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To study FTIR spectra of ketoconazole and CMC

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I. INTRODUCTION

A Fourier Transform InfraRed (FT-IR) Spectrometer is an instrument which acquires broadbandNearInfraRed(NIR)toFarInfraRed(FIR)spectra.Unlikeadispersiveinstrument, i.e.agratingmonochromatororspectrograph,FTIRspectrometerscollectallwavelengths simultaneously. This feature is called the Multiplex or FelgettAdvantage.

FT-IR Spectrometers are often simply referred to as FTIRs. But for the purists, an FT-IR is a method of obtaining infrared spectra by first collecting an interferogram of a sample signal usinganinterferometer,andthenperformingaFourierTransform(FT)ontheinterferogramto obtainthespectrum.AnFT-IRspectrometercollectsanddigitizestheinterferogram,performs the FT function, and displays the spectrum.

TheMichelsonInterferometer
AnFTIRistypicallybasedonTheMichelsonInterferometerExperimentalSetup;anexample isshowninFigure1.Theinterferometerconsistsofabeamsplitter,afixedmirror,andamirror that translates back and forth, very precisely. The beam splitter is made of a special material that transmits half of the radiation striking it and reflects the other half. Radiation from the sourcestrikesthebeamsplitterandseparatesintotwobeams.Onebeamistransmittedthrough the beam splitter to the fixed mirror and the second is reflected off the beam splitter to the moving mirror. The fixed and moving mirrors reflect the radiation back to the beamsplitte

AIM: ToStudyFTIRspectraOfKetoconazoleAndCMC
OBJECTIVE:ToPerformFTIRSpectraOfKetoconazoleAndCMCWeNeedToCheck Contradictions Ketoconazole And CMC

PLANOFWORK:
SelectionOfAPIAndExcipient
1)KetoconazoleDrugIsSelectedBecauseItTreats Fungal Or Yeast Infection Of The Skin.
CMC Is Selected Because It Is Commonly Used In BeveragesAnd Beverage Dry Mixes To Provide Rich Mouthfeel.

II. LITERATUREREVIEW:

1. PankajKumar (2011,685-694)

In this article they had studied solid dispersion of antifungal drug ketoconazole were prepared with plutonic f-127 and PvPk-30 with an intention to improve its dis-solution properties of dispersion.were performed using released studies FTIR.

2. AMsugar,SGAlsip,JNGalgiani(1987Dec,31(12)):

In this article show that One hundred sixty patients were entered in two multicenter protocolstoreceive400to2,000mgofketoconazoleoncedailyfornonmeningealor meningeal coccidiodomycosis. For 24 h after administration of all doses, mean concentrations in serumexceededMICsforCoccidioidesimmitis(troughconcentrations,greaterthan1 microgram/ml).

3. MdsaifurRahman1,Md.saifHasan2,Asissutradhar Nitai2+(20April2021,13(8))

In this article they had studied Carboxymethyl cellulose (CMC) is one of the most promising cellulose derivatives. Due to its characteristic surface properties, mechanical strength, tunable hydrophilicity, viscous properties, availability and abundance of raw materials, low-cost synthesis process, and likewise many contrasting aspects, it is now widelyusedinvariousadvanced applicationfields,forexample, food,paper,textile,and pharmaceutical industries, biomedical engineering, wastewater treatment, energy

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Volume 9, Issue 4 July-Aug 2024, pp: 205-215 www.ijprajournal.com ISSN: 2456-4494

production,andstorageenergyproduction,andstorage andsoon.Manyresearcharticles have been reported on CMC, depending on their sources and application fields. Thus, a comprehensive and well-organized review is in great demand that can provide an up-to- date and in- depth review on CMC.

4. TehseenRiaz,RabiaZeeshan",FaizaZarif",KanwalIlyas",NawshadMuhammad" (2018 vol 53 no 9,703-746)

Inthisarticletheyhadstudiedaboutidentifychemicalstructuralpropertiesofcollagen andFouriertransforminfrared(FTIR)appearstobeatechniqueofchoicetostudytheir chemical structure. This review aims to highlight the use of FTIR to study collagen- based biomaterials, using it for characterization of collagen extracted from various sources.

