

COMPARATIVE STUDY OF DIFFERENT MARKETED BRANDS OF FLUCONAZOLE DUSTING POWDERS

**A Project Submitted to
Jawaharlal Nehru Technological University Anantapur
in partial fulfilment of the requirements for the award of the
Degree of**

**BACHELOR OF PHARMACY
by**

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MAY-2025.



**JNTUA-OIL TECHNOLOGICAL AND
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CERTIFICATE

This is to certify that the project work entitled "**COMPARATIVE STUDY OF DIFFERENT MARKETED BRANDS OF FLUCONAZOLE DUSTING POWDERS**" is a bonafide project work done by **Mr. KOUTHARAM VENKATA SIVA RAM (21G41R0039)**, **Mr. KOVI ARAVIND (21G41R0040)**, **Ms. KUNTALA HEMALATHA (21G41R0041)**, **Ms. MANGALA MEGANA (21G41R0042)**, **Ms. MUKKAMALLA ANITHA (21G41R0047)** in partial fulfillment of the requirement for the award of degree of **Bachelor of Pharmacy**. The research work was carried out in **Jawaharlal Nehru Technological University Anantapur-Oil Technological and Pharmaceutical Research Institute** and submitted to Jawaharlal Nehru Technological University Ananthapuramu, under my supervision and guidance during the academic year **2024-2025**.

The result embodied in this project work has not been submitted to any other University or Institute for the award of any degree or diploma.

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This is to certify that the project work entitled **COMPARATIVE STUDY OF DIFFERENT MARKETED BRANDS OF FLUCONAZOLE DUSTING POWDERS** is a bonafide research work done by **Mr. KOUTHARAM VENKATA SIVA RAM (21G41R0039), Mr. KOVI ARAVIND (21G41R0040), Ms. KUNTALA HEMALATHA (21G41R0041), Ms. MANGALA MEGANA (21G41R0042), Ms. MUKKAMALLA ANITHA (21G41R0047)** in partial fulfillment of the requirement for the award of degree of **Bachelor of Pharmacy in Department of Pharmaceutics**, to Jawaharlal Nehru Technological University Anantapur, is a record of bonafide project work done in **Jawaharlal Nehru Technological University Anantapur-Oil Technological and Pharmaceutical Research Institute** and under supervision and guidance of **G. Nethra Vani, M.Pharm, (Ph.D),** during the academic year **2024-2025.**

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DECLARATION

We declare that the project work entitled "**COMPARITIVE STUDY OF DIFFERENT MARKETED BRANDS OF FLUCONAZOLE DUSTING POWDERS**" for the award of Bachelor of Pharmacy degree, comprises of the bonafide project work carried out at Jawaharlal Nehru Technological University Anantapur-Oil Technological and Pharmaceutical Research Institute under the supervision and guidance of **Ms. G. Nethra Vani, M.Pharm, (Ph.d)..**, The work is original and does not constitute any part of any thesis/ dissertation/ monograph submitted by us or any other person to any University/Institute.

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*Dedicated to
Beloved Parents, Gurus,
Almighty God*

Dear Friends

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Place: Ananthapuramu

Project Associates

Date:

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LIST OF ABBREVIATIONS

Abbreviation	Full form
API	Active Pharmaceutical Ingredient
QC	Quality Control
ISO	International Standard Organization
GLP	Good Laboratory practice
SOP	Standard Operating Procedure
CGMP	Current Good Manufacturing Practices
IP	Indian Pharmacopoeia
USP/NF	United States Pharmacopoeia/National Formulary

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Description of the project work:

Purpose: This study aims to compare the effectiveness and formulation differences among various marketed brands of fluconazole dusting powder, which is used to treat fungal skin infections. The objective is to evaluate the brands based on their chemical composition, antifungal efficacy, and consumer satisfaction.

Conclusion: Brand 3 was found to be the most effective in both laboratory tests and consumer feedback. While other brands were also effective, Brand B3 provided superior results, making it the recommended choice for treating fungal skin infections.

Method: Four popular fluconazole dusting powder brands were evaluated for their chemical composition, concentration of fluconazole, and antifungal efficacy against common fungal strains. The study also assessed the stability of the powders' pH over six months and gathered consumer feedback regarding the performance and side effects of each brand.

Results: Brand 3 showed the strongest antifungal activity in lab tests, while all brands maintained stable pH levels over time. Consumer reviews indicated a preference for Brand 3, as users reported faster relief and fewer side effects compared to the other brands.

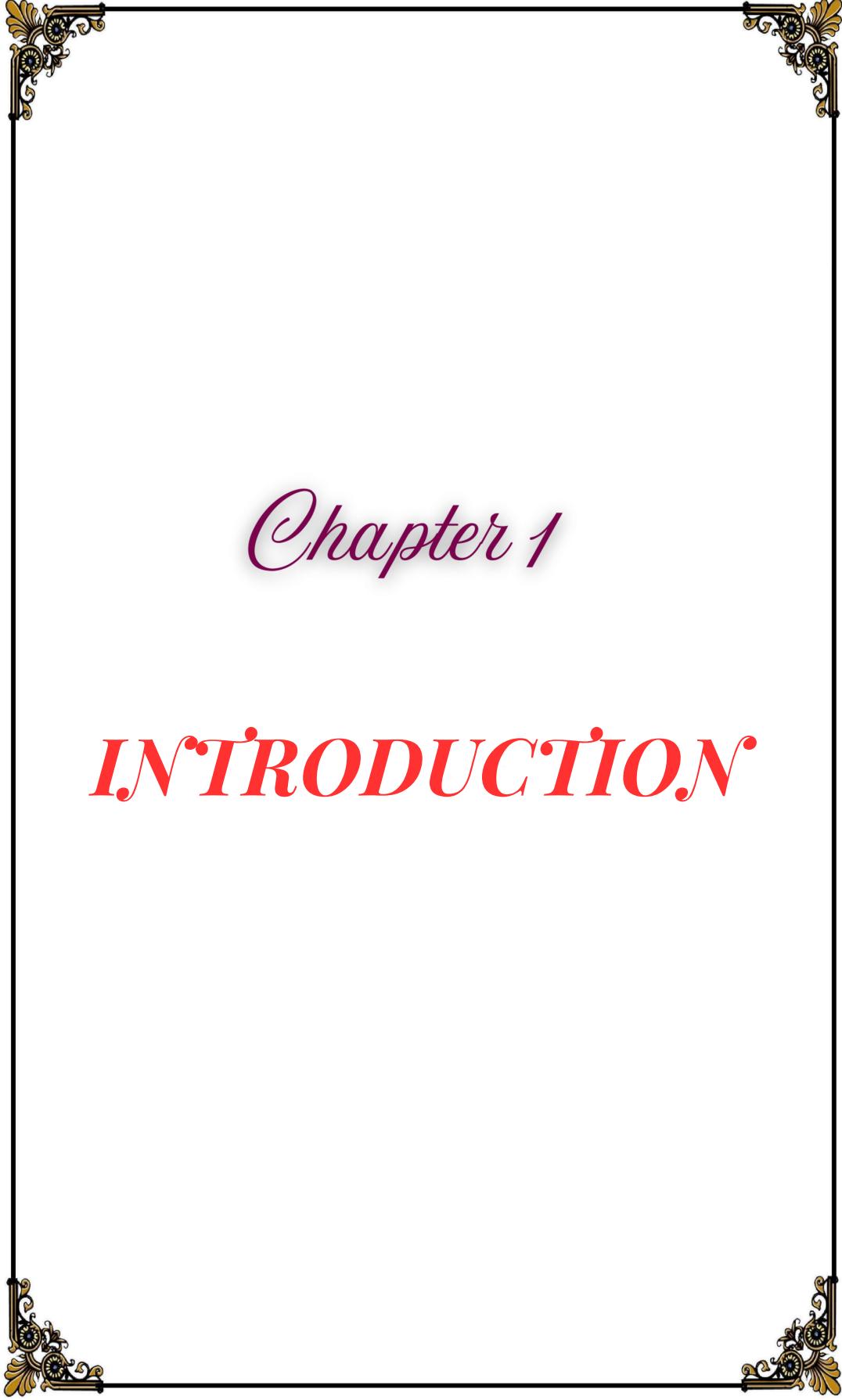
Keywords: Fluconazole, dusting powder, antifungal, pH stability, consumer satisfaction.

