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ORIGINAL RESEARCH

FTIR-Based Drug-Excipient Compatibility Study of Acyclovir during Preformulation and Tablet Development.

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ABSTRACT

Studies of active pharmaceutical ingredient (API) - excipient compatibility are an important part of the Preformulation stage of the development of new dosage forms. The potential physical and chemical interactions between an API and the excipients can affect the chemical nature, the stability and the bioavailability of the former and, consequently, its therapeutic efficacy and safety. Drug-excipient compatibility studies are a fundamental aspect of Preformulation research, aimed at ensuring the chemical and physical stability of the active pharmaceutical ingredient (API) within a dosage form. The present study investigates the compatibility of Acyclovir, an antiviral drug primarily used in the treatment of herpes simplex virus infections, with several commonly used pharmaceutical excipients using Fourier Transform Infrared (FTIR) spectroscopy. Upon comparison of FTIR spectra of physical mixtures with those of the individual components, no significant shifts in peak positions, disappearance of characteristic bands, or appearance of new peaks were observed, suggesting the absence of chemical interactions under ambient conditions. Minor variations in peak intensities were noted, possibly due to hydrogen bonding or physical adsorption phenomena, which are not considered detrimental to stability. These results confirm that Acyclovir is compatible with the selected excipients under dry mixing conditions, making them suitable candidates for further formulation development in solid oral dosage forms. The study underscores the utility of FTIR spectroscopy as a rapid, cost-effective, and reliable method for preliminary screening of drug-excipient compatibility and for reducing the risk of instability in the later stages of pharmaceutical product development.

Keywords: Compatibility studies, Preformulation, Fourier Transform Infrared Spectroscopy.

HIGHLIGHTS

- FTIR spectroscopy was used to assess acyclovir–excipient compatibility.
- Acyclovir showed compatibility with HPMC, MCC, talc and magnesium stearate.
- Characteristic FTIR peaks confirmed the presence of acyclovir and excipients.
- No major changes in characteristic peaks indicated no significant interactions.
- FTIR screening supported excipient selection for acyclovir tablet development

1. INTRODUCTION

Interactions between the API and the excipients affect an API's stability, chemical structure, and bioavailability. These alterations lead to lower safety and therapeutic efficacy [1]. Overall, the isolated API is more stable than solid dose forms. Furthermore, there is still no agreement on which test should be employed, despite the fact that API excipient compatibility testing is required whenever novel dosage forms are developed. The development of a stable and effective pharmaceutical dosage form is a complex and multi-stage process that requires a profound understanding of the physical and chemical characteristics of the active pharmaceutical ingredient (API) and its interaction with excipients. One of the most critical steps in the early phases of this process is the Preformulation stage, during which a detailed drug-excipient compatibility study is conducted. This foundational stage sets the

