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Article on Formulation and Evaluation of Itraconazole Anti-Fungal Emulsion

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ABSTRACT: ***Fungalinfectionshavebecomeaseriousandgrowinghealthconcernworldwide,particularlyamong immune compromised individuals such as HIV/AIDS patients, diabetics, and those undergoing cancer chemotherapy. Itraconazole,abroad-spectrumtriazoleantifungalagent,iswidelyusedforthe treatment of superficial and systemic fungal infections caused by Candida species, Aspergillus species, and various dermatophytes. However, its clinical utility is significantly limited by its extremelypooraqueoussolubilityandinconsistentoralbioavailability,asitbelongstoBCSClassII categoryofdrugs.***

This study focuses on the formulation and evaluation of an oil-in-water (o/w) emulsion of itraconazole fororaladministration,usingIndianPharmacopoeia(IP)gradeexcipients.TheformulationwasdevelopedusingCastorOilIPastheoilphase,AcaciaIPandPolysorbate80astheemulsifyingagents,andGlycerinIPasaviscosityenhancingstabilizertopreventphaseseparation. Threeformulations(F1,F2,F3)werepreparedbyvaryingtheconcentrationsofAcaciaandGlycerinandevaluatedforvariousphysicochemicalparameter.

Thepreparedemulsionswereevaluatedfororganolepticproperties,pH,viscosity,homogeneity,odprotipmleiztesdize,creamingindex,drugcontent,andstabilitystudies.Theresultsshowedthattheformulationproducedastable,uniform,andpatient-acceptableemulsionwithimproveddrug solubilization and promising drug release profile. The liquid dosage form makes it particularly suitable forpediatric,geriatric,anddysphagicpatientswhofacedifficultyswallowingconventionalcapsule formulations.

KEYWORDS: Itraconazole,Antifungal Emulsion, BCS Class II, Oil-in-Water Emulsion, Castor Oil, Acacia, Polysorbate80,IndianPharmacopoeia,OralBioavailability,Candida

I. INTRODUCTION

The word "emulsion" is derived from the Latin word emulgere, meaning "to milk out," which reflects its nature as a two-phase system where one liquid is dispersed in another immiscible liquid in the form of finedroplets.

Fungal infections, medically known as mycoses, are caused by pathogenic fungi and have become a majorpublichealthproblemacrosstheglobe.Theseinfectionsrangefrommildsuperficialskincoofnditions to severe, life-threatening systemic diseases.The growing population immunocompromisedpatients—includingthosewith HIV/AIDS, diabetes mellitus,organ transplants, and malignancies — has contributed to a dramatic rise in the incidence of both superficial andinvasivefungalinfectionsinrecentdecades.

ItraconazoleisasynthetictriazoleantifungalagentwithabroadspectrumofactivityagainstawidevarietyoffungiincludingCandidaspecies,Aspergillusspecies,Cryptococcusneoformans,dermatophytes, and many other pathogenic fungi. It acts by inhibiting the enzyme 14-α demethylase, whichisessentialforthebiosynthesisofergosterol—theprimarystructuralcomponentofthefungal cell membrane. Depletion of ergosterol disrupts the integrity and function of the fungal cell membrane,ultimatelyleadingtofungalcelldeath.

Despiteitsimpressiveantifungalspectrum,itraconazoleisclassifiedasaBCSClassIIdrug—meaning it has high permeability but very low aqueous solubility (less than 1 µg/mL at physiological pH). This poor solubility severely limits its dissolution and absorption from conventional solid dosage forms like capsules and tablets. The oral bioavailability of itraconazole from capsule formulations is highly variable and significantly influenced by food intake, gastric pH, and patient-specific factors, leadingtounpredictabletherapeuticoutcomes.

Theformulationofitraconazoleasanoraloil-in-wateremulsionoffersascientificallysoundand practically viable solution to these challenges. In an emulsion, the drug is already pre-dissolved in the oilphase, eliminatingthe slowandoftenincompletedissolutionstep.Thefineoildroplets,when ingested, mimic the physiological effect of a fatty meal and promote lymphatic absorption of the drug, effectivelybypassinghepaticfirst-passmetabolismand significantly improving bioavailability.

Additionally,theliquiddosageformofanemulsionoffersimportantadvantagesforspecialpatientpopulations.

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Pediatricpatientswhocannotswallowcapsules,elderlypatientswithswallowingdifficulties,andcriticallyillpatientswhorequireoralantifungaltherapyallstandtobenefitgreatlyfromawell-formulateditraconazoleemulsion.Theabilitytoaccuratelymeasureandadminister weight-baseddosesfurtherenhancesitsclinicalutility,particularlyinchildren.

Thus, the present work is aimed at formulating and evaluating a stable, phase-separation-resistant oral oil-in-wateremulsionofitraconazoleusingminimalIP-gradeexcipients,withthegoalofimproving drugdelivery,patientacceptability,andtherapeuticoutcomesinfungalinfections.



FigNo:1

II. TYPES OF FUNGAL INFECTIONS

- SuperficialMycoses
- CutaneousMycoses(Dermatophytosis)
- SubcutaneousMycoses
- Systemic/InvasiveMycoses
- OpportunisticMycoses
- OralCandidiasis
- Onychomycosis(NailFungalInfection)

1) Superficial Mycoses:

Theseinfectionsaffectonlytheoutermostlayersoftheskin,hair,andnailswithoutpenetratingtheviabletissue.Theycausemainlycosmeticproblemsandmilddiscomfort.Examplesincludetinea versicolorcausedbyMalasseziafurfurandpiedracausedbyTrichosporonspecies.

2) CutaneousMycoses(Dermatophytosis):

These infections involvethekeratinizedlayers of the skin, hair, and nails. They are caused by dermatophytes—fungibelongingtothegeneraTrichophyton,Microsporum,andEpidermophyton. Common conditions includetineacorporis(ringworm of the body), tinea capitis (scalp ringworm), tinea pedis(athlete'sfoot),tineacruris(jockitch),andtineaunguium(nailinfection).

3) SubcutaneousMycoses:

Theseinfectionsaffecttheskin,subcutaneoustissue,andsometimesbone.Theyusuallyfollow traumatic implantation offungal material from the soil or plant matter. Examples include sporotrichosis and chromoblastomycosis. They are more common in agricultural workers in tropical countries.