Signature of the guidance

Mrs. G. NETHRA VANI

Principal

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Chapter 1

INTRODUCTION

CHAPTER 1

INTRODUCTION

POWDERS

INTRODUCTION:

A pharmaceutical powder is a mixture of finely divided drugs or chemicals in a dry form which are meant for external use (dusting powders) and internal use (douche powders). A powder used on the skin or on wounds especially for allaying irritation or absorbing moisture is called as dusting powders. A powder is a homogenous mixture of more or less finely divided particulate material in dry form. Dusting powders are usually mixtures of two or more substances in fine powder intended for application on to the skin (wounds, burns, surgical incision). Dusting powders are used to prevent and treat minor skin infections caused by small cuts, scrapes, or burns. Some infections can also be treated by using dusting powders such as athlete's foot, jock itch and ringworm. The dusting powders are mainly used for their antiseptic, absorbent, antiperspirant and antipruritic action. Dusting powders are generally prepared by mixing two or more ingredients one of which must be either starch, talc, or kaolin as one the ingredients in formulation. (1)(2)

GENERAL PROPERTIES OF POWDERS:

- It should be homogenous.
- It should not cause local irritation.
- It should flow easily and spread uniformly.
- It should cling to the skin on application.
- It should have adsorptive and absorptive capacity.
- Fine particle size.

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- It should protect the skin from irritation caused by friction, moisture and chemical irritants. (1)

ADVANTAGES:

- Easy to carry than liquid dosage forms.
- Good chemical stability compared with fluids.
- Easy to apply for wounds.
- Economical.
- Rapid onset of action.
- Incompatibility is less in case of powders than liquids.
- The dose variation depending on the patient condition is possible.
- Physician has free choice of drug combination.(1)

DISADVANTAGES:

- Difficult to protect powders containing hygroscopic substances or aromatic substances.
- Not suitable for drugs which are unstable at normal atmospheric conditions.
- Time consuming to prepare.
- Drug may show physical instability.
- Powder may easily deteriorate on exposure to environment because of small particle size and large surface area.(1)

TYPES OF POWDERS:

There are 2 types of dusting powder:

- 1)Medical powders
- 2)Surgical powders

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- 1) MEDICAL POWDERS:** For superficial skin conditions, medical powders are used. They must be free from pathogens. Some mineral ingredients may contain spores of tetanus, gas gangrene etc. and so they must be sterilized properly. They are not used for open wounds or area of broken skin which is mentioned in the label also.(1)
- 2) SURGICAL POWDERS:** Surgical dusting powders are used in body cavities and major wounds, on burns and on umbilical cords of infants also. They are sterile powders.(1)

EXCIPIENTS:

- Excipients play an important role in formulating a dosage forms many dosage forms formulating today are complex system containing many other components along with the active pharmaceutical ingredient (API):these compounds are generally added along with the active pharmaceutical ingredients in order to:
 - Talc used in products in order to absorb moisture.
 - Prevent caking,, improve consistency.
 - Talc is an ingredient used in personal care products such as loose powders (eg::baby powders, talcum powders, blush, eye shadow.
 - It is used as a filler in ceramics, paints, paper, roofing materials.
 - Used as a carrier in insecticides.

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FLUCONAZOLE:

Fluconazole is an antifungal medication used to treat infections caused by fungi, including yeast infections. It works by inhibiting fungal cell membrane formation. Commonly prescribed for oral thrush, vaginal candidiasis, and systemic fungal infections, it is available in tablet, suspension, and intravenous forms. Fluconazole is generally well tolerated with minimal side effects.(1)

MECHANISM OF ACTION:

Fluconazole works by inhibiting the fungal cytochrome P450 enzyme 14 α -demethylase, which is essential for converting lanosterol to ergosterol, a key component of the fungal cell membrane. By blocking ergosterol synthesis, fluconazole disrupts cell membrane integrity, leading to leakage of cellular contents and ultimately fungal cell death. This selective inhibition makes fluconazole effective against a wide range of fungal infections while having minimal effects on human cells. (1)

EVALUATION TESTS FOR POWDERS:

I.ANGLE OF REPOSE:

The flow properties of powders can be studied by measuring angle of repose. It was determined by the funnel method. The funnel was fixed in a place, 4cm above the bench surface. After the cone from 5g of sample was built, height of the granules forming the cone(h) and the radius r of the base were measured. The angle of repose was calculated as follows: (l)

$$\text{Angle of repose} = \tan^{-1} (h/r)$$

Where,

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h = height of the powder cone

r = radius of the powder cone

2. PHYSICAL CHARACTERISTICS:

The colour, odour and appearance of the powder is evaluated by simple visualization.(1)

3. pH:

pH is a measure of the acidic or basic formulation. The pH of dusting powder is determined to avoid the irritation to the skin. (1)

4. BULK DENSITY:

The powder was passed through a no.18 sieve into a pre-weighed 25ml graduated cylinder with 0.5ml markings. The bulk volume was measured after manually tapping the cylinder two times on a flat tabletop surface. (1)

5. ABRASIVENESS: -

It was studied by rubbing the powder on a surface and then studying the effect on the surface by using microscope. (1)

6. CARR'S INDEX: -

The bulk and tapped densities were used to calculate Carr's compressibility index to provide measure of the flow properties and compressibility of powders. (1)

$$\text{Carr's index} = \frac{\text{Tap density} - \text{bulk density}}{\text{tapped density}} * 100 \cdot$$

7. HAUSNER'S RATIO: -

It is the indicative of flow properties. It is derived property from bulk and tapped density. Lower the Hausner ratio is indicating better flow whereas higher the ratio indicated poor flow of granules. (1)

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Hausner ratio is calculated by the following equation.

$$\text{Hausner ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

8. TAPPED DENSITY: -

The bulk volume was measured after manually tapping the cylinder two times on a flat table surface. The tapped volume was measured with the tapped density tester after tapping in increments of 500, 750, and 1250 taps with 250 drops per minute. (3)

$$\text{Tapped density} = \frac{\text{mass of granules}}{\text{volume of granules}}$$

9. ANTIMICROBIAL ACTIVITY: -

The antimicrobial activity of dusting powder was tested by well- diffusion using cup plate method against *Staphylococcus aureus* and *Escherichia coli* obtained from Microbiology Laboratory, M.I.B.P. Gonidia. (1)

Materials requirements: -

- Nutrient broth (for bacterial cultivation)
- Mix culture of both microorganism
- Different concentration of trial dusting powder
- Sterile Petri plates and sterile cork borer
- Incubator and autoclave

Well disc diffusion using cup plate method: -

Agar medium was prepared and autoclaved. Inoculums was added in 250 ml of the media under aseptic condition and then media was poured in Petri plates. After the medium was solidified wells were bored with help of sterile borer.

Sample preparation: -

About 1gm of powder was dissolve in the distilled water until it converts into a solution. After that, the bores on each plate were filled completely with the

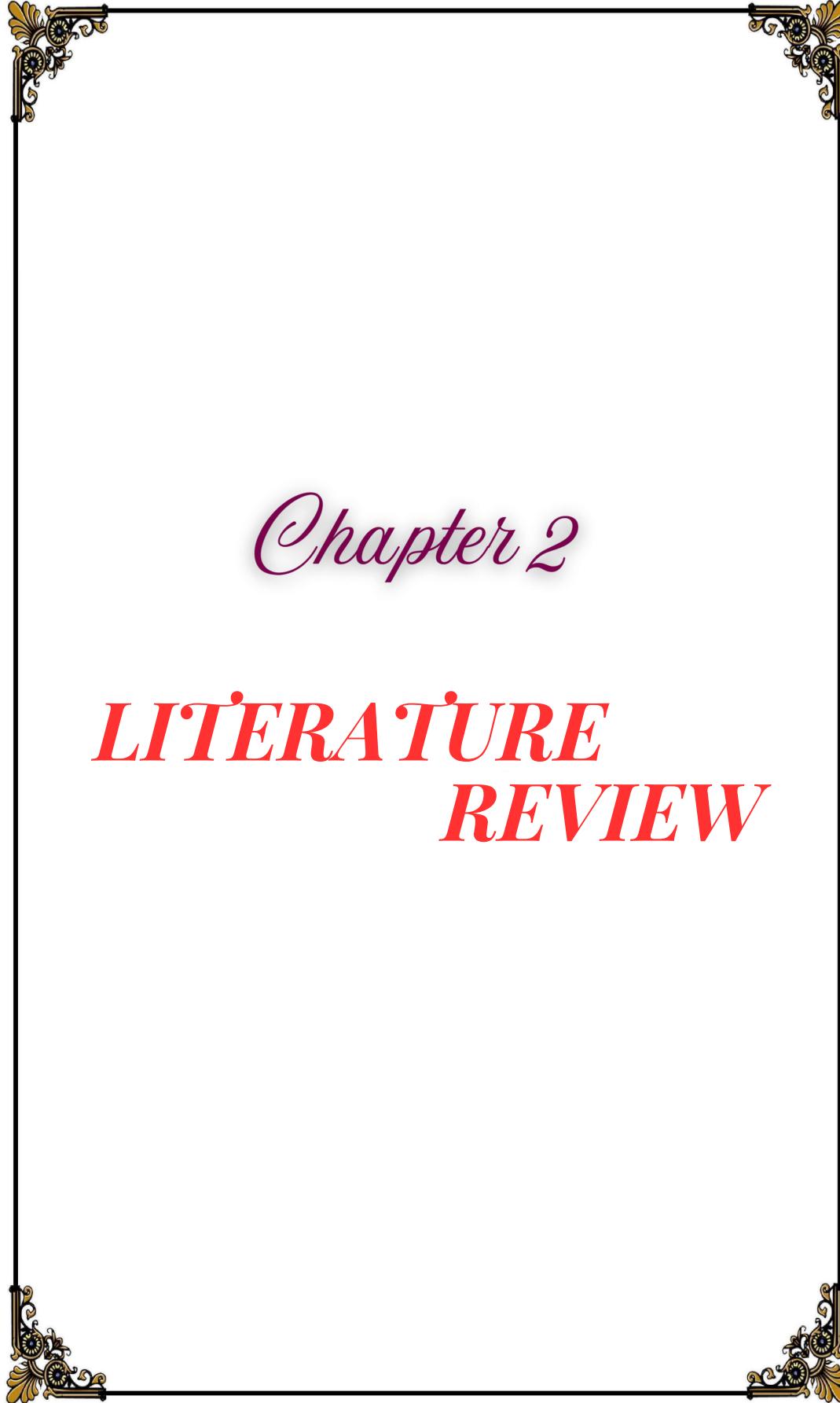
solution. In clockwise manner, the labelled wells were incubated at 32- 37°C for 48 hours.

