WWW.IJRPR.COM

International Journal of Research Publication and Reviews

Journal homepage: www.ijrpr.com ISSN 2582-7421

ANTIBIOTICS

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ABSTRACT:

This Practice School Report focuses on the pharmaceutics domain, with Amoxicillin selected as the study drug. The objective of this practice school was to foster collaboration between academia and industry and to gain insights into the formulation and evaluation of Amoxicillin Capsule. The report is structured into four modules: Module 1 provides an overview of antibiotics drug and the clinical aspects of amoxicillin, including its pharmacological profile; Module 2 covers preformulation studies and key physicochemical properties essential for dosage form development; Module 3 details the formulation considerations and preparation of Amoxicillin Capsule, and Module 4 presents the evaluation of the formulated Capsule, including tests for quality and performance. This comprehensive review aims to bridge theoretical knowledge with practical application, enhancing understanding of pharmaceutical processes involved in developing a Amoxicillin as an antibiotics drug.

KEYWORDS: Antibiotics, Amoxicillin Capsule, Preformulation, Formulation, Evaluation

ANTIBIOTICS:

Antibiotics are chemical substances produced by microorganisms that suppress the growth of the other microorganisms and may eventually destroy them. The pharmacology behind antibiotics includes destroying the bacterial cell by either preventing cell reproduction or changing a necessary cellular function or process within the cell.

AMOXYCILLIN :

Amoxicillin is an aminopenicillin which is active against many strains of Enterobacteriaceae. It is better absorbed from the gastrointestinal tract than ampicillin. Thus, amoxicillin is used whenever oral administration is appropriate and ampicillin is used parenterally. Peak plasma concentrations are reached after 1–2 hours. It is largely excreted in the urine both as unchanged drug and as metabolites

MECHANISM OF ACTION:

β-Lactam antibiotics are bactericidal agents that interrupt bacterial cell-wall formation as a result of covalent binding to essential penicillin-binding proteins (PBPs), enzymes that are involved in the terminal steps of peptidoglycan cross- linking in both Gram-negative and Gram-positive bacteria Amoxicillin binds to and inhibits **penicillin-binding proteins (PBPs)**, which are enzymes responsible for the final stages of peptidoglycan cross-linking in the bacterial cell wall. Peptidoglycan is a major component of the bacterial cell wall that provides rigidity and prevents cell lysis Cell death may occur as a result of inhibiting one or more of these PBPs.

USES

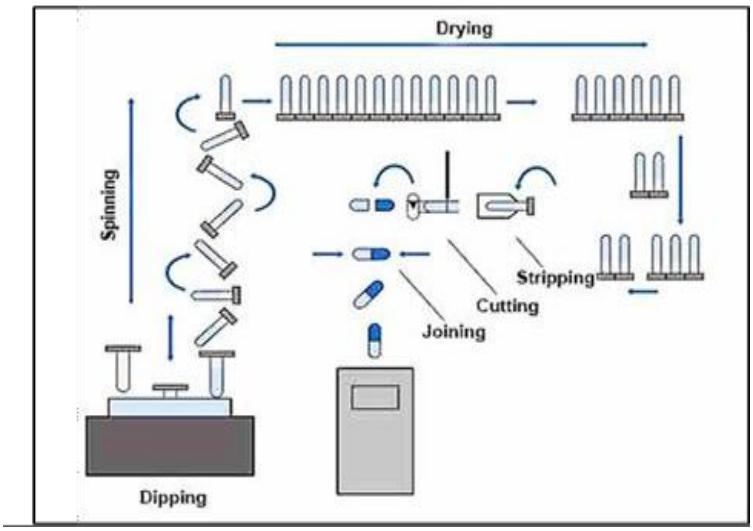
- Respiratory tract infection
- Ear infections (Otitis media), Especially common in children
- Helps clear bacteria from the urinary tract. hence, used to treat Urinary tract infections (UTIs),

FORMULATION OF AMOXYCILLIN CAPSULE

PRODUCTION OF EMPTY CAPSULE SHELL

Preparation of Gelatin Solution

Gelatin is dissolved in demineralized water heated to approximately 60–70°C to create a concentrated solution containing about 30–40% w/w gelatin. Vacuum is applied to remove air bubbles, ensuring uniformity and preventing defects in the final capsules. Colorants, opacifying agents, and preservatives may be added to achieve the desired capsule appearance and stability.



Calculation and Weighing

INGRIDIENTS	QUANTITY	USED AS
AMOXYCILLIN TRIHYDRATE	250 Mg	ACTIVE INGRIDIENT
LACTOSE MONOHYDRATE	q.s to 250mg	DILUANT
MAGNESIUM STEARATE	0.5Mg	LUBRICANT

Blending

- Mix Amoxicillin and lactose in a mortar using geometric dilution until a uniform blend is obtained.
- Add magnesium stearate last and blend gently for 1–2 minutes (avoid over-mixing to prevent poor dissolution).

