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AMOXICILLIN-EXCIPIENT COMPATIBILITY STUDIES FOR ADVANCED DRUG DELIVERY SYSTEMS DEVELOPMENT

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ABSTRACT

The main objective of the present study was to the preformulation studies were performed to know the development of formulation and evaluation of Amoxicillin Trihydrate Fast Dissolving Tablets to improve the bioavailability of Amoxicillin Trihydrate which shows 60%, Amoxicillin Trihydrate is classified as a biopharmaceutics classification system (BCS) Class-I, Class-II and Class-IV Drug according to the dose. Amoxicillin is a hydrophilic drug, increase the solubility and permeability improve the bioavailability and onset of action of Amoxicillin Trihydrate has been done. In API development process, a detailed characterization of the API and other formulation components is usually carried out during the preformulation stage. The drug-excipient compatibility studies were conducted to characterize the drug Amoxicillin Trihydrate present in Fast Dissolving Tablets Delivery System FDTs. Preformulation, formulation and evaluation of Amoxicillin Trihydrate to avoid problems associated with conventional delivery system such as limited permeation, low dissolution and bioavailability and also to improve bioavailability and one of the most used antibiotics. In the present study that the compatibility was assessed by, FTIR spectroscopy, and melting point apparatus, precompression parameters and powder flow properties. Results showed that physical mixtures of Amoxicillin Trihydrate and various excipients as mannitol, and MCC as diluents, and sodium starch glycolate, croscarmellose sodium, and crospovidone as superdisintegrants were evaluated for preformulation studies parameters. It was concluded that the drug Amoxicillin Trihydrate was found to be compatible with various excipients which were selected for the formulation development of the Amoxicillin Trihydrate FDTs. Formulation scientist from his experience and knowledge have to significantly in the preformulation study stage and is an important factor in the ADDS (Advanced Drug Delivery Systems) product development process.

KEYWORDS: Amoxicillin Trihydrate, Compatibility, Excipients, Development, Preformulation, Formulation, Antibiotics.

INTRODUCTION

Preformulation Studies[1-160]

Preformulation is essentials of pharmaceutical science that utilizes biopharmaceutical principles in the determination of physicochemical properties of the drug substance. Prior to the development of any dosage form new drug, it is essential that certain fundamental physical and chemical properties of drug powder are determined. This information may dictate many of subsequent event and approaches in formulation development. The safety, efficacy, quality and stability of a formulation are major concepts of any API development process. In API development process, a detailed characterization of the API and other formulation components is usually carried out during the preformulation stage. Formulation scientist from his experience and knowledge have to significantly in the preformulation study stage and is an important factor in the ADDS (Advanced Drug Delivery Systems) product development process.

One of the objectives of this study is to development of drug delivery systems by building scientific pharmaceutical research information depend on formulation scientists to join the knowledge and experience as well as experimental and practical results of this study with regard to information in previous studies, and approved references. It was found to be that the most important concepts and basics of preformulation studies such as definitions, methods, conclusion, idea, and types of pharmaceutical analysis techniques using in evaluation of preformulation studies parameters, in this study that we focused on developing drug delivery

systems and linking the formulation development to establish the basics of pharmaceutical research in studying the drug-excipient compatibility, dug with various excipients, which is important for the safety, effectiveness, quality, formulation, stability, bioavailability, and pharmacokinetics of the drug etc.

Determination of physical chemical properties of API substance with the goal of developing a new drug which is safe stable and efficacious, each API, has intrinsic chemical and physical properties that were considered prior to the development of pharmaceutical formulation, the purpose of preformulation study is to generate useful information for the formulator in the development of stable and bioavailable dosage form, inappropriate preformulation study results in poor stability of active ingredients increase the overall cost of development and increased development time, preformulation studies help to fortify the pharmaceutical scientific foundation of the guidance, provide regulatory relief and conserve resources in the drug development and evaluation process, enhance public safety standards, improve product quality, promote the implementation of new technologies, aids policy development and regulatory decision making and after compiling all data it is transferred to the development pharmacist and for the day work on formulation of dosage form.

Preformulation Study Objectives: To establish the Physico-chemical parameters of a new API entity, determine its kinetics and stability, establish its compatibility with common excipients, it provides insights into how drug products should be processed and stored to ensure their quality, estimate problem may arise during formulation that is stability problem poor *in-vivo* dissolution, poor bioavailability, to interpret BCS classification of drugs and its significance and develop optimal drug delivery system.

Drug-Excipient Compatibility Study: The primary objective of this investigation was to identify a stable storage condition for API in solid state and identification of compatible excipients for its formulation. Incompatibilities are major concerns in formulation development. Selection of the proper excipient during preformulation studies is of prime importance.

Dosage Forms: DF contain API and pharmaceutical excipients, which are intended to generate an ideal formulation and manufacturability of pharmaceutical products, thereby enabling a much safer and more effective administration. Pharmaceutical excipients are ideally inactive and have no impact on the stability or therapeutic effect of the active ingredient. On the other hand, there are studies that have presented that some pharmaceutical excipients are just allegedly described as inactive ingredient. Some pharmaceutical excipients have the capacity to affect API, efficacy by affecting its pharmacokinetics. Excipients can affect the physical and chemical form of pharmaceuticals by several factors such as hydrogen bond interaction, polymorphic conversion, and others. Accordingly, drug-excipient compatibility should be conducted so as to determine any drug-excipient interactions that may obstruct the stability, bioavailability, and manufacturability of pharmaceutical dosage forms.

Importance of Drug-Excipient Compatibility

Studies of active pharmaceutical ingredient (API)-excipient compatibility represent an important study in the preformulation stage of the development of new dosage forms, stability of the dosage form can be maximized, any physical or chemical interaction between API, and excipient can affect bioavailability and stability of drug, it helps to avoid the surprise problem, by performing drug excipient compatibility studies (DECS) we can know the possible reaction before formulating final dosage form, DECS data is essential for IND (investigational new drug) submission, and now, USFDA has made it compulsory to submit DECS data for any new coming formulation before its approval.

The potential physical and chemical interactions between an API, and the excipients can affect the chemical nature, the stability and bioavailability of the former and, consequently, its therapeutic efficacy and safety, solid dosage forms are generally less stable than their API components and despite the importance of API-excipient compatibility testing, there is no universally accepted protocol to assess such interactions.

Pharmaceutical Excipients: Excipients are additive substances used to improve the bulkiness, disintegration, dissolution rate, and bioavailability of a formulation etc. Different dosage forms like powders, granules, capsules, tablets, oral liquids, injectable products, implants, eye products, nasal products, inhalers, topical creams, ointments, gels, transdermal patches and suppositories etc, contains different types of excipients. To make it acceptable and compatible various pharmaceutical excipients are added in pharmaceutical dosage form for their direct therapeutic action, manufacturing process, to protect, support or enhance stability, for bioavailability or patient compliance. These must be physiologically and chemically stable, must not have any incompatibility with the API, and must meet the standards of regulatory requirements.

Evaluation of Drug-Excipient Compatibility

The compatibility study of API and excipients is important to predict the stability of the API, in the final pharmaceutical product. It's the first time that API was compatible with excipients promoted physical and chemical compatibility studies was achieved by thermal and non-thermal methods. As a part of preformulation study, a compatibility study of API with the other excipients was carried out using physical blends in analytical techniques for the evaluation of drug-excipient interactions. The most commonly used pharmaceutical analytical techniques include, thermal techniques such as

Differential Scanning Calorimetry (DSC), Thermogravimetric Analysis (TGA), Isothermal Microcalorimetry (IMC) and Hot stage microscopy (HSM) etc, and non-thermal techniques such as UV-Visible Spectrophotometric (UV), Infrared, Near-Infrared and Raman Spectroscopy (FT-IR), (NIR), Powder *X*-Ray Diffraction (PXRD), Solid-State Nuclear Magnetic Resonance Spectroscopy (ssNMR), Microscopic techniques: Scanning Electron Microscopy (SEM), Chromatographic techniques: Thin Layer Chromatography (TLC), and High-Performance Liquid Chromatography (HPLC) etc.

Preformulation Parameters: According to dosage form of API, mainly solid state, particle size, shape, pKa, pH determination, common ion effect, temperature, partition coefficient, solubility studies, dissolution rate, melting point, powder flow properties, crystallinity, polymorphism, hygroscopicity, stability study and drug-excipient compatibility etc. While other dosage forms according to important of preformulation parameters used in study before start in development of formulation.

Drug-excipient compatibility and formulation stability is not depended on API only but also its affected by excipient. Excipient play important role in dosage form but side by side it also increases compatibility problem so proper selection of excipient is very important in development of formulation. Incompatibility can be result mainly in any of following changes: Changes in organoleptic properties, changes in dissolution performance, decrease in potency, and increase in degradation rate etc.

Drug excipient physicochemical characterization is a systematic approach towards design of therapeutically active and stable dosage forms. The rapid advancements in novel drug delivery systems development have led to an interest by formulation scientists in the role and functionality of the excipients.

In the present study, it was proposed to Amoxicillin-excipient compatibility studies of the safety, efficacy, quality and stability of a formulation are major concepts of any API development process. In API development process, a detailed characterization of the API and other formulation components is usually carried out during the preformulation stage., with commonly different excipients using for formulation development of Fast Dissolving Tablets FDTs.

MATERIALS AND METHODS

As shown in Table 1.

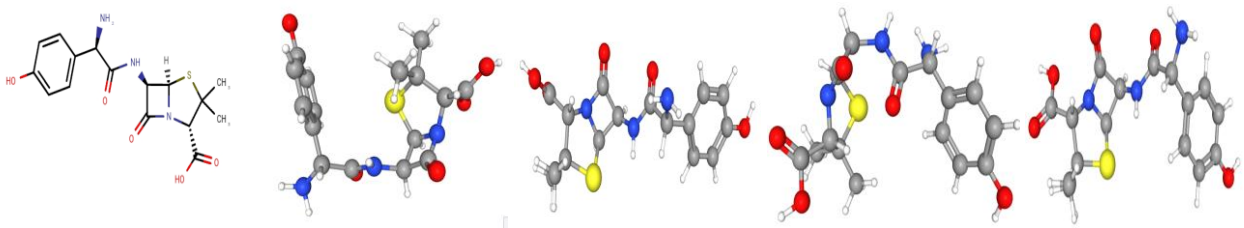
Table 1: List of Materials Used.

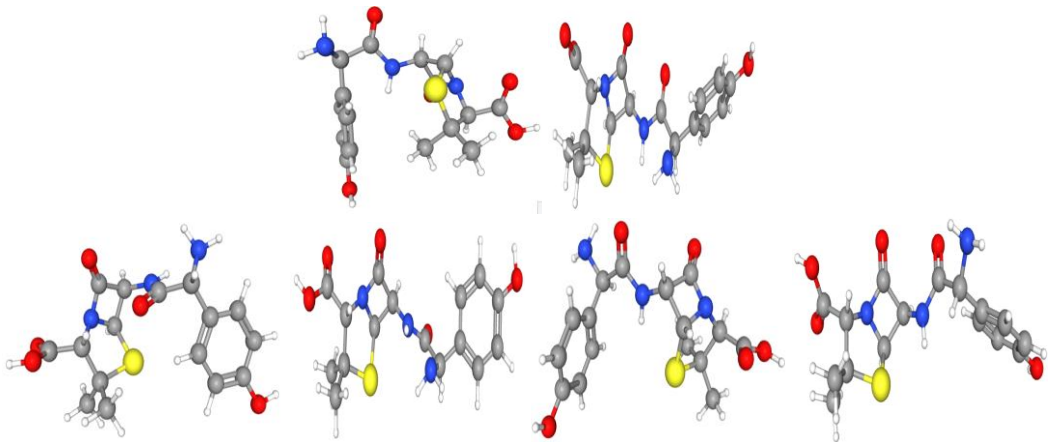
NO	Materials
1	Amoxicillin Trihydrate
2	Sodium Strach Glycolate
3	Microcrystalline Cellulose
4	Crospovidone
5	Croscarmellose Sodium
6	Magnesium Stearate
7	Talc
8	Aerosil
9	Sodium Saccharin
10	Mannitol
11	Dibasic Sodium Phosphate
12	Monobasic Potassium Phosphate (KH2PO4)
13	Calcium Carbonate
14	Orange Flavor
Most materials were a gift sample from (Shaphaco Pharmaceutical Industry Company-Yemen). While other materials were a gift sample from **(**Biopharm Pharmaceutical Industry Company-Yemen and Shiba Pharmaceutical Industry Company-Yemen).	

Evaluation of Drug-Excipient Compatibility Studies Methods[40-200]

Table 2: Amoxicillin Trihydrate Data.

Characterization of Amoxicillin Trihydrate





Amoxicillin Trihydrate Structure and 3D Conformer

Chemical Structure	(2S,5R,6R)-6-[[(2R)-2-amino-2-(4-hydroxyphenyl)acetyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid,trihydrate	**Appearance**	Typically appears as a white to pale cream colored, crystalline powder.
Molecular Formula	C16H25N3O8S	**Drug Solubility**	**Water Solubility:** is soluble in water, approximately 1 to 10 mg/mL depending on the pH.
Molecular Weight	419.5 g/mol	**BCS**	Class-I, Class-II and Class-IV Drug according to the dose of Amoxicillin.
Drug Action and Use	Amoxicillin is in a class of medications called penicillin -like antibiotics. It works by stopping the growth of bacteria. Amoxicillin is bactericidal, and work by inactivating an enzyme necessary for the cross linking of bacterial cell walls. Amoxicillin is used to treat bacterial infections in many different parts of the body (ear, lungs, nose, sinus, skin, urinary tract). It also used with other medicines to treat H. Pylori infection and duodenal ulcers.		
Amoxicillin Pharmacokinetics			
Drug Absorption	**Bioavailability:** 60%.	**Drug Distribution**	**Volume Disrtbution:** 27.7L. **Protien Binding:** 17% protien bound in serum.
Drug Metabolism	Studies have shown that Amoxicillin dose not affect the metabolic activity of P450 liver drug enzymes.	**Drug Excretion**	70-78% eliminated in the urine after 6 hours. **Drug Clearance:** The systemic clearance of Amoxicillin is 21.3 L/h.
The Elimination Half-Life (T1/2)	The elimination half-life is about 61.3 minutes.	**Availability**	Tablets , Capsules, Suspensions.

Table 3: Pharmaceutical Excipients Data.