The sensitivity of test organism to each antimicrobial agent was indicated by clear zones of inhibition around the well.

The antimicrobial activity is determined by measuring the diameter of zone of inhibition.

10. IRRITANCY TEST: -

Mark an area of (1sq.cm) on the left hand dorsal surface. Definite quantities of dusting powder were applied to the specified area and time was noted. Irritancy, erythema, oedema was checked regularly for upto 24 hours and reported. (3)



Chapter 2

**LITERATURE
REVIEW**

CHAPTER-2

LITERATURE REVIEW

The following literature on powders, antifungal dusting powders, Fluconazole dusting powders were collected for performing a better project work. The literature review also gives a good idea for doing the work throughout the project

2.1: LITERATURE REVIEW ON POWDERS REVIEW ARTICLES:

1. Gazi Jehangir Rather, Hamid Uddin*, Mohd Ikram, Shaista Fatima, MD Naquibuddin (2021) introduced polyherbal powder formulation used to treat Sexual disorders. Formulation consists of following herbs Orchis latifolia, Hygrophila auriculata, Asparagus racemosus and Elettaria cardamomum. Methods: The drugs were cleaned, dried in shade and powdered by passing through sieve # no. 80 as per the method described in UPI / National Formulary of Unani Medicine. This Safoof formulation was evaluated using physicochemical tests: powder characterization, extractive value, alcohol and water-soluble matter, Ash value, LOD at 1050 c, pH and HPTLC fingerprinting. Statistical Results: Organoleptic characters of the formulation are light brown color, characteristic odor, sweet taste and moderately fine texture. (4.76 ± 0.08) , acid insoluble ash (3.36 ± 0.01) , water soluble ash (0.89 ± 0.25) , LOD at 1050 C (11.38 ± 0.34) , pH of 1% and 10% solution were 6.6 ± 0.1 and 6.0 ± 0.1 respectively. Phytochemical qualitative analysis displayed presence of alkaloids, tannins, flavonoids, steroids, terpenoids, carbohydrates, volatile oil. HPTLC fingerprinting data was also set in. Conclusion: The standardization of this formulation was done and the data obtained would be used as a standard for future reference.(4)

2.Maryam Asachil, Ehsan Nourafkanl*, Ali Hassanpourl* (2020) blended a mixture of powders to a homogeneous system is a crucial step in many manufacturing processes. To achieve a high quality of the end product, powder mixtures should be made with high content uniformity. For instance, producing uniform tablets depends on the homogeneous dispersion of active pharmaceutical ingredient (API), often in low level quantities, into excipients. To control the uniformity of a powder mixture, the first required step is to estimate the powder content information during blending. There are several powder homogeneity evaluation techniques which differ in accuracy, fundamental basis, cost and operating conditions. In this article, emerging techniques for the analysis of powder content and powder blend uniformity, are explained and compared. In addition, the paper highlights the recent innovative on-line measurement techniques used for the noninvasive evaluation of the mixing performance.(5)

3..Oleg D. Neikov, Dina V. Lotsko (2021) evaluated the apparent density, tap density, angle of repose, flow rate, compressibility. These properties, for a certain powder composition, may depend on its granulometric composition, particle shape, particle morphology, specific surface, moisture content, etc. Knowledge of technological parameters coupled with the physical properties enables evaluation of the behavior of powder during processing that is accomplished by their consolidation. The procedures described in standards are used to determine the technological properties of powders in delivery condition. Usually, in contrast to ISO, a feature of these standards is the fact that they contain additional or refined specific cations. Appendix I at the end of the book contains the list of the standard methods of powder characterization and testing. (6)

4. Shaveta Sharma*, Teenu Sharma, Ashima Sharma and Mahak Deep (2023)

developed an orderly assessment of flow of powders and granules using compendial and non-compendial procedure. Angle of repose, tapped density, Carr's compressibility file, Bulk density, Hausner's ratios were assessed. Moreover, flow was described utilizing powder rheometer wherein delicate force transducer screens the forces created as consequence of the sample displacement, another technique FT4 powder rheometer. The Freeman Technology (FT4 powder rheometer) is intended to describe powders undergoing different circumstances in manners that look like wide scale creation climate. The FT4 application connect to filling, hopper flow, Tablet pressure, wet granulation, end point, flow added substance determination and enhancement, moisture impacts, static change, feeding, stirring, separation, caking, processing, Wall grating, grip, hopper configuration etc. (7)

2.2. LITERATURE REVIEW ON DUSTING POWDERS:

1. **A Review on Fluconazole Kaur Sharanpreet¹, Kaur Navreet², Kaur Gursimran³ and Kumar Prabhat⁴ (2025)** evaluated the significant dissolution method for drug products with limited water solubility had been a challenge to the pharmaceutical industry. Fluconazole (a BCS Class I drug) was an anti-fungal agent. In the present study, parameters such as solubility, medium pH, surfactant type, dissolution behaviour formulations, impact of sink conditions, stability, and discriminatory impact of dissolution testing were studied for the selection of an appropriate dissolution medium. The drug and marketed formulations remained stable in the dissolution media used. An agitation speed of 50 rpm showed a more discriminating drug release profile than 75 rpm. The discriminating dissolution method for fluconazole formulations was paddle at 50 rpm, 900 mL pH6.8 phosphate buffer, with more than 80% of the labeled amount released over 60 minutes (8)

2. Fluconazole Ameish Govindarajan; Karlyle G. Bistas; Curtis J. Ingold; Preeti Patel; Ayham Aboeed (2023) described that fluconazole was a member of the triazole family and stood as a cornerstone in the realm of antifungal agents, offering widespread therapeutic utility. This medication addressed a spectrum of fungal afflictions, including vaginal candidiasis, oropharyngeal and oesophageal candidiasis, urinary tract infections, peritonitis, and systemic Candida infections. Its efficacy extended to candidemia, disseminated candidiasis, pneumonia, and cryptococcal meningitis. Beyond the treatment of active disease, fluconazole served a crucial prophylactic role by reducing the incidence of candidiasis in patients who underwent bone marrow transplantation and were subjected to cytotoxic chemotherapy or radiation therapy. This activity detailed the drug's indications, mechanism of action, optimal dosing, noteworthy adverse effects, contraindications, monitoring parameters, and potential toxicity. Equipping healthcare providers with this understanding empowered them to navigate patient therapy effectively, fostering optimal outcomes in the battle against fungal infections. (9)

3. Formulation and Characterisation of Fluconazole Loaded MCM-41

Powder for Topical Drug Delivery By Ankita U. Goswami, Mihir Raval and Navin Sheth (2024) studied the use of common carriers like talc for topical drug delivery had led to diminished efficacy due to poor aqueous solubility and low dissolution rate. The objective of the study was to improve the efficiency of fluconazole topical dosage forms using MCM-41 as a carrier material. The aim was to load fluconazole into carriers such as MCM-41 and β -Cyclodextrin, and to compare the prepared powder formulations with marketed formulations. Methods: Fluconazole complexes were formulated using MCM-41 and β -CD as carriers in different proportions by melt, solvent evaporation, and kneading methods. The complexes were developed into powder formulations. These formulations were subjected to in vitro antifungal activity tests on *Candida albicans*(10)

