Formulations of AMOXIL contain amoxicillin, a semisynthetic antibiotic, an analog of ampicillin, with a broad spectrum of bactericidal activity against many Gram-positive and Gram-negative microorganisms. Chemically, it is (2S,5,R,6,R)-6-[(,R)-(-)-2-amino-2-(p-hydroxyphenyl)acetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid trihydrate.

The amoxicillin molecular formula is $C_{16}H_{19}N_3O_5S•3H_2O$, and the molecular weight is 419.45.

Creams are considered an important part of the cosmetic product as topical preparations from time immemorial due to their ease of application to the skin and also their removal. For cosmetic purposes, Pharmaceutical creams have a variety of applications such as cleansing, beautifying, altering appearance, moisturizing, etc. for skin protection against bacterial, and fungal infections as well as healing cuts, burns, and wounds on the skin. These semi-solid preparations are safe to use by the public and society. The human skin is easily vulnerable to injury but it can heal on its own. However, the natural healing process can take time and there is also the risk of infection, especially in the early stages of injury. In such cases, medicated creams can be applied to the site of injury to speed up the healing process as well as protect the wound from infection. In this review, we have focused on the use of topical drug delivery systems i.e. pharmaceutical creams for wound healing with detailed discussion relating to the wound healing process, suitable methods of preparation of creams, their classification based on their function, their advantages and disadvantages, characteristics and the various types of creams, ingredients used in the formulation of creams and their various evaluation parameters. Keywords: Creams, Skin, Topical drug delivery system, wound healing.

PREFORMULATION STUDY

1. APPREARANCE – colour, odour and texture of amoxicillin were examined. Results show in Table no.1.

2. SOLUBILITY- Qualitative solubility studies of the drug shown in table 1 depicted that the drug is more soluble in aqueous solvent as compared to hydrophobic solvents so it can be concluded that the drug is hydrophilic in nature Result shown in Table no.1.

3. PARTITION COEFFICIENT- Amoxicillin was added into an equal volume of aqueous and organic solution for 6. Hour and kept overnight then separate it and take the reading by UV spectroscopy Result show in Table no.1.

4. MELTING POINT- By using melting point apparatus with a glass capillary Result is shown in Table no.1.

5. pH- By using a pH meter found to be approx 4 Result is shown in Table no.1.

IDENTIFICATION OF DRUG

The identification of the drug was done by the UV spectroscopy method. 1 mg drug was dissolved in water and the volume was made up to 100 ml to obtain a stock solution of 100 µg/ml. The one ml of this stock solution was again diluted with water up to 10 ml to obtain a solution of 10 µg/ml. the resulting solution was scanned between 200 nm to 300 nm in a double beam UV/Visible Spectrophotometer and a higher peak range Result is shown in Table no.1.

Table No. 1: Calibration curve of amoxicillin

Concentration (ug/ml)	Absorbance(nm)
5	0.26
10	0.55
15	0.78
20	1.0
25	1.3

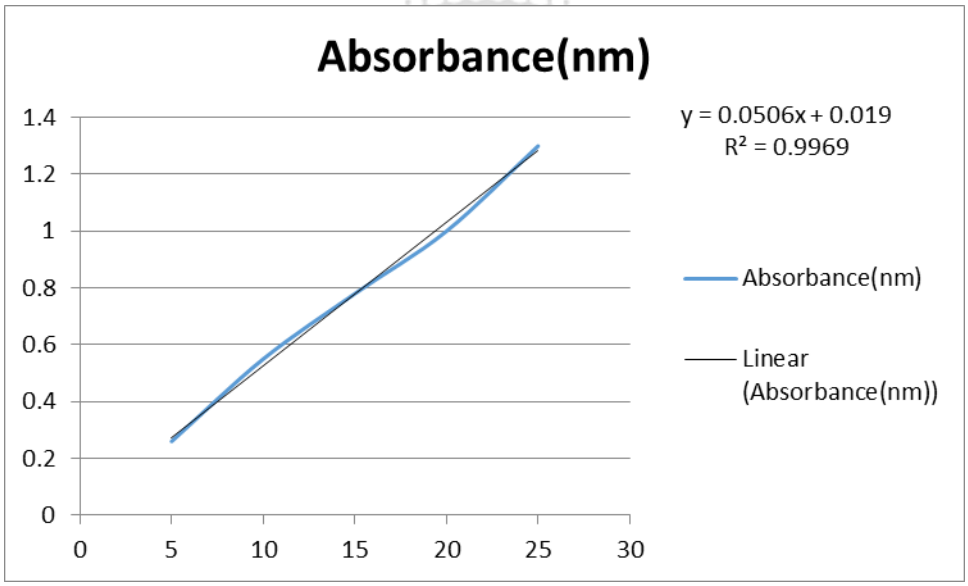


Figure No. 1: Calibration curve of amoxicillin

RESULT OF PREFORMULATION –

Parameter	Value
APPEARANCE	Color-CREAMY
SOLUBILITY	WATER- EXCELLENT ETHANOL – GOOD SOLUBLE METHANOL- GOOD SOLUBLE ACETONE – SLIGHTLY SOLUBLE FORMALDEHYDE – SPARINGLY SOLUBLE
PARTITION COFFICIENT	0.9
Melting Point	194
pH	4

Identification of drug

UV Spectrophotometric method was used for the analysis of Amoxicillin.

Figure No. 2: Peak detection λ_{max} for Amoxicillin

METHOD OF PREPRATION AND EXCIPIENTS-

Dissolve borax in Rose water at 70°C on the water bath Melt the wax with mineral oil in another beaker on a water bath. Keep the temperature at about the 70°C. On another side take one beaker add 10 ml water with drug (amoxicillin) then give temperature at 70°C. Pour the borax 50% into molten wax at the same temperature with constant stirring. After that mix, the organic phase into the aqueous phase Stirr the mass constantly when the temperature drop to about 45°C.

