2026 Volume: 02 Issue: 03 www.ijrpa.com ISSN 2456-9995 Review Article

International Journal Research Publication Analysis

Page: 01-28

ADVANCING QUALITY STANDARDS IN ANTIFUNGAL EMULGEL DEVELOPMENT

***Mahesh Pawar, Prof. Anjali Rathod , Trupti Erkhede**

Gawande College of pharmacy, Sakharkherda.

Article Received: 23 January 2026
Article Revised: 13 February 2026
Published on: 05 March 2026

***Corresponding Author: Mahesh Pawar**
Gawande College of pharmacy, Sakharkherda.

DOI: https://doi-doi.org/101555/ijrpa.4116

INTRODUCTION

Throughout history, various diseases have adversely affected human health, prompting continuous efforts to develop new drug molecules and delivery methods. The selection of a drug's route of administration depends on several factors, including the severity and type of the disease, the urgency of treatment, and the location of the affected area. Each drug delivery system and route of administration has its own advantages and limitations. Topical drug delivery refers to the application of a drug formulation—such as a cream, gel, lotion, emulsion, or suspension—directly to the skin for localized action. The skin, being the largest organ of the human body, accounts for approximately 10–15% of total body weight. It is composed of four distinct layers, each with unique cellular structures and compositions. Most topical preparations are meant to be applied to the skin, so basic data on the skin and its physiological functions are very important for designing topical dosage forms. The skin of an average adult body covers a surface area of approximately $2m^2$ and receives about one-third of the blood circulating through the body. When a drug is applied to the skin for localized therapeutic effect, it is classified as a topical route. However, when the same formulation is intended to deliver the drug into the systemic circulation through the skin, the route is referred to as transdermal. The skin is readily accessible and convenient for drug administration, and once a formulation is applied, the drug permeates the skin depending on its physicochemical properties and permeability. On average, human skin contains 40-70 hair follicles and 200-300 sweat ducts per square centimetre. The pH of the skin varies from 4 to 5.6, influenced by sweat and fatty acids secreted from sebum. The skin can be considered to have four distinct layers of tissue

Introduction to Antifungal Agents

An antifungal (or antimycotic) is a medication that kills or stops the growth of fungi, a type of microorganism that causes infections like athlete's foot, ringworm, and candidiasis in humans, animals, and plants. Antifungals are available in different forms, including topical creams, ointments, powders, shampoos, and oral tablets or liquids, and they are used to treat various fungal diseases, from superficial skin infections to more severe systemic infections. Antifungals work by targeting specific components of fungal cells, such as their cell walls or membranes, to either destroy the fungi or inhibit their ability to grow and reproduce. Antifungal agents are pharmacological compounds used to prevent or treat fungal infections by targeting specific components of fungal cells, such as the cell membrane (ergosterol), cell wall, or nucleic acid synthesis. Unlike bacteria, fungi are eukaryotic organisms with complex cellular structures, making selective toxicity a challenge. The major classes of antifungal drugs include polyenes (e.g., amphotericin B), azoles (e.g., fluconazole, itraconazole), echinocandins (e.g., caspofungin), allylamines (e.g., terbinafine), and antimetabolites (e.g., flucytosine) Fungal infections have emerged as a significant public health concern worldwide, ranging from superficial mycoses such as dermatophytosis and candidiasis to life-threatening systemic infections like aspergillosis and cryptococcosis. The increasing prevalence of opportunistic fungal infections is largely associated with the rise in immunocompromised populations, including patients with HIV/AIDS, cancer, diabetes, and those undergoing organ transplantation or receiving immunosuppressive therapies Despite advances in antifungal therapy, issues such as drug resistance, limited spectrum of activity, toxicity, and drug–drug interactions continue to pose challenges. Current research focuses on novel antifungal targets, nano carrier-based delivery systems, and repurposing of existing drugs to enhance efficacy and safety profiles. Thus, antifungal agents play a vital role in modern medicine, and ongoing efforts are directed towards overcoming resistance, improving patient outcomes, and developing safer, broad-
spectrum therapies.

Emulgel

Emulgels are a mix of two things: emulsions and gels. An emulsion is a mixture where either oil is spread out in water (called oil-in-water) or water is spread out in oil (called water-in-oil). When this emulsion is mixed with certain special ingredients called polymers, it becomes thicker and turns into a gel. Emulgels are very useful for delivering hydrophobic drugs (drugs that do not mix well with water) and have a high ability to penetrate the skin.

Because they combine the benefits of both emulsions and gels, emulgels are one of the best options for applying such medicines to the skin and has been extensively used to formulate cosmetics and pharmaceutical products.

Advantages of emulgel :-

Emulgel is an evolving field for the topical drug delivery, few of the benefits of emulgel have been mentioned below.

1. Improved patient acceptability.
2. Offer targeted drug delivery.
3. Termination of the therapy at any time.
4. Enhanced bioavailability as well as the low doses can be effective in comparison with other conventional semi solid preparation.
5. Became a stable formulation by decreasing surface interfacial tension which leads to increase the viscosity of aqueous phase.
6. Hydrophobic drug can be easily incorporated in emulgel form by using emulsion as the drug barrier which is finally dispersed into gel.
7. Providing the controlled effect of that helps to prolong the effect of the drug with a short half-life.
8. Easy to formulate and cost effective preparation.
9. Drug loading capacity is better than other novel dosage forms like niosomes and liposomes
10. Skin penetration is enhanced due to both hydrophilic and hydrophobic nature.

Disadvantages of emulgel

1. Poorly soluble and poorly permeable drugs cannot be given through skin.
2. Air entrapment may happen during manufacturing which leads to foam generation in the formulation.
3. Drug molecule with high molecular cannot be given through Emulgel.
4. Drug molecule with large particle size not easily permeable through the skin.
5. Skin irritation or allergic reaction may develop on contact dermatitis.

1. Permeation enhancers should not have affinity to receptor sites.

Example :- Dimethyl sulfoxide, Diethylene glycol monoethyl ether, N-methyl pyrrolidone, laurocapram, ethanol, menthol, propylene glycols, etc.

i. Preservatives

Antimicrobial Preservatives are a synthetic or non-synthetic chemical substance which reduces the microbial growth in drug, Excipient and formulation and increases the shelf-life. Each preservative has antimicrobial activity in the specified range. Selection of preservative must be done based on antimicrobial activity in specified pH range. Preservative should protect the finished formulation from both gram positive and gram-negative micro-organism. The topical formulation contains 50.0-80.0% of purified water and purified water is the most favourable environment for microbial growth. So, preservatives are the essential component of the topical formulations.

ii. Anti oxidant

Antioxidants are the synthetic or non-synthetic chemical substance which retards the oxidation of active substances and excipient in final formulation and increases the shelf-life of the formulation.Examples:

Butylated hydroxyl toluene (BHT), Ascorbyl palmitate, butylated hydroxyl anisole (BHA), Ascorbic acid, Vitamin E, etc.

For each antioxidant and antimicrobial preservative, the application should contain:

1. Reason must be justified for inclusion in the formulation
2. Safety and Efficacy of the agent must be proven.
3. The analytical method to estimate the concentration in the finished product to have control.
4. ntioxidant or anti-microbial preservative concentration must be labelled on the finished product label.

iii. Humectant

The humectant is a substance added in the formulation to retain or hold the water or moisture in the formulation. Humectants are the group of hydrophilic compounds which are frequently used in skin care formulations with the purpose to diminish the clinical symptoms of skin dryness. Hydration of skin has an impact on the permeation of drug through the skin. Humectants are used especially in a skin lotion or a food additive, to reduce the loss of moisture. Humectant helps the skin to retain the moisture in the skin. Examples: Glycerine, Propylene glycol, Urea, hyaluronic acid.