4. FLUCONAZOLE: A REVIEW Addetla Sagarika^{1*}, Boreda Sowmya², Aprajitha Bhatnagar³ Dr. Kameswari⁴ (2023) studied the fluconazole was a bis-triazole antifungal drug with novel pharmacokinetic properties (metabolic stability and relatively high water solubility), which contributed to its therapeutic activity. Fluconazole was administered either orally or intravenously. It was used to treat a variety of fungal infections, particularly Candida infections of the vagina (yeast infections), mouth, throat, and bloodstream Fungal resistance to drugs in the azole class tended to occur gradually over the course of prolonged drug therapy, resulting in clinical failure in immunocompromised individuals. Fluconazole was also used to prevent infections in people with neutropenia due to cancer chemotherapy, in transplant recipients, and in premature infants. (11)

5. FLUCONAZOLE (DIFLUCAN): A REVIEW By M Zervos¹, F Meunier (2024) introduced fluconazole was a triazole antifungal agent available for oral or intravenous use in the treatment of various localized and disseminated mycoses. Animal models had demonstrated in vivo activity against infections caused by Candida spp. And Cryptococcus neoformans. Fluconazole was also found to be active in animal infections caused by Blastomyces dermatitidis, Coccidioides immitis, Histoplasma capsulatum, and dermatophytes. Fluconazole acted by inhibiting the synthesis of ergosterol, an essential sterol in fungal cell membranes. It was excreted largely unchanged in the urine and had an elimination half-life of approximately 30 hours, allowing for once-daily dosing. Extensive clinical trials had documented its clinical efficacy in candidiasis-including oropharyngeal, oesophageal, and disseminated forms-as well as in the acute or suppressive therapy of cryptococcal meningitis. (12)

6. Fluconazole-Resistant Vulvovaginal Candidosis:An Update on Current Management by **Karolina Akinosoglou (2023)** described rising prevalence of resistant Candida species-particularly *Candida albicans*, as well as non-albicans isolates such as *Candida glabrata* and *Candida krusei*-represented significant challenges in their management. In that review, the aim was to explore the current management of fluconazole- resistant vulvovaginal candidiasis (FRVVC). The findings highlighted the need for tailored treatment regimens, considering the variability in resistance patterns across different regions. Instead of high-dose maintenance regimens involving weekly doses of 150 to 200 mg of fluconazole for six months or longer, it had been advisable to use an individualized degressive regimen (ReCiDiF regimen) to tailor treatment for each patient at the lowest effective dosage necessary to maintain disease control. (13)

7.Biodegradable Polymers-based Nanoparticles to Enhance the Antifungal Efficacy of Fluconazole against *Candida albicans* By Noha Saleh, Soha Elshaer and Germeen Gergis (2025) studied the fluconazole, a potent antifungal medication, was characterized by poor water solubility, which reduced its antifungal efficacy. Objective: This study aimed to prepare FLZ-loaded polymeric nanoparticles (NPs) using different polymers and techniques as a method to enhance the antifungal activity of FLZ. Methods: NP1, NP2, and NP3 were prepared using the double emulsion/solvent evaporation method with PLGA, PCL, and PLA, respectively. The ionotropic pre- gelation technique was applied to prepare an alginate/chitosan-based formulation (NP4). Particle size, zeta potential, encapsulation efficiency, and loading capacity were characterized. FT-IR spectra of FLZ, the polymers, and the prepared NPs were analyzed. NP4 was selected for further in vitro release evaluation. (14)

8. Topical Delivery of Fluconazole via Microemulsion Incorporated Hydrogel for the Management of Fungal Dermatophytosis By Mahendra Singh, Nidhi Gangwar, Poonam Parashar, Chandra B. Tripathi, Malti Arya (2024) described fungal infections through the oral route had been avoided due to the advantages of topical delivery, which included ease of application and improved patient compliance. Topical drug delivery was utilized for the local administration of the drug directly to the affected area, resulting in drug localization .. Methods: Triacetin was used as the oil phase, Tween 80 as the surfactant, and ethanol as the cosurfactant- these components were screened for their suitability in forming microemulsions. Pseudoternary phase diagrams were constructed using the titration method, and various MEs were prepared and evaluated for parameters such as globule size, polydispersity index (PDI), viscosity, pH, and stability. Finally, the optimized microemulsion (ME9) was selected for gel formulation and evaluated for drug content, viscosity, pH, and spreadability. (15)

9. New Generation of Fluconazole: A Review on Existing Researches and Technologies By Afsaneh Behtash, Shohreh Nafisi and Howard I. Maibach (2022) reviewed that fluconazole is used for treating skin fungal infections for over 35 years. FLZ, with its relatively large molecular size and hydrophobicity, improved bioavailability via intravenous or oral routes but posed challenges in topical application. In recent years, nano-based strategies were examined to reduce FLZ's adverse effects and enhance its efficiency. This overview surveyed nano-drug delivery systems used to improve FLZ efficiency, analyzing their strengths, weaknesses, and relevant achievements in pharmaceutical technology. Methods: A systematic literature search was conducted using key search terms and a matrix-based strategy with Boolean logic. Nano-formulations influencing dermal permeation and experimental setups for studying skin absorption of FLZ-nanomaterials were analyzed. (16)

CHAPTER 2

LITERATURE REVIEW

10. PROCESS VALIDATION OF FLUCONAZOLE By Bodavula Samba Siva

Rao K.Raveendra Babu And D.Praveen Kumar(2024) validated the process of demonstrating and documenting that a procedure operates effectively. According to U.S. Food and Drug Administration (FDA) guidelines, process validation provides documented evidence that offers a high degree of assurance that a specific process will consistently meet its intended outcomes. Fluconazole is a triazole antifungal drug used to treat and prevent both superficial and systemic fungal infections. In its bulk powder form, it appears as a white crystalline powder, slightly soluble in water, and soluble in alcohol. It is chemically designated as 2,4-difluoro-bis(1H-1,2,4-triazol-1- ylmethyl) benzyl alcohol, with an empirical formula of C₁₃H₁₂F₂N₆O and a molecular weight of 306.3.

(17)

11.NANO-COMBINATION FOR REVIVING THE ACTIVITY OF

FLUCONAZOLE AGAINST *RHIZOPUS DELEMAR* By Mutasem Rawas-Qalaji, Jayalakshmi Jagal, Bahgat Fayed, Rania Hamdy and Sameh S.M. Soliman (2024) studied the primary pathogen responsible for lethal mucormycosis and a significant threat during the COVID-19 pandemic, is resistant to most antifungals, including fluconazole, a commonly used selective antifungal drug. Antifungals are also known to promote fungal melanin synthesis, which plays a critical role in the pathogenesis of Rhizopus and helps it evade the human immune system, complicating the effectiveness of current antifungal treatments. In this study, a strategy was employed to revive and improve the effectiveness of fluconazole against *R. delemar*. UOSC-13, a compound synthesized in-house to target Rhizopus melanin, was combined with fluconazole either directly or after encapsulation in poly(lactic-co-glycolic acid) nanoparticles (PLG-NPs). Both combinations were tested for *R. delemar* growth, and the MIC₅₀ values were calculated and compared. (18)

12. In-vitro Interactions between Fluconazole and Diphenyl Diselenide against Various *Candida Species* Authors: Sweety Dahiya¹ and Anil Kumar Chhillar¹ (2023) analysed the immunocompromised population, *Candida species* are the most aetiologic agents causing severe nosocomial fungal infections. *Candida species*, irrespective of being commensals in the human microbiome, are the fourth most prevalent source of potentially fatal yeast infections. Monotherapy is frequently employed to treat invasive fungal infections, but sometimes, patients do not favor the monotherapy treatment regime. Antimycotic drug combination therapy could be a better choice in such specific circumstances. In our study, we evaluated the interactions of fluconazole with diphenyl diselenide.(19)

COMPARATIVE STUDY

1. Anand Kakde , Nileema Modhave , Arati Patil (2024) compared the same dosage forms are available in the Indian market with the common assertion that they are all bioequivalent. The main objective of the present study was to conduct the comparative dissolution studies of different brands of same dosage forms to determine whether all the formulations used were bioequivalent or significantly different. An Immediate release tablets dosage form disintegrate rapidly after administration with enhanced rate of dissolution. Three different brands of Fluconazole (Antifungal) of 150 mg Immediate release tablets from different manufacturers were selected in the study and dissolution testing in 6.8 pH Phosphate buffer was conducted from each brands for 30 minutes by using dissolution testing apparatus USP type-II. The result show that all brand fulfill the specification of dissolution profile and Fumycin' manufactured by Pfizer was comparatively better dissolution than other Fluconazole tablets used in experiments. Results and discussion The response of the drug was found to be linear in the investigation concentration range and the linear regression equation was $y=0.0982x-0.0086$ with correlation coefficient is 0.9989.(20)

