WWW.IJRPR.COM

International Journal of Research Publication and Reviews

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

Doxycycline Tablet: An Overview

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ABSTRACT

This report focuses on the formulation and evaluation of Doxycycline tablets, linking academic knowledge with industrial practice. It covers antibiotic basics, preformulation studies, tablet formulation, and quality evaluation to provide practical insights into pharmaceutical development.

KEY WORDS: Antibiotics, Doxycycline, Preformulation studies, Formulation, Evaluation.

INTRODUCTION

Antibiotics are chemical substances that kill or inhibit the growth of bacteria and are used extensively to treat bacterial infections in both humans and animals.

Various antimicrobial agents act by interfering with, cell wall synthesis, Protein synthesis, nucleic acid synthesis, plasma membrane integrity.

DOXYCYCLINE

Doxycycline is a tetracycline antibiotic that inhibits bacterial growth and is thought to have anti-inflammatory effects

USES:

- Bacterial infections
- Acne
- Sexually transmitted infections

ADVERSE EFFECT:

- Nausea or vomiting
- Diarrhea
- Itchy skin and rash

CONTRA INDICATIONS:

- Pregnancy
- Children under 8 years
- Severe Liver Disease

MECHANISM OF ACTION

Its mechanism of action involves inhibiting bacterial protein synthesis. It does this by binding to the 30S ribosomal subunit of bacteria, preventing the attachment of aminoacyl-tRNA to the ribosome. This disruption inhibits the elongation of the protein chain, leading to a halt in protein synthesis and ultimately bacterial growth.

AVAILABLE MARKETED FORMULATIONS

Tablets: Doxycycline Hyclate Tablets – 100 mg.

PREFORMULATION STUDIES OF DOXYCYCLINE

Preformulation studies are a critical phase in drug development that involve the characterization of a drug's physical and chemical properties to design a suitable dosage form.

A. ORGANOLEPTIC PROPERTIES

- **APPEARANCE**: The tablets are usually yellow, reflecting the crystalline nature of doxycycline salts such as doxycycline monohydrate or doxycycline hyclate.
- **ODOUR:** The tablets may emit a faint odor reminiscent of ethanol, a characteristic of doxycycline hyclate.
- **TASTE:** Doxycycline has a bitter taste.

B. PHYSICAL PROPERTIES

- **SOLUBILITY**: Doxycycline is highly soluble in water and acidic solutions.
- **MELTING POINT**:201–205°C
- **HYGROSCOPICITY**: Doxycycline tablets are moderately hygroscopic, meaning they can absorb moisture from the environment.
- **POLYMORPHISM**: Exists in multiple crystalline forms, which can affect solubility and bioavailability.

C. CHEMICAL PROPERTIES

- **pka :** Doxycycline has two pka values around 3.3 and 7.7, which affect its solubility and stability in different pH environments.
- **PARTITION COEFFICIENT**: Log P (Octanol/Water): Approximately −0.77
- **STABILITY:** Doxycycline is sensitive to light, heat, and alkaline PH.

D. **MICROMERITIC PROPERTIES**

- **ANGLE OF REPOSE:**22.1°- 27.7°
- **BULK DENSITY AND TAPPED DENSITY**:
  - Bulk Density: Approximately 0.4 to 0.6 g/mL
  - Tapped Density: Approximately 0.5 to 0.7 g/mL
- **CARR'S INDEX**:15-20
- **HAUSNER'S RATIO**:1.20- 1.35

E. **STABILITY STUDIES**

- Degradation Pathways: Doxycycline is sensitive to light, heat, and alkaline pH, and it can degrade into inactive compounds under such conditions. The most common degradation pathways involve oxidation and hydrolysis.
- Photodegradation: Doxycycline undergoes photodegradation when exposed to light, which leads to a reduction in its potency. This can be mitigated by using light-protective packaging.

F. **EXCIPIENTS COMPATIBILITY STUDIES**

- Assessing the compatibility between doxycycline and excipients is vital to prevent potential interactions that could affect the stability or efficacy of the tablet.
- Fourier-Transform Infrared Spectroscopy (FTIR): Identifies chemical interactions between the drug and excipients.
- Differential Scanning Calorimetry (DSC): Detects changes in thermal properties that may indicate incompatibilities.

FORMULATION OF DOXYCYCLINE TABLET

Pharmaceutical formulations are the processes used to design and produce a final medicinal product that delivers the active pharmaceutical ingredient (API) to the patient in a safe, effective, and stable form.