Nonproprietary Name	Chemical Name	Functional Category	Concentration %	Solubility	Incompatibilities	Notes
Croscarmellose Sodium (Ac-Di-Sol)	Cellulose, carboxymethyl ether, sodium salt, crosslinked	Tablet and capsule disintegrant.	0.5-5% 10-25%	Insoluble in water	Incompatible with strong acids or with soluble salts of iron and some other metals such as aluminum, mercury, and zinc.	White or grayish-white powder
Sodium Starch Glycolate (Explotab)	Sodium carboxymethyl starch	Tablet and capsule disintegrant.	2–8%	Gives a translucent suspension in water	Incompatible with ascorbic acid.	Very hygroscopic

Microcrystalline Cellulose (Avicel)	Cellulose	Adsorbent, suspending agent, tablet and capsule diluent; tablet disintegrant.	5–20% 20–90%	Practically insoluble in water	Incompatible with strong oxidizing agents.	Crystalline powder
Crospovidone (PVPP)	1-Ethenyl-2-pyrrolidinone homopolymer	Tablet disintegrant.	2–5%	Practically insoluble in water	Compatible with most organic and inorganic pharmaceutical ingredients.	Hygroscopic powder
Mannitol (Emprove)	Mannitol	Diluent, plasticizer, sweetening agent, tablet and capsule diluent, therapeutic agent, tonicity agent.	10–90%	Freely soluble in water	Incompatible with may be salted out by potassium chloride or sodium chloride. Sodium cephapirin. xylitol infusion and may form complexes with some metals such as aluminum, copper, and iron.	Crystalline powder
Magnesium Stearate (magnesium salt)	Octadecanoic acid magnesium salt	Tablet and capsule lubricant.	0.25 - 5.0%	Practically insoluble in water	Incompatible with strong acids, alkalis, and iron salts.	Greasy
Aerosil	Aerosil; Cab-O-Sil, Cab-OSil M-5P, colloidal silica, fumed silica, fumed silicon dioxide, SAS, silica colloidalis anhydrica	Adsorbent; anticaking agent glidant; viscosity-increasing agent	0.1–1.0% 2.0–10.0% widely used in oral and topical pharmaceutical products and is generally regarded as an essentially nontoxic and nonirritant excipient.	Practically insoluble in organic solvents, water. -hygroscopic but adsorbs large quantities of water without liquefying. When used in aqueous systems at a pH 0–7.5, colloidal silicon dioxide is effective in increasing the viscosity of a system.	Incompatible with diethylstilbestrol preparations.	A submicroscopic fumed silica with a particle size of about 15 nm. It is a light, loose, bluish-white-colored, odorless, tasteless, amorphous powder.
Sodium Saccharin	1,2-Benzisothiazolin-3-one 1,1-dioxide, sodium salt, Crystallose, E954, gendorf 450, sucaryl sodium	Sweetening agent. Saccharin can be used to mask some unpleasant taste characteristics or to enhance flavor systems. Its sweetening power is approximately	0.02–0.5% w/w.	Readily dissolved by dilute ammonia solutions, alkali hydroxide solutions, or alkali carbonate solutions. 1 in 290 water.	Saccharin can react with large molecules. Saccharin sodium does not undergo Maillard browning.	White crystals or a white crystalline powder.

		300–600 times that of sucrose.				
Talc	Altalc, E553b, hydrous magnesium calcium silicate, hydrous magnesium silicate, Luzenac Pharma, magnesium hydrogen metasilicate. $Mg_6(Si_2O_5)_4(OH)_4$.	Anticaking agent, glidant, diluent, lubricant.	1.0–10.0% 5.0–30.0%	Practically insoluble in dilute acids and alkalis, organic solvents, and water.	Incompatible with quaternary ammonium compounds.	is a very fine, white to grayish-white, crystalline powder.

According to Amoxicillin Trihydrate and excipients data as shown in Tables 2 and 3, it was selected that the different excipients to preformulation study with Amoxicillin Trihydrate in the present study, the equipments used as shown in Table 4.

Table 4: The Equipment's Used.

No	Equipment's
1	Fourier Transform Infrared Spectrophotometer
2	UV/VIS Spectrophotometer
3	Melting Point Tester
4	Moisture Tester
5	Density Tester
6	pH Meter
7	Ultra-sonic
8	Accelerate Stability Study Chamber
9	Electronic Balance

Determination of The Organoleptic Properties

Organoleptic properties like color, odour and taste of Amoxicillin Trihydrate were studied. Color: a small amount of Amoxicillin Trihydrate was taken in paper and investigated by the eye in well-illuminated place. Taste and odour: Very small amount of Ticagrelor was used to assess the taste with the help of tongue as well as smelled to get odor.

UV-Visible Spectrophotometric Method

Determination of λ Max for Amoxicillin Trihydrate

The standard solution of Amoxicillin Trihydrate was scanned in the range of 200-400 nm and the λ max was determined.

Preparation of Sorenson's Phosphate Buffer pH 6.8

24.5ml of 0.2M of dibasic sodium and 25.5 ml of 0.2M of monobasic sodium phosphate was placed in 100ml volumetric flask and make up the volume 100ml with purified water. Taken 5ml of buffer Sorenson's and then dissolving 50mg of active ingredient Amoxicillin Trihydrate and volume was made to 100ml of buffer Sorenson's and shake the volumetric flask by sonicator device. Let the volumetric flask sit undisturbed for several hours to allow any undissolved particles to settle. Filtration of solution that contains the active ingredient, then measure the solubility under UV spectrophotometer.

UV Visible Spectrophotometer

UV Scanning of Amoxicillin Trihydrate in Sorenson's Buffer pH 6.8

The sample was scanned with UV-V spectrophotometer in the range 200 -800nm against Sorenson's phosphate buffer pH 6.8 as blank and the wavelength corresponding to maximum absorbance was noted.

Preformulation Studies

Preformulation studies are initiated to define the physical and chemical properties of the agent. The key goals of preformulation studies are to ensure the delivery of drug product with acceptable stability, bioavailability, and manufacturability.

Melting Point Determination of Amoxicillin Trihydrate

The most common and most basic method of determination is the capillary method. Melting point of the Amoxicillin Trihydrate was determined by capillary method; one sided closed capillary filled with drug and put into the melting point apparatus. Temperature was noted at which solid drug changed into liquid.

Drug-Excipient Compatibility Studies

A physical mixture including Amoxicillin Trihydrate and excipient was created in a 1:1 ratio, and it was subjected to analytical techniques such as FTIR spectroscopy. FTIR, of both pure drug and physical mixes were obtained, and the spectra of the both drug and mixture of excipient with drug were compared to look for any incompatibilities.

FTIR Spectroscopy Study

FTIR study KBr-disc method was used to record the FTIR spectra and KBr pellets were made in 1:100 ratio of sample and KBr. FTIR spectra was recorded using FTIR spectrum in a range of 4000-400cm^{-1}. Different functional groups of test compound for distinctive vibrational frequencies are identified using FTIR spectroscopy. FTIR spectra were used for the investigation of interaction in the physical mixture of API and excipient through shifting of peaks to lower or higher wavenumbers and appearance or disappearance of characteristic peaks of functional groups for pure API in physical mixture. FTIR spectroscopic study was performed to check the compatibility between API, and different excipients in amount (5mg:5mg) as ratio (1:1) as shown in Table 5. The FTIR spectra of a API alone and API with excipients were obtained by KBr method and compared with the standard FTIR spectrum of the pure API. Infrared spectrophotometer is not only used for determining the compatibility of excipients with the APIs, but also for API identification.

Preparation of IR Samples

The sample was determined by the disc method. Triturate 5mg of the substance to be examined with 300-400 mg of finely powdered and dried potassium bromide R or potassium chloride R. Each excipient was mix with Amoxicillin Trihydrate equally then of potassium bromide is added to the mixture. Carefully grind the mixture, spread it uniformly in a suitable die, and submit it to a pressure of about 800 MPa (8 t·cm^{-2}). Then the tablets were inserted to the device and the Infrared spectra was recorded at mild-infrared light in wavenumber range of 4000 cm^{-1} to 400 cm^{-1}. After that the spectra were compared with the reference.

Infrared Spectral Study of Samples in Room Condition

Compatibility studies were performed by preparing blend of different excipients with Amoxicillin Trihydrate in room condition as shown in Table 5.

Infrared Spectral Study of Samples after Stored Two Weeks

Compatibility studies were performed by preparing blend fresh of different excipients with drug and stored at 25°C and 50°C for two weeks. The blend was evaluated after two weeks for changes like caking, liquefaction, discoloration and odor formation and by IR spectra. The drug excipient compatibility studies as shown in Table 5.

Table 5: Samples of Amoxicillin Trihydrate and Different Excipients for Compatibility Studies.

No	Component(s)	Amount(5mg:5mg)
1	Amoxicillin Trihydrate	1
2	Amoxicillin and MCC	(1:1)
3	Amoxicillin and SSG	(1:1)
4	Amoxicillin and Crospovidone	(1:1)
5	Amoxicillin and Calcium Carbonate	(1:1)
6	Amoxicillin and Saccharin Sodium	(1:1)
7	Amoxicillin and Mannitol	(1:1)
8	Amoxicillin and CCS	(1:1)
9	Amoxicillin and Mg. Stearate	(1:1)
10	Amoxicillin and Talc	(1:1)
11	Amoxicillin and Aerosil	(1:1)
12	Amoxicillin and Orange Flavor	(1:1)

RESULTS AND DISCUSSION

Preformulation Studies

Characterization of Amoxicillin Trihydrate

The organoleptic properties of Amoxicillin Trihydrate were shown in Table 6.

Table 6: Organoleptic Properties of T Amoxicillin Trihydrate (API).

Tests	Specification	Observation
Color	White to off-white	White to off-white
Odor	Odorless	Odorless
Taste	Tasteless	Tasteless

Physical Identification of Amoxicillin Trihydrate

Amoxicillin Trihydrate is white to off-white, crystalline powder.

The organoleptic properties like color, odor and taste of the API were evaluated. The color of Amoxicillin Trihydrate was found to be white to off-white powder, no characteristic odor and no taste were observed in the study. Amoxicillin Trihydrate showed similar color, taste and odor.

Characterization of Amoxicillin Trihydrate by UV Spectroscopy

Wave length of Amoxicillin Trihydrate in Sorenson's phosphate buffer (pH 6.8) by UV scanning show in Figure 1, at 272.6nm.

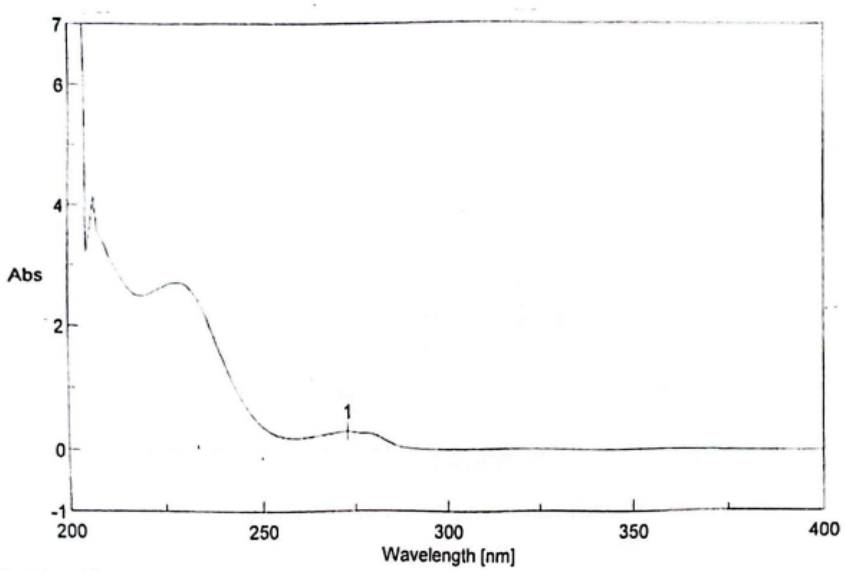


Fig. 1: UV Scanning of Amoxicillin Trihydrate in Sorenson's Phosphate Buffer (pH 6.8).

Melting Point Determination of Amoxicillin Trihydrate

Melting point of pure Amoxicillin Trihydrate was determined by open capillary method. The capillary tube was closed at one end by fusion and was filled with Amoxicillin Trihydrate by repeated tapings. The capillary tube was placed in a digital melting point apparatus. The instrument was set to automatically increase the temperature of the heating bath. The rise in temperature was viewed through screen. The temperature at which the drug started d melting was recorded. The melting point range of Amoxicillin Trihydrate was identical to reference melting point stated in MP (190-204°C). The sample started to melt at 194°C, and turned into liquid at 194°C, indicating that the sample used is pure. That reading has stated in melting point tester.as shown in Table 7.

Table 7: Results of Melting Point of Amoxicillin Trihydrate.

Test	Temp Rang Analyzed (Melting)	Results
Test I Amoxicillin Trihydrate	(190-204°C)	194°C
Test II Amoxicillin Trihydrate	(190-204°C)	194°C

Characterization of Amoxicillin Trihydrate by FTIR

FTIR spectrum studies indicated that major functional groups present in Amoxicillin Trihydrate show characteristic peaks in IR spectrum. Figures (2) to (35) show peaks observed at different wave numbers and the functional group associated with these peaks for drug and drug with different excipients fresh and stored at 25°C and 50°C for two weeks. The major peaks are identical to functional group of Amoxicillin Trihydrate. Hence, it was confirmed that there was compatibility between drug and various excipients, thus conforming that no interaction of drug occurred with the components of the formulation excipients.

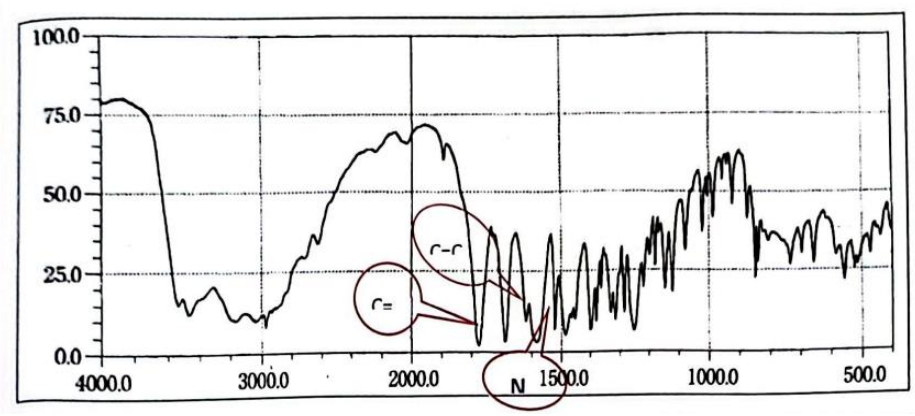


Fig. 2: FTIR Spectrum of Pure Amoxicillin Trihydrate.

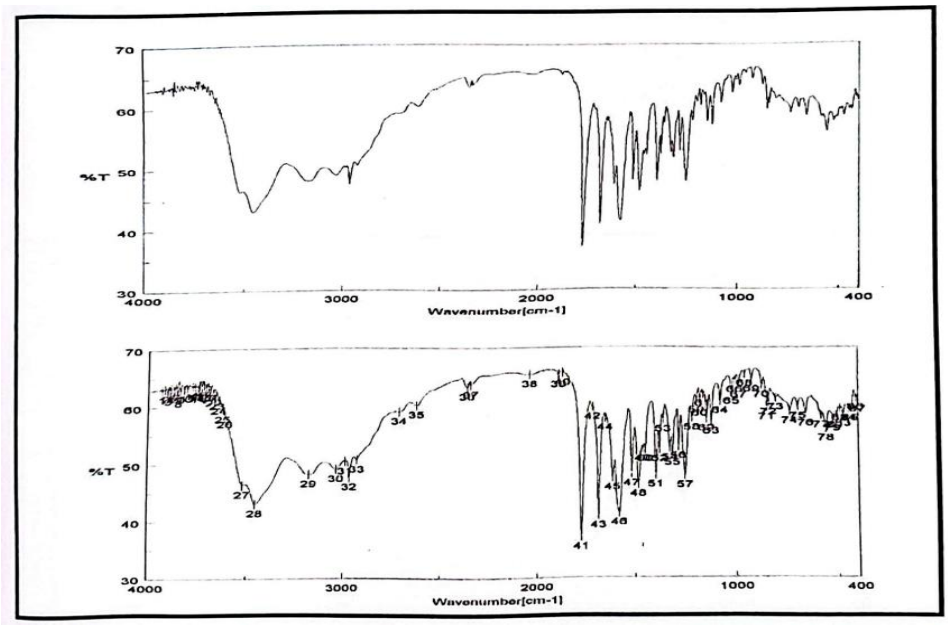


Fig. 3: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate Fresh.