4) Systemic/InvasiveMycoses:

These are the most serious fungalinfections, involving the internal organs and blood. They are caused byhighlyvirulentfungisuchasHistoplasmacapsulatum,Blastomycesdermatitidis,andCoccidioides immitis, and can affect even healthy individuals through inhalation of fungal spores from the environment.

5) OpportunisticMycoses:

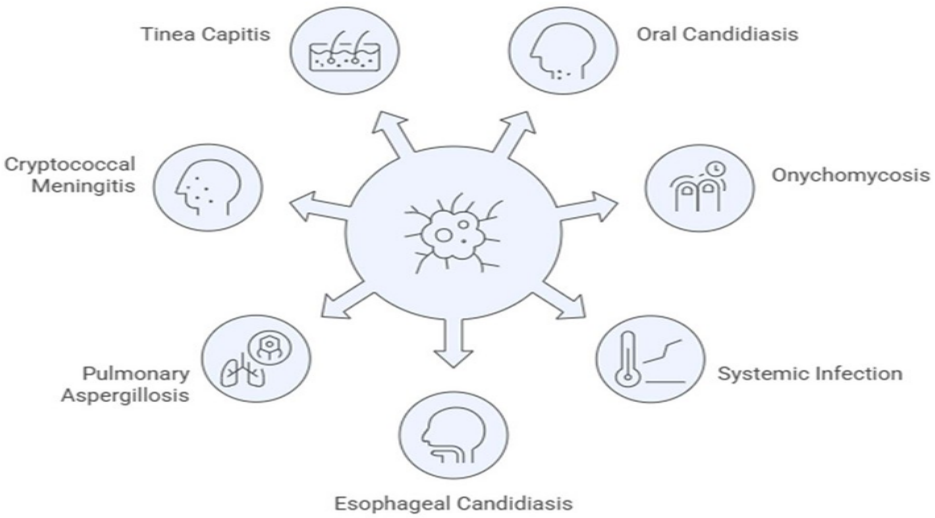
Theseinfectionsarecausedbynormallyharmlessfungithatbecomepathogenicwhenthehost immune system is weakened.The most important examples are invasive candidiasis, invasive aspergillosis,cryptococcalmeningitis, andmucormycosis.Thesecarryveryhighmortalityratesin immunocompromisedpatients.

6) OralCandidiasis(Thrush):
Thisisoneofthemostcommonfungalinfections,characterizedbycreamywhiteplaquesontheoralmucosalsurfaces.ItiscausedprimarilybyCandidaalbicansandiscommonlyseenininfants,the elderly,HIV-positivepatients,andthoseonantibioticorcorticosteroidtherapy.

7) Onychomycosis:
This is a fungal infection of the nails, causing nail thickening, discoloration, brittleness, and separationofthenailfromthenailbed.Itaccountsfornearly50%ofallnaildisordersandisoneoftheprimaryindicationsforsystemicitraconazoletherapy.

III. SYMPTOMS

1) SkinSymptomsI:tching,burning,andrednessofskinornails
2) OralCandidiasisW: hitecurd-likeplaquesonoralmucosa,painwhileswallowing
3) OnychomycosiNsa:ilthickening,discoloration,brittleness,andonycholysis
4) SystemicInfectioPne:rsistentfeverunresponsivetoantibiotics
5) EsophagealCandidiasDisif:ficultyswallowing(dysphagia),chestpain,weightloss
6) PulmonaryAspergillosCiso:ugh,chestpain,haemoptysis,andbreathlessness
7) CryptococcalMeningitHise:adache,neckstiffness,confusion,andalteredsensorium
8) TineaCapitisH:airlosswithscaling,brokenhairshafts,lymphadenopathy



IV. CAUSES

1) WeakenedimmunesystemduetoHIV/AIDS,cancer,diabetes,ororgantransplant
2) Prolongeduseofbroad-spectrumantibioticsthatdisruptnormalmicrobialflora
3) Long-termcorticosteroidorimmunosuppressivetherapy
4) Environmentalexposuretofungalspores(soil,birddroppings,decayingmatter)
5) Poorpersonalhygiene,excessivesweating,andwearingtightorwetclothing
6) Traumaorinjurythatintroducesfungiintotheskinorsubcutaneous tissue
7) Hospitalizationanduseofinvasivemedicaldeviceslikecathetersandventilators
8) Nutritionaldeficienciesthatimpairimmunefunction
9) Hotandhumidclimatethatpromotesfungalgrowthandproliferation
10) Oldage,asimmunitynaturallydeclineswithadvancingage

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V. PATHOPHYSIOLOGY

A. Candidiasis:

1) Candidaalbicansnormallylivesharmlesslyintheoralcavity,gut,andvaginalmucosa.
2) Whenhostdefensesareweakened,Candidashiftsfromyeastformtoinvasivehyphalform.
3) Thehyphal phospholipases). forminvadesmucosal epitheliumusing secretedenzymes (proteases and
4) Inflammatoryresponsegeneratesthecharacteristicwhiteplaquesandrednessseeninoralthrush.
5) Inseverecases,Candidaentersthebloodstream(candidemia)andspreadstointernalorgans.
6) Liver,spleen,kidneys,eyes,andheartarecommonlyinvolvedindisseminatedcandidiasis.
7) Biofilmformationoncathetersandmedicaldevicesmakestheinfectionverydifficulttotreat.

B. Dermatophytosis:

1) Dermatophytespores(arthrospores)adheretothekeratinizedsurfaceofskin,hair,ornails.
2) Theorganismproduceskeratinasesthatbreakdownkeratin,allowingittopenetratethetissue.
3) Infectionspreadsoutwardinacircularpattern,formingthecharacteristicring-shapedlesion.
4) Hostimmuneresponse(delayedhypersensitivity)causesinflammation,itching,andscaling.
5) Innailinfections,theorganisminvadesthroughthenailplateanddestroysthenailbed.
6) Chronic,relapsingcourseiscommon,especiallyintoenailinfections(onychomycosis).
7) Systemicspreadisrareinhealthyindividualsbutpossibleinimmunocompromisedpatients.