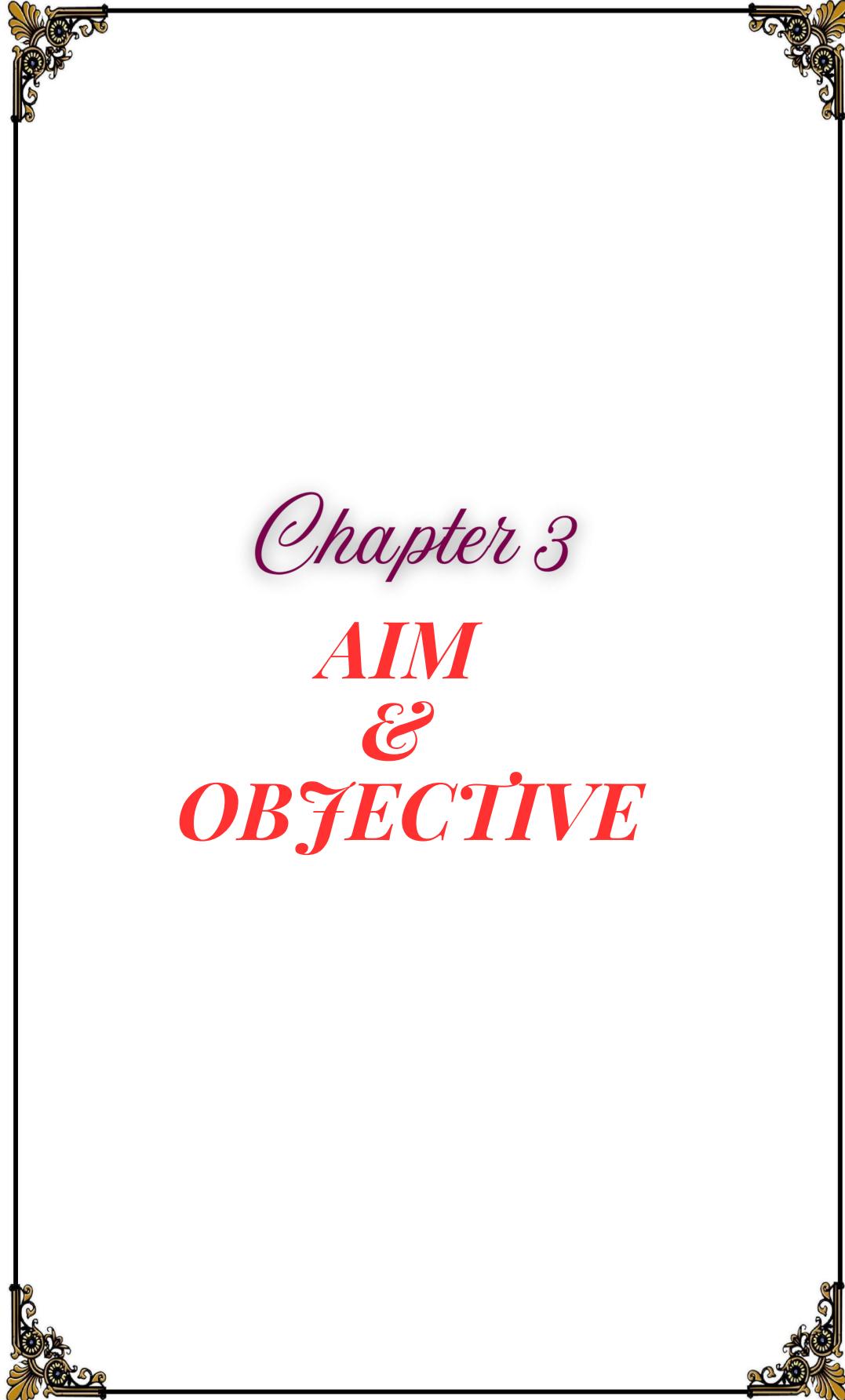
2. Hetal Jilubhai Jebaliya , Madhavi Patel, Batuk Dabhi (2024) described the simplest stability indicating reversed phase Isocratic HPLC and UPLC methods has been developed and validated for the determination of fluconazole in bulk and solid pharmaceutical dosage form. A Sun Fire C18 (250 × 4.5 mm, 5 µm particle size) column has been used for HPLC and BEH C18 (100 × 2.1 mm, 1.7 µm particle size) column used for UPLC. The Mobile phase consisted of Methanol: Water (70: 30) for HPLC and Methanol: Water (55 : 45 v/v) for UPLC. Isocratic flow was set at 1 mL/min and 0.30 mL/min, respectively, for HPLC and UPLC. For both HPLC and UPLC system detection has been performed at 211 nm with 30°C column oven temperature (good elution was obtained at 30°C) and injection volume, respectively, 2 µL and 20 µL for HPLC and UPLC.(21)

3.Mohammed mm , Haneen Abdulhadi Kharaba (2024) compared the main pharmacokinetic parameters of a newly developed generic formula of fluconazole as a test product with the standard reference fluconazole product of Pfizer company under the brand name Diflucan®. Subjects and methods: Twenty-eight volunteers of healthy Iraqi male were involved in this study. The formulations were administered as a single 150 mg dose of the tested and reference fluconazole after an overnight fasting state. Plasma concentration of fluconazole from each volunteer were measured over 24-hour interval using high performance liquid chromatography (HPLC) assay. From serum concentration versus time, data of each subject, the pharmacokinetic parameters represented by the mean ± SD maximum concentration (C max) of fluconazole, time to reach maximum fluconazole concentration (T max), area under the curve (AUC_{0-t}) were calculated. .(22)

4. Multicentre comparative study between fluconazole and itraconazole in vulvovaginal candidiasis (VVC) Newton De Carvalho , E. Baract , P.S.V.

Naud, Giraldo Cesar Paulo(2024) compared the effect of fluconazole and itraconazole in treatment of vulvovaginal candidiasis. Methodology: In a multicenter comparative study 181 patients were randomized to receive one of two therapeutic schemes: Fluconazole - 150 mg single dose or Itraconazole - 400 mg one day dose. The evaluation was made 8 to 10 days (first control) and 28 to 32 days (second control), after the treatment. Clinical and mycological (laboratory yeast culture) data was obtained at the start of the treatment and two subsequent controls. Clinical efficacy was considered positive for patients that were cured or improved and negative in case of failure or relapse. The micologic efficacy was considered positive when no yeast were observed in culture and negative when the yeast remained, relapsed or in case of superinfection. The statistic level of significance to analyse was 5%.(23)

5. Comparative Study of Fluconazole and Clotrimazole for the Treatment of Vulvovaginal Candidiasis (2024) introduced the triazole antifungal agent fluconazole, which can be used via an oral route and single dose, has had a significant impact on patient compliance. There were 53 women in the group treated with fluconazole and 50 in the group treated with clotrimazole. There was no significant difference between the two groups regarding clinical characteristics (age and length of follow-up period). Mycological cure rates approximately 1 week after treatment were 79.2% in the fluconazole group and 80.0% in the clotrimazole group. Approximately 4 weeks after treatment, these rates were 60.4% and 66.0%, respectively. The side effects were minimal and did not warrant any treatment. The differences in the results were not statistically significant.(24)