2. Permeation enhancers should not have affinity to receptor sites.

Example :- Dimethyl sulfoxide, Diethylene glycol monoethyl ether, N-methyl pyrrolidone, laurocapram, ethanol, menthol, propylene glycols, etc.

iv. Preservatives

Antimicrobial Preservatives are a synthetic or non-synthetic chemical substance which reduces the microbial growth in drug, Excipient and formulation and increases the shelf-life. Each preservative has antimicrobial activity in the specified range. Selection of preservative must be done based on antimicrobial activity in specified pH range. Preservative should protect the finished formulation from both gram positive and gram-negative micro-organism. The topical formulation contains 50.0-80.0% of purified water and purified water is the most favourable environment for microbial growth. So, preservatives are the essential component of the topical formulations.

v. Anti oxidant

Antioxidants are the synthetic or non-synthetic chemical substance which retards the oxidation of active substances and excipient in final formulation and increases the shelf-life of the formulation.Examples:

Butylated hydroxyl toluene (BHT), Ascorbyl palmitate, butylated hydroxyl anisole (BHA), Ascorbic acid, Vitamin E, etc.

For each antioxidant and antimicrobial preservative, the application should contain:

5. Reason must be justified for inclusion in the formulation
6. Safety and Efficacy of the agent must be proven.
7. The analytical method to estimate the concentration in the finished product to have control.
8. ntioxidant or anti-microbial preservative concentration must be labelled on the finished product label.

vi. Humectant

The humectant is a substance added in the formulation to retain or hold the water or moisture in the formulation. Humectants are the group of hydrophilic compounds which are frequently used in skin care formulations with the purpose to diminish the clinical symptoms of skin dryness. Hydration of skin has an impact on the permeation of drug through the skin. Humectants are used especially in a skin lotion or a food additive, to reduce the loss of moisture. Humectant helps the skin to retain the moisture in the skin. Examples: Glycerine,

Propylene glycol, Urea, hyaluronic acid.

ANALYTICAL TECHNIQUES

An analytical technique is a procedure or systematic method used to identify, separate, and quantify components within a sample, often by utilizing the physical, chemical, or biological properties of the material. These techniques are employed across various fields, from chemistry and biology to computer science, to gain insights, solve problems, and understand the composition and structure of substances.

Types of Analytical Techniques

1. **Chemical Analysis Techniques**

- Titration – measuring concentration by reacting with a standard solution.
- Gravimetric Analysis – measuring mass of a substance after separation.

2. **Spectroscopic Techniques**

- UV-Vis Spectroscopy – studies light absorption.
- IR Spectroscopy – identifies functional groups.
- NMR (Nuclear Magnetic Resonance) – determines molecular structure.
- Mass Spectrometry (MS) – identifies compounds by mass-to-charge ratio.

3. **Chromatographic Techniques**

- Thin Layer Chromatography (TLC) – quick compound separation.
- High-Performance Liquid Chromatography (HPLC) – precise separation & quantification.
- Gas Chromatography (GC) – separation of volatile compounds

4. **Microscopic & Imaging Techniques**

- Scanning Electron Microscopy (SEM)
- Transmission Electron Microscopy (TEM)
- Atomic Force Microscopy (AFM)

5. **Thermal Analysis**

- Differential Scanning Calorimetry (DSC) – studies phase transitions.
- Thermogravimetric Analysis (TGA) – measures weight change with temperature.

6. **Molecular Biology Techniques**

- PCR (Polymerase Chain Reaction) – DNA amplification.
- Gel Electrophoresis – separation of DNA/proteins.

APPLICATION :-

1. **Clinical and Biomedical:**

- Measuring blood glucose, cholesterol, and other biomarkers for disease diagnosis and monitoring.
- Analyzing drug concentrations in biological samples for pharmacokinetic studies.
- Used in PCR testing for diseases like COVID-19.

2. **Environmental Monitoring:**

- Testing water, air, and soil for pollutants, heavy metals, and other toxic substances.
- Identifying pesticides and other contaminants in various environments.
- Assessing air and water quality.

3. **Pharmaceuticals:**

- Ensuring the purity and shelf-life of drugs.
- Identifying and quantifying impurities and active ingredients in drug formulations.
- Studying the stability of drug molecules and evaluating therapeutic drug monitoring.

4. **Forensic Science:**

- Analyzing evidence from crime scenes, such as blood, fingerprints, and other trace substances.
- Detecting drugs and toxins in biological samples through toxicology studies.

5. **Food and Agriculture:**

- Detecting contaminants, additives, and harmful chemicals in food products.
- Assessing the nutritional content of food, including proteins, carbohydrates, and fats.
- Monitoring mineral content in soil to ensure optimal conditions

6. **Materials Science and Manufacturing:**

- Quality control of industrial products, including semiconductors and nanomaterials.

p. Research and development of new materials with specific chemical and physical properties.

UV-VISIBLE SPECTROSCOPY

Ultraviolet and visible spectroscopy deals with the recording of the absorption of radiations in the UV and visible regions of the electromagnetic spectrum. The UV region extends from 10-400nm. It is sub -divided into the near UV (quartz) region (200-400nm) and the far or vacuum UV region (10-200nm). The visible region extends from 400-800nm.

Absorption of electromagnetic radiations in the UV and visible regions induces the excitation of an electron from a lower to higher molecular orbital (electronic energy level). Since UV and visible spectroscopy involves electronic transitions, it is often called electronic spectroscopy . Organic chemists use UV and visible spectroscopy for detecting the presence and elucidating the nature of conjugated multiple bonds or aromatic ring.