5. ParasPapneja,MaheshKumarKataria,AjayBilandi.(ejpmr,2015,2(5),990-1014.

In this article they are studied Ketoconazole is the member of imidazole class that is currently used in the treatment of systemic infections. Ketoconazole is classified in the Biopharmaceutics Classification Scheme (BCS) as a class II drug, since it has a high permeabilityandpoorsolubility.Ketoconazoleisbestabsorbedathighlyacidiclevels,so antacidsorothercausesofdecreasedstomachacidlevelswilllowerthedrugsabsorption. Absorption can be increased.

FTIR:

- Fourier Transform Infrared Spectroscopy, also known as FTIR Analysis or FTIR Spectroscopy, is an analytical technique used to identify organic, polymeric,and,insomecases,inorganicmaterials.TheFTIRanalysismethod uses infrared light to scan test samples and observe chemical properties.
- The first FT-IR spectrum was recorded in 1949 by Peter Fellgett. For several years thereafter it required hours to transform the
- interferometer to the useful spectrum using large and expensive computer systems
- The Michelson interferometer which had been invented in 1881 replaced the need for isolation of single wavelength bands as all wavelengths could be scanned simultaneously. The first FT-IR spectrum was recorded in 1949 by Peter Fellgett

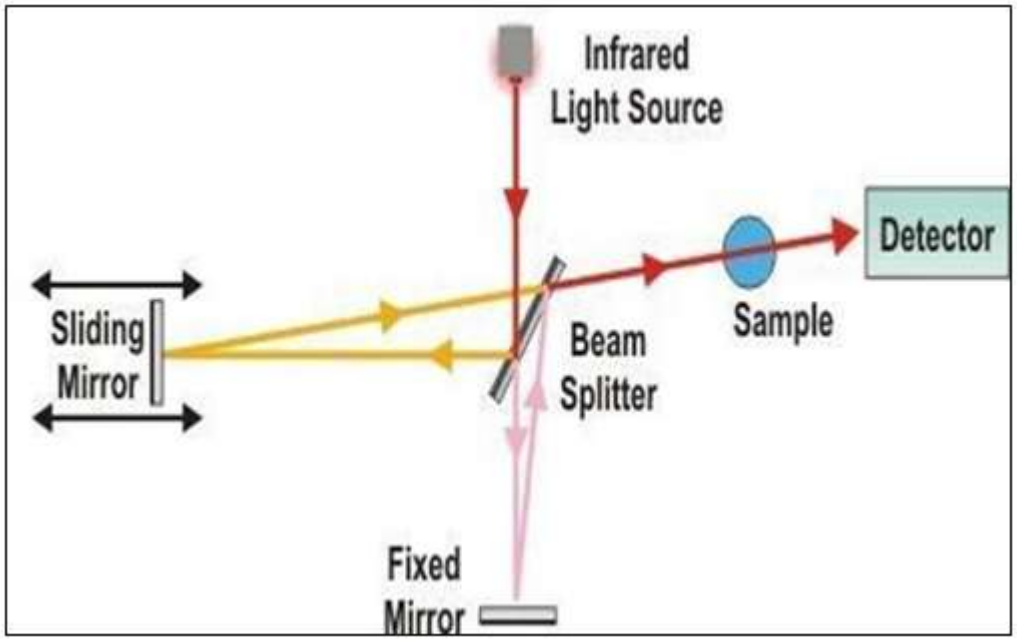

Fig.No.:-1.1FTIR

International Journal of Pharmaceutical Research and Applications
Volume 9, Issue 4 July-Aug 2024, pp: 205-215 www.ijprajournal.com ISSN: 2456-4494

InstrumentationofFTIRPrinciple

1) FTIR relies on the fact that the most molecules absorb light in the infra- red region of the electromagnetic spectrum.
2) This absorption corresponds specifically to the bonds present in the molecule. The frequency range are measured as wave numbers typically over the range 4000-600 cm-1.
3) The background emission spectrum of the IR source is first recorded, followed by the emission spectrum of the IR source with the sample in place.
4) The ratio of the sample spectrum to the background spectrum is directly related to the sample's absorption spectrum.
5) The resultant absorption spectrum from the bond natural vibration frequencies indicates the presence of various chemical bonds and functional groups present in the sample.
6) FTIR is particularly useful for identification of organic molecular groups and compounds due to the range of functional groups, side chains and cross- links involved, all of which will have characteristic vibrational frequencies in the infra-red range.