Chapter 3

***AIM
&
OBJECTIVE***

CHAPTER 3**AIM AND OBJECTIVE****3.1 AIM:**

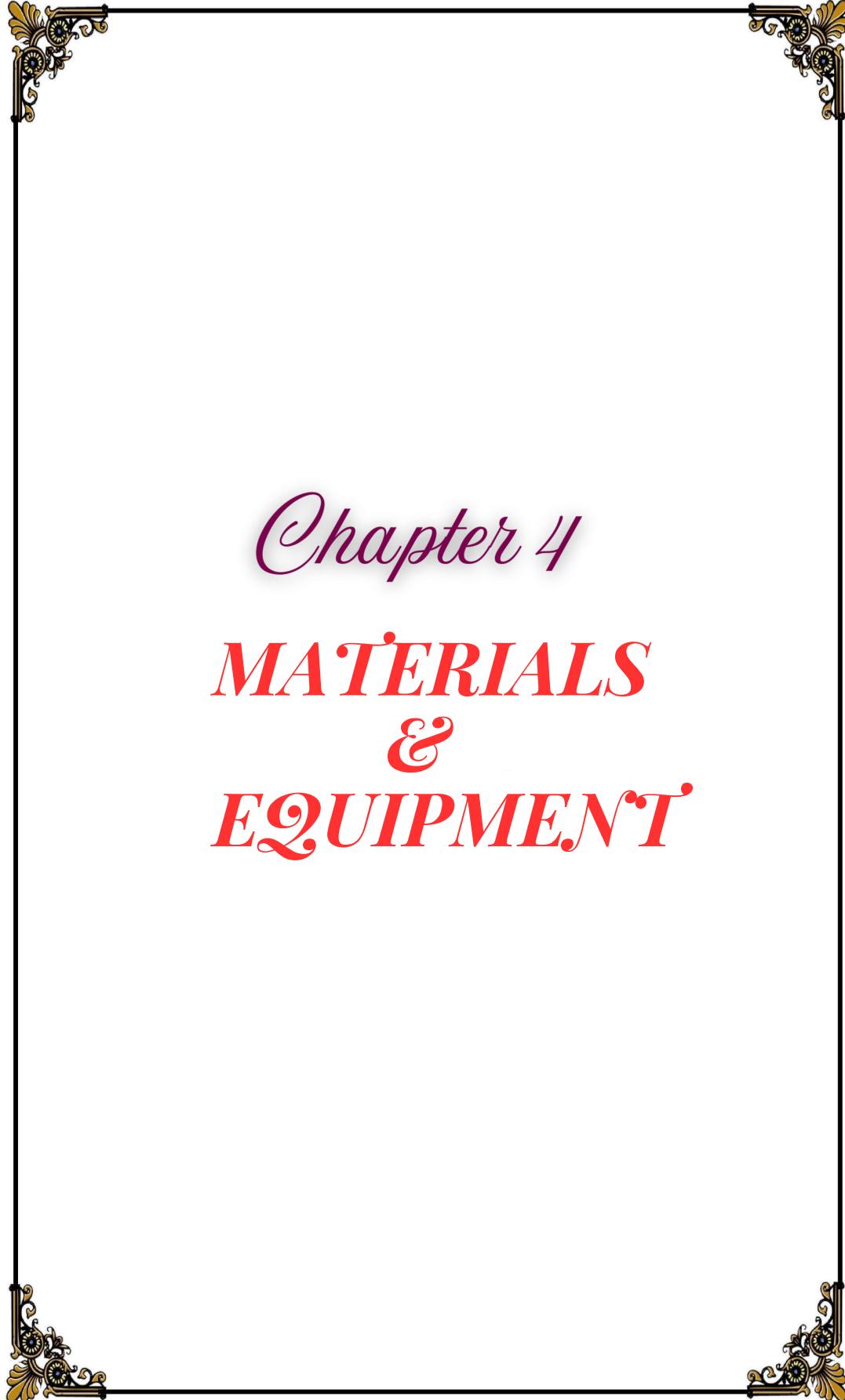
The main aim of this research is to compare and evaluate different marketed brands of fluconazole (1%w/w) dusting powders.

3.2 OBJECTIVES:

The main objective of this study is to evaluate four different brands (B1-B4) of commercially available fluconazole (1%w/w) dusting powders, which are used in the treatment of fungal infections, to get awareness that which pharmaceutical company gives appropriate active ingredient present in dosage forms released into the market.

3.3 PLAN OF WORK:

1. Collection of literature review
2. Selection and collection of different marketed brands of fluconazole dusting powders.
3. Evaluation of different marketed brands of fluconazole dusting powders
 - ❖ Bulk density
 - ❖ Tapped densit
 - ❖ Angle of repose ,Carr's index , Moisture content
 - ❖ pH
 - ❖ Hausner's ratio , Antimicrobial activity
 - ❖ Abrasiveness
 - ❖ Physical characteristics



Chapter 4

**MATERIALS
&
EQUIPMENT**

CHAPTER 4**MATERIALS AND EQUIPMENTS****4.1 MATERIALS:**

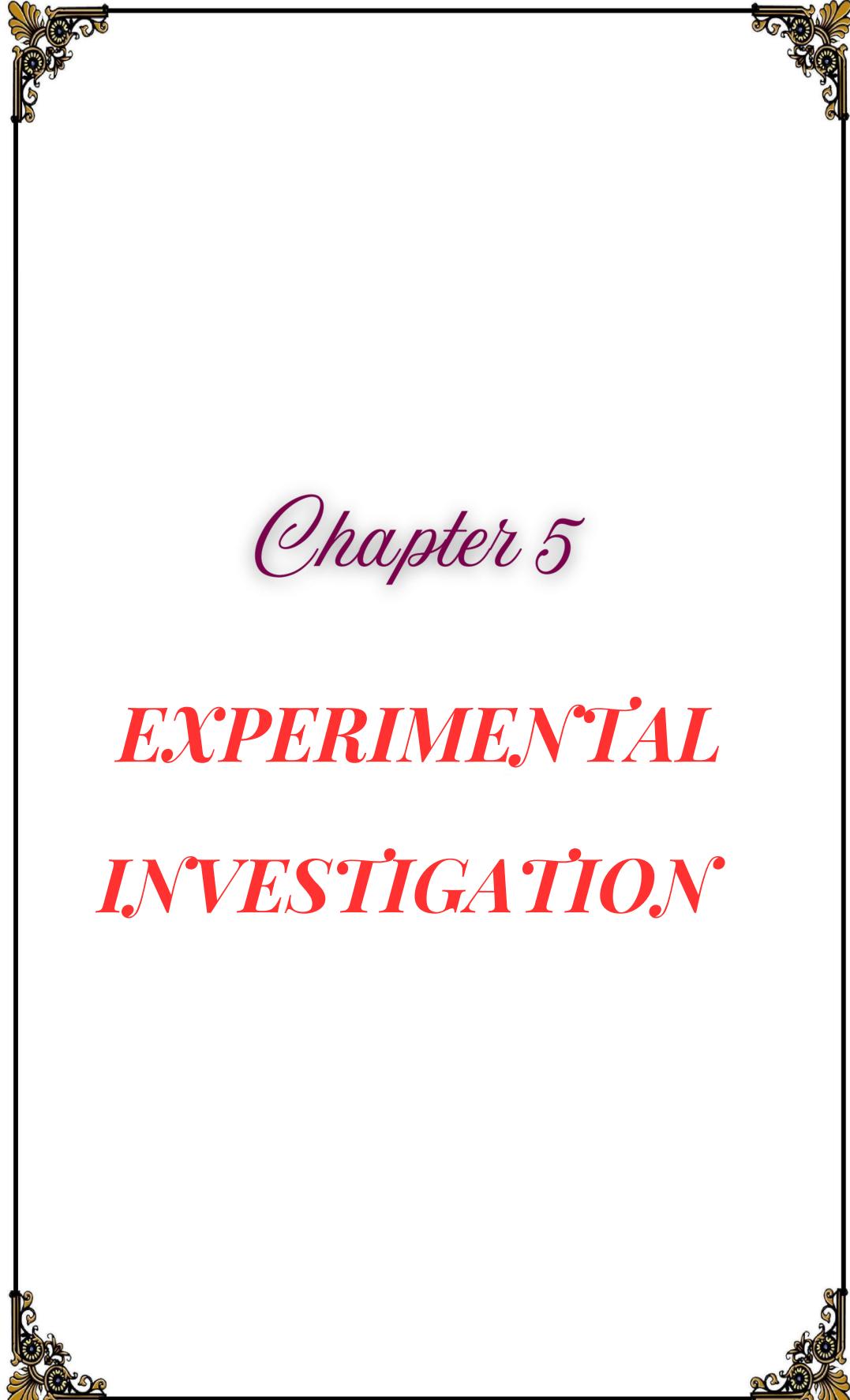
Sl. No	Materials	Manufacturer
1.	Fluconazole	Nanzmed Sciences Pharma pvt.ltd (Himachal Pradesh) Leeford Health Care pvt.ltd (Punjab) Swastic Life Sciences pvt.ltd (Haryana) Oaknet Health Care pvt.ltd (Mumbai)

4.2 EQUIPMENTS :

Sl.No	Instrument	Manufacturer
1.	Digital Weighing balance	Vibra technologies
2.	pH meter	Electronic India
3.	Funnel	Medical equipment India
4.	Hot air oven	Remi Elecktrotechnik Ltd
5.	Measuring cylinder	Medical equipment India
6.	Incubator	Yatherm scientific
7.	Petri plates	Medical equipment India

4.3 TABLET INFORMATION:

Code assnd	Brand name	Manufacturer	Batch no	Mfd.date	Exp.date
B1	Swiss Flu	Swastic Life Sciences pvt.ltd	JE91014	SEPT 2023	AUG 2025
B2	Flumet	Leeford Health Care pvt.ltd	LSP20047	AUG 2024	MAY 2026
B3	One Can	Nanzmed Sciences Pharma pvt.ltd	N2840016	JULY 2024	FEB 2026
B4	Flubec	Oaknet Health Care pvt.ltd	VDCP-021	JAN 2022	JUNE 2025



Chapter 5

**EXPERIMENTAL
INVESTIGATION**

CHAPTER 5
EXPERIMENTAL INVESTIGATION

5. EXPERIMENTAL METHODS:**5.1 ANGLE OF REPOSE: -**

The angle of repose was determined by fixed funnel method. The funnel was fixed in a place, 4cm above the bench and then weigh 10gm of each powder and then powder was allowed to flow from the funnel, the height of cone and radius of cone was measured.

$$\text{Angle of repose} = \tan^{-1}(h/r)$$

5.2 PHYSICAL CHARACTERISTICS:

The colour, odour and appearance of powder is evaluated by simple visualization of powders.