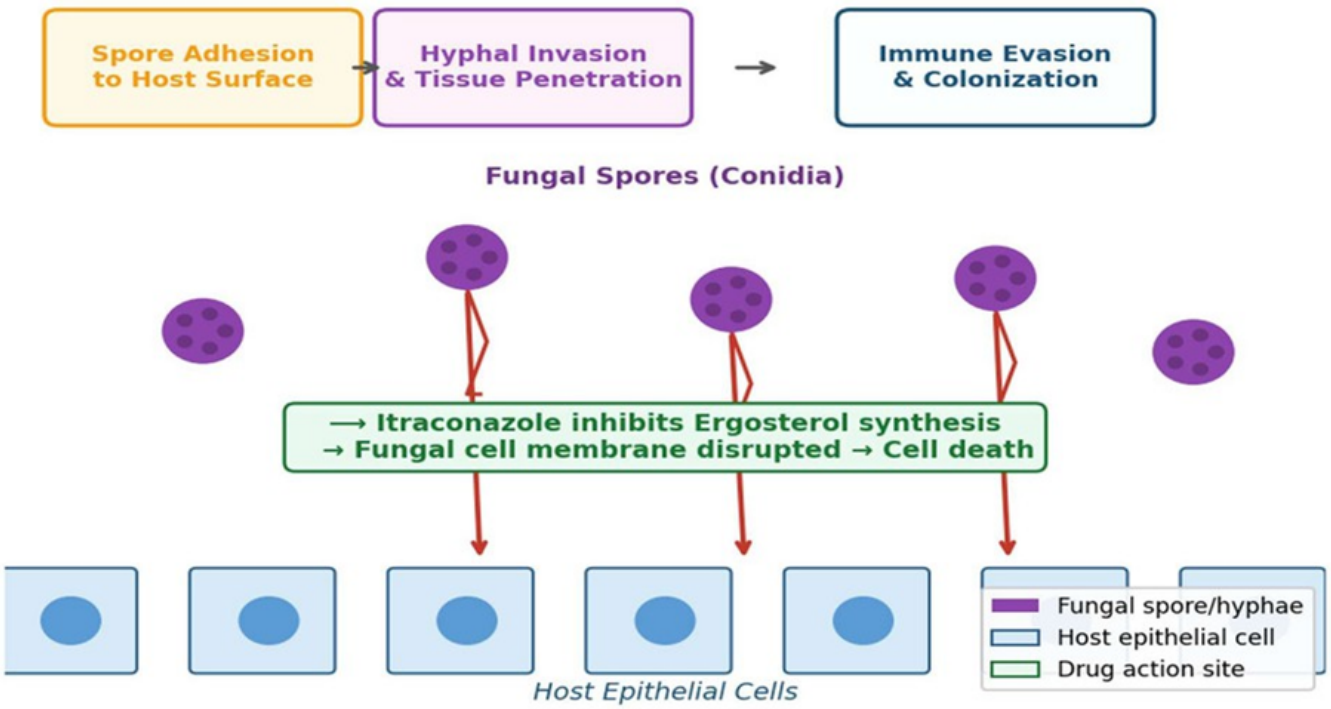


Fig No.2

VI. MATERIAL

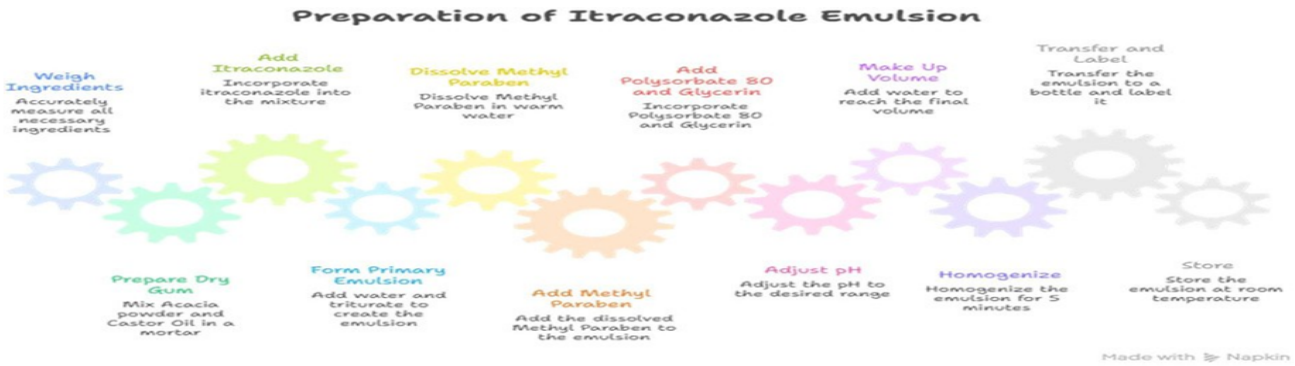
1) Drug:ItraconazoleIP
2) Excipients: Castor Oil IP, Acacia IP, Polysorbate 80, Glycerin IP, Methyl Paraben IP, Citric Acid IP, Purified Water IP.
3) Equipment:Beaker,GlassRod,MortarandPestle,SeparatingFunnel,TripodStand,WaterBath,TestTubes,MeasuringCylinder,Funnel ,FilterPaper.
4) Instruments: Weighing Balance, pH Meter, Brookfield Viscometer, Optical Microscope, Homogenizer.

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VII. METHOD

PreparationofItraconazoleEmulsionbyDryGumMethod:

1) Accuratelyweighallingredientsaspertheformulationtable.
2) TakeAcaciaIPpowderinadrymortarandpestle—thisisthedrygum.
3) AddCastorOiltotheAcaciapowderandtriturateswelltoformasmooth,uniformmixture.
4) Add itraconazole to the oil-acacia mixture and continue trituration until the drug is evenly distributed.
5) Add one-third of the total water quantity all at once and triturate vigorously until a white, creamy primaryemulsionisformed(youwillhearacharacteristicclickingsound—thisconfirmsprimary emulsionformation).
6) DissolveMethylParabenIPinasmallquantityofwarmpurifiedwaterandaddtotheprimary emulsion.
7) AddPolysorbate80andGlycerinIPtotheemulsionwithcontinuousstirring.
8) AdjustpHto4.5–5.0usingCitricAcidIPsolution.
9) Makeupthevolumeto30mLwithPurifiedWaterIPandhomogenizefor5 minutes.
10) Transfertoacleanamber-coloredbottle,label,andstoreatroomtemperature.