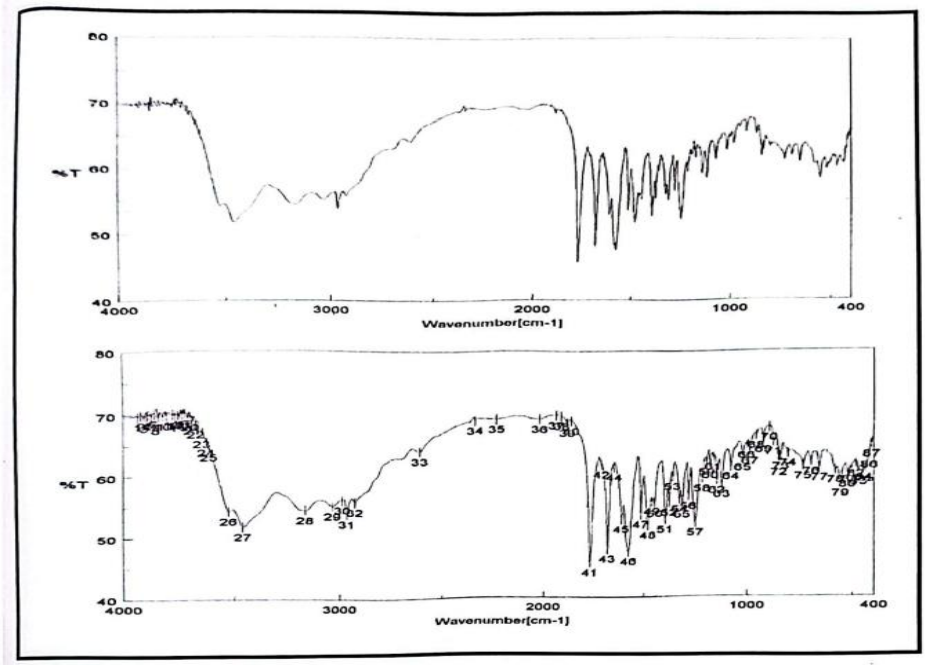


Fig. 4: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate Fresh and CCS.

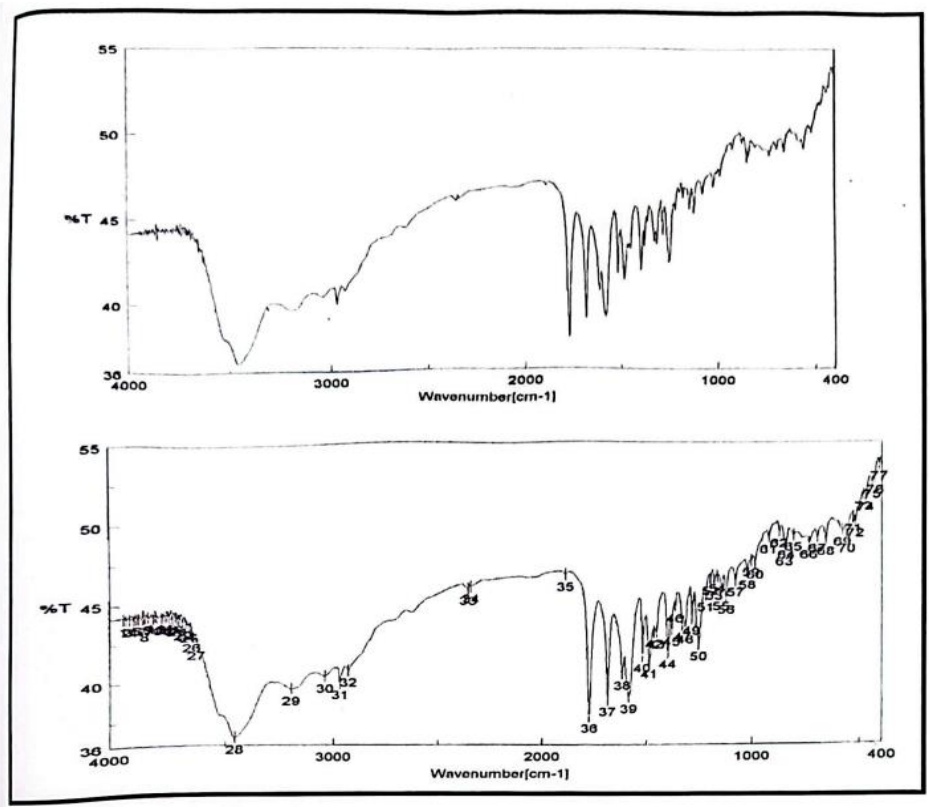


Fig. 5: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate Fresh and SSG.

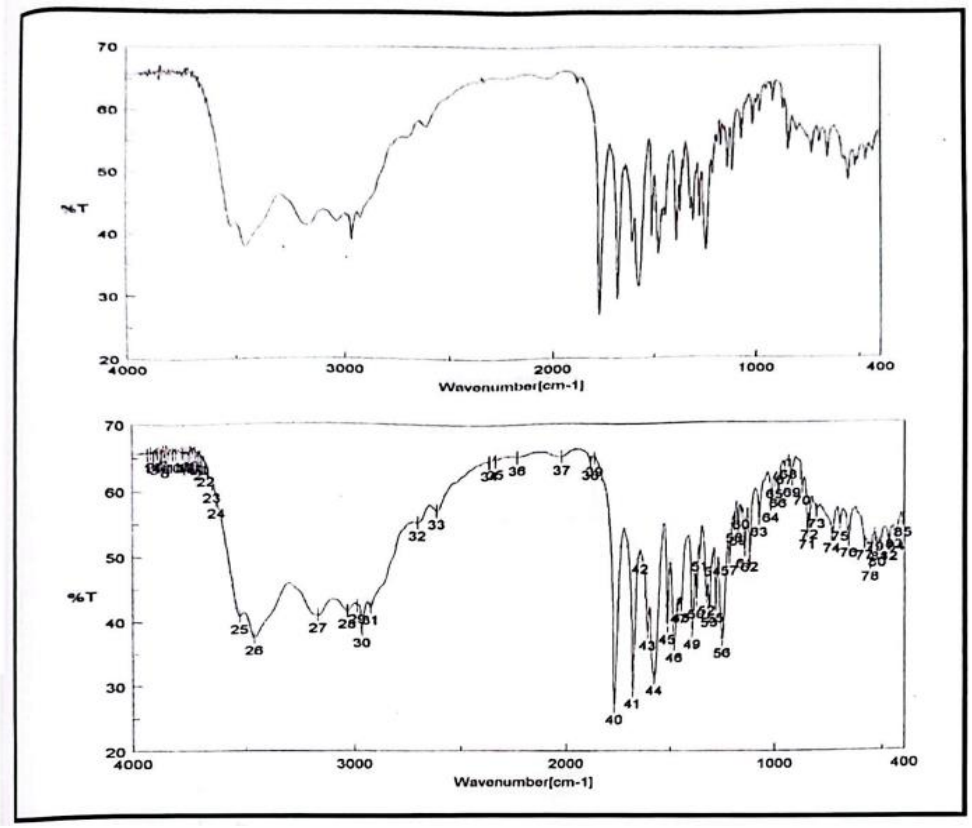


Fig. 6: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate Fresh and Crospovidone.

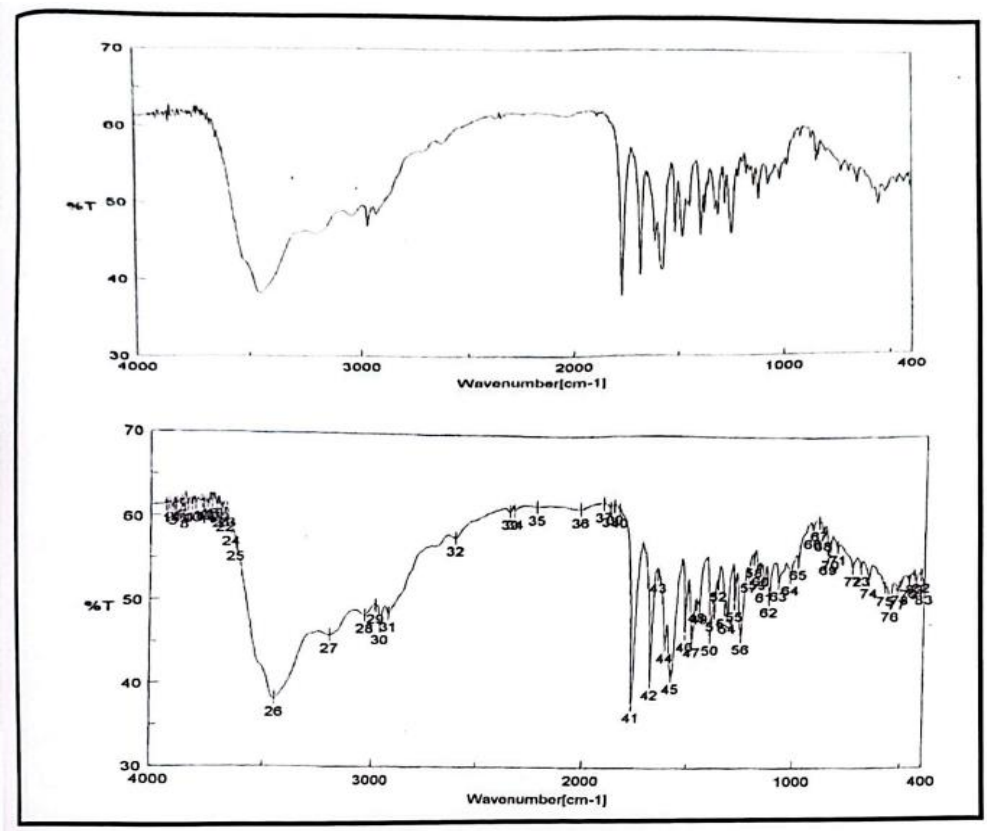


Fig. 7: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate Fresh and MCC.

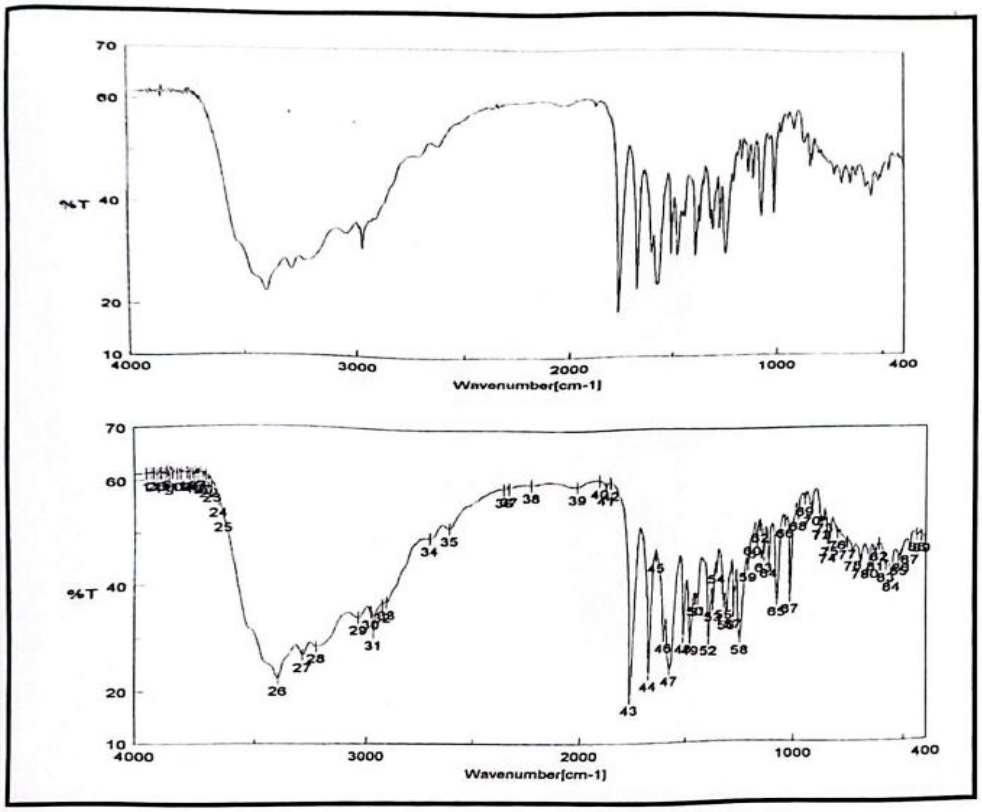


Fig. 8: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate Fresh and Mannitol.

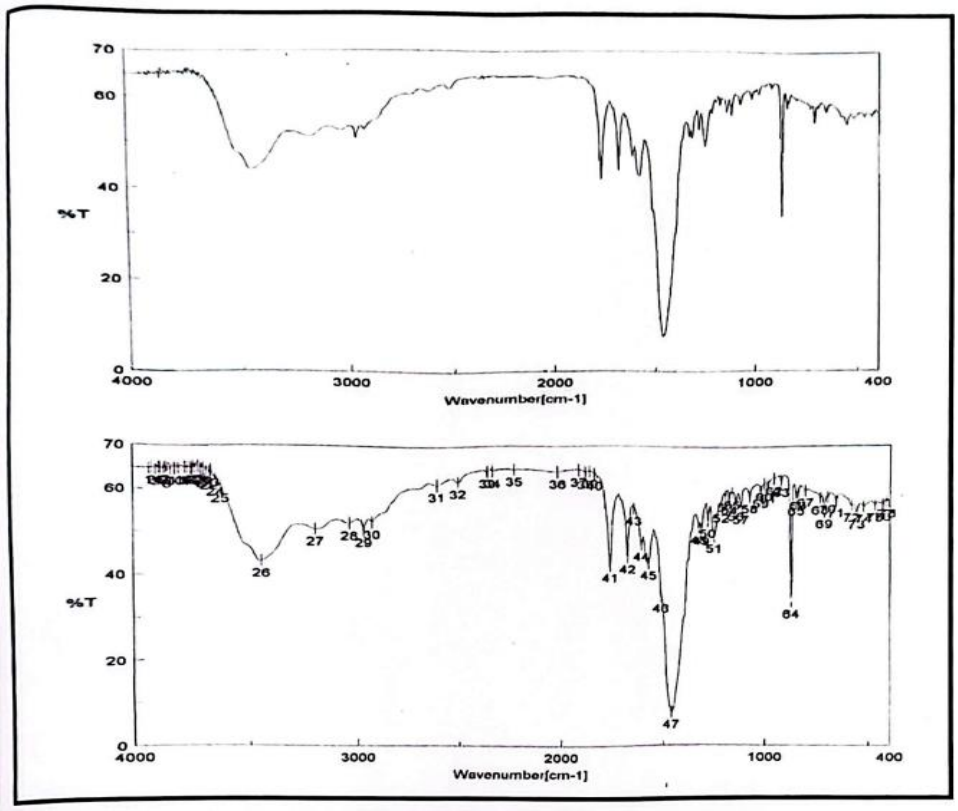


Fig. 9: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate Fresh and Calcium Carbonate.