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groundwork for the rational design of the final dosage form, guiding the selection of suitable excipients, optimising the formulation, and ensuring long-term stability, bioavailability, and therapeutic efficacy [2,3]. Changes in colour, taste, odour, polymorphic form, or crystallisation (pharmaceutical incompatibility) are the most common signs of an API's degradation. These alterations are the result of chemical reactions with the excipient, which cause the API to degrade [4]. To prevent undesirable reactions (stability problems) between the API and the excipient, thermo-analytical methods have been developed to predict the appropriateness of excipients for use in dosage forms [4]. In this regard, differential scanning calorimetry (DSC) facilitates the evaluation of physicochemical interactions between the API and excipients. Drug-excipient compatibility studies* involve evaluating potential physicochemical interactions between the API and various formulation excipients under stress conditions. These interactions may be physical (e.g., changes in solubility, crystallinity, or dissolution rate) or chemical (e.g., degradation, hydrolysis, oxidation, or complex formation), and they can significantly impact the safety, efficacy, and stability of the final dosage form. Compatibility studies help to predict and prevent such adverse interactions, enabling the formulator to select excipients that are inert, non-reactive, and capable of supporting the stability and performance of the drug. In the case of acyclovir tablet formulation, the selection of suitable excipients such as diluents, binders, disintegrants, lubricants, and coatings must be guided by compatibility assessments. Given that acyclovir is a weakly basic compound with a pKa of 2.27 and exhibits polymorphism, its interaction with acidic or basic excipients, moisture-sensitive components, or oxidative agents can lead to degradation or reduced bioavailability. Furthermore, the formulation of acyclovir into solid oral dosage forms such as tablets necessitates careful consideration of excipient functionalities including compressibility, flowability, and disintegration behaviours, all of which can be compromised by incompatibility [5-16]. However, some authors argue that the interactions observed at high temperatures during DSC tests may not be representative of those happening in usual storage conditions, and that thermal method data is difficult to interpret [17]. Other methods for determining API-excipient compatibility include powder X-ray diffraction (PDRX), Fourier transform infrared spectroscopy (FTIR), and isothermal stress testing-high-performance liquid chromatography (IST-HPLC). The API excipient blends are held at high temperatures in the IST-HPLC, and the API content is subsequently measured via HPLC [18-21]. PDRX is used by certain writers to determine an API's compatibility with excipients [22-25]. Because the vibrational changes detected by this method provide evidence for possible intermolecular interactions among the dosage components, FTIR spectroscopy is useful not only for studying the behaviour of solid-state APIs and their excipients, but also for compatibility testing. FTIR is recommended as a simple approach for detecting interactions between API and excipients, or between APIs Common techniques employed in drug-excipient compatibility studies include differential scanning calorimetry (DSC), thermogravimetric analysis (TGA), Fourier-transform infrared spectroscopy (FTIR), powder X-ray diffraction (PXRD), high-performance liquid chromatography (HPLC), and isothermal stress testing (IST). These analytical methods help identify potential interactions through shifts in thermal behaviours, changes in spectral patterns, and the emergence of degradation products. The application of these techniques in the compatibility evaluation of acyclovir with standard excipients such as microcrystalline cellulose, lactose, starch, magnesium stearate, and croscarmellose sodium is vital for formulating a robust and stable tablet product. Moreover, regulatory guidelines issued by organisations such as the International Council for Harmonisation (ICH) and United States Pharmacopoeia (USP) emphasise the importance of Preformulation studies in ensuring product quality, safety, and efficacy. The ICH Q8 guideline on pharmaceutical development advocates a Quality by Design (QbD) approach, where understanding of drug-excipient interactions contributes to the definition of a design space and the control strategy for product development. [16, 21, 22, 26]. A drop in peak intensity, the appearance of an absorption peak, or the introduction of new peaks are all indicators of excipient-API interactions [17, 18]. **Figure 1** shows the drug excipient compatibility study.

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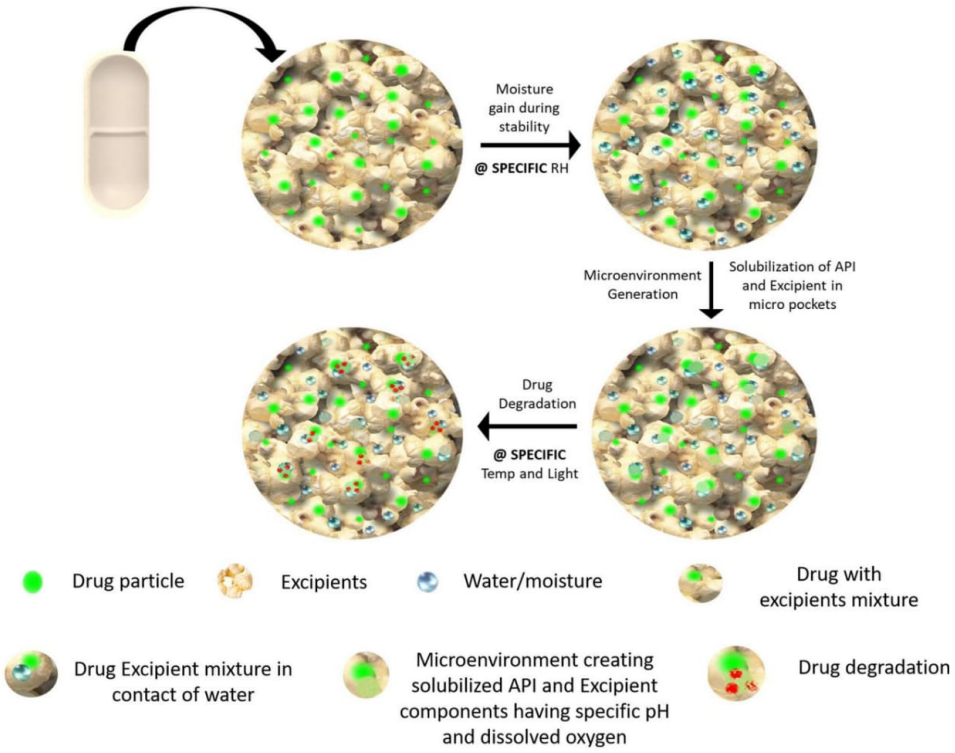