VIII. DRUG PROFILE

Itraconazole

OfficialName:Itraconazole(asperIP,USP,BP)

ChemicalName:(2R,4S)-rel-1-(Butan-2-yl)-4-[4-[4-[4-[[(2R,4S)-2-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]-1-piperazinyl]phenyl]-4,5-dihydro-1H-1,2,4-triazol-5(4H)-one

MolecularFormula:$C_{35}H_{38}Cl_2N_8O_4$ Molecular Weight: 705.64 g/mol Category:AntifungalAgent—Triazoleclass

DrugClass:BCSClassII(HighPermeability,LowSolubility)

Description:

- Colour:Whitetoalmostwhite powder.
- Odour:Practicallyodourless.
- Taste:Practicallytasteless.
- MeltingPoint:Approximately165–169°C.

Solubility:

- Practicallyinsolubleinwater(<1µg/mLatphysiologicalpH).
- Slightlysolubleinalcoholanddilutehydrochloricacid.
- Freelysolubleindichloromethaneanddimethylformamide.
- Solubilityincreasesmarkedlyinacidicp H.

IMtreaccohnaanzoisleminhoifbAitsctthieofnun:gal cytochrome P450-dependent enzyme lanosterol 14-α demethylase. Thisenzymeisresponsibleforconvertinglanosteroltoergosterolthemainstructuralsterolofthefungalcellmembrane.Inhibitionofthisenzym edepletesergosterolandcausesaccumulationoftoxic methylated sterol precursors, leading to disruption of the fungal cell membrane integrity and ultimately fungal cell death.

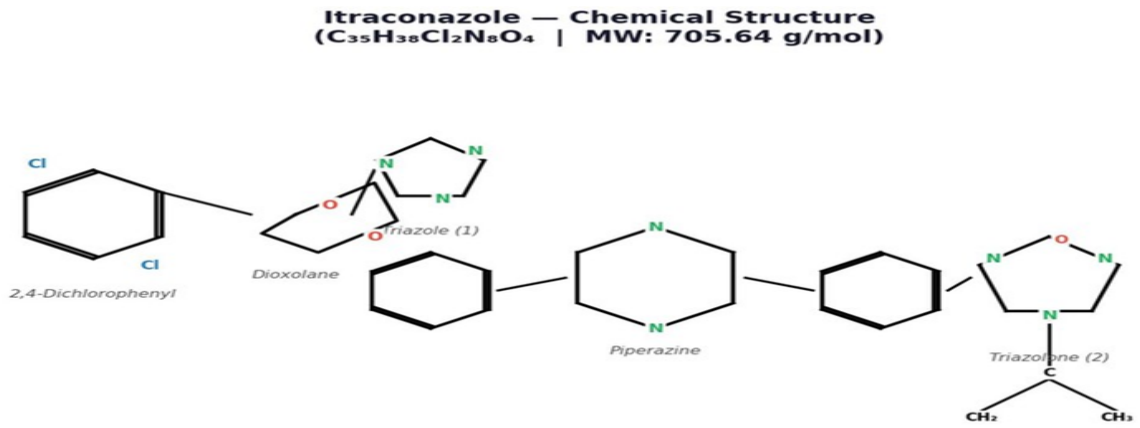
Pharmacokinetics:

- Absorption:Enhancedwhentakenwithfoodorinacidicconditions.
- Distribution:Extensivelydistributedintissues(Vd=796L);proteinbinding>99%.
- Metabolism:Extensivelymetabolizedintheliverby CYP3A4enzyme.
- Elimination:Excretedprimarilyinfeces(54%)andurine(35%)asmetabolites.
- Half-life:16–28hoursaftermultipledoses.

Indications:

- Oralcandidiasisandesophagealcandidiasis
- Onychomycosis(nailfungalinfections)
- Dermatophytosis(tineacorporis,tineapedis,tineacruris)
- Invasive aspergillosis
- Histoplasmosisandblastomycosis
- Prophylaxisoffungalinfectionsinimmunocompromisedpatients

StorageS:torebelow25°C,protectedfromlightandmoisture.

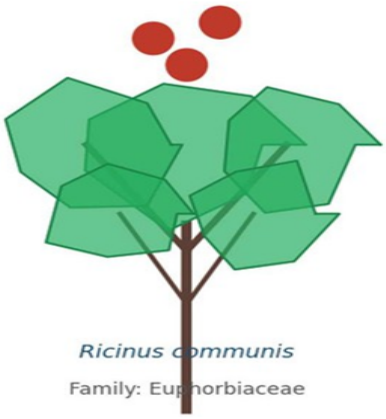


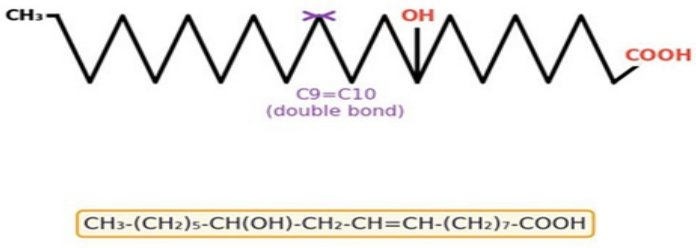
IX. EXCIPIENTS

1) CastorOilIP

OfficialNameC:astorOil(IP,BP,USP)

BiologicalSourcFei:xedoilobtainedbycoldexpressionofseedsofRicinuscommunisLinn.,Family: Euphorbiaceae.





ChemicalConstituents:

- Ricinoleicacid(85–90%)—majorfattyacid
- Linoleicacid(4–5%)
- Oleicacid(3%)
- PalmiticacidandStearicacid(minoramounts)
- Glyceridesoffattyacids

MorphologicalCharacteristics:

- Colour:Paleyellowtoalmostcolourless,viscousliquid.
- Odour:Faint,characteristicodour.
- Taste:Bland,slightlynauseatingoilytaste.
- Consistency:Viscous,oilyliquidatroomtemperature.

Solubility:

- Miscible with dehydrated alcohol, glacial acetic acid, ether, and chloroform.
- Insoluble in water and petroleum ether.