5.3 pH :

The pH of powder was measured by using the pH meter. Weigh 0.1gm of powder and dissolve it in the distilled water and then place the solution in the pH meter and it gives visual reading of pH.

5.4 BULK DENSITY:

The 10gm powder of powder is weighed and passed through the sieve no.18 in a pre-weighed graduated cylinder and noted the volume of the powder.

5.5 ABRASIVENESS:

Abrasiveness was studied by rubbing the powder on a surface and then studying the surface under the microscope.

5.6 TAPPED DENSITY:

The tapped density was measured with the tapped density tester after tapping the measuring cylinder in increments of 50,100,150 times with 50 drops per minute.

$$\text{Tapped density} = \frac{\text{mass of granules}}{\text{volume of granules}}$$

5.7 CARR'S INDEX:

The bulk and tapped densities were used to calculate Carr's compressibility index to provide measure of flow properties and compressibility of powders.

Carr's index calculated by the following equation

$$\text{Carr's index} = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \times 100$$

5.8 HAUSNER'S RATIO:

It is derived from the tapped density and bulk density. It is the indicative of flow properties.

Hausner ratio is calculated by the following equation

$$\text{Hausner ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

5.9 ANTIMICROBIAL ACTIVITY:

The antimicrobial activity of powders was tested by using well diffusion method using cup plate method against *Staphylococcus aureus* and *Escherichia coli*.

Agar preparation:

Ingredients	Quantity
Peptone	5gm
Sodium citrate	5gm
Beef extract	3gm
Agar	20gm
Distilled water	1000ml

- Put the weighed amount of ingredients in 500ml distilled water.
- Heat with agitation to dissolve the constituents.
- Makeup the volume to 1 litre with the distilled water.

- Adjust the pH of medium to 7 by using pH meter or by adding alkaline.
- Pour 10ml per test tube.
- Put cotton plug to the test tubes.
- Autoclave at 121°C , 15lb pressure for 15-20mins.
- Pour the broth into the Petri plates.

Well Disc diffusion method:

Clean every one of the instruments, jars and media that are expected for the pouring procedure. Clean your workspace utilizing a sanitizer. Set up the Bunsen burner in your workspace. Clean up with a germ-free arrangement prior to taking care of any microbial arrangement. Streak the plate with the microorganism and then make the holes on the plate by using the borer. About 1gm of powder was dissolved in the distilled water until it converts into a solution. Pour the solution about $1\mu\text{g}/\text{ml}$ into each bore. Incubate the plates at 32-37°C for 48hours. Then measure the zone of inhibition around the well.

5.10 IRRITANCY TEST:

Mark an area of (1sq.cm) on the left-hand dorsal surface. Definite quantities of dusting powder were applied to the specified area and time was noted. Irritancy, erythema, oedema was checked regularly for up to 24 hours and reported.

Chapter 6

***RESULTS
&
DISCUSSION***

CHAPTER 6**RESULTS AND DISCUSSION**

In the present study, 4 brands of marketed Fluconazole dusting powders formulations were taken and evaluated for physical parameters.

6.1 COMPARISION OF PHYSICAL PARAMETERS OF MARKETED FLUCONAZOLE DUSTING POWDERS

The following physical parameters were evaluated for the marketed Fluconazole dusting powders

Parameters	B1	B2	B3	B4
Colour	White	White	White	White
Odour	characteristic	characteristic	characteristic	characteristic
Appearance	smooth	smooth	smooth	smooth
Abrasiveness	No grittiness	No grittiness	No grittiness	No grittiness
Bulk Density	0.39 g/cm ³	0.44g/cm ³	0.46g/cm ³	0.36g/cm ³
Tapped Density	0.41 g/cm ³	0.47 g/cm ³	0.50 g/cm ³	0.40 g/cm ³
pH	6.4	6.3	6.5	5.8
Angle of repose	34	33	30	35
Hausner's ratio	1.05	1.06	1.08	1.11
Carr's Index	4.87	6.3	8	1
Moisture Content	15.7 %	9.5 %	6.3 %	8.2 %
Zone of Inhibition	20mm	21 mm	23mm	18mm
Irritancy test	No	No	No	No

- Physical Characteristics** - The Physical Characteristics of the Powder was evaluated. The Colour of the Powder was White with characteristics odour and Smooth appearance.

CHAPTER 6

RESULTS AND DISCUSSION

2. **pH of the Formulation** - The pH of the dusting powder was determined by digital pH meter. 1gm of powder was dissolved in 100 ml of distilled water and the pH was measured. The pH was found to be Acidic
3. **Particle Size** - The Particle size of the powder was found and range was found to be 0.125mm [125 microns]
4. **Abrasiveness** - The powder was found for absence of grittiness
5. **Bulk density** - The bulk density of the powder was found to be 0.36g/cm³
6. **Tapped Density** - The Tapped density of the powder was found to be 0.40g/cm³
7. **Angle of repose** - The Angle of Repose of the powder was found to be 35
8. **Carr's index** - The Carr's Index of the powder was found to be 1
9. **Hausner's ratio** - The Hausner ratio of the powder was found to be 1.11
10. **Moisture Content** - The Moisture content was found to be 8.2 %



All the brands of marketed Fluconazole dusting powders passed all the performed evaluation parameters as prescribed. Even though all the brands passed the evaluation parameters, there was variation in Fluconazole dusting powders from brand to brand in the zone of inhibition which tells us about the therapeutic activity. Based on the zone of inhibition values, the brand-3(B3) had better zone of inhibition i.e;23 mm in the nutrient dextrose agar media against *Candida albicans* with good antifungal activity.

Chapter 7

**SUMMARY
&
CONCLUSION**

CHAPTER 7

SUMMARY AND CONCLUSION

7.1 SUMMARY:

The main objective of the work was to evaluate fluconazole marketed dusting powders of various brands to indicate which brand shows good antifungal activity. The marketed dusting powders was then evaluated for various parameters such as physical characteristics (colour, odour, grittiness, appearance), pH, micromeritic properties such as particle size, density (bulk, tapped), angle of repose, carr's index, hausner's ratio. This preference stems from various factors including the non-invasiveness, ease-of-use, antifungal activity, patient compliance and reliability of topical dosage forms.

The project work entitled "**COMPARITIVE STUDY OF DIFFERENT MARKETED BRANDS OF FLUCONAZOLE DUSTING POWDERS**" described in the research to create awareness that which pharmaceutical company gives appropriate active ingredient and therapeutic activity present in dosage forms released into the market.

The colour of the marketed dusting powders was white with characteristic odour and smooth appearance.

The pH of the marketed dusting powders was determined by digital pH meter and it was found to be acidic.

The particle size of the marketed dusting powders was found to be 0.125mm [125 microns]

The Angle of Repose of the marketed dusting powders was found to be in the range of 30-35. The marketed powders have excellent flow properties.

The Carr's Index of the marketed dusting powders was found to be 1-8. The Hausner ratio of the marketed dusting powders was found to be 1.08-1.11.

The Moisture content of marketed dusting powders was found to be in the range of 6.3%-8.2%.

The zone of inhibition of marketed dusting powders was found to be in the range of 18-23mm.

7.2 CONCLUSION:

The main objective of the present study was to evaluate four different brands of commercially available Fluconazole dusting powders. Fungal skin infections are common worldwide, but are more likely to develop in people living in tropical climates. Dermatophytes are the most common pathogens causing superficial fungal infections. Successful management of dermatophytosis is challenging due to the change in epidemiological factors and the emergence of drug resistant organisms. Appropriate dose and duration of drug in a compliant patient helps achieve successful clinical and mycological curc. Topical antifungal medication particularly Fluconazole is frequently prescribed for localized superficial fungal infections. It is an effective, safe and well tolerated drug. In addition to pharmacological therapy, general measures and lifestyle changes also play a crucial role in preventing recurrences.