Figure 1. Drug Excipient Compatibility Study

The primary objectives of this study were to identify suitable excipients for the formulation of API and a stable storage condition for API in its solid state. One of the main issues with formulation development is incompatibilities. During pre-formulation investigations, choosing the right excipient is crucial. Since constant stability, safety, and effectiveness of a pharmaceutical product of a drug product are most desirable, a thorough characterization and comprehension of an active pharmaceutical ingredient's (API) physical interactions in the dosage forms is an essential component of the pre-formulation stage in development of new dosage form. An API directly interacts with other formulation ingredients (excipients) in a dosage form to help administer and release an active ingredient while shielding it from the environment. Excipients can interact with pharmaceuticals in the dosage form to alter stability of drug product in physical features including organoleptic characteristics, slow down dissolving, or by causing drug degradation by chemical method, even when they are pharmacologically inactive. A strong and efficient Development of dose forms that are simpler for administration, enhance prolong the medicine's shelf life, promote drug release and bioavailability, and ensure patient compliance. requires careful excipient selection. Under quality by design prototype of drug development, a thorough comprehension of the drug excipient compatibility study in dosage forms is anticipated. Incorporating analytical techniques into the preliminary stages of pre-formulation research has greatly aided in the early detection, tracking, and characterization of API incompatibility, preventing expensive material waste and cutting down on the amount of time needed to develop a suitable product formulation [27-28].

2. MATERIALS AND METHODS

Materials: The Chemicals such as Acyclovir (API), HPMC E15 M, MCC, Magnesium stearate and Talc were procured from Loba Chemie Pvt. Ltd.

METHODS:

2.2.1. Preformulation Analysis: The Initial phase of drug-excipient compatibility analysis is focused on understanding the physical and chemical properties of the drug.

2.2.2. Sample preparation:

For Pure drug Samples (API): Weigh 1–2 mg of API (Acyclovir) and grind gently to make a fine powder.

For Excipients-Weigh 1-2 mg of all the Excipients (HPMC, MCC, Magnesium Stearate, Talc) and grind gently for making a fine powder sample of all those excipients. These steps are repeated for each excipient we are taking. Take a small amount (1-2 mg) of powder sample and place it on the FTIR sample holder and lock the knob properly.

2.2.3. Binary Mixtures Preparations (API + All Excipients): Mix the previously prepared fine powder sample of API and all excipients in a fixed ratio (generally 1:1 w/w or in formulation-relevant ratios). Keep the prepared binary mixture of API and all excipients in a well-closed container, free from moisture and any type of contamination.

2.2.4. Acyclovir tablet preparation: Prepare 400 mg Acyclovir tablet by the direct compression method. For the preparation of Acyclovir tablet, take Acyclovir API and all the essential excipients in the actual amount. After the preparation of all Acyclovir tablets, crush them properly and prepare a fine powder sample for further analysis by FTIR. **Table 1** lists the drug/excipients name along with its quantity.