PRINCIPLE

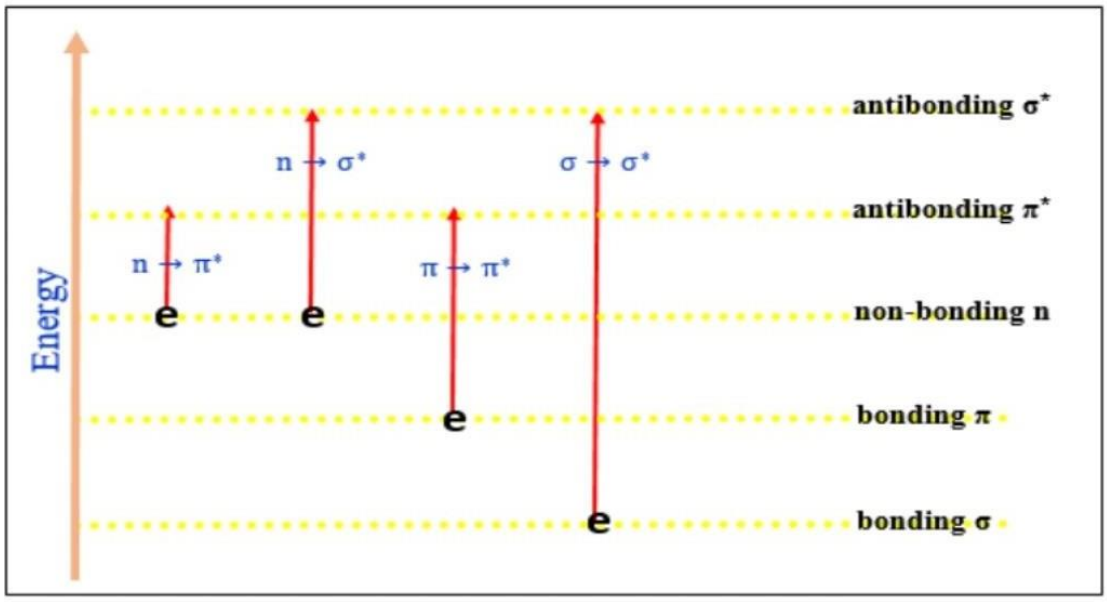
Spectroscopy is unique spectra that are based on the principle of ultraviolet-visible radiation. These spectra are produced when ultraviolet or visible light is absorbed by chemicals. Spectroscopy is based on the interaction of light and matter. The material will undergo phases of excitation and re-excitation when light is absorbed by it, creating a spectrum. When an electromagnetic wave hits matter, it can undergo a number of processes, including transmission, absorption, reflection, and dispersion. When the structure of a molecule or ion is electronically transformed by radiation, the object will exhibit absorption in the visible or ultraviolet range. When light is absorbed by the sample in the ultraviolet or visible range, the molecules of the sample will be electronically altered, Therefore; the electrons will be promoted from their ground state orbit to higher energy orbits excited by the energy of absorbed light or antibonding orbit. There are three possible types of ground state orbits involved: σ (bonding) molecular Orbital and n (bonding) atomic orbital, in addition to two types of antibonding orbitals that may participate in the transition process: Σ* (sigma star) orbital and π* (pi star) orbital. Note that there is no antibonding orbital n* because the n electrons don't form bonds, and as a result electronic transitions can occur by absorbing ultraviolet and visible light.

Absorption of ultraviolet and visible light leads to types of electronic transformations, the most important of which are

1. σ-σ* Transitions: The electron in the bonding orbital σ is stimulated to the anti-orbit that it corresponds to, and this stimulation requires a lot of energy.
2. N-σ* Transitions: These transformations occur in saturated compounds that contain atoms with lone pairs, or unpaired electrons, and they usually require less energy than the energy

needed to convert σ to σ*.

3. N-π* and π -π* Transitions: Electron transitions from n or π to the excited state π*. It is the basis for most absorption spectroscopy of organic compounds. This is because of the spectral range (between 200 and 700 nanometers) suitable for experimentation[1



Electronic Transition

Limitation:

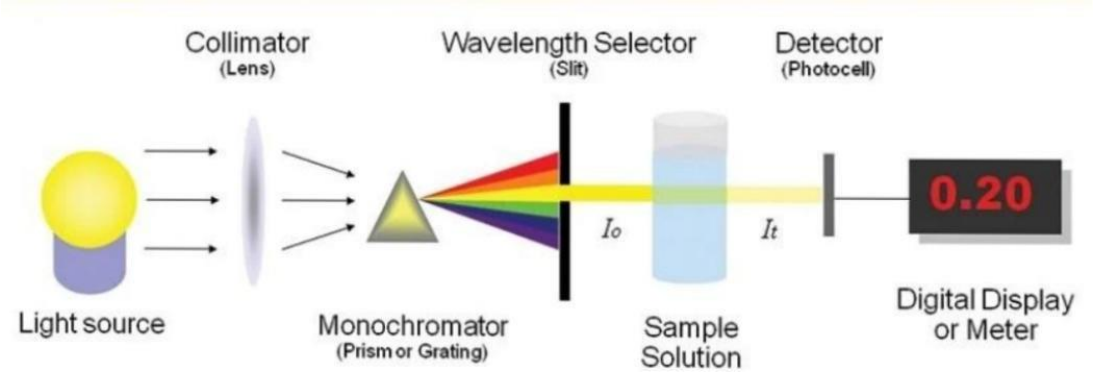
Scattering and reflection can modify the absorption Reported.

1. Reaction with the solvent High concentration

Affects charge distribution, the average Distance between ion decreasing, making particles close to each other.

2. Presence of stray lig.

INSTRUMENTATION



Instrumentation of UV Spectrophotometer

A. Light Source :-

a. Hydrogen lamp: They are highly reliable and stable lamps. The radiation emitted from it is continuous and its range ranges between (160-380) nm.

b. Xenon Lamp: It is a high-energy light source. The wavelength of the light emitted from it ranges from about (250-600) nm in the ultraviolet and visible spectra. The xenon lamp flashes at a frequency of 80 Hz, making it longer lasting than other lamps. In terms of manufacturing, it is the highest cost

c. Deuterium lamp: It is the source that emits ultraviolet radiation and is symbolized by the symbol D2. The wavelength of the radiation emitted from it ranges from about (160-450) nm, and it is more expensive than a hydrogen lamp.

d. Tungsten lamp: It is the most common source used in spectrophotometers, as it operates in the wavelength range between 330 and 900 micrometers

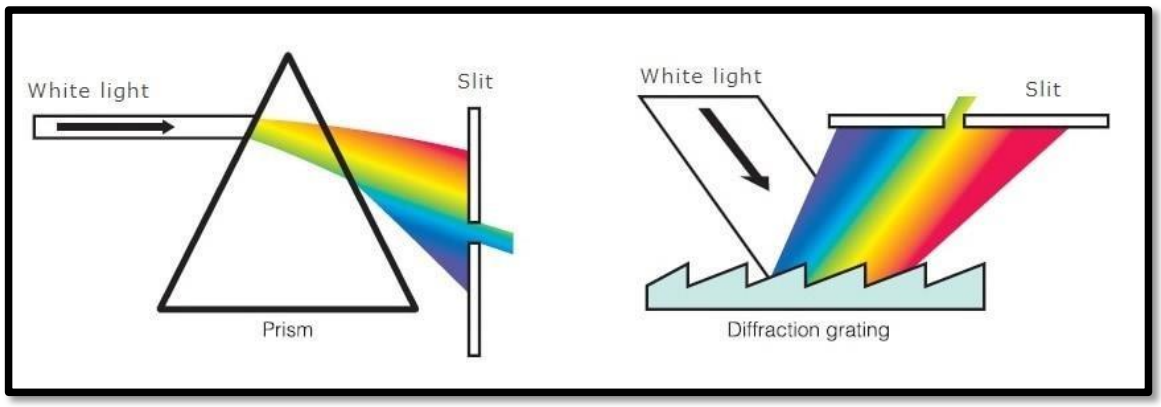
B. Wavelength Selector :-

1. Filters

- Filter permits certain bands of wavelength (bandwidth of ~50nm) to pass through.
- They are used in visible region.
- The simplest kind of filter is absorption filters , the most common of this type of filter is colored glass filters.
- The colored glass absorbs a broard portion of the spectrum and transmits other portion.

2. Monochromators:

Monochrome devices are used to convert multicolored or heterochromatic light into monochromatic light, and are considered better and more efficient than filters.There are two types of Monochromators: prism monochromator and grating monochromator.



C. Sample Compartment (Cells) :-

- For visible and uv spectroscopy, a liquid sample is usually contained in a cell called a **Cuvette**.