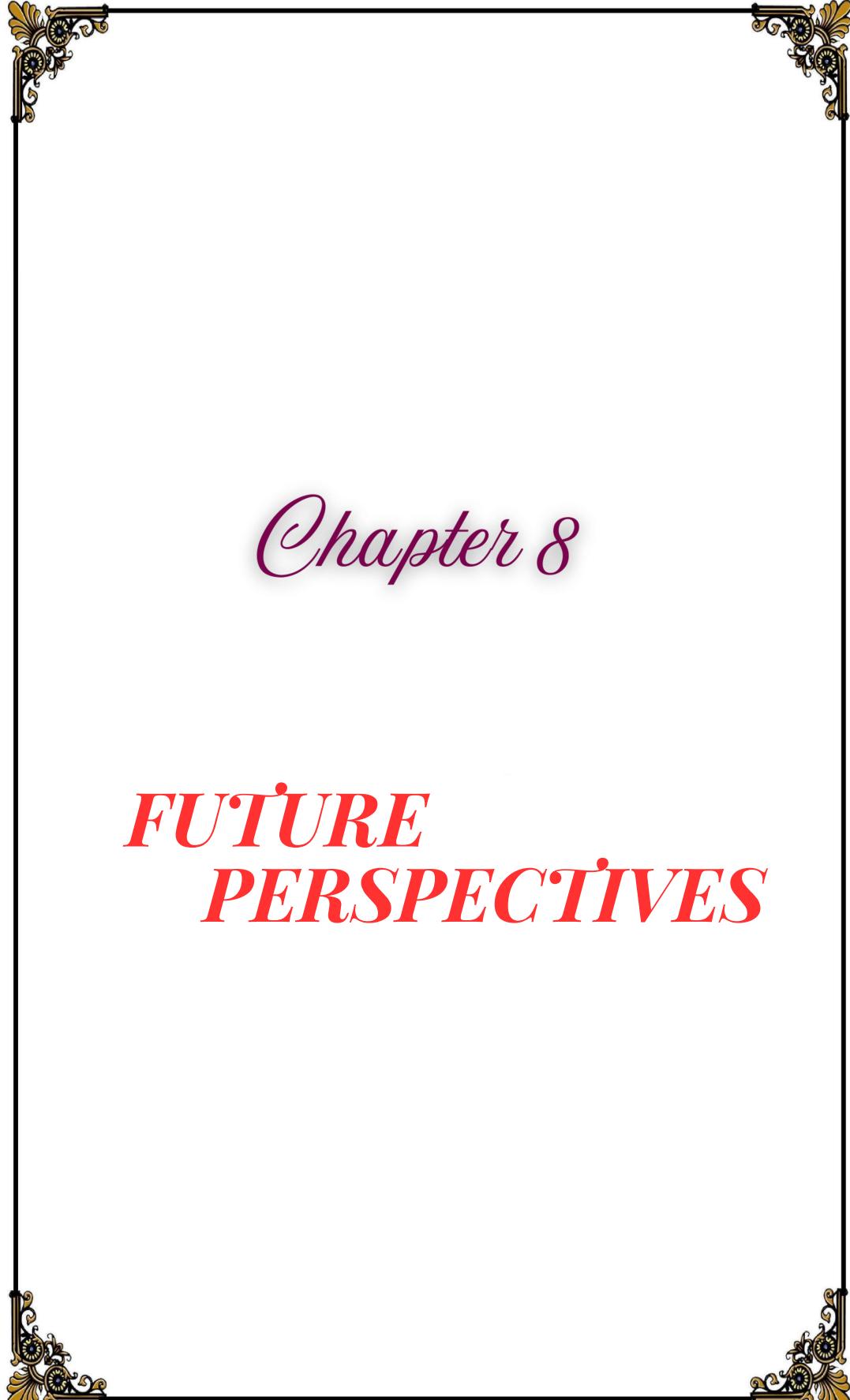
From the results of this pilot study, it can be inferred that the tested brands passed all the tests as prescribed. Formulation excipients added in the powder during manufacturing processes vary from manufacturer to manufacturer which may be one of the reasons for the variation in the observed zone of inhibition and physical parameters. So, it is concluded that it is highly important to assess the performance of drug products post marketing and there is need for strengthening the role of the

Drug testing laboratory wing of Drug and Food control organisation (DFCO) by the Government. DFCO should take further necessary steps with the manufacturing units to ensure the continuity in the enhancement of quality of generic products

We strongly recommend the manufacturers to change their manufacturing process to meet the requirements regarding the amount of the drug and therapeutic activity present in the dosage form as per label claim so that there will be better in-vitro performance and on application of powder dosage form good therapeutic activity will also be seen.

All brands passed the physical parameters and they were be within the limits.

The formulation no B3 of marketed dusting powder was found to be in compliance with all properties of powder and exhibited satisfactory results. The evaluation studies of B3 formulation shown good antifungal activity than other formulation batches. From the given study, it can be concluded that all the four formulations of dusting powder prepared were good and had all the properties, but formulation B3 exhibited satisfactory results for the treatment of fungal infections.



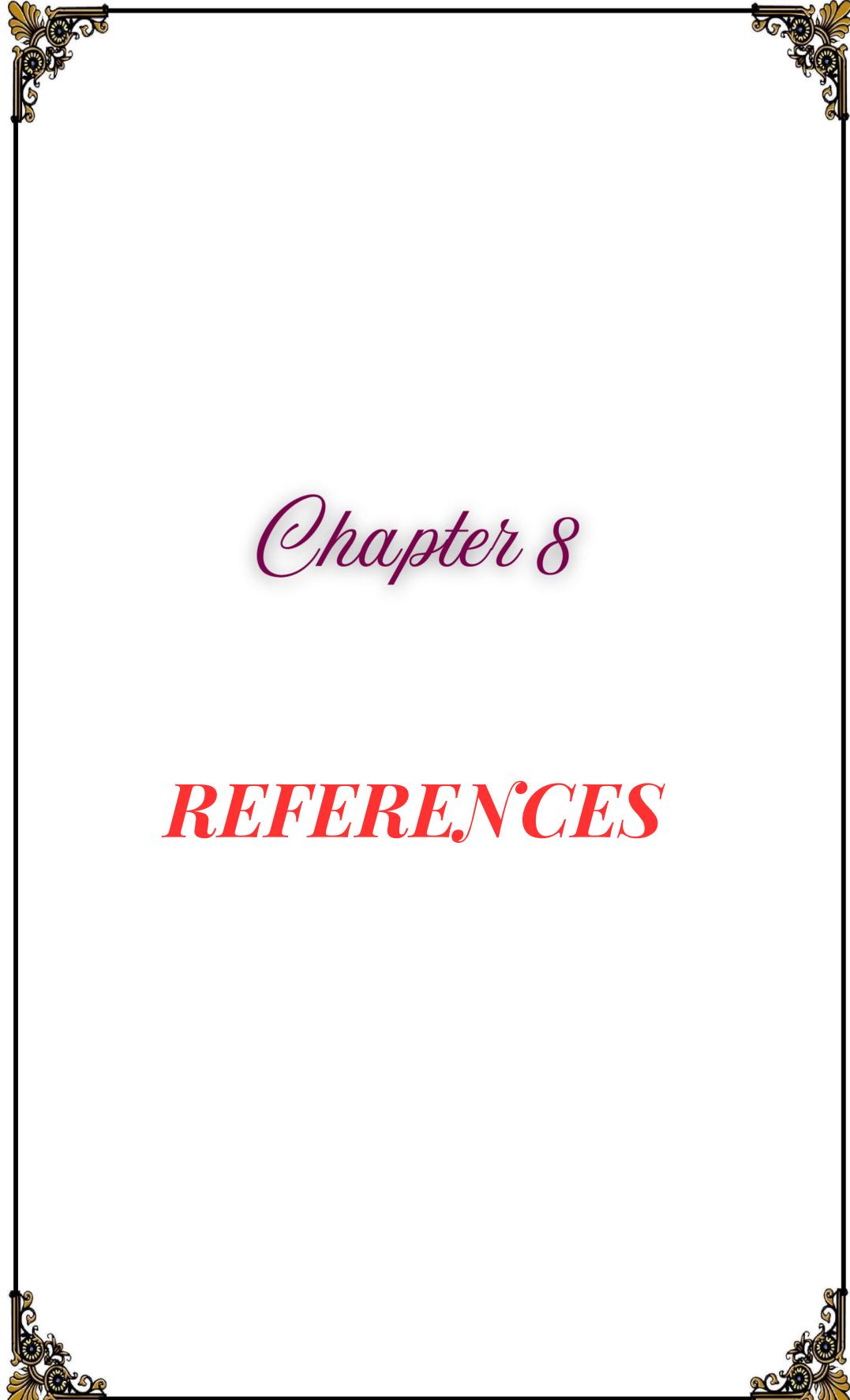
Chapter 8

**FUTURE
PERSPECTIVES**

CHAPTER 8
FUTURE PERSPECTIVES

The future perspectives of the study is that further experiments can be carried out by

- Accelerated and long term stability studies.
- ANNOVA studies
- *In-vivo* studies using different animals and to study the pharmacokinetic and Pharmacodynamics parameters.



Chapter 8

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