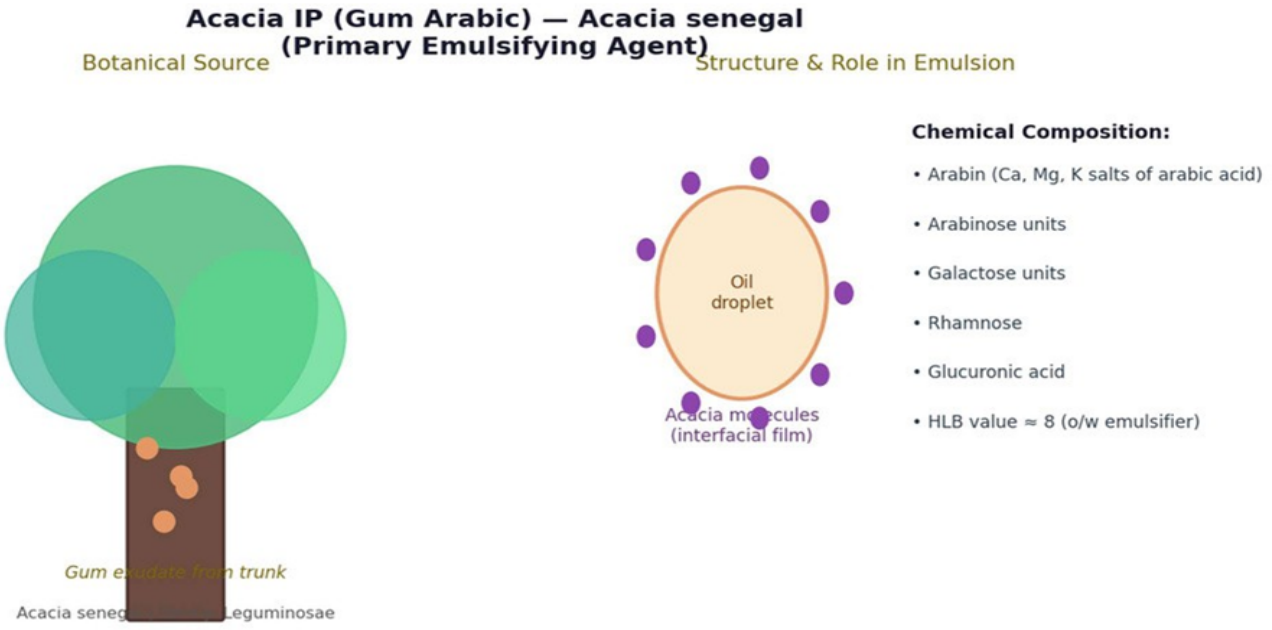
Uses:

- Oil phase in emulsion formulations—excellent solubilizing capacity for poorly soluble drugs.
- Used as a laxative in higher doses.
- Emollient and lubricant in pharmaceutical formulations.
- Vehicle for poorly water-soluble drugs in oral and topical preparations.

2) AcaciaIP

OfficialNameA:cacia(IP,BP,USP)—alsoknownasGumArabic

BiologicalSourceD:riedgummyexudateobtainedfromthestemsandbranchesofAcaciasenegal(Linn.)Willdenoworrelatedspecies,Family :Leguminosae.



ChemicalConstituents:

- Arabin—calcium,magnesium,andpotassiumsaltsofarabicacid
- Arabinose,Galactose,Rhamnose,Glucuronicacid
- Oxidases(traceenzymes)
- Moisturecontent:notmorethan15%

MorphologicalCharacteristics:

- Colour:Whitetoyellowish-whitetears,flakes,orpowder.
- Odour:Odourless.
- Taste:Bland,mucilaginous.
- Texture:Brittle,translucentpieces(tears)oroff-whitepowder.

Solubility:

- Freelysolubleinwater,formingaviscous,mucilaginoussolution.
- Practicallyinsolubleinalcoholandorganicsolvents.

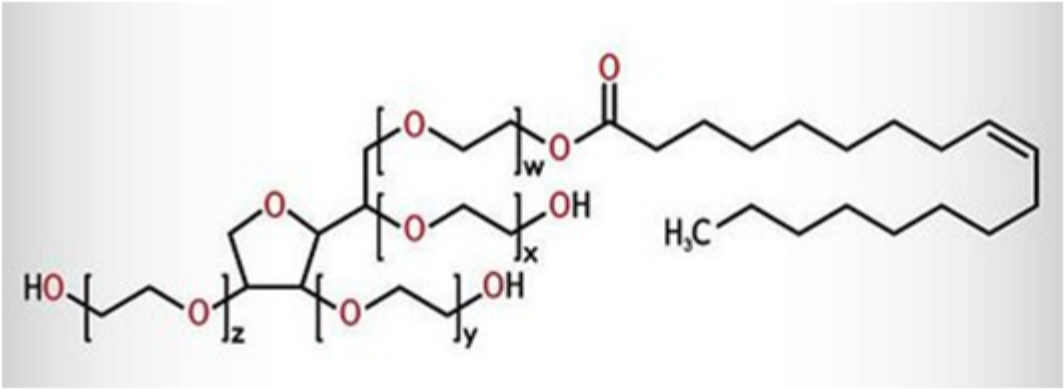
Uses:

- Primaryemulsifyingagentinoraloil-in-wateremulsions—formsastronginterfacialfilm.
- Bindingagentintablets.
- Suspendingandthickeningagentinoralliquidpreparations.
- Demulcenttosootheirritatedmucousmembranes.

3) Polysorbate80(Tween80)

OfficialNameP:olysorbate80(IP,USP,BP)

ChemicalNamPeo:lyoxyethylene(20)sorbitanmonooleate



MolecularFormula:$C_{64}H_{124}O_{26}$ MolecularWeigh1t:,310g/mol

HLBValue:15—stronghydrophiliccharacter,idealforo/wemulsions

Category:Non-ionicsurfactant,Co-emulsifier,Solubilizer,Stabilizer

Description:

- Colour:Amber-yellowtoorangeoilyliquid.
- Odour:Faint,characteristic.
- Consistency:Viscousliquid.

Solubility:

- Freelysolubleinwater,ethanol,andmethanol.
- Misciblewithoilsandaromatichydrocarbons.