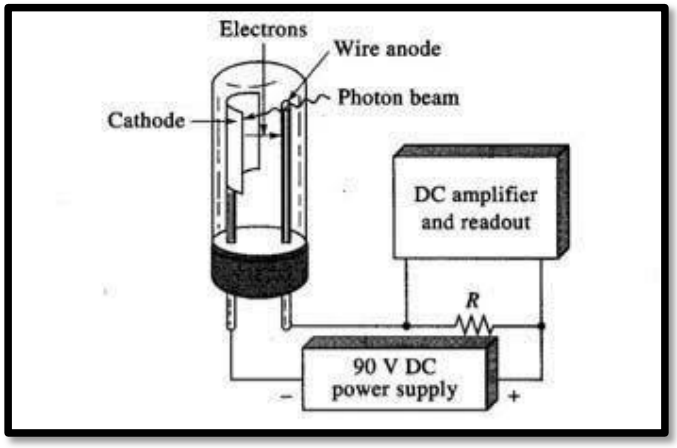
Cuvette

- Glass is suitable for visible but not for uv spectroscopy because it absorbs UV radiation. Quartz can be used in UV as well as in Visible spectroscopy.

D. Detector :-

- The detectors are device that convert radiant energy into electric signal
- A detector should be sensitive, and has fast response over a considerable range of wavelenghts.
- In addition, the electrical signal produced by the detector must be directly proportional to the transmitted intensity (linear response).

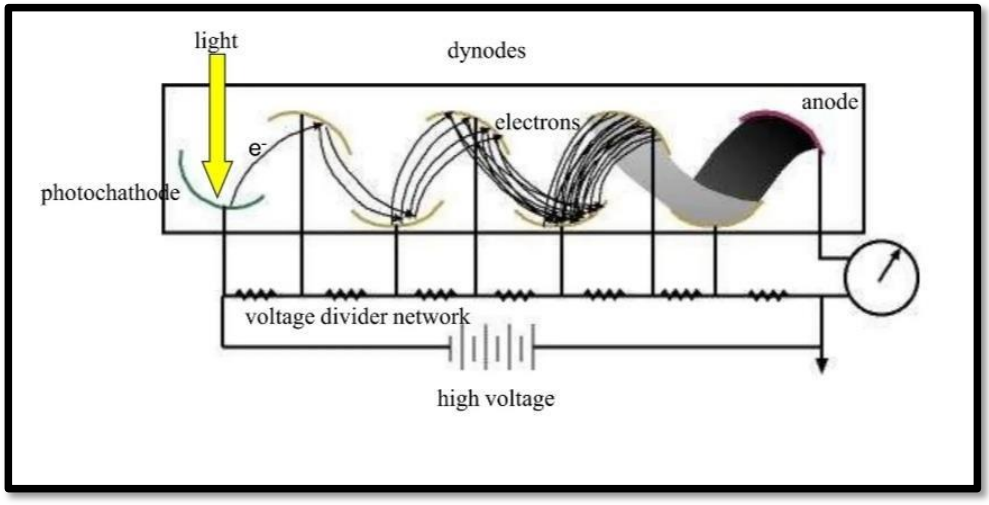
1. Phototube :-



Phototube

- Phototube emits electrons from a photosensitive, negatively charged cathode when struck by visible or UV radiation
- The electrons flow through vacuum to an anode to produce current which is proportional to radiation intensity.

2. Photomultiplier tube



Photomultiplier Tube

- It is a very sensitive device in which electrons emitted from the photosensitive cathode strike a second surface called dynode which is positive with respect to the original cathode.
- Electrons are thus accelerated and can knock out more than one electrons from the dynode.
- If the above process is repeated several times, so more than 105 electrons are finally collected for each photon striking the first cathode.

Application Of UV Spectroscopy :-

1. Quantitative Analysis: UV-Vis spectroscopy measures the concentration of molecules in solution by relating absorbance to concentration using Beer's Law.

2. Qualitative Analysis: It identifies compounds by comparing their unique absorption spectra to known reference spectra.

3. Purity Testing: The technique is used to assess the purity of a sample by detecting impurities that absorb at different wavelengths.

4. Pharmaceutical Analysis: Used for quality control, determining drug content, and verifying the purity and efficacy of pharmaceutical products.

5. Biochemistry: Applied to determine the concentration of proteins, nucleic acids, and to track bacterial growth by measuring optical density.

6. Food and Beverage Analysis: Utilized to measure sugar, lipid, protein content, and detect contaminants in food products.

7. Environmental Science: Helps in the identification and quantification of various pollutants and contaminants in environmental samples.

8. Forensics: Used to analyze dyes and pigments in inks, fibers, and paint chips, and in toxicology.

9. Material Science: Used for characterizing nanoparticles, determining the thickness of thin films, and analyzing the composition of materials like coal and petroleum.

10. Chemical Kinetics: Can monitor the progress and rate of chemical reactions over time.

REVIEW OF LITURATZRE

- **Chaudhari M et.al., (2023)** :- A UV-spectrophotometric method was successfully developed for the quantitative analysis of antifungal agent in both bulk and pharmaceutical formulations. The method employed the Area Under the Curve (AUC) approach, integrating absorbance over the wavelength range of 279–305 nm. The absorption maximum

(λ_{max}) of antifungal agent in methanol was determined to be 295 nm. The method demonstrated linearity over the concentration range of 3–18 µg/mL, with a correlation coefficient (R^2) of 0.997, indicating a strong linear relationship between concentration and absorbance. This confirms the suitability of the method for routine analysis of anti fungal drug in quality control laboratories.

- **Yun-liang L et.al., (2019)** :- The structural characterization of anti fungal drugs was comprehensively studied using a variety of spectroscopic and analytical techniques. Infrared (IR) Spectroscopy, Ultraviolet (UV) Spectroscopy, Nuclear Magnetic Resonance (NMR) Spectroscopy, and Mass Spectrometry (MS) were employed to determine the molecular structure and functional groups present in antifungal agents.In addition, Differential Scanning Calorimetry (DSC) and X-ray Powder Diffraction (XRD) were used to analyze the physical properties of the compound, including thermal behavior and crystallinity. Elemental analysis further supported the molecular characterization of the drug.

- **Masuda T et.al., (2018)** :- had filled patent on Pharmaceutical Composition of anti fungal agents. Disclosed is an antifungal agent for external use, which is characterized by containing a compound represented by the general formula below, 50-95% by mass of an alcohol, and 01-35% by mass of Water and/or an anionic surfactant. They claimed as an antifungal composition for external use, consisting essentially of: 1) Luliconazole; 2) 50 to 95 mass % of an alcohol; and 3) 0.1 to 35 mass % of a third component selected from the group consisting of Water, an amount of an anionic surfactant, and the combination of Water and anionic surfactant Whereby isomerization of the steric structure of the anti fungal agents is suppressed.

- **Desai N J et.al., (2015)** :- has developed UV Spectrophotometric Method for determination of Luliconazole drug content in Marketed product. Simple, more accurate, reproducible, accurate and précised method has been developed. Analysis of Luliconazole was carried out at lambda max 296 nm in the concentration range of 5- 25 ppm with mean recovery of Luliconazole 99.97%. The Limit of detection and Limit of quantification were found to be 0.38ppm and 1.06 ppm respectively. Validation of UV spectrometric analytical method was conducted as per ICH Guidelines.