FILLING OF CAPSULE SHELL

a) Manual filling:

Manual filling can be opted when the number of capsules to be filled are very less. This method is also known as punch method.

b) **Hand operated or semi-automatic filling**:

Small scale filling of capsules can be carried out using semi-automatic hand operated filling machines. These machines have capacities ranging from 24-60 capsules and are capable of producing about 200-2000 capsules per hour when efficiently operated.

c) Automatic capsule filling :

On an industrial scale which requires production of hundreds to thousands of capsule per a day, the manufacturing is carried out using fully automatic filling machines, development by various companies around the world. The production output varies from 4000-200000 capsules per hours.

Polishing of capsule

Before final packing, the filled and sealed capsules are subjected to dusting and polishing to remove any adhering particle and to make them glossy.

a) **Cloth Dusting**:
b) Brushing
c) Pan coating

EVALUATION F AMOXYCILLIN

1. PHYSICAL EVALUATION TEST:

This involves checking the appearance and size of the capsules to ensure uniformity. Color and Appearance: The capsules should be consistent in color and appearance. Any discrepancies might indicate contamination or issues during manufacturing. Shape and Size: Capsules should have a consistent shape and size to ensure accurate dosing.

2. WEIGHT VARIATON TEST:

This test checks the uniformity of the capsule content. A capsule is weighed, and the average weight is calculated. The weight of individual capsules is then compared with the average weight. Any significant deviation could suggest issues with the filling process.

3. CNTENT UNIFORMITY TEST:

To perform the test, randomly selected 10 capsules from the batch to ensure are presentative sample. Each capsule is carefully opened, and the contents are removed and weighed accurately. The content of the active ingredient in each capsule is then determined using an appropriate analytical method,

such as High-Performance Liquid Chromatography (HPLC) or UV-Visible Spectroscopy. The average content and the relative standard deviation (RSD) of the active ingredient across the 10 capsules are calculated to assess uniformity.

4. DISINTEGRATION TEST:

Six capsules are placed in the basket tubes, and the apparatus is operated under the specified conditions. The capsules are observed at the end of the prescribed time limit (usually 30 minutes). Disintegration is considered complete when the capsule shell is no longer visible, and only fragments of the shell remain. If 1 or 2 capsules fail to disintegrate completely, the test is repeated on an additional 12 capsules, and the requirement is met if not fewer

5. DISSOLUTION TEST

Dissolution refers to the process by which the capsule releases its active ingredient into the gastrointestinal tract. The capsule is placed in the basket, which is then submerged in the dissolution medium. The basket rotates at the specified speed, allowing the capsule to dissolve over time. At predetermined intervals, samples of the dissolution medium are withdrawn and analyzed to determine the amount of API released. This is performed to evaluate how a drug dissolves and becomes available for absorption.

6. INVIVO EVALUATION TEST

These evaluations help to determine the absorption, distribution, metabolism, and excretion (ADME) characteristics of the drug, ensuring its efficacy and safety. Evaluation experiment is performed using both rodents (rats, mice) and non-rodents (dogs, cats, horses).The experiment done by administering the capsule orally to the selected animalmodel. Doses are typically based on body weight, and multiple dose levels may be tested to assess dosedependent effects. Blood samples are collected at predetermined time points (e.g., 0, 0.25, 0.5, 1, 2, 4, 6, 8, 12, 24 hours) post-administration to measure plasma concentrations of amoxycillin. Plasma is separated by centrifugation and stored at -20 °C until analysis. Additional samples, such as urine and feces, may be collected to assess excretion pathways. High-Performance Liquid Chromatography (HPLC) is commonly used to quantify Amoxicillin in biological samples.

LABELLING REQUIREMENTS

The label should include the name of the medication, strength of tablet, dosage instructions, storage instructions, name and address of manufacturer, date of manufacture and expiry, precaution, caution, direction of use etc.

The label should be legible, and the font size should be clear and easy to read.

PACKING:

PRIMARY PACKAGE

- **Blister Packs**: These consist of a thermoformed plastic cavity sealed with aluminum foil.
- **Plastic Bottles:** They are often accompanied by desiccants to control humidity and are sealed with tight-fitting caps to prevent moisture ingress**.**
- **Alu-Alu Packs:** Also known as cold-form foil packs, these provide superior protection by enclosing the capsule between two aluminum foil layers, offering excellent barriers against moisture, oxygen, and light.

SECONDARY PACKAGE

.The package external to primary package is known as secondary package. This package provides additional protection during warehousing and also provides information about drug product for example. Leaflets.

TERTIARY PACKING

It is outer package of secondary packaging and prevents damage to the products. It is used for bulk handling and shipping. Examples: Barrel, crate, container, pallets, slip sheet.

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