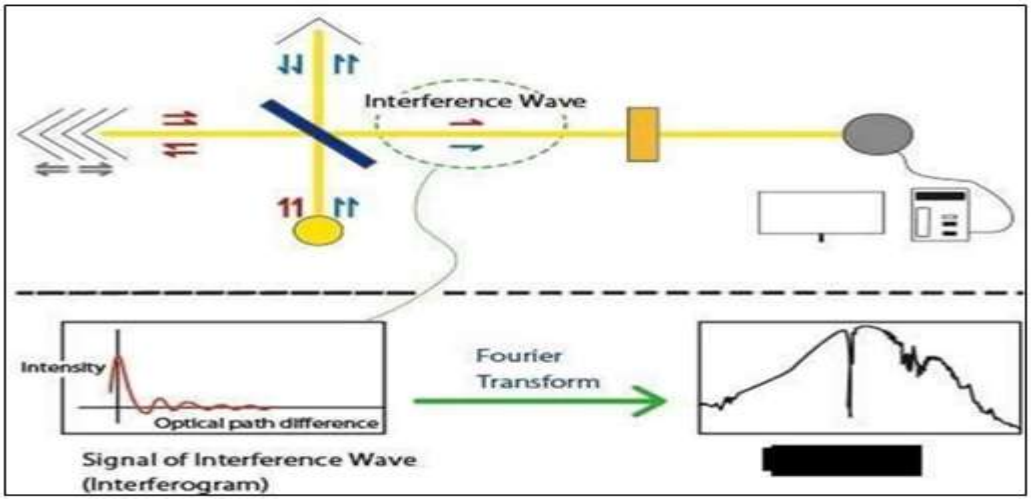

Fig.no.:-1.2FTIR Principle

1 Source: Infrared energy is emitted from a glowing black-body source. Ends at thedetector
2 Interferometer: beam enters the interferometer where the "spectral encoding" takes place
3 Interferogram:signalthenexitstheinterferometer
4 Beamsplitter:takestheincoming beamanddividesit into twooptical .
5 Sample:beamentersthesamplecompartmentwhereitistransmittedthroughor reflected off of the surface of the sample

SAMPLINGTECHNIQUES:

1:LiquidSamples:
Neatsample
Dilutedsolution
Liquid cell

2. SolidSamples
Neatsample
Castfilms
Pressedfilms KBr pellets
Mull

3. GasSamples:
ShortPathCellLong Path Cell

6) Detector:
Thebeamfinallypassestothedetector forfinalmeasurement

FTIRDetectors:
Thetwomostpopulardetectorsfor aFTIRspectrometerare:

1) Deuterated triglycinesulphate (DTGS): ByIs a pyroelectric detector that deliversrapidresponsesbecauseitmeasuresthechangesintemperaturerather than the value of temperature. It operates at room temperature.
2) MercurycadmiumTelluride(MCT):

- Is a photon (or quantum) detector that depends

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on the quantum nature of radiation and also exhibits very fast responses. It must be maintained at liquid nitrogen temperature (77 °K) to be effective

- Ingeneral,theMCTdetectorisfasterandmoresensitivethanDTGSdetector.

7) Computer:measuredsignalisdigitizedandsenttothecomputerwherethe Fourier transformation takes place

8) Movingmirror:intheinterferometeristheonlymovingpartoftheinstrument

9) Fixedmirror:

AdvantagesofFTIR

FT-IRAdvantages

1) Follett's(multiplex)Advantage(HighS/Nratiocomparingwithdispersive instruments)

- FT-IRcollectsallresolutionelementswithacompletescanoftheinterferometer.
- Successive scans oftheFT-IR instrument are coded andaveragedto enhance the signalto-noise of the spectrum.
- Theoretically,aninfinitelylongscanwouldaverageoutallthenoiseinthe baseline.
- Thedispersiveinstrumentcollectsdataone wavelengthatatimeand collectsonlya single spectrum.
- Thereisnogoodmethodforincreasingthesignal-to-noiseofthedispersive spectrum.
- ConesAdvantage High resolution, reproducibility and highly accurate frequency determination
- Techniqueallowshighspeedsamplingwiththeaid of laser
- lightinterferencefringes
- Requiresnowavenumbercorrection
- Provideswavenumbertoanaccuracyof0.01cm[21]