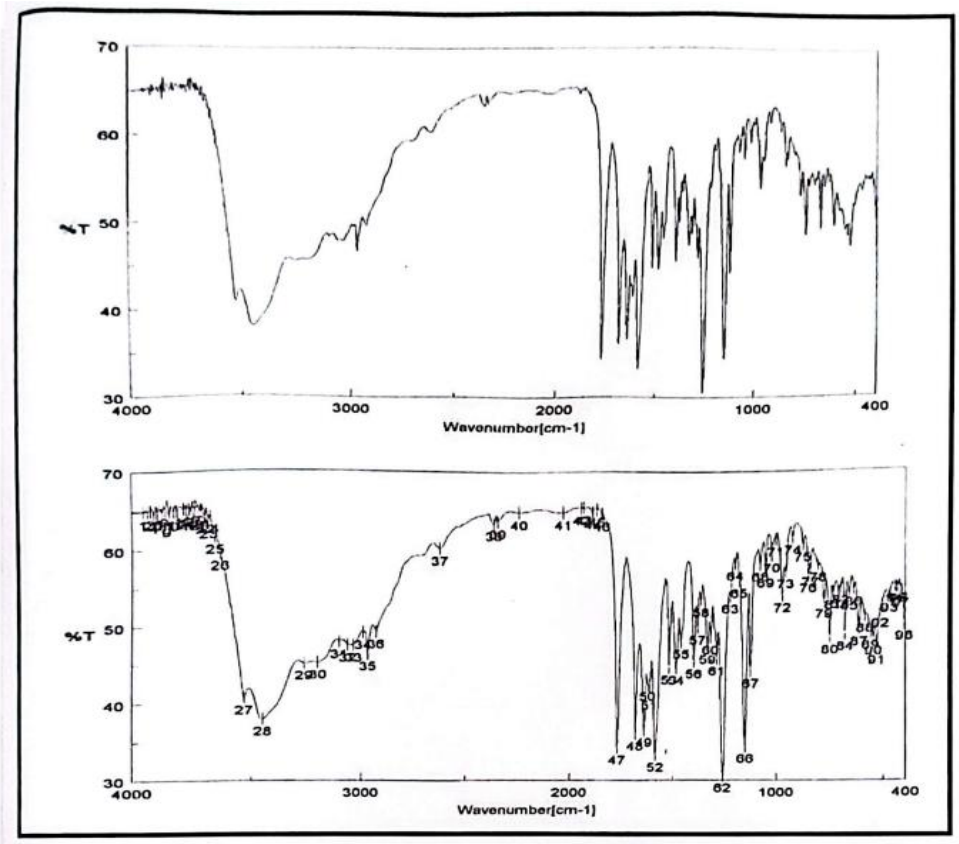


Fig. 10: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate Fresh and Sodium Sacharrin.

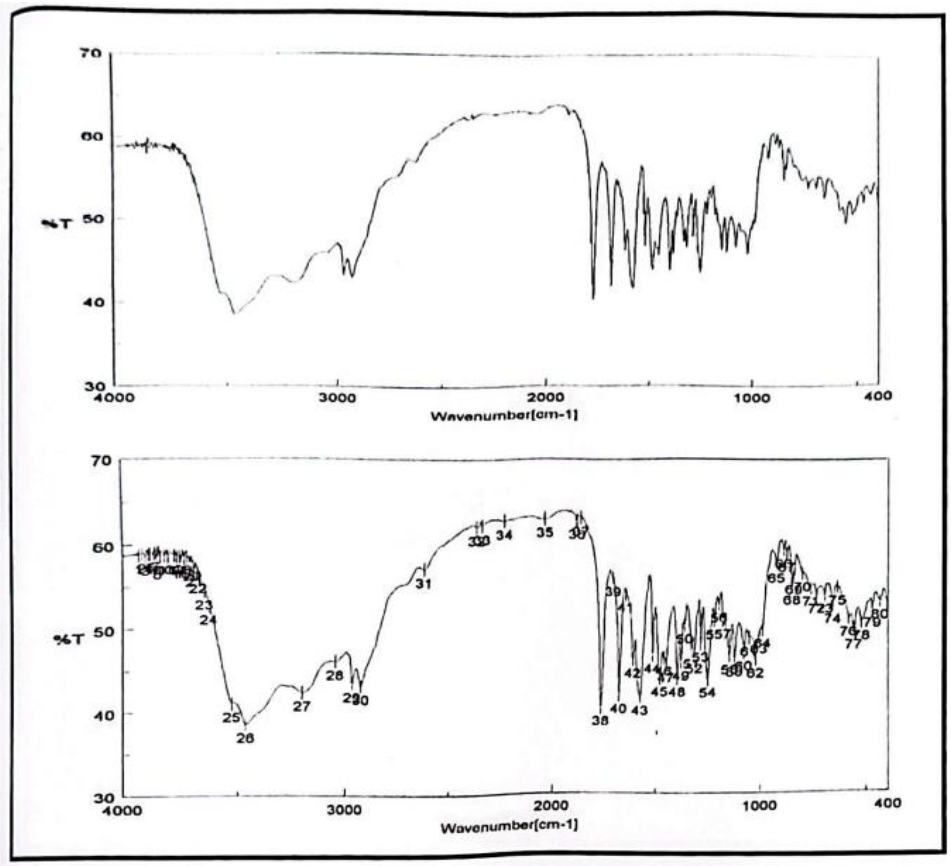


Fig. 11: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate Fresh and Orange Flavor.

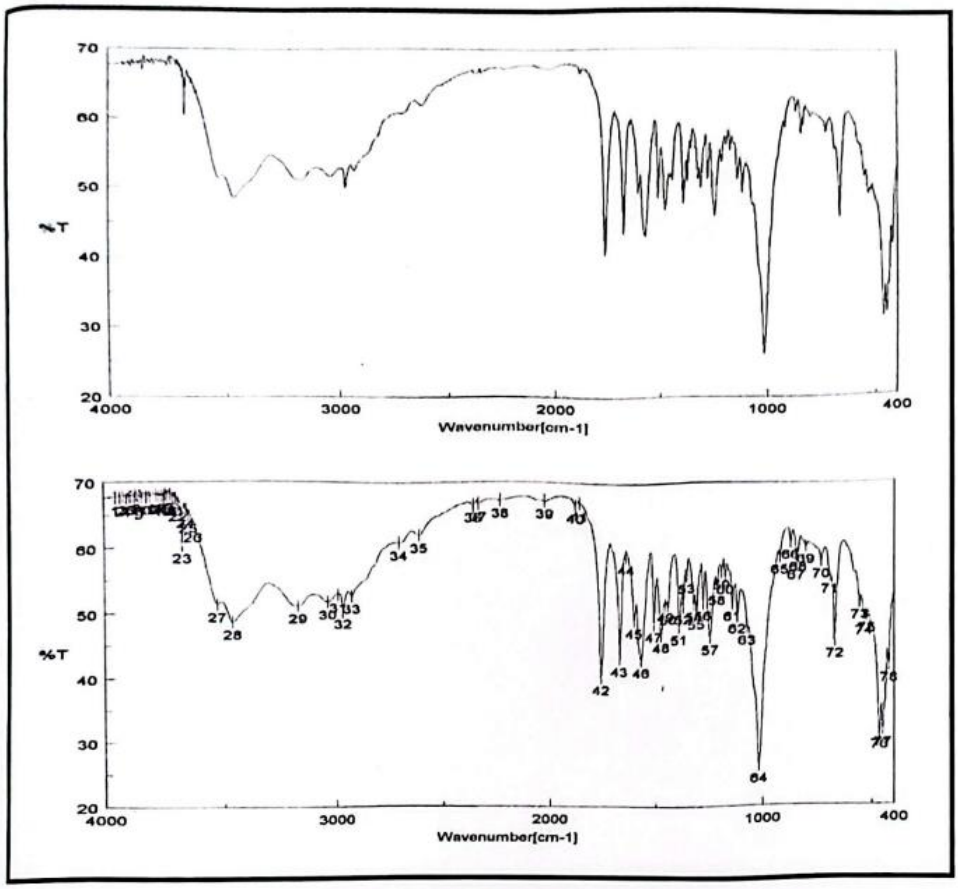


Fig. 12: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate Fresh and Talc.

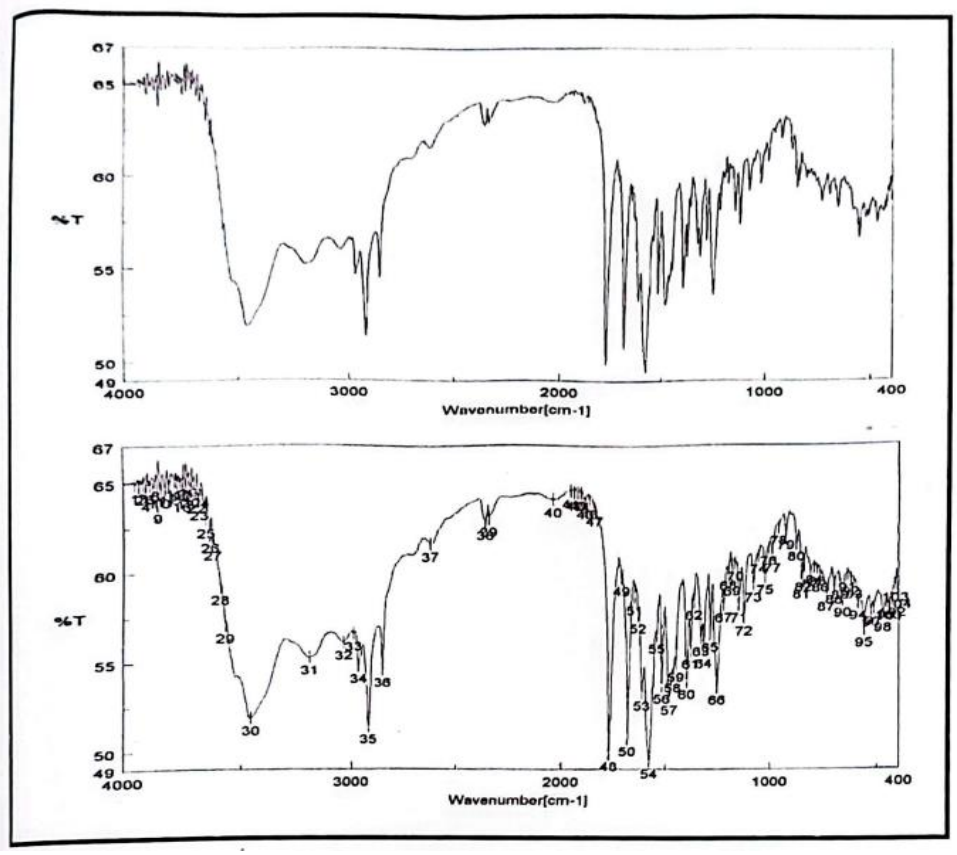


Fig. 13: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate Fresh and Mg. Stearate.

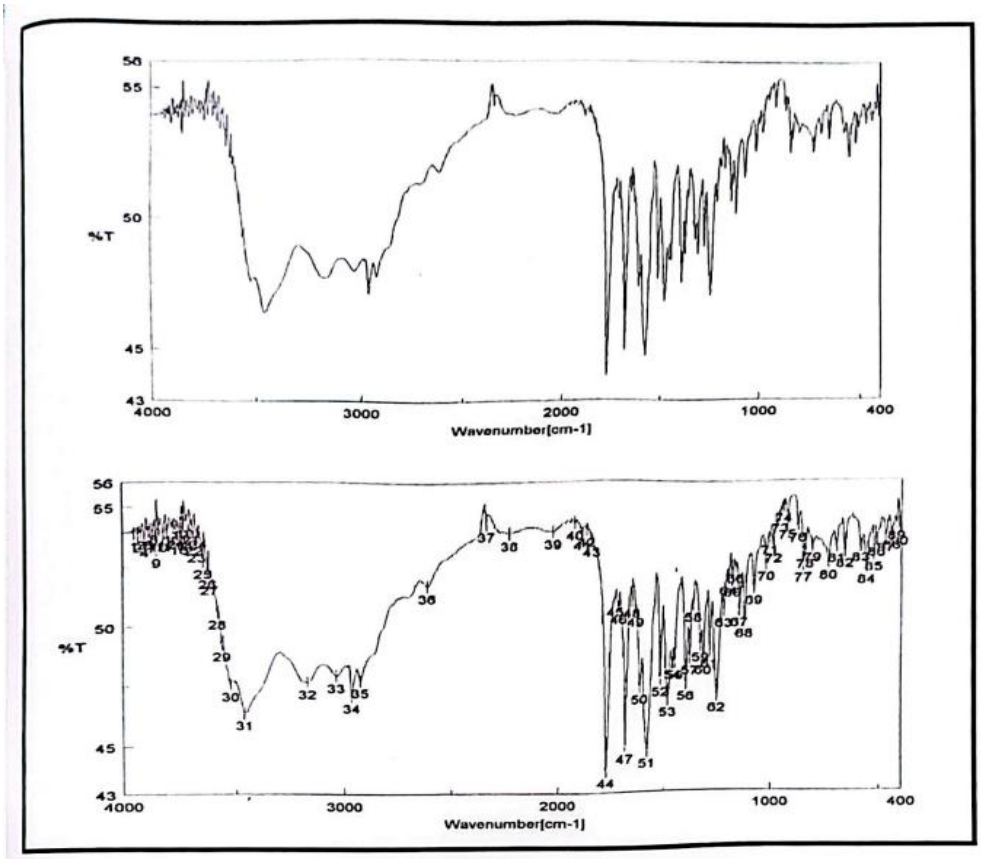


Fig. 14: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate at 25°C.