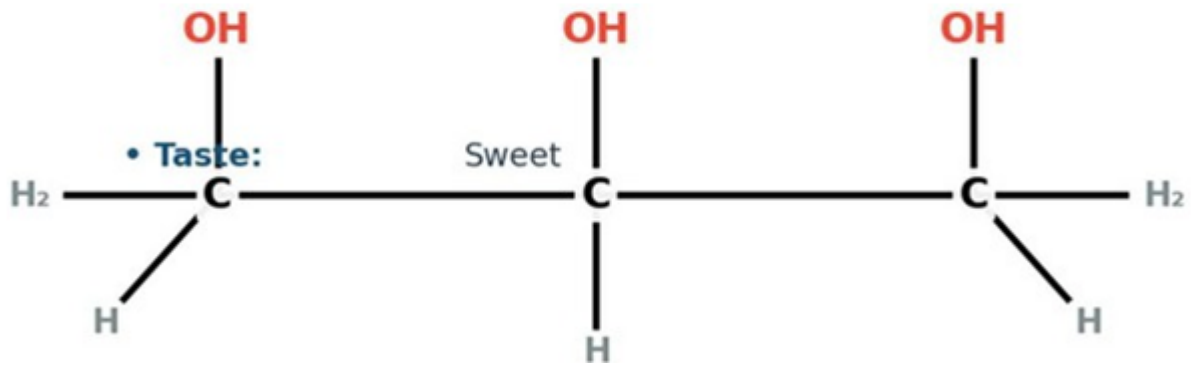
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Uses:

- Co-emulsifierinoralandtopicalemulsionformulations—boostsHLBofemulsifiersystem.
- Solubilizerforpoorlywater-solubledrugs.
- Wettingagentanddispersing agent.
- Stabilizesemulsionagainstdropletcoalescenceandphaseseparation.

4) GlycerinIP

OfficialNameG:lycerin(IP,USP)/Glycerol(Ph.Eur.)
Chemical NamPer:opane-1,2,3-triol MolecularFormulaC:$_3H_8O_3$
MolecularWeigh9t:2.09g/mol
Category:Humectant,Viscositybuilder,Sweeteningagent,Pharmaceuticalexcipient



Description:

- Colour:Clear,colourless,viscousliquid.
- Odour:Odourless.
- Taste:Sweet,warm.
- Nature:Hygroscopic—absorbsmoisturefromthe atmosphere.

Solubility:

- Freelysolubleinwaterandalcohol.
- Misciblewithchloroformandpropyleneglycol.
- Practicallyinsolubleinoilsandfats.

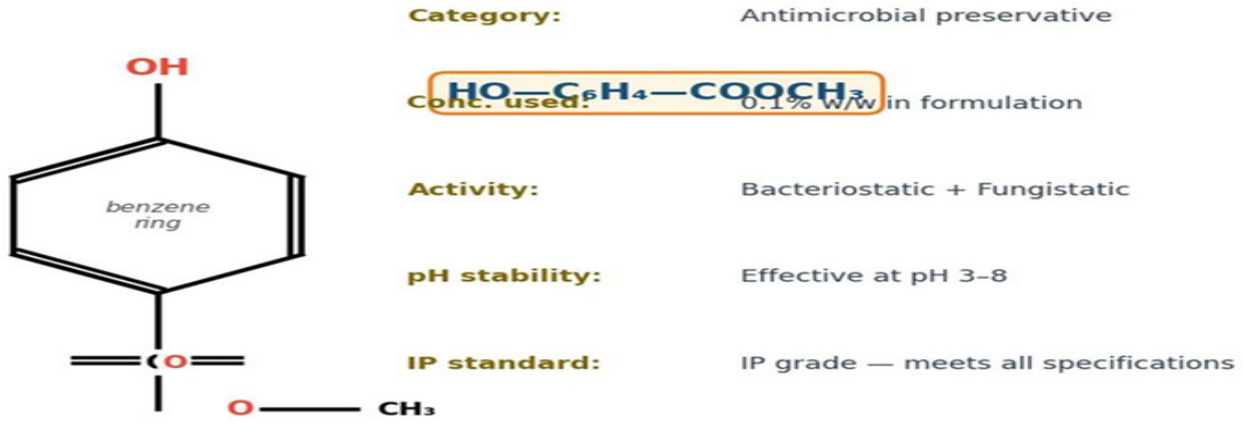
Uses:

- Humectant—preventsdryingoutoftheemulsionduringstorage.
- Viscosity builder — increases the viscosity of the aqueous phase, slowing droplet movement and preventingphaseseparation.
- Sweeteningagentinoralliquidpreparations.
- Co-solventfordrugsinoralformulations.
- Emollientandplasticizerinpharmaceuticalformulations.

5) MethylParabenIP

OfficialNameM:ethylparaben(IP,USP,BP)—alsoknownasMethyl4-hydroxybenzoate
ChemicalNamMe:ethyl4-hydroxybenzoate
MolecularFormulaC:$_8H_8O_3$

MolecularWeigh1t:52.15g/mol
Category:Antimicrobialpreservative,Pharmaceuticalexcipient,Foodpreservative(E218)



Description:

- Colour:White,crystallinepowderorcolourlesscrystals.
- Odour:Practicallyodourlessorveryfaintcharacteristicodour.
- Taste:Slightlyburning.

Solubility:

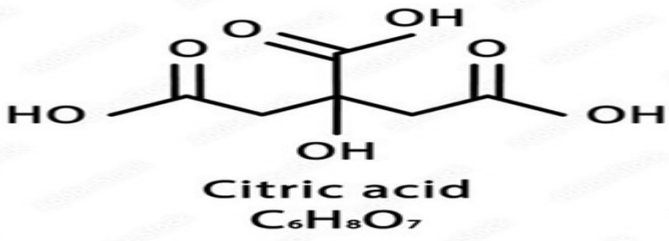
- Solubleinethanol,ether,acetone,andpropyleneglycol.
- Slightlysolubleinwater(about0.25%at25°C).
- Freelysolubleinalkalinesolutionsduetosaltformation.

Uses:

- Widelyusedantimicrobialpreservativeinoralliquidandtopicalpharmaceuticalpreparations.
- Effectiveagainstbacteria,yeasts,andmolds.
- Usedat0.1–0.18%inoralformulationsasperIPguidelines.
- Oftencombinedwithpropylparabenforbroaderspectrumpreservation.

6) CitricAcidIP

OfficialNameC:itricAcidMonohydrate(IP,USP,BP)
ChemicalNam2e-:hydroxy-1,2,3-propane-tricarboxylicacid
MolecularFormulaA:nhydrous:$C_6H_8O_7$|Monohydrate:$C_6H_8O_7 \cdot H_2O$
MolecularWeight:Anhydrous:192.12g/mol|Monohydrate:210.14g/mol
Category: Acidulant, pH adjuster, Antioxidant synergist, Chelating agent, Buffering agent, Food additive(E330)



Description:

- Colour:Colourless,odourlesscrystalsorwhitecrystallinepowder.
- Odour:Odourless.
- Taste:Strong,pleasantacidictaste.

Solubility:

- Freelysolubleinwaterandethanol(95%).
- Practicallyinsolubleinetherandchloroform.