3.Much higherE throughput (Jacquinot orThroughput advantage):

- Becausenotusingclassicalmonochromator.
- Requiresnoslitdevice,makinggooduseoftheavailable beam

4. Better sensitivity.

- In the interferometer, the radiation power transmitted on to the detector is very high which results in high sensitivity.
- Allowssimultaneousmeasurementovertheentire wavenumber range

5. NoStraylight

- FourierTransformallowsonlyinterferencesignal stocontributetospectrum.
- Backgroundlighteffectsgreatlylowers.
- Allowsselectivehandlingofsignalslimitingintreference

6. Wavenumberrangeflexibility

Simpletoaltertheinstrumentwavenumber

Disadvantage of FTIR

1) Single-beam,requirescollecting blank
2) Can'tusethermaldetectors–tooslow
3) CO_2andH2Osensitive
4) Destructive
5) Toosensitivethatitwouldddetectthesmallest contaminant

6) Easytoobtaininaccurate dataifnotanalyzedcorrectly
7) Skilledspectroscopiesneededfor properanalysisand validationofresults
8) Existing FTIR-based EPA methods are somewhatcomplexandoftenrequire adaptation.
9) Extractionofreactivecomponentscanbechallenging
10) Requiresroutinemaintenance 11)Mobility – heavy and bulky 12)Relatively expensive

ApplicationofFTIR

1 Identification of simple mixtures oforganic and inorganic compounds both as solids or liquids.
2 Identificationofpolymersandpolymerblends.
3 Indirectverificationoftraceorganiccontaminants onsurfaces
4 AnalysisofAnalysisofadhesives,coatingsandadhesionpromotersorcoupling agents.
5 Smallvisibleparticlechemicalanalysis..
6 Identificationofrubbers andfilledrubbers.
7 Determinationofdegrees ofcrystallinityinpolymers(egLDPEandHDPE).
8 Comparativechainlengthsinorganics.
9 Extentofthermal,UVorotherdegradationordepolymerisationofpolymersandpaint coatings.
10 Analysisofagaseoussamplesusingagascellforheadspaceanalysisorenvironmental monitoring.
11 Analysisofunknownsolvents,cleaningagentsand detergents.

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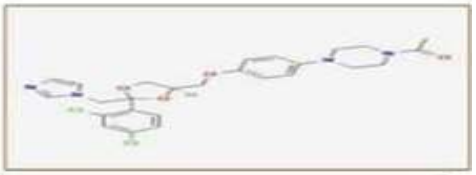
Drug profile



Sr. No.	Properties	Ketoconazole
1	IUPAC Name	1-[4-[4-[[2-(2,4-dichlorophenyl)-2-(imidazol-1-ylmethyl)-1,3-dioxolan4-yl] methoxy] phenyl] piperazin-1-yl] ethenone
2	Appearance	Solid
3	Colour	White crystalline powder
4	Molecular formula	$C_{26}H_{28}Cl_2N_4O_4$
5	Molecular weight	531.4 g/mol
6	Melting point	148-152 °C
7	logP	4.35
8	Category	Antifungal agent
9	Dissolution constant	**4.6**
10	BCS Class	Class II (low solubility , high permiability)
11	Half life	2-8 hours
12	Bioavailability	Poor absorption by mouth (tab), negligible absorption through intact skin as topical bioavailability is about 0.5 -10%
13	Solubility	Freely soluble in DMSO. Soluble in methanol, dichloromethane, ethanol. insoluble in water. (In water, 0.29 mg/L at 20 °c)
14	Dose	200 mg taken once per day for up to 6 months.
15	Mechanism of action	Ketoconazole is an imidazole antifungal agent used in the prevention and treatment of a variety of fungal infections. It functions by **preventing the synthesis of ergosterol, the fungal equivalent of cholesterol, thereby increasing membrane fluidity and preventing growth of the fungus.**

TableNo.:-1

International Journal of Pharmaceutical Research and Applications
Volume 9, Issue 4 July-Aug 2024, pp: 205-215 www.ijprajournal.com ISSN: 2456-4494

Ketoconazole is a drug used in the management and treatment of fungal infections. It is in theimidazoleantifungalclassofmedications.Thisacti vitydescribestheindications,actions, and contraindications of ketoconazole as a valuable agent in treating fungal infections.This activity will highlight the mechanism of action, adverse event profile, and other key factors pertinent to members of the interprofessional team in the treatment of patients with fungal infection.