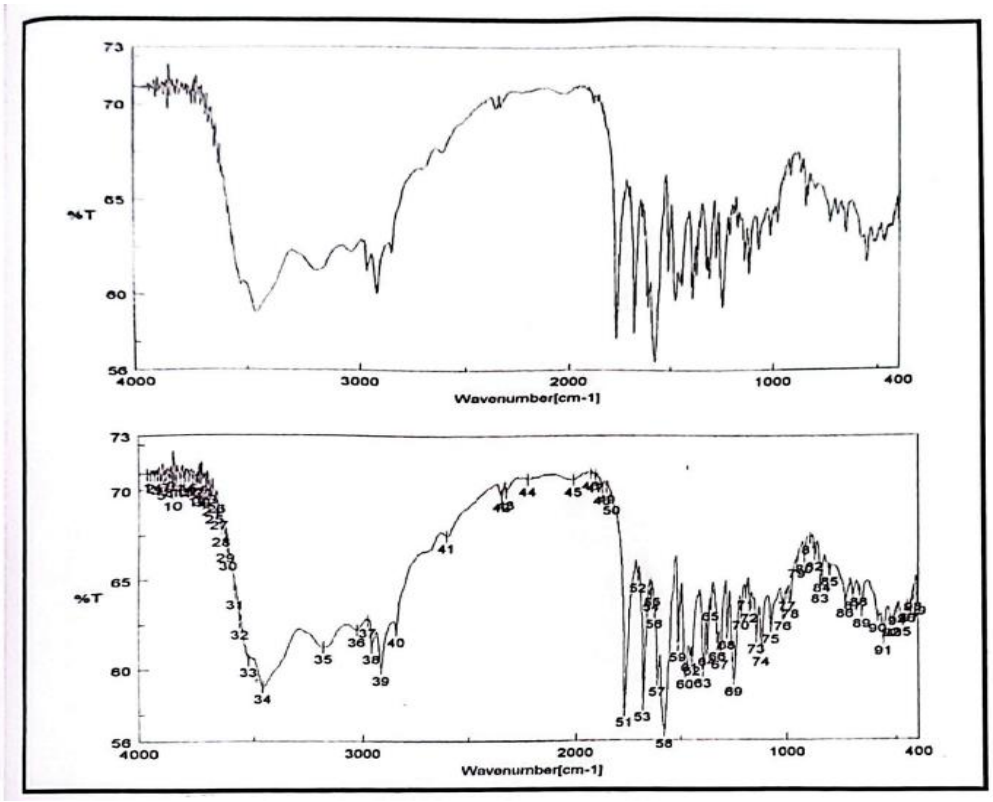


Fig. 15: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate and CCS at 25°C.

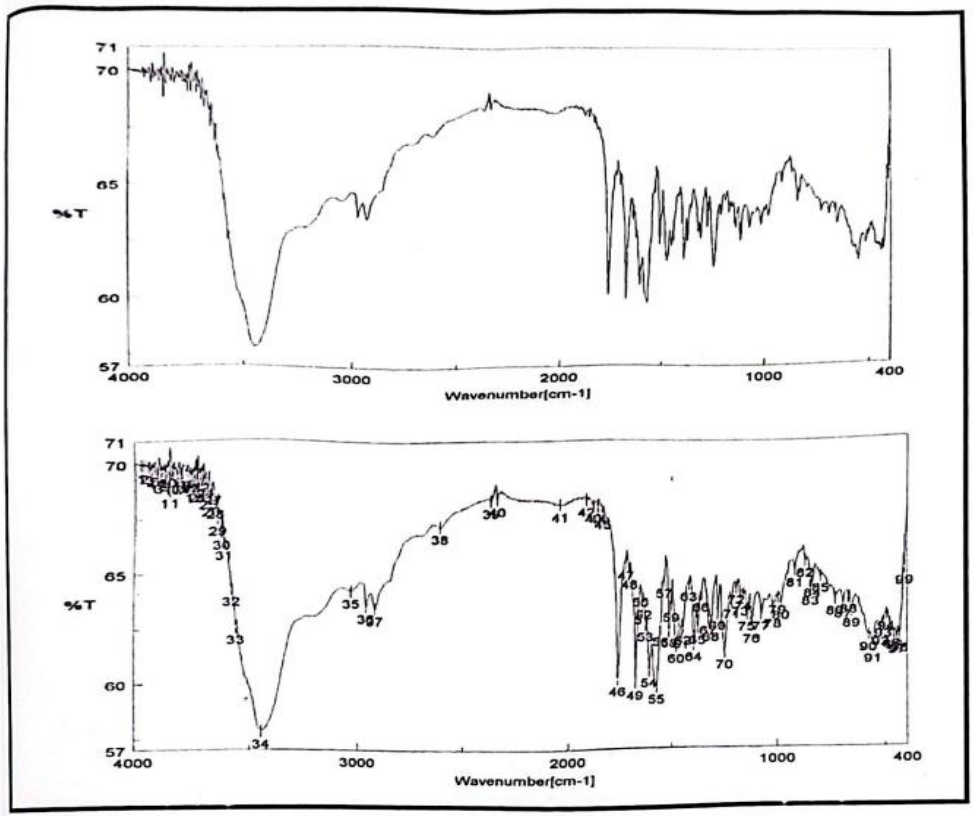


Fig. 16: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate and SSG at 25°C.

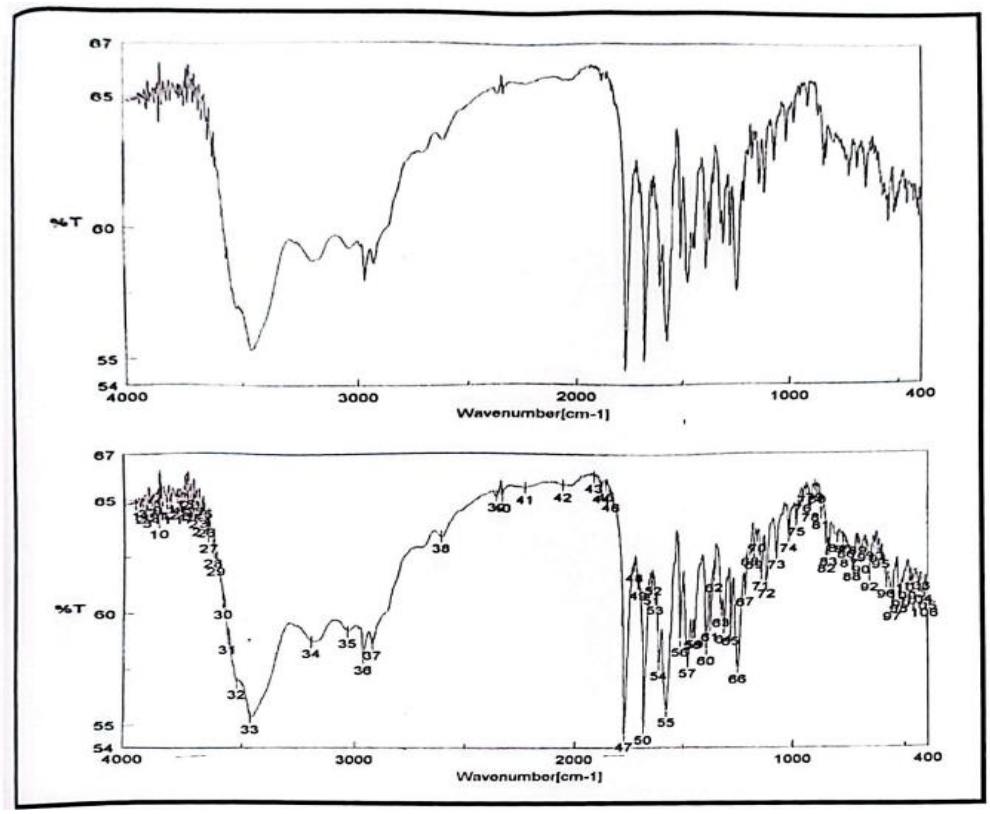


Fig. 17: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate and Crospovidone at 25℃.

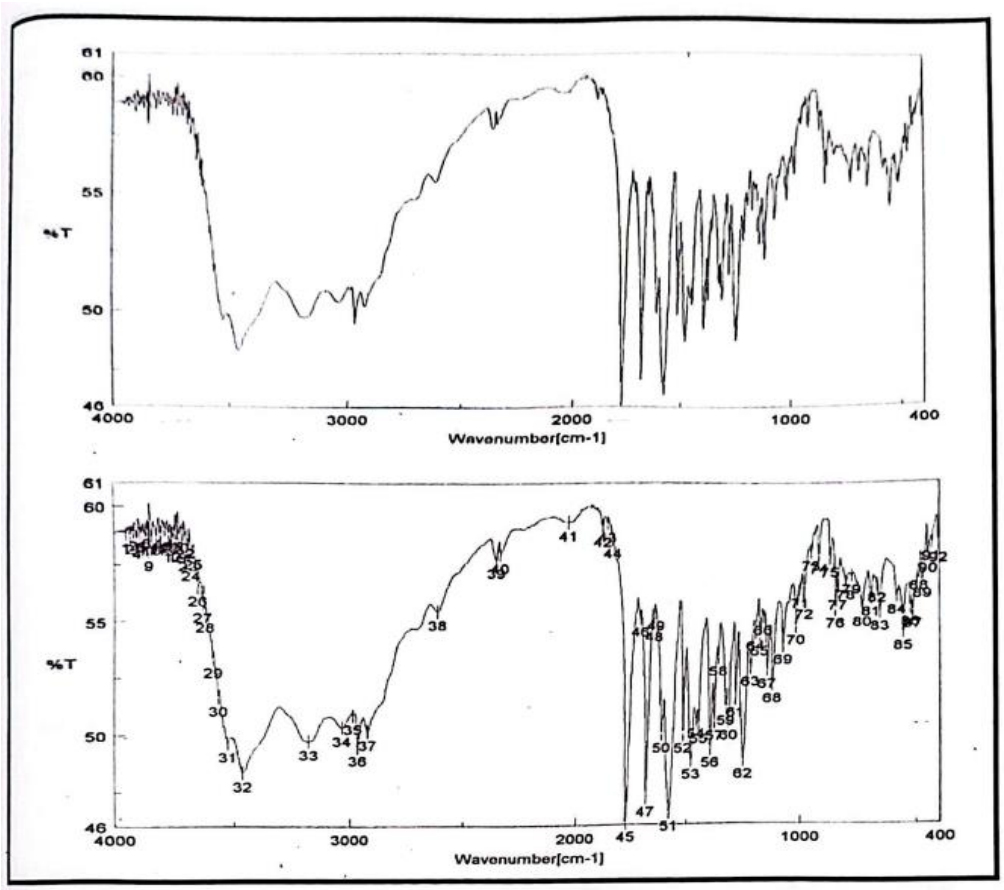


Fig. 18: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate and MCC at 25℃.

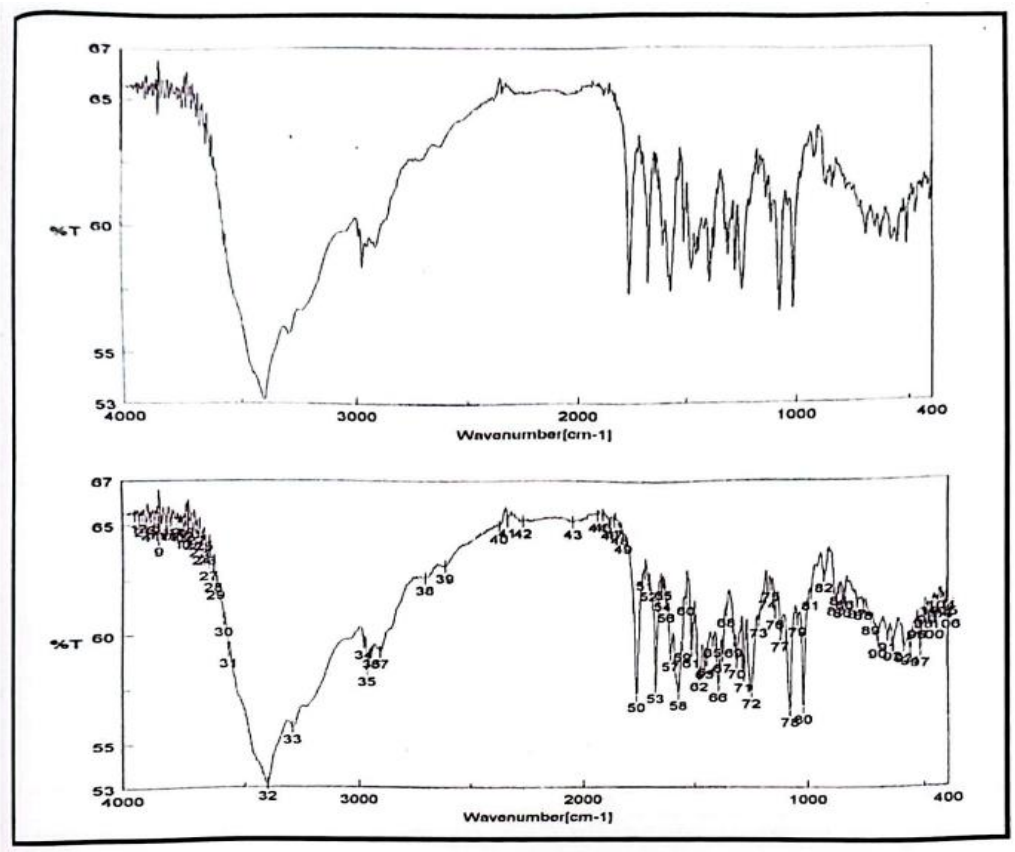


Fig. 19: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate and Mannitol at 25°C.

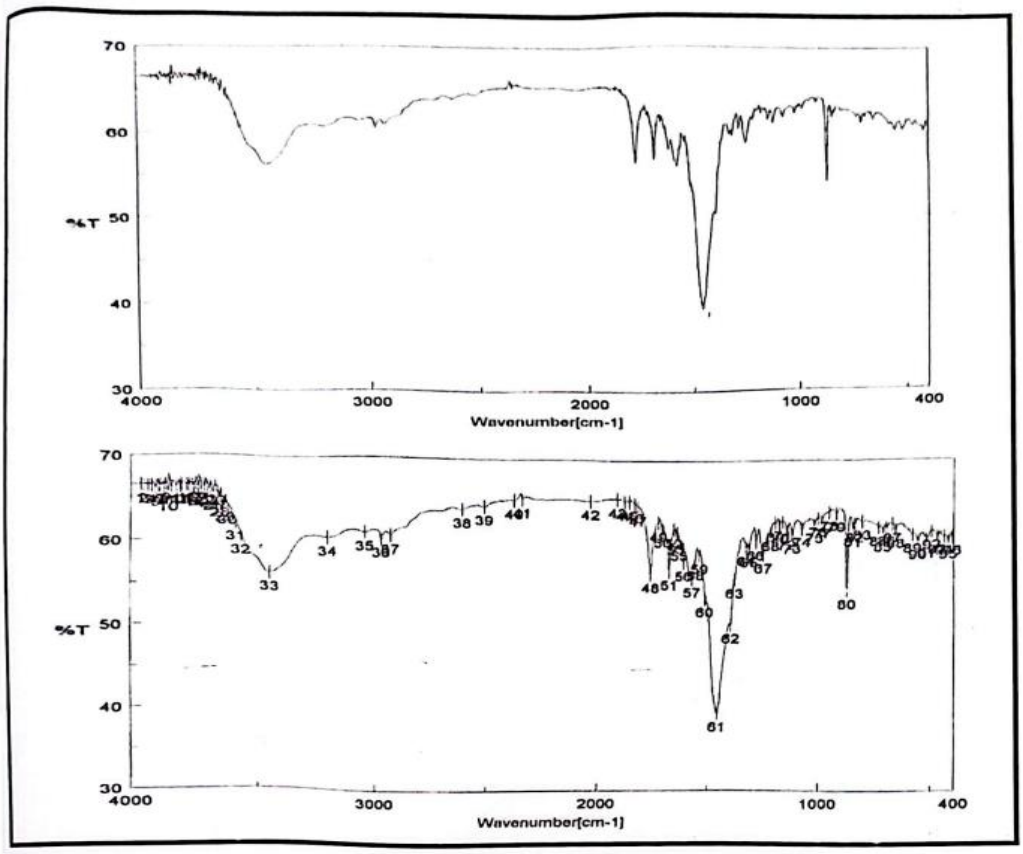


Fig. 20: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate and Calcium Carbonate at 25°C.