Uses:

- pHadjuster—maintainsoptimalpH(4.5–5.0)fordrugstabilityandmucosalcompatibility.
- Antioxidantsynergist—preventsoxidativedegradationoftheemulsioncomponents.
- Chelatingagent—bindsmetalionsthatcouldcatalyzeoxidationreactions.
- Bufferingagentinpharmaceuticalformulations.

X. FORMULATION TABLE

(BatchSize:30mL|AllingredientsareIPgrade)
Sr.
No.
Ingredient Role
1) ItraconazoleIP
2) CastorOilIP
3) AcaciaIP
4) Polysorbate80
5) GlycerinIP
6) MethylParabenIP
7) CitricAcidIP
8) PurifiedWaterIP
9) ActiveAntifungalDrug

OilPhase+Drug Solubilizer
Primary Emulsifying Agent Co-emulsifier+Stabilizer
ViscosityBuilder+ Humectant
Preservative
pHAdjuster(pH4.5–5.0) Vehicle(AqueousPhase)

XI. EVALUATION PARAMETER

1) Organoleptic/PhysicalProperties

This test evaluates the prepared emulsion for its appearance, colour, odour, taste, and consistency. A well-preparedemulsionshouldbeuniformincolour,haveapleasantoracceptableodour,smoothtexture,andshouldshownosignsofoilingout,creaming,orphaseseparation.Thesepropertiesdirectlyreflecttheproduct'sstabilityandpatientacceptability.

2) pHDetermination

The pH of the emulsionismeasured using a calibrated digital pH meter at room temperature. For oral emulsions,apHrangeof4.5to5.5isconsideredideal.ThispHrangeensuresmucosalcompatibility, minimizes irritationtothe oral and gastric mucosa, and maintains optimal drug stability, since itraconazoledegradesinalkalineconditions.

3) Viscosity

ViscosityoftheemulsionismeasuredusingaBrookfieldViscometerataspecificspindlespeedand temperature(25°C). Appropriate viscosity ensures that the emulsion pours easily for dose administrationwhileremainingstableagainst phaseseparation.Higherviscosityreducesdropletmobilityandhelpsmaintainemulsionstabilityovertime.

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4) Homogeneity

Homogeneityisassessedbyvisualexaminationandmicroscopicobservationoftheemulsion.Ahomogeneousemulsionshouldbefreefromlumps,undissolvedparticles,orvisibleoildropletson thesurface.Itcanalsobeexaminedbyspreadingathinfilmonaglassslideunderanoptical microscopetoconfirmuniformdropletdistribution.

5) CercereaammiinngginIndedxeixsd,TEST

PtehramsieneSdebpyatraaktiniogankTnoewstnvolumeofemulsioninagraduatedmeasuringcylinderandallowingittostandundisturbedatroomtemperaturefor24hours.Theheightofthe separated cream or oil layer, if any, is notedand calculated as a percentage of total emulsion height.Alowercreamingindexindicatesbetteremulsionstability.

6) DropletSizeandSizeDistribution

Averagedropletsizeandpolydispersityindex(PDI)oftheemulsionaredeterminedusingaparticlesizeanalyzeroropticalmicroscope.Smaller dropletsize(<10μmformacroemulsions)ensuresbetterstability,greatersurfaceareaforabsorption,andimprovedbioavailability.Anarrowsize distribution(lowPDI)reflectsformulationuniformity.

7) ZetaPotential

Zetapotentialindicatestheelectrostaticstabilityoftheemulsiondroplets.Itismeasuredusinga Zetasizer. A zetapotential value above ±30 mV suggests adequate electrostatic repulsion between droplets, which prevents coalescence and ensures long-term physical stability of the emulsion.

8) DrugContentUniformity

Drug content is determined byUV spectrophotometry at the λmax of itraconazole (approximately 258 nm). A known volume of emulsion is diluted with methanol, filtered, and the absorbance is measured. Thedrugcontentshouldbewithin90–110%ofthelabeledamountasperIPspecificationstoensure
accuratedosingandtherapeuticconsistency.

9) StabilityStudies

AcceleratedstabilitystudiesarecarriedoutasperICHQ1A(R2)guidelines.Samplesarestoredat40°C±2°C/75%RH±5%for3months.Physicalappearance,pH,viscosity,creamingindex,and drug content are evaluated at 0, 1, 2, and 3-month intervals. Stable formulations show no significant changesintheseparametersthroughoutthestudyperiod.

10) CentrifugeTest(PhysicalStability)

Centrifugationat3500rpmfor30minutesisusedasanacceleratedtestforphysicalstability.Theemulsionisexaminedforanyphaseseparationaftercentrifugation.Absenceofphaseseparation indicatesastableemulsionsystemthatislikelytoremainstableduringstorageandhandling.

XII. CHEMICAL TESTS (DRUGIDENTIFICATION—ITRACONAZOLE)

1) ColourReactionwithSulfuricAcid

Procedure:Dissolveasmallquantityofitraconazolein2mLofconcentratedsulfuricacid.Observation:
A characteristic reddish-brown to brownish coloration is produced, which indicates the presenceofitraconazole.

2) ChlorideIdentificationTest

Procedure:Dissolveitraconazoleindilutenitricacidandaddafewdropsofsilvernitratesolution.
Observation: Formationof a white curdy precipitate of silver chloride, which is soluble in dilute ammonia,confirmsthepresenceofchlorineatomsinthemolecule.

3) TriazoleRingTest

Procedure:Dissolveitraconazoleinmethanolandaddafewdropsofcoppersulfatesolutionand sodium hydroxide.
Observation:Formationofacharacteristiccomplexcolorconfirmsthepresenceofthetriazoleringstructureinthemolecule.

4) EmulsionDrugRelease(In-vitroDissolution)

Procedure:Place5mLofemulsionin500mLsimulatedgastricfluid(pH1.2)orsimulatedintestinalfluid(pH6.8)inadissolutionapparatus.Withdraw5mLsamplesat15,30,45,60,and90minutes. Filterandmeasureabsorbancebyspectrophotometryat258nm.

Observation: Drug release profile is plotted. The emulsion should show significantly faster and more completedrugreleasecomparedtoconventionalitraconazolecapsules.