INGREDIENTS	QUANTITY	FUNCTION
Doxycycline hyclate	100 mg	Active Ingredient
Microcrystalline cellulose	~30–100 mg	Fillers / Diluents
Croscarmellose sodium	~5–15 mg	Disintegrants
HPMC, polyvinyl alcohol	~5–15 mg	Binders
Magnesium stearate	~1–5 mg	Lubricants
PEG / coating polymers	~10–30 mg	Coating agents
Titanium dioxide	~5 mg	Colorants

METHOD OF PREPARATION

Wet granulation is used to enhance the flow, compressibility, and uniformity of poorly flowing drugs like doxycycline hyclate. The process involves:

1. **Weighing & Sieving**: Accurate weighing and sieving of API and excipients.
2. **Dry Mixing**: Blending doxycycline with diluents and Disintegrants.
3. **Binder Preparation**: Making a binder solution (e.g., PVP K30 in water).
4. **Wet Massing**: Adding binder to form a cohesive wet mass.
5. **Granulation:** Passing the wet mass through a sieve to form granules.
6. **Drying**: Drying granules at 45–60 °C to reduce moisture.
7. **Sizing**: Milling dried granules for uniformity.
8. **Final Blending:** Mixing with lubricants, glidants, and remaining disintegrant.
9. **Compression:** Pressing into tablets and checking quality.
10. **Film Coating (Optional):** Applying a protective coat for stability and appearance.

EVALUATION OF DOXYCYCLINE TABLET

Tablet evaluation ensures drug identity, quality, and purity.

A. Non-Official Tests:

1. **General Appearance**

- Shape: Round, biconvex
- Color: Yellowish, film-coated, odorless, no defects

2. **Unique Markings**

- Imprint: “DOX 100”
- Verified with manufacturer code

3. **Hardness**

- Measures mechanical strength
- Avg: 6.4 kg/cm² (within acceptable range)
- Tested using Monsanto hardness tester (10 tablets)

4. **Friability**

- Tests resistance to chipping
- Loss: 0.40% (Pass, limit <1%)

- Tested using Roche friabilator (20 tablets)

B. Official Tests:

1. **Content Uniformity**

- Ensures potency within 85–115% of label claim
- Tested by HPLC or UV (10 tablets)

2. **Weight Variation**

- Checks uniformity across tablets
- 20 tablets; must meet USP % deviation limits

3. **Disintegration Test**

- Ensures breakdown in ≤30 mins
- Medium: Water or pH 1.2 buffer
- Apparatus: USP disintegration tester

4. **Dissolution Test**

- Measures drug release rate
- ≥80% release within 30–45 mins
- Apparatus: USP Dissolution Type II (Paddle)
- Medium: 0.1N HCl or pH 6.8 buffer, 37°C, 75 rpm

PACKAGING AND LABELLING OF DOXYCYCLINE TABLET

PACKAGE

Packaging is the science, art, and technology of enclosing or protecting products for distribution, storage, sale, and use.

TYPES OF PACKAGES

Primary Packaging

- **Blister packs**
  - **PVC/Alu**: Common for moisture- and light-stable formulations.
  - **Alu/Alu (cold-form foil)**: Offers near-total protection—virtually zero moisture/oxygen penetration—ideal for light- or moisture-sensitive tablets
- **HDPE bottles**
  - Often include silica gel desiccants; used for multi-dose/bulk packaging. Provide good barrier until first opening.
- **Glass/amber bottles or vials**
  - Less common for tablets, used for highly sensitive formulations or liquids

Secondary Packaging

- **Carton boxes**
  - Enclose backings or bottles; show essential labeling: drug name, strength, batch, expiry, storage, warnings; include patient leaflets.
- **Bulk wrap / cardboard cases**
  - Used for transportation; offer mechanical protection and tamper evidence

LABEL

Key Labeling Components

1. **Product Identification**
    - **Name**: "Doxycycline Tablets, USP,"
    - **Strengths**: 50 mg, 75 mg, 100 mg, 150 mg,
    - **Route**: Oral,
    - **NDC Code**: Unique to each strength/packaging configuration
2. **Inactive Ingredients**
    - Must list all non-active components (e.g., colloidal silicon dioxide, Hypromellose, magnesium stearate, microcrystalline cellulose, polysorbate 80, sodium starch glycolate, color lakes, PEG, titanium dioxide)
3. **Dosage & Administration**
    - Clear instructions specifying usual regimens (e.g., 200 mg on day 1, then 100 mg daily; pediatric dosing by weight, etc.)
4. **Storage & Container Specifications**
    - "Dispense in a tight, light-resistant container with a child-resistant closure"; storage below 30 °C (86 °F)
5. **Patient Counseling & Warnings**
    - Include FDA-approved patient information, such as:
        - Risk of tooth discoloration in children ≤ 8 years/pregnancy,
        - Photosensitivity warnings,
        - Advice to take with fluids to avoid esophageal irritation,
        - Potential for C. difficile–associated diarrhea,
        - Drug interactions

CONCLUSION

This Practice School Report explored the pharmaceutics domain using Doxycycline as the model drug. The primary objective was to strengthen collaboration between academia and industry while gaining practical insights into the formulation and evaluation of Doxycycline tablets. The study was organized into four key modules: Module 1 provided an overview of antibiotics and the clinical profile of doxycycline; Module 2 focused on preformulation studies and the physicochemical properties vital for dosage form development; Module 3 discussed formulation strategies and tablet preparation; and Module 4 evaluated the finished tablets through quality and performance tests. Overall, this report successfully bridged theoretical learning with real-world application, deepening the understanding of pharmaceutical development processes involved in creating effective antibiotic therapies.

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