Emulgel

- **Dhobale S et.al., (2024)** :- has formulated an Emulgel with Carbomer Homopolymer type

B as gelling agent, sorbitan laurate and Polysorbate 20 as emulsifiers, PEG 400 as cosurfactants, Mineral oil as oil phase, methyl paraben and propyl paraben as preservative, and propylene glycol and ethanol as permeation enhancer. All the formulations were evaluated for rheological properties, drug content and physical properties such as description, homogeneity, grittiness and separation. Highest drug release found with high concentration of surfactant and low level of oils.

- **Drais H et.al., (2021)** :- has formulated Nono emulgel of Meloxicam to have better therapeutic activity and reduce systemic side effects. Concentration of oil phase, surfactants and double distilled water for Nano emulsion was optimized with the help of Pseudo ternary phase diagram. Peppermint oil and almond oil were used in concentration ratio 1::2. Concentration of Polysorbate 80 and ethanol were used 1:1, 2:1, 3:1, and 4:1. Formulation with 2.0% oil phase (ratio almond oil 1: peppermint oil 2), 22.5% surfactant (ratio polysorbate 20 3: ethanol was the optimized formulation and it has highest drug release profile among all. Formulations were evaluated for physical, chemical and release kinetics.

- **Navaneetha K et.al., (2021)** :- formulated an emulgel formulation capsaicin. Mineral oil is used as Oil phase in fixed concentration 7.5%w/w. Carbomer Homopolymer Type B in concentration 1-2%, Carbopol 930 1-2%, Hydroxypropyl methyl cellulose in concentration 2-2.5% and Hydroxyethyl cellulose in concentration 5% were used as polymers. Polysorbate 80 in concentration 1% w/w and Sorbitan oleate in concentration 1.0% were used as emulsifiers. Ethanol 2.5% and Clove oil 8% were used as permeation enhancers. Formulation with 1% Carbomer Homopolymer type B has highest drug release and drug release profile follows zero order kinetics.

- **Ambhore N et.al.,(2019)** :- formulated an emulgel of Tapentadol to enhance permeability. Saturation solubility is carried out for oils, surfactants and co-surfactants. Microemulsion was optimized with the pseudo ternary phase diagram and concentration of Light mineral oil, Polysorbate 20 and Polyethylene glycol 400 was finalised. Different grades of carbomer homopolymers are used for formulation with concentration 1.5%-2.0%w/w. Optimized formulation with 1.5%w/w Carbomer
homopolymer has better drug release in-vitro and ex vivo.

- **Pakhare A et.al.,(2018)** :- Formulated emulgel formulation of Diclofenac potassium. Emulsifiers Polysorbate 20 and sorbitan laurate are used along with gelling agent Carbomer

homopolymer Type C (Carbopol 940) and propylene glycol as humectant. Drug excipient compatibility study shows diclofenac potassium is compatible with all the excipients Carbomer, Propylene glycol, methyl paraben, span 20, liquid paraffin, tween 20, propyl paraben and ethanol. The formulation with 2.0% Carbomer homopolymer Type C, 10% mineral oil, 6.0% Polysorbate 20 and 6.0% Sorbitan laurate has maximum drug release 89.72% in 6hr

- **Sonegaonkar Y et.al., (2017)** :- formulated microemulsion based gel of triamcinolone acetonide. The pseudo-ternary phase diagrams were used for optimization of ratios of medium chain triglycerides, Polyoxyl 35 Hydrogenated Castor Oil as surfactant and diethylene glycol monoethyl ether as cosurfactant. Triamcinolone acetonide has the highest solubility in Glyceryl Caprylate. PEG-35 Castor oil has the highest emulsification efficiency with Glyceryl Caprylate to form a stable homogeneous emulsion. The combination PEG-35 castor oil and transcutol p has the highest transmittance and more spontaneous emulsification. Glyceryl Caprylate is more effective in solubilising hydrophobic drug molecule. Carbomer homopolymer type C is used as a gelling agent. Optimized microemulsion base gel sample was studied for in vitro release study and it has shown 98% drug release in 24hr.

- **Sabu K R et.al., (2017)** :- Formulated Terbinafine Hydrochloride Emulgel for Fungal Infections of skin and evaluated for in-vitro drug release from formulations. Factorial design 22 was applied to optimize the concentration of Carbopol, mineral oil, Sorbitan laurate and polysorbate 20. The developed emulgels formulations were evaluated for defined test parameters. Formulation with Mineral oil concentration 8%w/w and emulsifier concentration 3.5%w/w has better stability. The optimized formulation has higher invitro drug release profile than marketed Terbinafine hydrochloride cream. Formulation were stable for 3months at accelerated and room temperature storage condition.

UV – Visible Spectrophotometer

- **Dr. Hemant Kamble et.al., (2024) :-** UV spectroscopy stands as a pivotal and in dispensable characterization technique, offering Profound insights into the properties of diverse samples through the analysis of their interaction with electromagnetic radiation. If used with the right standard curve and applied to pure substances, UV-visible spectroscopy is a reliable, straight forward, and analyzing affordable approach for estimating the concentration of absorbing species. One of the crucial methods for the optical characteristics

of PMCs is UV-visible is spectroscopy. It clarifies the relationship between the matrix and the nanofiller and examines how the nanofillers contribute to the enhancement of the properties of the nanocomposites. To assess the intended optical properties of nanofillers in a polymer matrix, UV-Vis spectroscopy is a crucial technique. The review paper contains all information about UV visible spectroscopy, its principle, theory, instrumentation, advantages, Disadvantage's & its applications. The identification of impurities are Carried out by using UV visible spectroscopy more Accurately & UV visible spectroscopy is a very crucial Spectroscopy.

- **Harshika Jain et.al., (2023) :-** Calibration of UV result was accurate and specific range. A UV spectrophotometric method was developed and validated for pure and formulated letrozole. The UV spectrophotometric methodpd was an accurate and cost- effective method and it is a fast and accurate result. The method is accurate, selective, precise and linear in the studied concentration range. The proposed method is suitable for quality control, routine analysis and determination of letrozole in pure and pharmaceutical dosage form.

- **Jothi Mane et.al., (2023) :-** The fundamental principle of UV spectroscopy lies in the absorption of specific wavelengths of light by samples, and it provides valuable insights into the responses of substances to this absorption. The application of Beer's law, a universal principle in UV spectroscopy, elucidates the absorption of radiant energy by samples. Notably, this method is characterized by its accuracy, simplicity, and a broad spectrum of applications, including drug discovery, structural elucidation of organic molecules, molecular weight determination, and the detection of impurities. Both quantitative and qualitative analyses can be conducted effectively using UV spectroscopy. The equipment operates within a wavelength range of 200nm to 800nm, allowing the analysis of both colorless and colored compounds in both the UV and visible regions. In summary, UV spectroscopy stands as a robust analytical technique with wide-ranging applications.

- **Sargar Komal Bharat et.al., (2023) :-** spectroscopy is used for two measurements techniques; how much analyte is in the sample (quantitative analysis) and Which analyte is in the sample (qualitative analysis). An Area under curve method is "the area under two points on The mixture spectra is directly proportional to the Concentration of the compound of interest" particularly Suitable for the compounds where there are no sharp peak or Broad spectra are obtained. The pharmaceutical analysis by UV-Visible Spectroscopy comprises the procedures Necessary to

determine the "identity, strength, quality and Purity" of compounds. Present review concludes various Applications of UV spectroscopy qualitatively as well as Quantitatively.