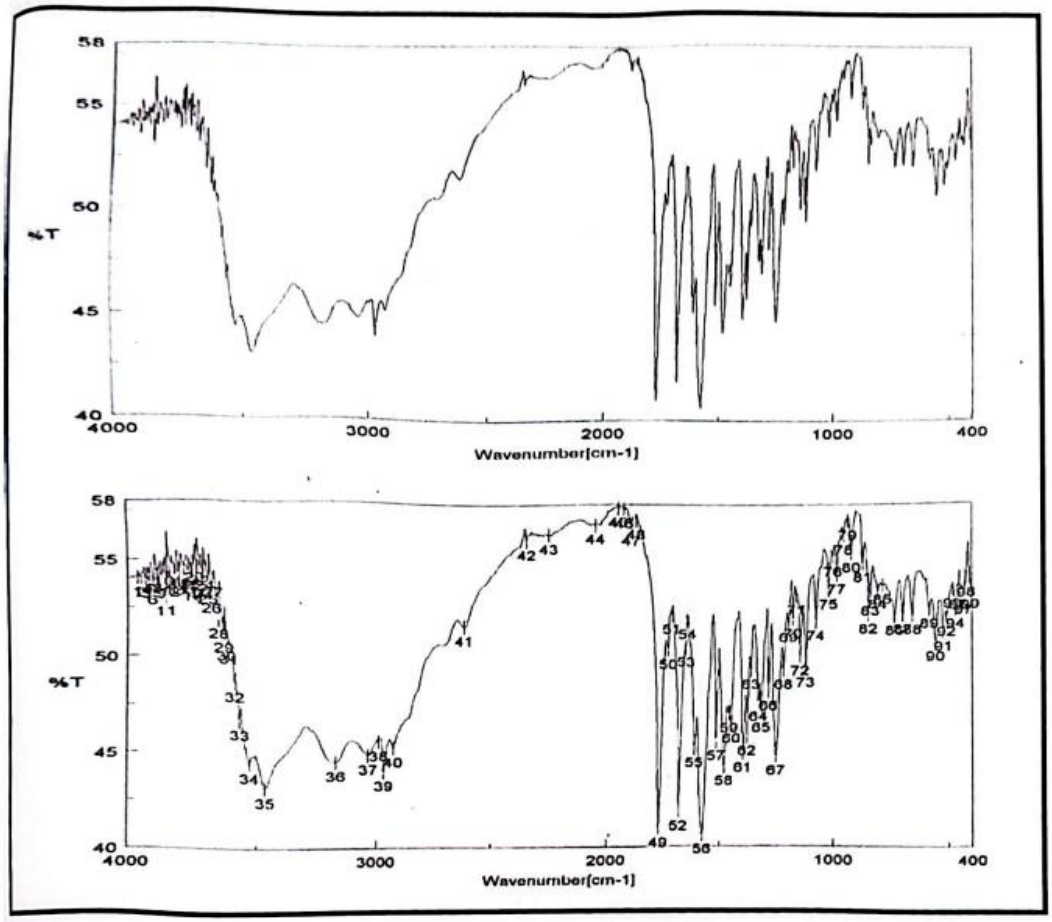


Fig. 21: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate and Sodium Sacharrin at 25°C.

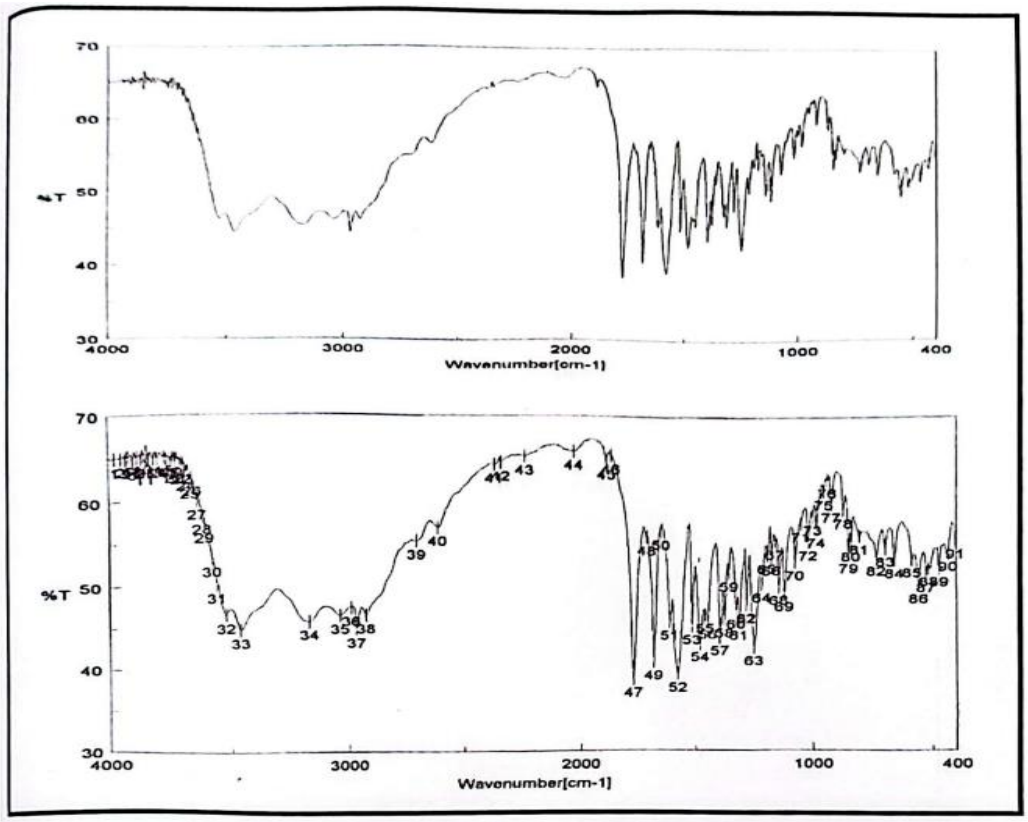


Fig. 22: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate and Orange Flavor at 25°C.

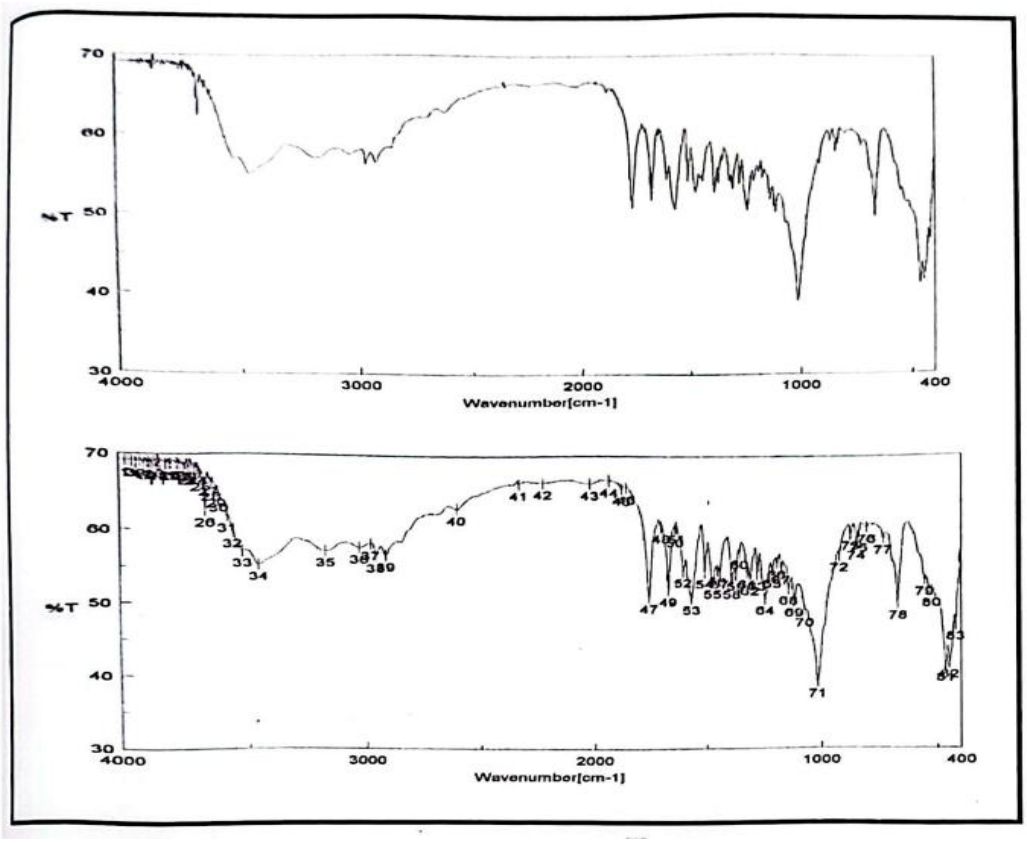


Fig. 23: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate and Talc at 25°C.

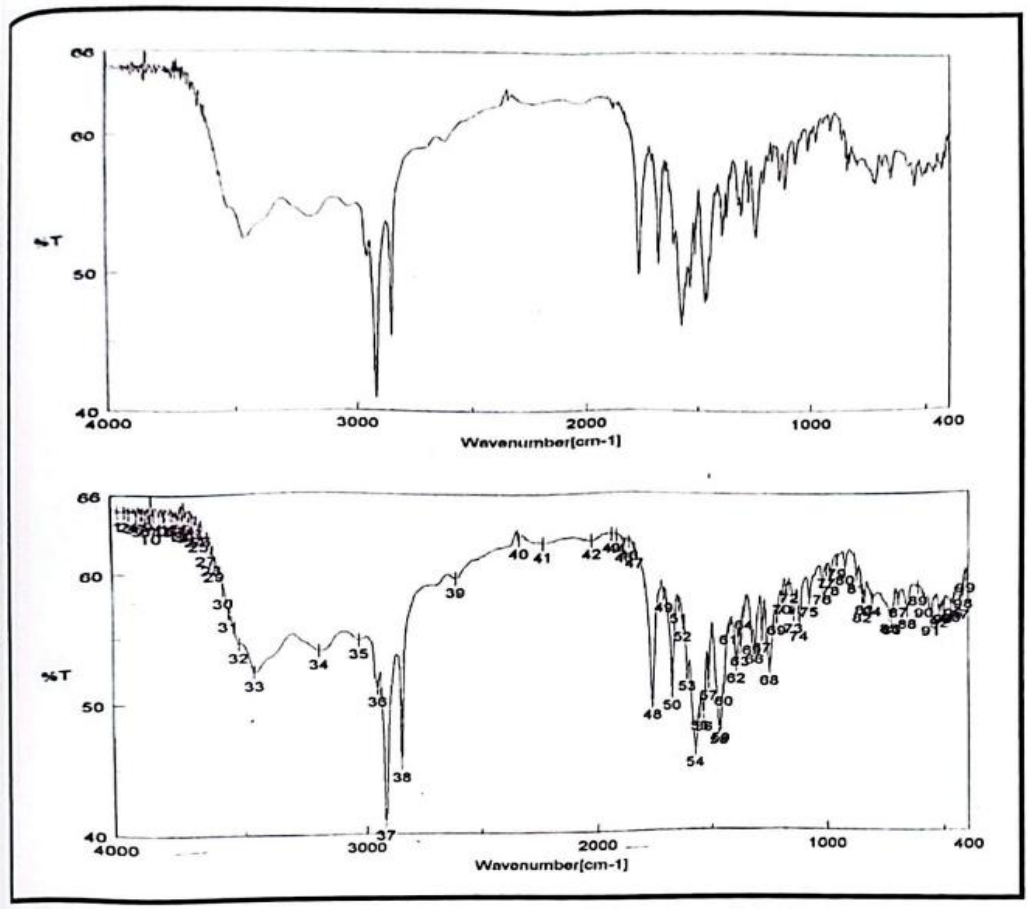


Fig. 24: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate and Mg. Stearate at 25°C.

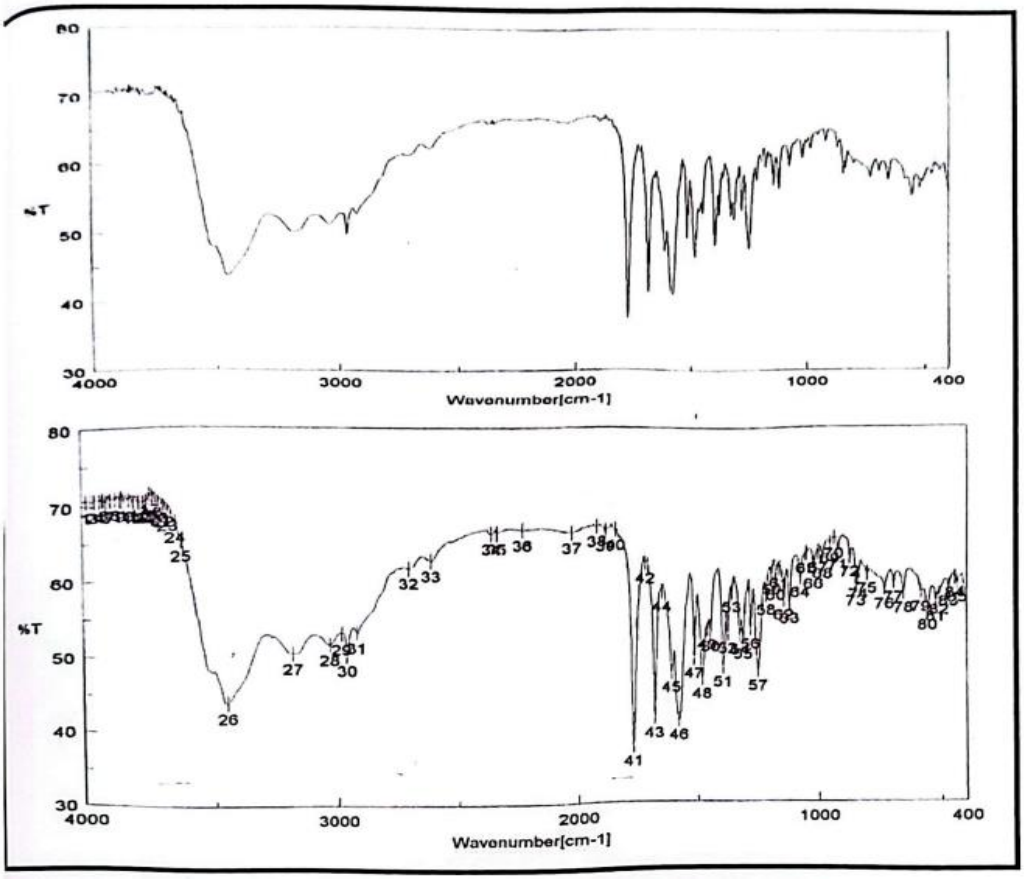


Fig. 25: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate at 50°C.