Objectives:

1 Identifythemechanism ofactionofketoconazole.
2 Describetheadverseeffectsofketoconazole.
3 Reviewtheappropriatemonitoringofketoconazol e.
4 Summarize some interprofessional team strategies for improving care coordination and communication to advance ketoconazole and improve outcomes.

Indications

Ketoconazole has approval for use in the treatment of fungal infections of the skin and systemic fungal infections. These include blastomycosis, histoplasmosis, paracoccidioidomycosis, coccidioidomycosis, and chromomycosis.

The use of this drug requires a careful risk-benefit analysis when selecting ketoconazole as the treatment of fungal infections. Clinicians should avoid using ketoconazole in the treatment of onychomycosis, cutaneous dermatophyte, and candida infections.

MechanismofAction

Ketoconazole works as an antifungal agent by inhibiting the cytochrome P450 14αdemethylase enzyme. This enzyme is responsible for inhibiting the biosynthesis of triglycerides and phospholipids by fungi. More specifically, ketoconazole inhibits the synthesis of lanosterol, a necessary precursor for ergosterol biosynthesis. Ergosterol is neededtomaintaintheintegrityofthemembraneoffung i.[6]Withoutergosterol,thefluidity of the membrane increase, which in turn prevents fungal growth. Ketoconazole, in high doses, can competitively bind to androgen receptors, such as that of testosterone and dihydrotestosterone,whichcandecreasetheactivityoft estosteroneanddihydrotestosterone in prostate cancer. Ketoconazole can also inhibit the enzymes 17-alphahydroxylase and 17,20-lyase,whicharenecessaryforthesynthesisofsteroidsin theadrenalcortex,including testosterone.

Administration

Ketoconazole is available in tablet form and as a topical agent in creams, foams, and shampoos.Itisalsoavailableinmixtureproducts.Theor alformofketoconazoleisusedfor systemicadministration and must betaken at least two hoursbefore any antacids.The high pH of the gastric contents would decrease absorption, so appropriate timing of administration is paramount to its absorption and subsequent efficacy.Adult and pediatric patients with achlorhydria should be given ketoconazole tablets with an acidic beverage to decreasepHandallowforoptimalabsorption.Topicalk etoconazoleisonlyforexternaluse. It should not be ingested or used intravaginally. The eyes and mucous membranes should also be avoided. Patients should apply the cream and gel only to the affected area and the areas immediately surrounding it. The foam should be applied directly to the infected area to avoid melting in the hands. Handwashing is necessary after the application of the cream and gel to prevent any adverse reactions from the medication. The shampoo application should be slathered onto the scalp and rinsed thoroughly.

AdverseEffects

Systemic ketoconazole administration most commonly causes gastrointestinal side effects.Theseincludenausea,vomiting,constipation,a bdominalpain,drymouth,flatulence, and tongue discoloration. It can also cause adrenal insufficiency due to its role in the inhibition of enzymes in the steroid synthesis pathway. Decreases in cortisol synthesis can lead to orthostatic hypotension.In high doses, it can also cause gynecomastia in males.Ketoconazole can cause severe liver injury and jaundice.

Contraindications

Ketoconazole is contraindicated in patients with acute or chronic liver disease due to its association with hepatotoxicity, which can be fatal. It is contraindicated in adrenal insufficiency because high doses of ketoconazole inhibit adrenocortical function.Ketoconazole should not be given to patients with a known hypersensitivity reaction to ketoconazole.Ketoconazole should never be co-administered with HMG-CoA reductase inhibitors because it can increase the risk of myopathy.

International Journal of Pharmaceutical Research and Applications
Volume 9, Issue 4 July-Aug 2024, pp: 205-215 www.ijprajournal.com ISSN: 2456-4494