- **Dr. Umesh Upadhyay et.al., (2022) :-** UVvisible spectroscopy is a reliable, straightforward, and affordable approach for estimating the concentration of absorbing species. One of the crucial methods for analyzing the optical characteristics of PMCs is UV-Vis spectroscopy. It clarifies the relationship between the matrix and the nanofiller and examines how the nanofillers contribute to the enhancement of the properties of the nanocomposites. To assess the intended optical properties of nanofillers in a polymer matrix, UV-Vis spectroscopy is a crucial technique. The polymer nanocomposites with some optically responsive nanofillers, such as metals, semiconductor nanocrystals, and nano oxides, are characterized using the UV-Vis spectroscopic approach in order to produce functional materials with significant technological applications. UV-Vis Spectroscopy (or Spectrophotometry) is a quantitative technique used to measure how much a chemical substance absorbs light.

- **Yuchen Guo et.al., (2020) :-** UV-Vis spectroscopy techniques have been widely used to detect pollutants in different water environments, including organic and inorganic substances. In this paper, the detection method of water quality parameters, data analysis method, and existing problems are introduced in detail. UV-Vis spectroscopy has become a rapid analysis tool for qualitative and quantitative detection of water quality. Although these studies show the ability of UV-Vis spectroscopy to detect pollutants in water environments, the practical application of UV-Vis spectroscopy in water quality detection is still difficult. One of the main problems is the detection limit. At present, the detection limit of many studies has been below the environmental safety value; however, it is worth noting that the experimental processes have been performed in the laboratory rather than in true field environments. The field environment is complex and contains many pollutants, which have significant impacts on the detection results.

- **David Newport et.al., (2019) :-** There are several molecules of environmental and domestic significance, which show strong deep-UV absorption. This intrinsic property can be exploited for the development of a gas sensor using absorbance measurement at a specific wavelengths range. UV absorption spectrophotometry provides a sensitive, reliable, self-referenced, and selective approach for gas sensors development. Recently, portable and efficient UV optoelectronic and optofluidics components have been developed, for example

LEDs, HCWs, and photodiodes. These portable devices can be utilized to develop a portable deep-UV absorption spectrophotometer, which can rival the analytical performance of a lab-based deep- UV absorption spectrophotometer. LEDs offer a stable, efficient, portable, and a narrow emission-band UV source for analytical applications with ease of alignment, low cost, and enhanced lifetime. The challenges faced by deep-UV LEDs are the need for a highly stable power supply source, low power emission, and their susceptibility to thermal fluctuation. Advances in nitride semiconductors have pushed LEDs into the UV-C band with improved power (1.5 mW) and low parasitic emission, however thermal-induced noise issue is still present. A constant power supply, a well-designed thermal management, and self-reference scheme can minimize this noise and can enhance the stability and intensity of the output signal. Aluminum-based HCWs are an attractive option to be employed as a gas cell due to their efficient UV transmission, ease of alignment, and fabrication process.

- **Karthik Vishwanath et.al., (2010) :-** quantitative UV-visible optical spectroscopy may prove to be a viable alternative to more invasive, or less practical, methods for evaluating biomarkers of cancer for a variety of applications. Recent reports in which quantitative optical cancer biomarkers are clinically validated with currently accepted methods are a welcome addition to the field, as they will set the stage for optical technologies to gain widespread clinical acceptance. It is our hope that the number of groups employing quantitative approaches to tissue optical spectroscopy will only increase, and that continued research will reduce or eliminate any barriers to widespread clinical application of these technologies.

AIM

Advancing quality standards in antifungal emulgel development.

OBJECTIVES

1. Pre formulation Studies – To characterize the physicochemical properties of the antifungal drug and excipients suitable for emulgel formulation.
2. Formulation Development – To design and optimize novel antifungal emulgel formulations using appropriate gelling agents, emulsifiers, and penetration enhancers.
3. Quality Assurance Parameters – To assess physicochemical properties such as pH, viscosity, spreadability, homogeneity, and stability of the formulations as per QA guidelines.
4. In-vitro Evaluation – To evaluate drug release, antifungal activity, and permeation

characteristics of the emulgel formulations.

5. Stability Studies – To conduct accelerated and real-time stability studies in accordance with ICH guidelines to ensure product quality and shelf life.
6. Regulatory & Safety Perspective – To ensure compliance with QA regulatory standards for topical dosage forms, focusing on safety, efficacy, and reproducibility.
7. Comparative Study – To compare the developed formulation with marketed antifungal formulations in terms of efficacy, stability, and quality attributes.

Need of the Study

Conventional topical antifungal formulations often show poor spreadability, low skin penetration, and limited patient compliance, leading to inadequate therapeutic outcomes. Emulgels, by combining the advantages of emulsions and gels, offer enhanced drug solubility, controlled release, non-greasy texture, and better patient acceptability. To ensure safety, stability, and efficacy, it is essential to develop antifungal emulgel formulations under a robust Quality Assurance framework, which guarantees consistency, regulatory compliance, and improved clinical performance.

PLAN OF WORK

1. **Literature Survey**
2. **Preformulation Studies**

a. Drug Characterization: Solubility, partition coefficient, stability, pKa.

b. Excipient Compatibility: Screening oils, surfactants, gelling agents, and preservatives.

c. Analytical Method Development: Validated methods (UV Spectroscopy) for drug quantification.

3. **Formulation Development :-**

a. Emulsion Phase Optimization: Oil-to-water ratio, surfactant blend, HLB value adjustment.

b. Gel Phase Selection: Gelling agents (e.g., Carbopol) optimized for viscosity and spreadability.

c. Prototype Batches: Preparation of trial formulations with varying excipient ratios.

4. **Evaluation & Characterization :-**

a. Physicochemical Tests: pH, viscosity, spreadability, extrudability, particle size.

Antifungal Testing

b. Microbial Testing: Preservative efficacy and sterility tests.

Stability Studies

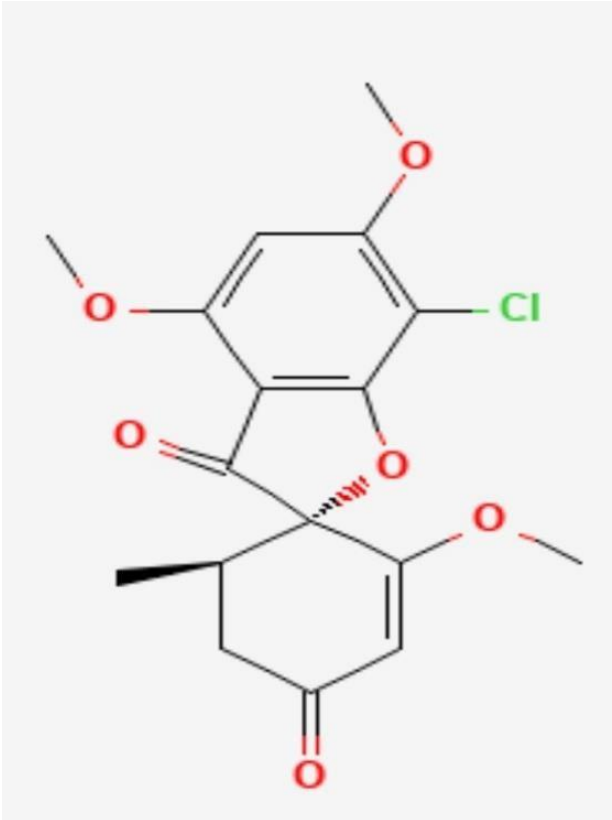
c. **Accelerated Stability Testing:** As per ICH guidelines (temperature/humidity).

d. **Long-term Stability:** Shelf-life prediction.

e. **Packaging Evaluation:** Compatibility with containers/tubes.