XIII. DRUG-EXCIPIENT COMPATIBILITY STUDY

Sr.No.	Test	MethodUsed	Observation
1	Itraconazole+CastorOil	Visual&IRSpectroscopy	Nophysical chemical of incompatibilityobserved — clearsolutionformed
2	Itraconazole+AcaciaIP	Visualexaminationafter48Nohours	discoloration or precipitation—compatible
3	Itraconazole +Polysorbate80	Visual&solubility test	Enhanced solubilization observed — no incompatibility
4	Itraconazole+GlycerinVisual&DSC IP		Nointeraction—stable mixture
5	Itraconazole + Methyl Paraben	Visual after 1 week at 40°C	No colour change or degradation—compatible
6	Itraconazole+CitricAcid	pHmonitoringover7days	StableatpH4.5–5.0—no degradationobserved

XIV. CONCLUSION

Itraconazole-based oil-in-water emulsion represents a highly promising and pharmaceutically innovative approach for the oral delivery of this poorly water-soluble antifungal drug. The formulation wassuccessfullypreparedusingminimal IndianPharmacopoeiagradeexcipients—CastorOilIPas the oil phase, Acacia IP and Polysorbate 80 as the emulsifying system, and Glycerin IP as a viscosity-enhancingstabilizer—ina30mLbatchsize.

The dry gum method of emulsion preparation produced a stable, uniform, and creamy white emulsion withnophase separation.Theoptimizedformulationdemonstratedacceptablephysicochemical properties including appropriate pH (4.5–5.0), adequate viscosity, uniform droplet size distribution,satisfactorydrugcontent,andgoodphysicalstabilityonacceleratedtesting.

Theemulsiondosageformeffectivelyovercomesthemajorlimitationsofconventionalitraconazolecapsulesnamelypooranderraticoralbioavailability—bypre-dissolvingthedrugintheoilphase and enhancing absorption through the lymphatic pathway. This approach minimizes first-pass hepatic metabolismandproducesmorereliableandconsistenttherapeuticdruglevelsinthebloodstream.

Furthermore,theliquidnatureoftheformulationmakesitparticularlysuitableandpatientfriendlyforpediatricpatients,elderlyindividuals,andthosewithswallowingdifficulties,whorepresenta significant proportion of patients requiring antifungal therapy. The formulation offers the additionaladvantageofallowingprecise,weight-baseddosinginchildren.

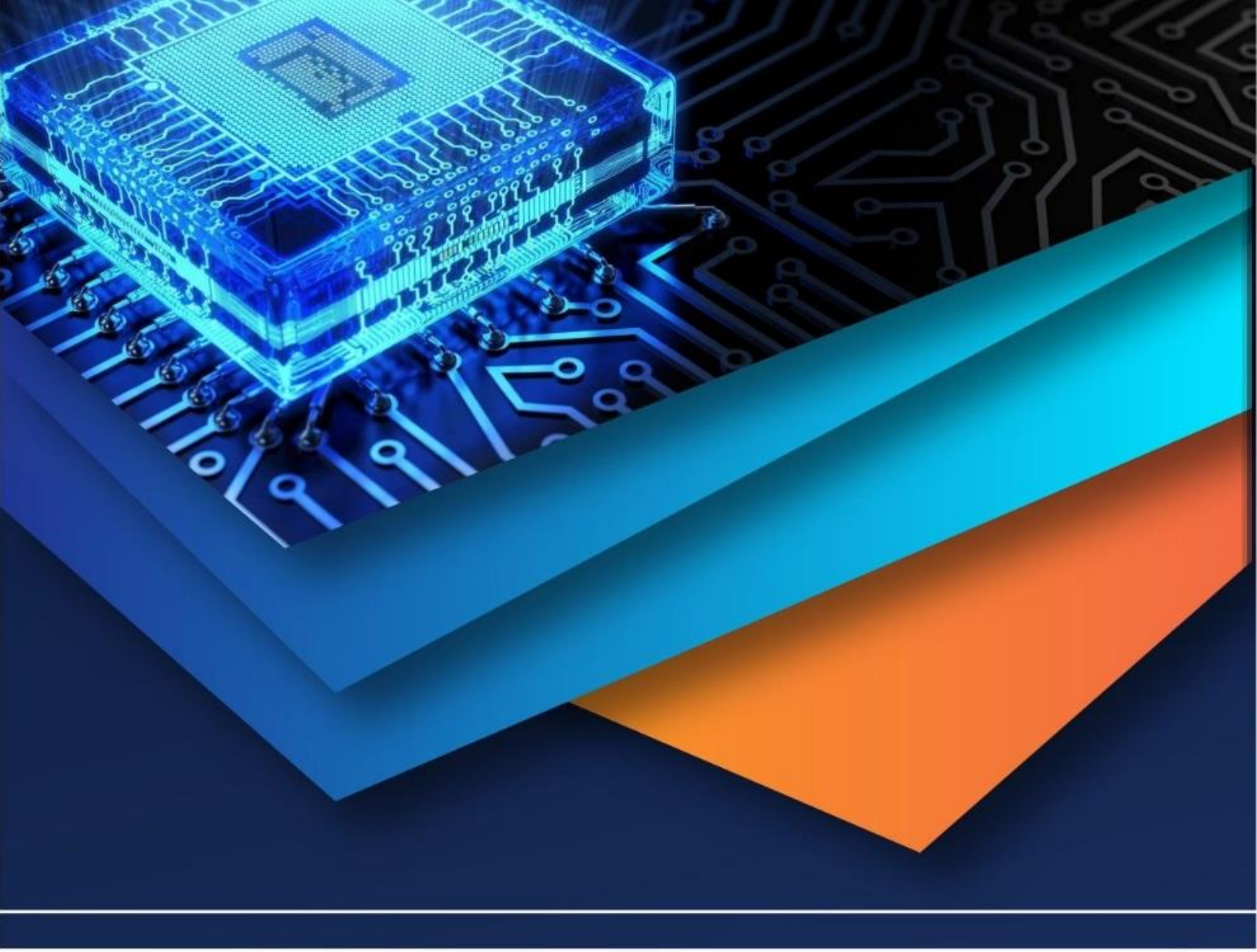
Inconclusion,theitraconazoleantifungalemulsionformulatedusingIPgradeexcipientsstandsasasafe,effective,stable,andpatient-friendly oraldosageformthatofferssignificanttherapeuticadvantagesoverconventionalsolidformulations,andholdsgreatpotentialforfurtherdevelopmentandclinicalapplicationinthetreatmentoffungalinfections.

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