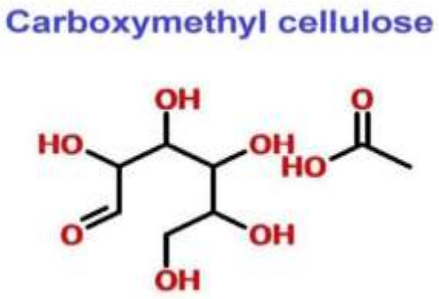
Ketoconazole is contraindicated in patients taking benzodiazepines because it can increase plasma concentrations and lead to sedation. Ketoconazole should never be administered to patients on antiarrhythmic drugs, cisapride, pimozide, quinidine, and ranolazine because it cancauseQTprolongationandtorsadedepointes.Inpatientswithincreasedbonefragility, suchaspost-menopausal womenandthe elderly,ketoconazoleshouldbeusedwithcaution to avoid the riskof fracture.The CYP3A4 liver enzyme metabolizes ketoconazole, and use requires caution in patients taking drugs that inhibit CYP3A4 or are metabolized by CYP3A4.[19] Ketoconazole can also be present in breast milk, so breastfeeding is not recommended when using the drug.

Toxicity

The Food and Drug Administration warns that oral dosing of ketoconazole can lead to hepatotoxicity and adrenal insufficiency and that ketoconazole-associated hepatotoxicity is common. There are many off-label uses for ketoconazole. Therefore, careful selection of ketoconazole as a treatment is necessary due to serious hepatoxic side effects.[21]

EXCIPIENTPROFILE:-CMC

EXCIPIENTS: CMC (carboxyl methylcellulose)



Carboxymethyl cellulose (CMC) is one of the most promising cellulose derivatives. Due to its characteristic surface properties, mechanical strength, tunable hydrophilicity, viscous properties, availability and abundance of raw materials, low-cost synthesis process, and likewise many contrasting aspects, it is now widely used in various advanced application fields, for example, food, paper, textile, and pharmaceutical industries, biomedical engineering, wastewater treatment, energy production, and storage energy production, and storage and so on. Many research articles have been reported on CMC, depending on their sources and application fields.

SR.No	PROPERTIES	CMC
1.	IupacName	AceticAcid;2,3,4,5,6pentahydroxyhexanal
2.	Appearance	White to almost white, odourless, tasteless, Granular powder.
3.	Molecularformula	C8H1608
4.	MolecularWeight	250000 g/mol

TableNo.:-1.2

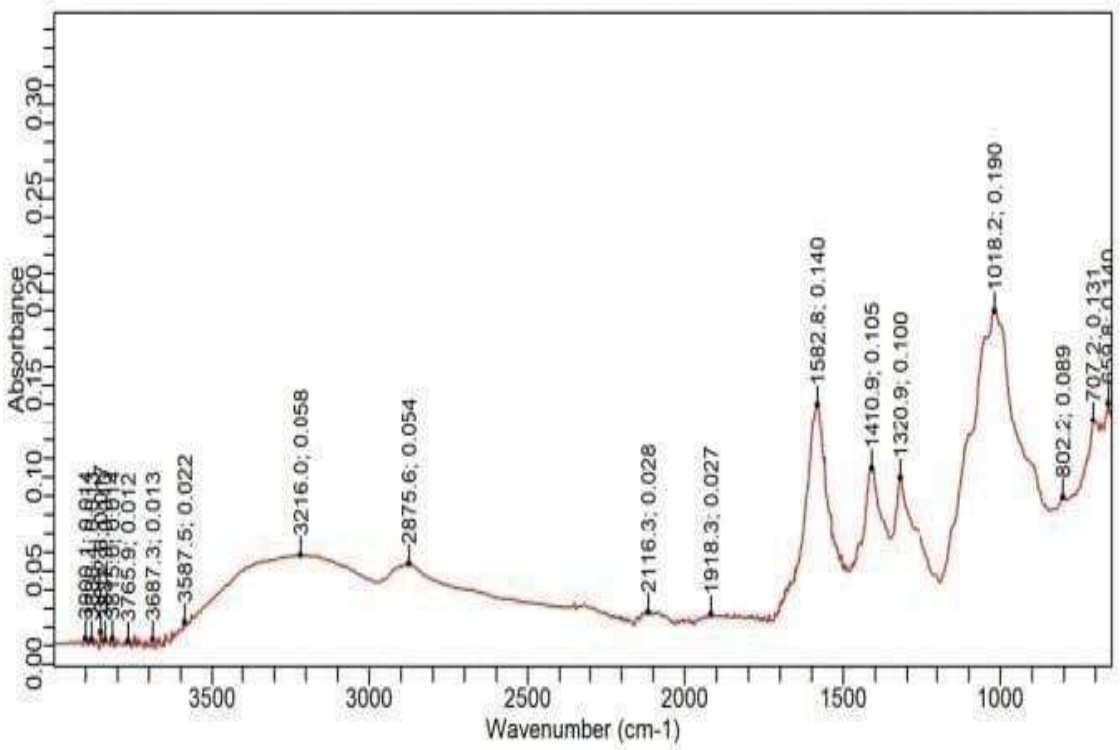
International Journal of Pharmaceutical Research and Applications
Volume 9, Issue 4 July-Aug 2024, pp: 205-215 www.ijprajournal.com ISSN: 2456-4494