5. **Documentation & Reporting :-**

UG PROFILE :-



Griseofulvin

1. **General Information**:

a. Generic Name: Griseofulvin

b. Brand Names: Gris-PEG, Grifulvin V, Gris-PEG, Fulvicin, others.

c. Drug Class: Antifungal (Systemic)

d. Mechanism of Action: Fungistatic (inhibits fungal cell division)

2. **Chemical Properties**:

a. Chemical Name: 2-(4-(2,4-Dimethylpyrimidin-5-ylthio)-3,5-dimethylphenyl)-2-phenylthiazole

b. Molecular Formula: C17H17NO6S

c. Molecular Weight: 366.39 g/mol

3. Side effects :-

a. Skin irritation: Burning, itching, redness application site

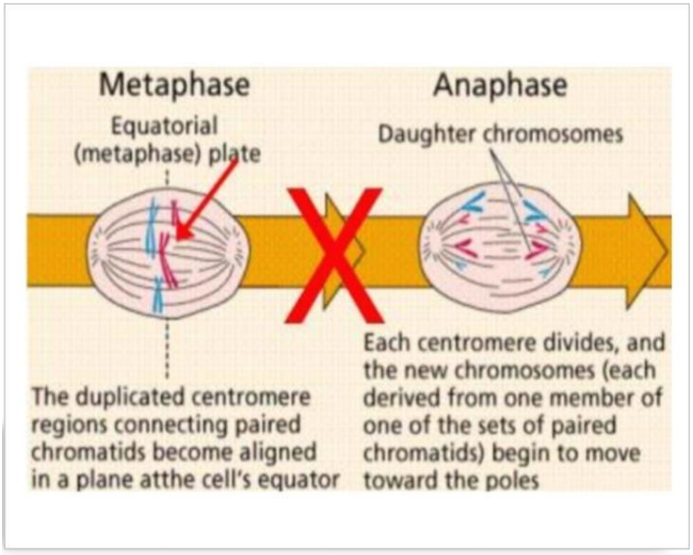
b. Gastrointestinal upset: Nausea, vomiting, diarrhoea (if absorbed systemically)

c. Headache

d. Rarely: Liver toxicity

4. Mechanism of action

It binds to the fungal microtubules and alters the fungal metaphase, i.e., fungal mitosis, thus inhibiting the formation of the mitotic spindle and resulting in the inhibition of separation of daughter nuclei. It is used to treat fungal infections of the body, feet, groin and thighs, scalp, skin, fingernails, and toenails.



Using griseofulvin topically is more beneficial; on topical application, it persists with the skin for a minimum of 4 days or more. It is a better prophylactic agent than miconazole or cotrimoxazole. Emulgel is a new type of novel drug delivery system which is a combination of an emulsion and a gel. Emulsions are biphasic systems in which one immiscible liquid phase is dispersed into another phase, and to prevent instability of this biphasic system, emulsifying agents are added. Gels are formulations in which a network of polymers entraps water molecules. However, hydrophobic drugs cannot be incorporated into gel formulations.

MATERIALS AND METHODS:-

Materials:-

All ingredients (API and Excipients) used are of quality grade, without any further Chemical modifications

Griseofulvin was obtained as a gift sample from Raptakos Laboratory.

Methods :-

a. Pre-formulation Studies:-

Solubility Studies: The solubility of the antifungal API in different solvents should be evaluated to identify the best solvent system for formulation.

Compatibility Studies: The compatibility of the API with excipients (e.g., emulsifiers, gelling agents, preservatives) should be assessed using techniques such as Differential Scanning Calorimetry (DSC) or Fourier Transform Infrared Spectroscopy (FTIR) to detect any potential interaction between components.

b. Screening of excipients:-

All excipients were screened with the criteria of solubility of drug in surfactants and oil.

c. Experimental section :-

Formulation of Emulgel

Selection of oils, surfactants for formulation study:

Oils and excipients were selected on the basis of solubility of drug in oil(Castor oil,Sesame oil, Liquid paraffin, Corn oil) and surfactant(Span 20,Tween 20,Span 80,Tween 80) The drug showed higher solubility in Surfactants such as Tween20, span 20 and oils such as corn oil were selected.

d. Selection of concentration of oil and surfactant :-

For formulation of emulsion Various concentrations (5, 10, 15, 20, 25 %) of oils were tried for preparation of emulsion and selected on the basis of solubility of the drug. Surfactants of two different concentrations were selected for preparation of emulsion based on the HLB method.

PROBABLE OUTCOMES:-

1. Formulation Consistency and Stability:

- One of the primary goals is to achieve consistent formulations with optimal antifungal activity, ensuring that the emulgel remains stable over time under different Environmental conditions.
- Quality assurance (QA) processes will monitor the physicochemical properties of the emulgel, such as pH, viscosity, spreadability, and drug release profile. Stability studies (accelerated, long-term) would also be crucial for determining shelf life and efficacy over time.

2. Safety Profile and Toxicity Testing:

- The emulgel formulation must be safe for dermatological application and not cause skin irritation, sensitization, or toxicity.
- QA processes will involve in-vitro and in-vivo testing for safety, including cytotoxicity, irritation testing (e.g., patch tests), and biocompatibility assessments. Regulatory requirements (e.g., FDA, EMA) would dictate the safety protocols.

3. Microbial Efficacy Testing:

- The antifungal emulgel must demonstrate effective inhibition of target fungal species (e.g., Candida, Dermatophytes, Aspergillus).
- Quality assurance would involve validating the antifungal potency through microbiological testing (e.g., minimum inhibitory concentration (MIC) tests, diffusion methods, or time-kill studies). The emulgel's ability to deliver the active antifungal ingredient at the site of infection would be key.

4. Manufacturing Process Validation:

- Reproducibility and scalability of the formulation process, ensuring that each batch of the emulgel meets the required standards.
- QA will ensure that the formulation process, including mixing, emulsification, gelling, and filling, is standardized and controlled. There may be specific checks for equipment calibration, raw material consistency, and operator competency.

5. Packaging and Storage Conditions:

- Proper packaging materials and storage conditions will preserve the integrity and effectiveness of the formulation throughout its shelf life.
- The emulgel packaging must prevent contamination, preserve the antifungal activity, and protect the product from environmental factors like light and temperature. QA would ensure that packaging meets the necessary standards (e.g., child-resistant packaging if required).

6. Regulatory Compliance and Documentation:

- Development of a product that not only functions effectively but also provides patient satisfaction.
- QA processes would evaluate consumer-centric aspects such as the emulgel's cosmetic appeal (e.g., texture, ease of application, and non-greasy feel), along with its clinical efficacy. Feedback from clinical trials and consumer studies would guide refinements.

7. Risk Management and Continuous Improvement:

- Minimization of risks associated with product defects, contamination, or inefficacy.
- A continuous improvement cycle where data from post-market surveillance, customer feedback, and ongoing research inform quality assurance practices. The use of risk management strategies (e.g., failure mode effects analysis, root cause analysis) would be crucial.