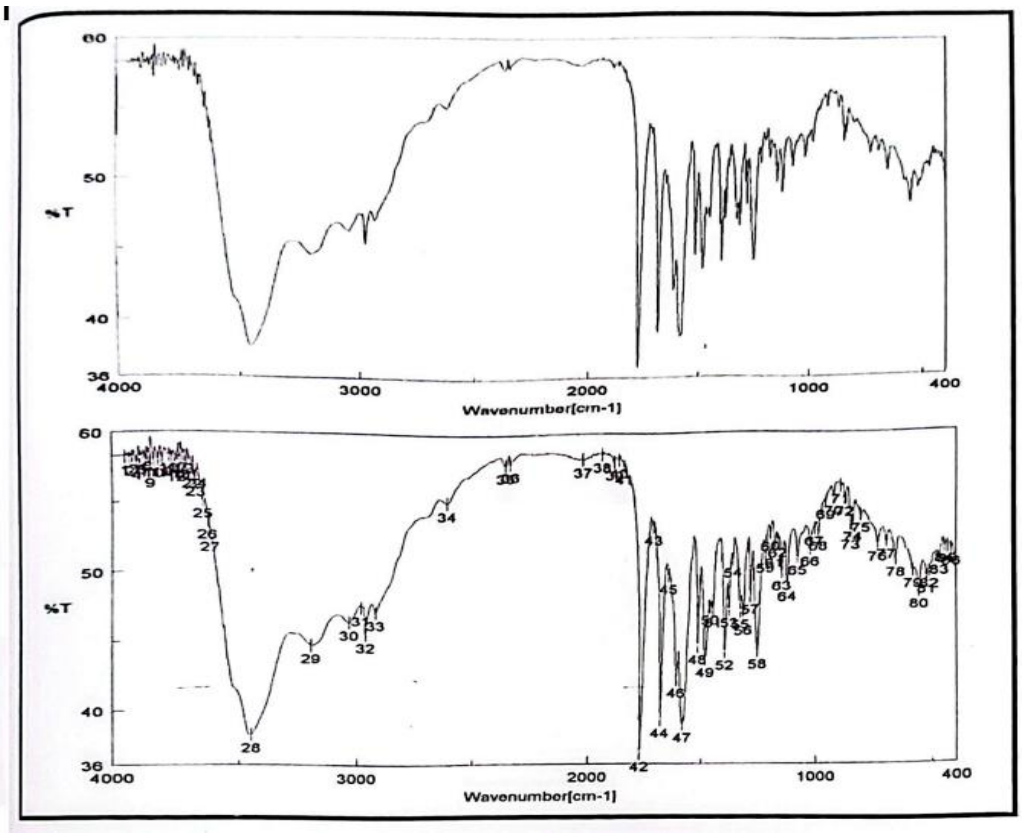


Fig. 26: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate and CCS at 50°C.

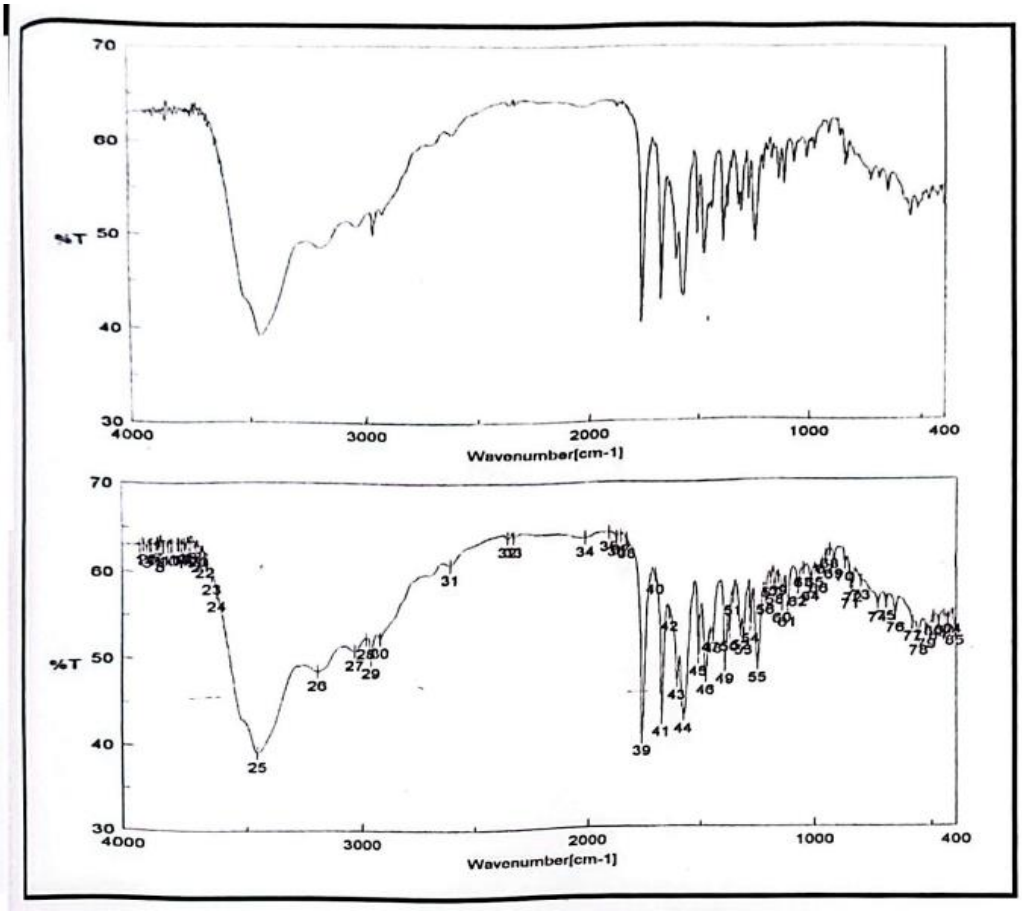


Fig. 27: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate and SSG at 50°C.

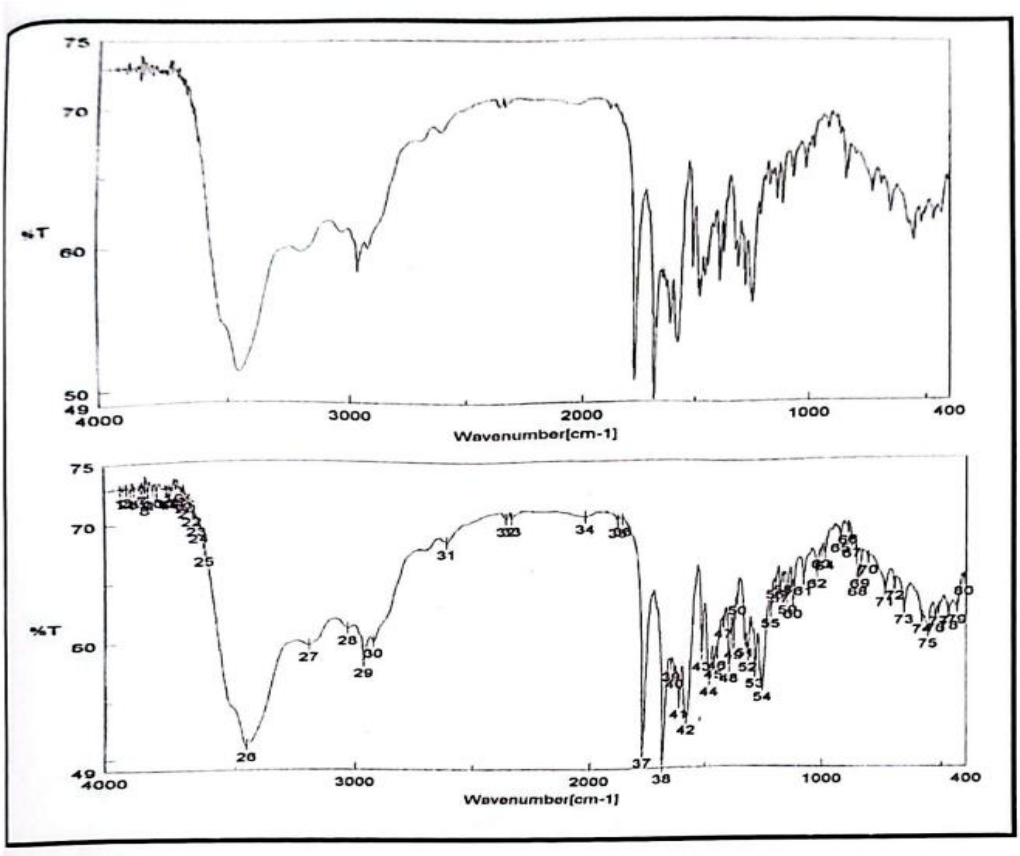


Fig. 28: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate and Crospovidone at 50°C.

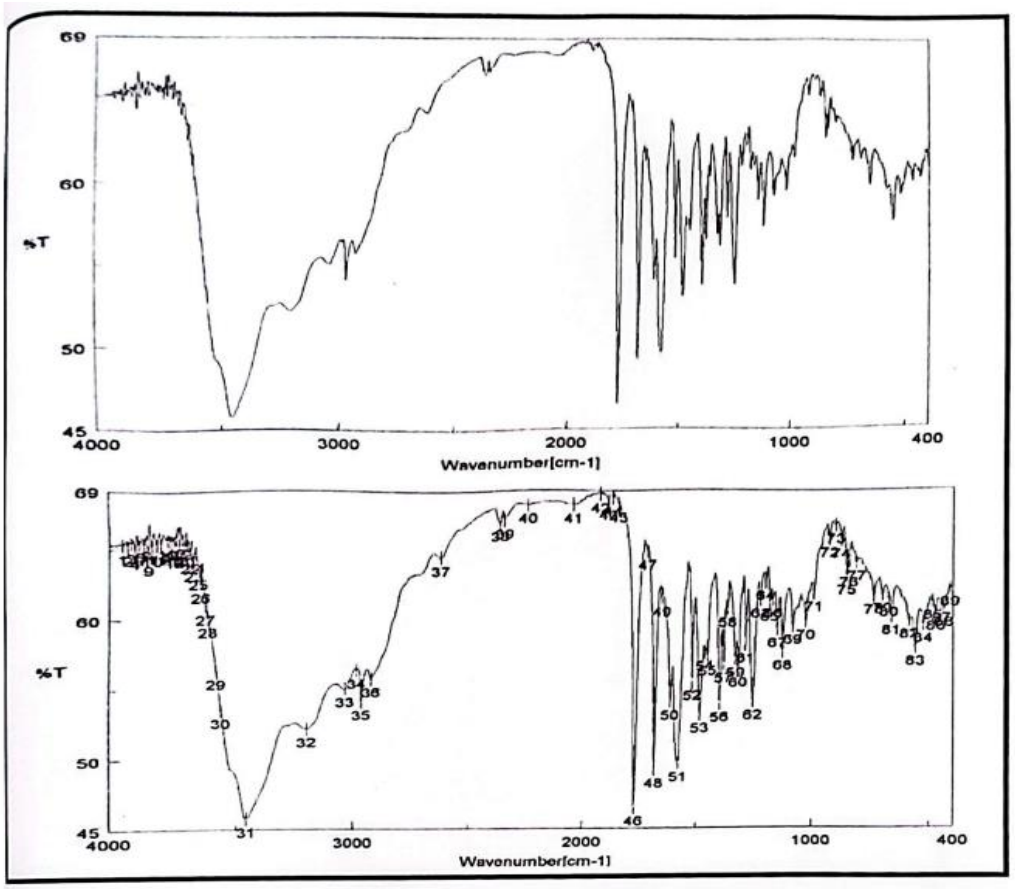


Fig. 29: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate and MCC at 50°C.

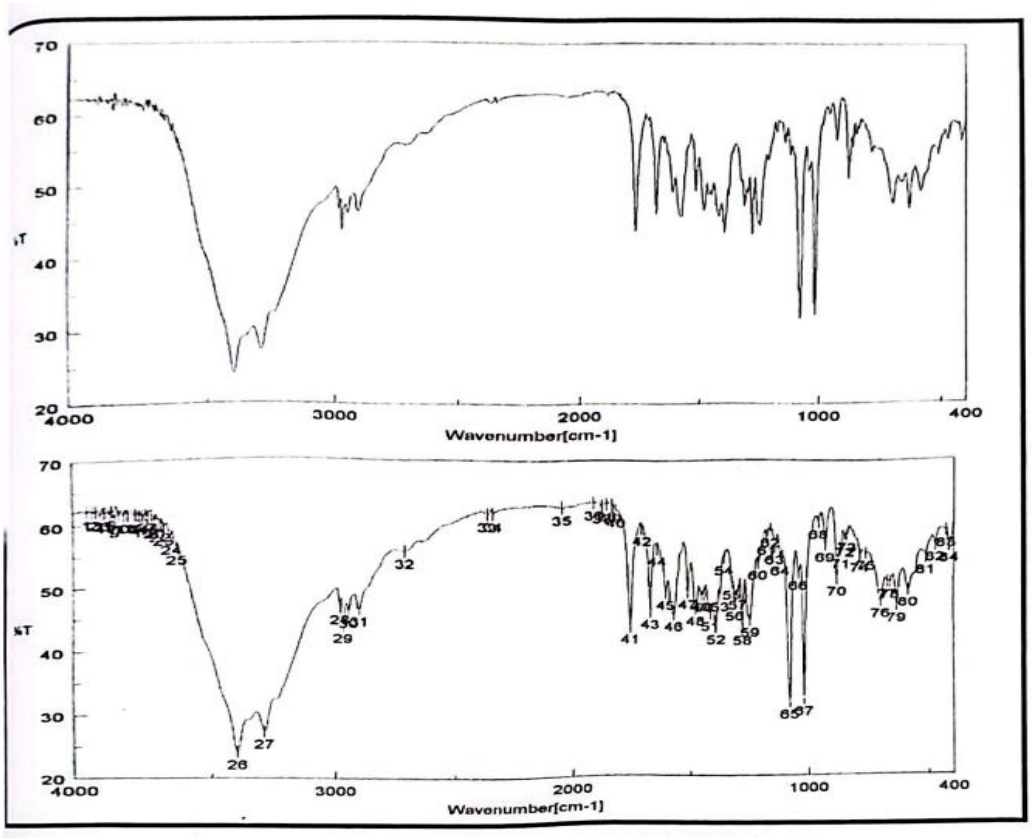


Fig. 30: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate and Mannitol at 50°C.