OPTIMIZATION AND FORMULATION

Batch	**Ingredients**						**Spreadibility** (g cm /s)
	Amoxicillin (mg)	**White Bees Wax (gm)**	**Mineral Oil (ml)**	**Borax (gm)**	**Aloe Vera (gm)**	**Rose Water (ml)**	
F_1	10	2	5	10.5	1	29.5	23.3
F_2	10	2	3	10.5	1	29.5	17.2
F_3	10	2	8	10.5	1	29.5	25

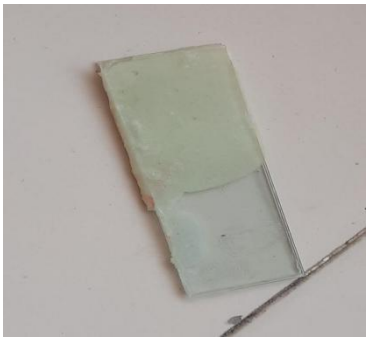
EVALUATION PARAMETERS OF CREAMS:

1. Determination of pH: The pH of the cream can be measured on a standard digital pH meter at room temperature by taking an adequate amount of the formulation diluted with a suitable solvent in a suitable beaker Result is shown in Table no.2.

2. Physical appearance: The physical appearance of the cream can be observed by its color, roughness, and graded Result are shown in Table no.2.

3. Spreadability: Adequate amount of sample is taken between two glass slides and a weight of 100gm is applied to the slides for 5 minutes. Spreadability can be expressed as, Result shown in Table no.2.

S= m*l/t Where m = weight applied to the upper slide. l = length moved on the glass slide. t = time taken.



S= 100 × 3.5/ 15 = 23.3 g cm /s

4. Saponification value: 2gm of substance refluxed with 25ml of 0.5 N alcoholic KOH for 30min, to this 1ml of phenolphthalein added and titrated immediately, with 0.5N HCl, note the reading as ‘a’. Repeat the operation omitting the substance being examined. Result show in Table no.2.

Note the reading as ‘b’. Saponification value = (b-a)*28.05/w Where, w = weight of substance

= (17-3)×28.05/2

=196

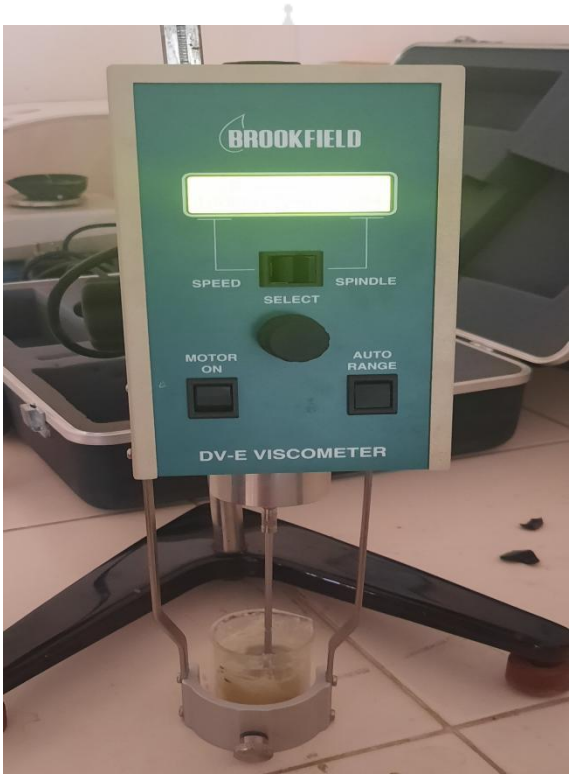
5. Acid value: 10gm of substance is dissolved in an accurately weighed 50ml mixture of an equal volume of alcohol and solvent ether, the flask was connected to a reflux condenser and slowly heated, until the sample was dissolved completely, to this 1ml of phenolphthalein was added and titrated with 0.1N OH until faintly pink color appears after shaking for 30 seconds. Results are shown in Table no.2.

Acid value = n*5.61/w Where, n = the no. of ml of 0.1 N KOH solution. w = the weight of the substance in grams.

= 8×5.62/10

= 4.4

6. Viscosity: The viscosity of formulated creams can be determined by using the Brookfield Viscometer Result shown in Table no.1.



7. Homogeneity: The formulation was tested for homogeneity by visual appearance and by touch.

8. Removal: The ease of removal of the creams applied was examined by washing the applied part with tap water.

9. Dye test: The scarlet dye is mixed with the cream. Place a drop of cream on a slide and cover with a cover slip and examine it under a microscope. If the disperse globule appears red and the ground colorless then it is o/w type and the reverse condition appears in w/o type of creams.

10. After feel: Emolliency, slipperiness, and amount of residue left after the application of the fixed amount of cream was checked.

11. Type of smear: After the application of the cream, the type of film or smear formed on the skin was checked.

12. Irritancy study: Mark an area of 1sq.cm on the left-hand dorsal surface. The cream was applied to the specified area and time was noted. Irritancy, erythema, and edema were checked, if any, for regular intervals up to 24hrs and reported.

Result of evaluation parameter of cream-

Table no. 2

Parameter	Value
pH	7 to 7.6
Acid Value	4.4
Spreadability:	23.3 g cm/s
Viscosity	22 cp (centipoise)
Saponification value	196

CONCLUSION:-

The study concludes that mineral oil can be used as a different Concentration in antibiotic Cream and then show good spreadability found in Formulation no. 1. In addition, this new formulation showed advantageous rheological properties.

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