III. RESULTS:

Jeevanrekha Analytical Services

Sample ID:KCMC PS 01	Method Name:C:\Users\Public\Documents\Agilent\MicroLab\Methods\J R _ ATR.a2m
Sample Scans:140	User:Admin
BackgroundScans:140	Date/Time:05/06/2024 3:30:22 PM
Resolution:4	Range:4000 -650
System Status:Good	Apodization:Triangular

File Location:C:\Users\Public\Documents\Agilent\MicroLab\Results\KCMC 2024-05-06T15-30-57.a2r



FigerNo.:-1.1

International Journal of Pharmaceutical Research and Applications
Volume 9, Issue 4 July-Aug 2024, pp: 205-215 www.ijprajournal.com ISSN: 2456-4494

Peak Number	Wavenumber (cm^{-1})	Intensity
1	659.77362	0.14034
2	707.23254	0.13085
3	802.15037	0.08925
4	1018.17026	0.18993
5	1320.92542	0.09961
6	1410.93371	0.10465
7	1582.76772	0.13974
8	1918.25316	0.02673
9	2116.27140	0.02787
10	2875.61406	0.05371
11	3216.00904	0.05830
12	3587.49780	0.02243
13	3687.32518	0.01332
14	3765.87786	0.01231
15	3814.97329	0.01376
16	3837.88450	0.01333
17	3852.61312	0.01698
18	3880.43387	0.01329
19	3900.07204	0.01360

TableNo.:-1.3

FTIR interpretation Date: 11/05/24

Sample name: KCMC/PS/01		
peaks	actual	Functional groups
730-665	659,707	C=C bending (disub) c-i-s strong
800-860	802	C-H1,4 Disub(para)
1055-1000/1005-925	1018	Cyclohexane ring vibretation
1342-1250	1320	Strong CN stretching aromatic amine
1450	1410	Medium C-H bending alkyne(methyl group)
1610-1550	1582	Carboxylate (carboxylic acid salt)
2100-1800	1918,2116	Transition metal carbonyls
2800-3000	2875	Strong ,broad ,NH stretching (amine salt)
3570-3200	3216,3587	Hydroxy group ,H bonded OH stretch
4000-3000	3687,3765,3814,3837,3852,3880,3900	OH stretching, alcohol free

TableNo.:-1.4

International Journal of Pharmaceutical Research and Applications
Volume 9, Issue 4 July-Aug 2024, pp: 205-215 www.ijprajournal.com ISSN: 2456-4494

IV. CONCLUSION:

Compatibilitystudyofdrugand excipient

1) FTIR (Fourier transform infrared spectroscopy) FTIR spectra of drug ketoconazole and excipient CMC. The drug ketoconazole contain functional groups C=C,C-H, Cyclohexne, CN, COOH And excipient CMC cantain functional groups C=C,C-H, Cyclohexne,CN,COOH. These two drugs are compatible with each other.

2) FTIR Spectroscopy Is a Rapid, Economical, EasyAnd Non-destructive tech- nique wider Use In Clay mineral Investigation. The Progress In FTIR Spectrome- ter Designs Has Greatly Enhanced The Field OfTheir application. MordenInstru- ments Offer High Sensitivity,SpeedyDataCollection,EnhancedSpectralPreci-sionAndReproducibity.In FTIR Spectra Of Ketoconazole and CMC Obtained FunctionalGroupsC=CBending(Disub)C-I-SStrong,C-H1,4Disub(Para), CyclohexaneRingVibretation,StrongCNStretchingAromaticAmine,Medium C-HBendingAlkyne(MethylGroup)Carboxylate,TransitionmetalCarbonyls,StrongBoard, NH Stretching, Hydroxy Group, H Bond OH Stretch, OH Stretch- ing,Alcohol free

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