FUTURE SCOPE:

1. Advanced Analytical Techniques for QA:

- Adoption of modern analytical tools (HPLC, FTIR, DSC, NMR, Raman spectroscopy) for better characterization of emulgels.
- Development of stability-indicating methods to ensure long-term effectiveness of antifungal formulations.

2. Stability and Shelf-life Enhancement :

- QA can develop improved stability protocols for antifungal emulgels under different environmental conditions.
- Ensuring consistent drug release profiles throughout the shelf life.

3. Regulatory Compliance and Global Standards :

- QA will focus on meeting stringent global regulatory guidelines (FDA, EMA, ICH) for topical antifungal products.
- Establishment of standardized quality benchmarks for emulgel formulations.

4. Nanotechnology Integration :

- Use of nanoemulsions and nanogels in emulgel formulations to enhance antifungal activity and skin penetration.
- QA will evolve to include nano-specific quality tests like particle size distribution, zeta potential, and release kinetics.

5. Personalized & Targeted Therapies :

- QA may adapt to personalized antifungal emulgel formulations tailored to patient-specificTherapi
- Focus on targeted drug delivery with minimal systemic absorption.

6. Patient-Centric Quality Assurance :

- QA will ensure skin compatibility testing, reduced irritation, and improved patient compliance.

- Post-marketing surveillance to monitor real-world safety and efficacy.

REFERENCES :-

1. Redkar, M. R. Hasabe, P. S., Jadhav, S. T., Mane, P. S., & Kare, D. J. (2019).Optimization- based emulgel formulation review. Asian Journal of Pharmacy and Technology, Page no. 228- 237.
2. Aggarwal N, Goindi S. Development of hydroalcoholic gels of griseofulvin containing terpenes for the treatment of topical fungal infections. Ijrp. 2012 Dr. Baviskar DJ. Dr. Jain DK. Novel drug delivery systems, 1st ed. Nirali Prakashan, 2012
3. Dr. Baviskar DJ. Dr. Jain DK. Novel drug delivery systems, 1st ed. Nirali Prakashan, 2012
4. Jain A. Development of antifungal emulsion based gel for topical fungal infection. Int J Pharm Res. 2003.Gupta AK, Cooper EA. Update in Antifungal Therapy of Dermatophytosis. Mycopathologia. 2008; Page no. 353-67.
5. Gupta AK, Paquet M. Systematic review of systemic treatments for onychomycosis of the toenails.Journal of the American Academy of Dermatology. 2003; Page no. 211-217
6. ISO 10993-10 (2009). International Standard. Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization. https://www.iso.org/standard/40884.htm
7. Kullar R, Saini S, Steth N, Rana AC. Emulgel a surrogate approach for topical used hydrophobic drugs. Int J Pharm Biol Sci 2011 ; 117-28 · Single V, Saini S, Joshi B, Rana AC. Emulgel: a new platform for topical drug delivery. Int J Pharm Biol Sci 2012; page no. 485- https://innovareacademics.in/journals/index.php/ijcpr/article/view/16628
8. Patel B. M, Kuchekar A. B, Pawar S. R. Emulgel Approach to Formulation Development: A Review. Bio sci Biotech Res Asia 2021;18.[Physical parameter evaluation, PH, marketed preparations]
9. Khullar RE .Emulgels: A Surrogate Approach For Topically Used Hydrophobic Drug. International Journal of Pharmacy and Biological Sciences. 2011, Page no. 117-28.3
10. Jain A, Gautam S, Gupta Y, Khambete H, Jain S. Development and characterization of ketoconazole emulgel for topical drug delivery. Der Pharm Sin 2010; Page no. 221-31
11. Allemann I, Baumann L. Antioxidants Used in Skin Care Formulations. Skin therapy letter, 2008;13; Page no.05-09
12. Cathrine A. Humectants and Skin; Effects of hydration from molecule to man. Malmo University health and society doctoral dissertation, 2015; 01:Page no. 15-41

13. Kumar A, Jha A, Chapter 3- Antifungals Used Against Candidiasis. Anticandidal Agents, 2017; 01: Page no.11-39
14. Masuda T, Kobayashi N, Sasagawa H. Pharmaceutical Composition. United States Patent, 2013; US8,513,296B2: Page no. 01-11
15. Mustarichie R, Singh S, Gozil D, Bambang M. Ketoconazole Emulgel Formula Activity Test against Microsporum gypseum and Candida albicans. Journal of Pharmaceutical Sciences and Research, 2017; 09; Page no. 2458-2464.
16. Dhobale S, Shelke G, Jadhav S, Gaikwad D. Formulation and Evaluation of Luliconazole Emulgel for Topical Drug Delivery. International Research Journal of Science and Engineering, 2018;01: Page no. 85-90
17. Ashara K, Paun J, Soniwala M, Chavda J. Microemulgel of Voriconazole: An Unfathomable Protection to Counter Fungal Contagiousness. Folia Medica, 2017; 59: Page no. 461-71.
18. Jain V, Thakur M. Development and characterization naproxen gel bearing eucalyptus oil for topical delivery. Applied Medical Research, 2015; 01: Page no. 48-52
19. Khaled M, Rambo S, Al-zahrani M, Al-subhi S, Fahmy U. Ketoprofen Emulgel: Preparation, Characterization, and Pharmacodynamic Evaluation, 2013; 20: Page no. 306-310.
20. Lundqvist T, Bredenberg S. Chapter 16: Pharmaceutical development. Drug Discovery and Development, 2013; 02:Page no. 227-238
21. Rowe R, Sheskey P, Quinn M. Butylated Hydroxytoluene, Handbook of Pharmaceutical Excipients; Published by Pharmaceutical Press and American Pharmacist Association; Sixth Edition, 2009;06:Page no. 75-77
22. Gandhimathi R, Vijayaraj S, Jyothirmaie MP. Analytical process of drugs by ultraviolet (UV) spectroscopy–a review.International Journal of Pharmaceutical Research & Analysis. 2012;2: Page no. 72-8.
23. Antonov L, Stoyanov S. Analysis of the overlapping bands in UV-vis absorption spectroscopy. Applied spectroscopy. 1993 Jul 1;47: Page no. 1030-5.
24. R.Barik, R&D Bulletins, NOCIL, Thane, (1987, 1988, 1989, 1990).
25. Chandrashekara KN and Srinivasa K, New analytical method development for the active Pharmaceutical ingredients using visible spectrophotometry. Int J Gen Med Pharm. 2013; 2:Page no. 55-64.
26. Chatwal GR and Anand SK. Instrumental Methods of Chemical Analysis. Maharashtra: Himalaya Publications. 1979:Page no.107-2.109.

27. Chauhan A, Mittu B and Chauhan P. Analytical method development and validation: A Concise review. J Anal Bioanal Tech. 2015; 6:Page no. 233-240.
28. Gadkari P. Challenges in Analytical Method Development for Drug Products. Pharma Times.2012; 44:Page no. 22-24.
29. Jatar T, Kachave RN and Chaudhari SR. A review on development and validation of Analytical method, World J Pharmaceut Res. 2014, 3:Page no. 298-304.
30. Jatto E and Okhamafe A. An overview of pharmaceutical validation and process controls in Drug development. Trop J Pharm Res. 2002; 1:Page no. 115-122.
31. Sharma. Y.R. Elementary Organic Spectroscopy. First edition S.Chand Publisher: 2010
32. Chatwal G.R. Instrumental methods of chemical analysis. First edition. Himalava Publisher: 2010