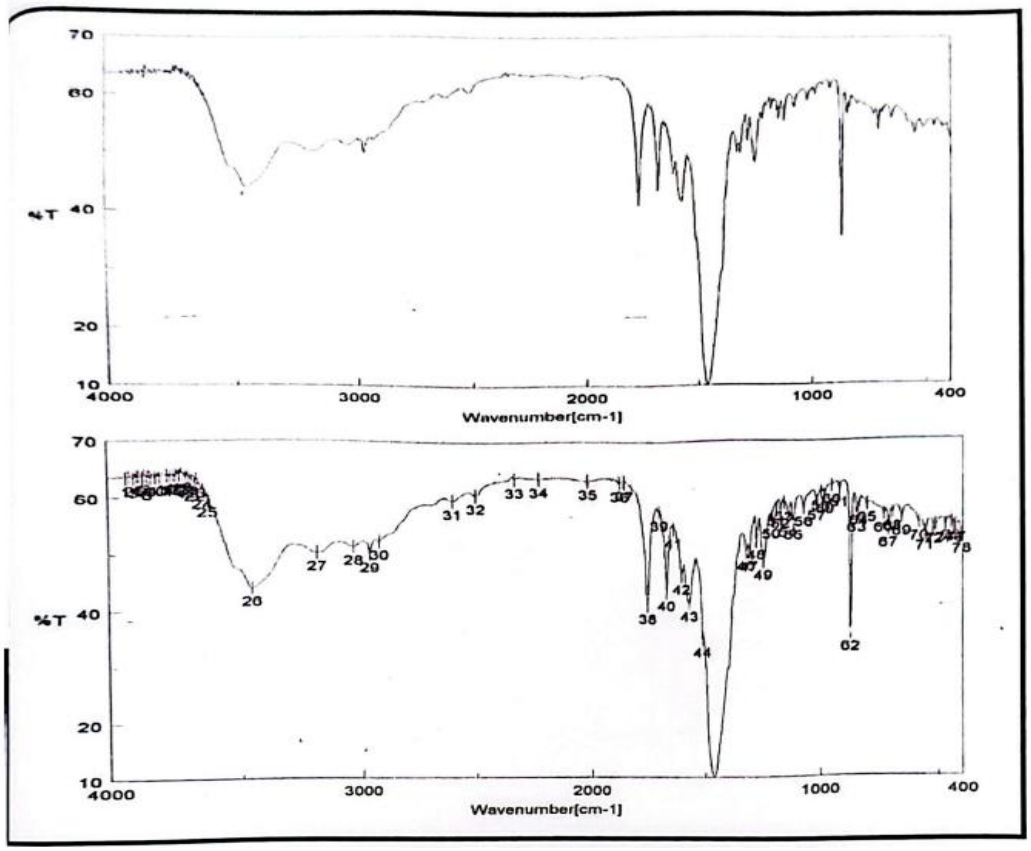


Fig. 31: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate and calcium Carbonate at 50°C.

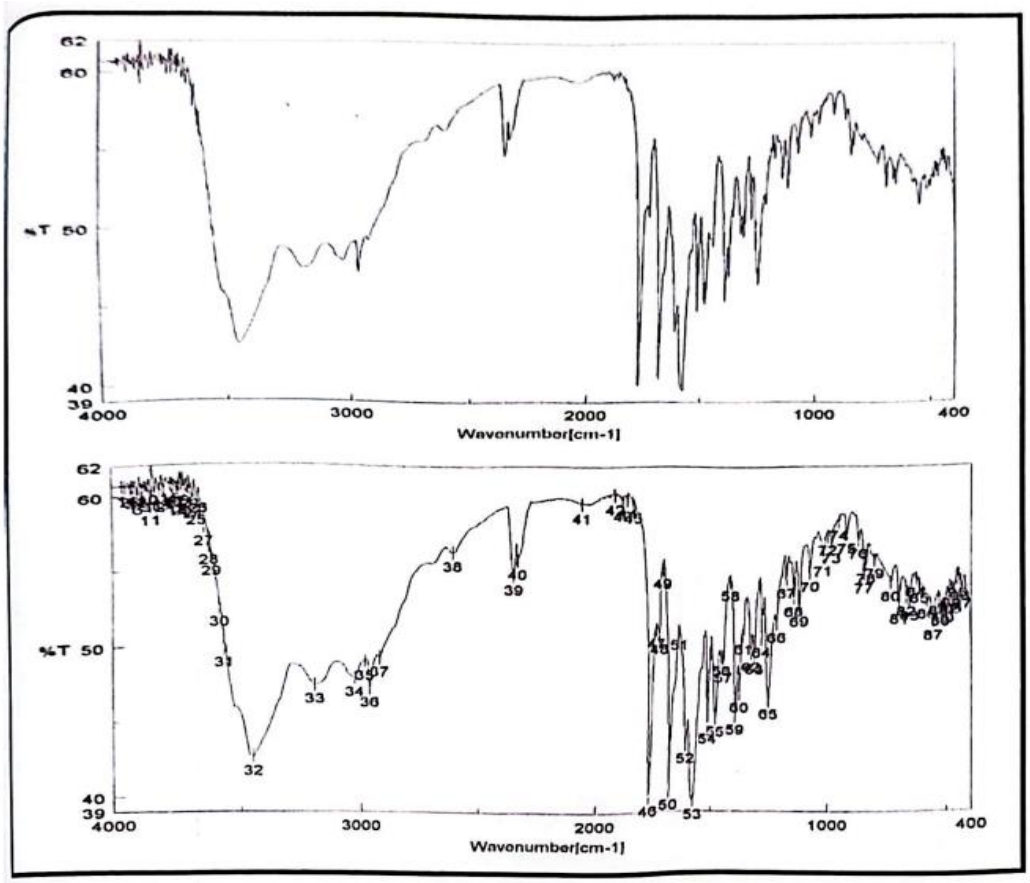


Fig. 32: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate and Sodium Sacharrin at 50°C.

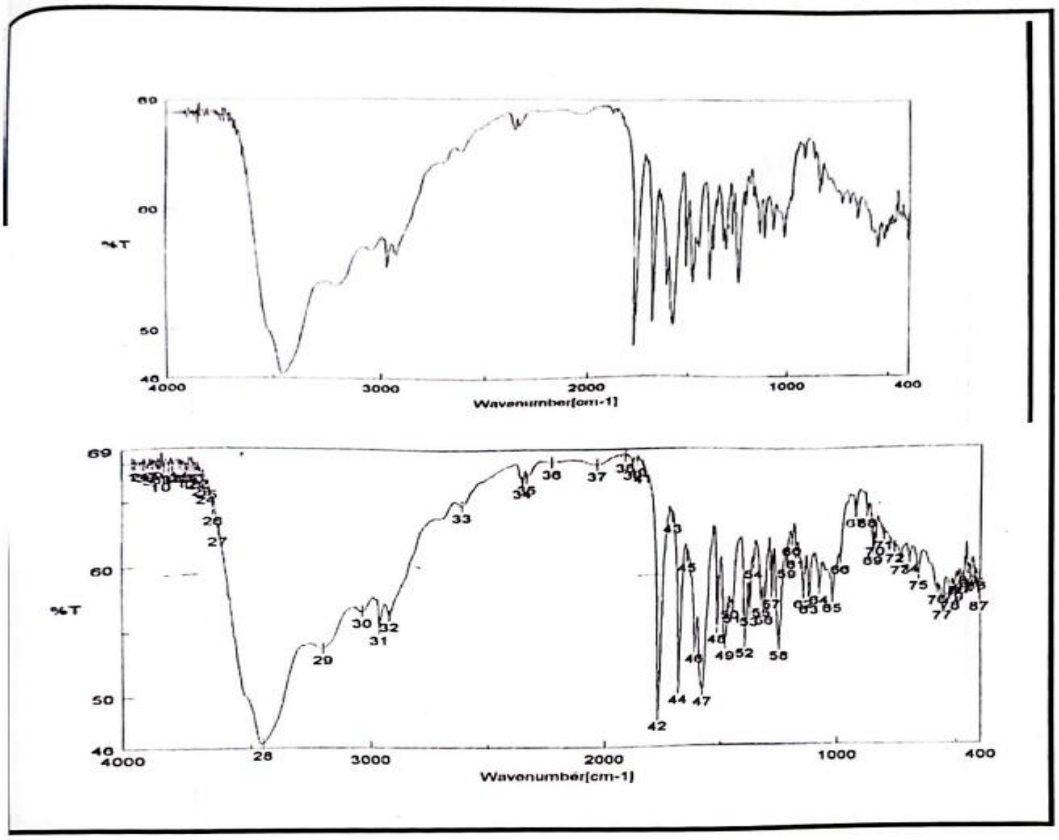


Fig. 33: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate and Orange Flavor at 50°C.

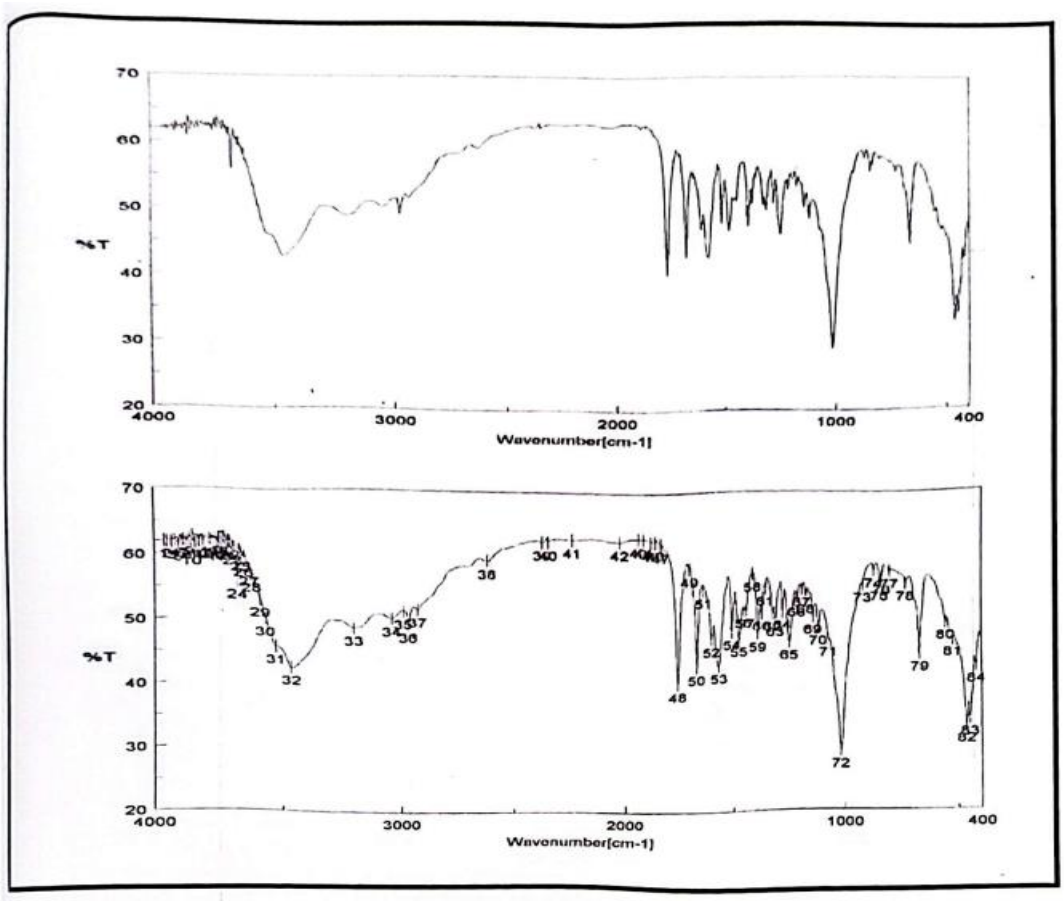


Fig. 34: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate and Talc at 50°C.

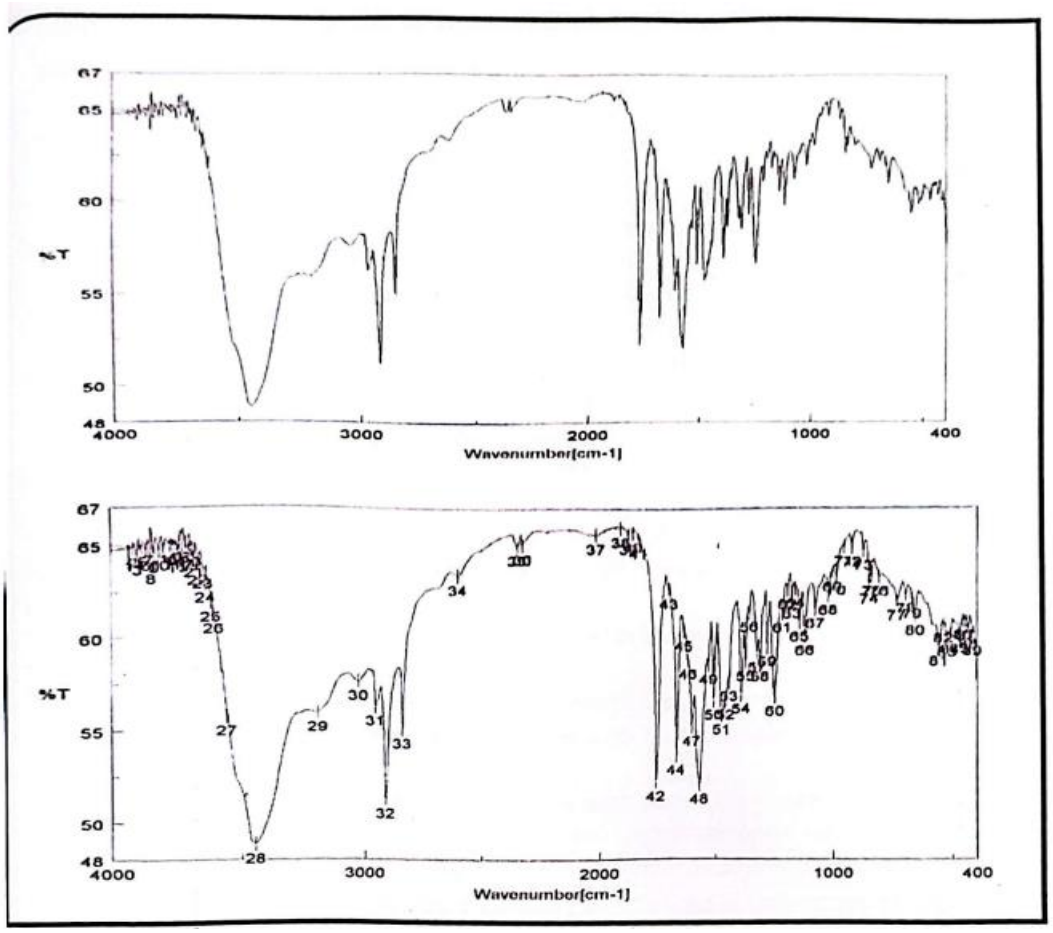


Fig. 35: FTIR Spectrum of Physical Mixture Amoxicillin Trihydrate and Mg. Stearate at 50°C.

CONCLUSION

The compatibility studies of physical mixtures of Amoxicillin Trihydrate with different used excipients such as mannitol, and MCC as diluents, and sodium starch glycolate, croscarmellose sodium, and crospovidone as superdisintegrants were investigated by FTIR it was detected that there was no variation or minor deviation in the characteristic peaks in FTIR spectroscopy. The Amoxicillin Trihydrate formulations prepared were evaluated for precompression parameters and powder flow properties which were found to be within limits. It was concluded that the drug Amoxicillin Trihydrate was found to be compatible with various excipients which were selected for the formulation development of the Amoxicillin Trihydrate Fast Dissolving Tablets FDTs. Formulation scientist from his experience and knowledge have to significantly in the preformulation study stage and is an important factor in the ADDS (Advanced Drug Delivery Systems) product development process.

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