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Table 1. List of drug/excipients name along with its quantity

SL.NO	Drug and Excipients Name	Quantity(mg)
1.	Acyclovir (API)	200
2.	HPMC	75
3	MCC	105
4.	Talc	10
5.	Magnesium Stearate	10

2.2.5. Analysis of Drug-Excipient compatibility of all samples by using FTIR

Step-1: Background Scan: - Run a blank (e.g., air or KBr pellet) to record baseline signal

Step-2: Sample analysis: - First, place the fine powder sample API in FTIR for compatibility study in the IR range of 4000–400 cm^{-1} and scan each sample 15-25 times by the instrument. After that, place the powder sample of all the excipients one by one and check the IR data for all excipient individually. After that place the physical mixture of the API along with all excipients and analysis the FTIR data for that mixture of samples. In the next step, the finely crushed powder sample of the Acyclovir tablet after formulation is checked by FTIR in the IR range of 4000–400 cm^{-1}.

Step-3: Interferogram Collection: - The IR beam passes through the interferometer, and the sample interferogram is recorded.

Step-4: Generate Fourier Transform: - Generally, it converts the interferogram into an absorbance (or transmittance) vs. wavenumber spectrum.

Step-5: Spectrum Analysis: - Analyse peaks at characteristic wavenumbers (cm^{-1}) to identify functional groups and interactions that occur. The above steps are repeat for each excipient we are taking.

2.2.6. Interpretation of FTIR data

a. Spectrum Comparison

Compare FTIR spectra of pure drug, pure excipients, and their mixtures.

It mainly focuses on the following-

Shifts in characteristic peaks (e.g., O-H, C=O, N-H, C-H)

Appearance/disappearance of peaks

Changes in peak intensity

New peaks indicating interaction or degradation

b. Key Functional Groups should be monitored in the resulting data

O-H / N-H stretching: 3200–3600 cm^{-1}

C=O stretching (carbonyl): 1650–1750 cm^{-1}

C-H stretching: 2800–3000 cm^{-1}

C-O / C-N stretching: 1000–1300 cm^{-1}

3. RESULTS

Here we identify and confirm the presence of Acyclovir along with all the excipients. Where the Acyclovir API has the N-H and O-H stretching in 3373.54 and with the excipients 3329.02, similarly, C=O stretching of acyclovir API in 1630.04 and with other excipients it is 1635.79 and C=C stretching of API at 1550.92 and with excipients it is 1541.73 and CH2 bending of API at 1404.56 and with excipients it is 1413.79. similarly, C-N and C-O stretching of API 1102.01 and 1180.52 respectively and with excipients it is 1102.97 and 1181.96 respectively and it also has aromatic C-H bending of API at 750.12 and along with excipients it is seen 748.24. **Table 2** summarizes the Comparative FTIR spectral analysis of pure acyclovir and its physical mixture with formulation excipients for the assessment of drug–excipient compatibility. **Figure 2-6** shows the IR spectra of Acyclovir API, HPMC, MCC, Magnesium stearate, and talc respectively. **Figure 7** shows the IR spectra of physical mixture of API with other excipients and **Figure 8** shows the IR spectra of Acyclovir tablet (API with all excipients).

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Table 2. Comparative FTIR spectral analysis of pure acyclovir and its physical mixture with formulation excipients for the assessment of drug–excipient compatibility.

Functional group	Wave number actual range	Wave number observed range(cm^{-1})	Wave number observed range(cm^{-1})
Feasible	(cm^{-1})	**Acyclovir**	**Acyclovir with other excipients**
N-H and O-H Stretching (broad, Hydrogen bonding)	3400-3200	3373.54	3329.02
C=O Stretching	1750-1600	1630.04	1635.79
C=C and C=N Stretching	1600-1500	1550.92	1541.73
CH2 bending	1450-1400	1404.56	1413.79
C-N Stretching and C-O Stretching	1300-1000	1102.01 1180.52	1102.97 1181.96
Aromatic C-H bending	850-700	750.12	748.24

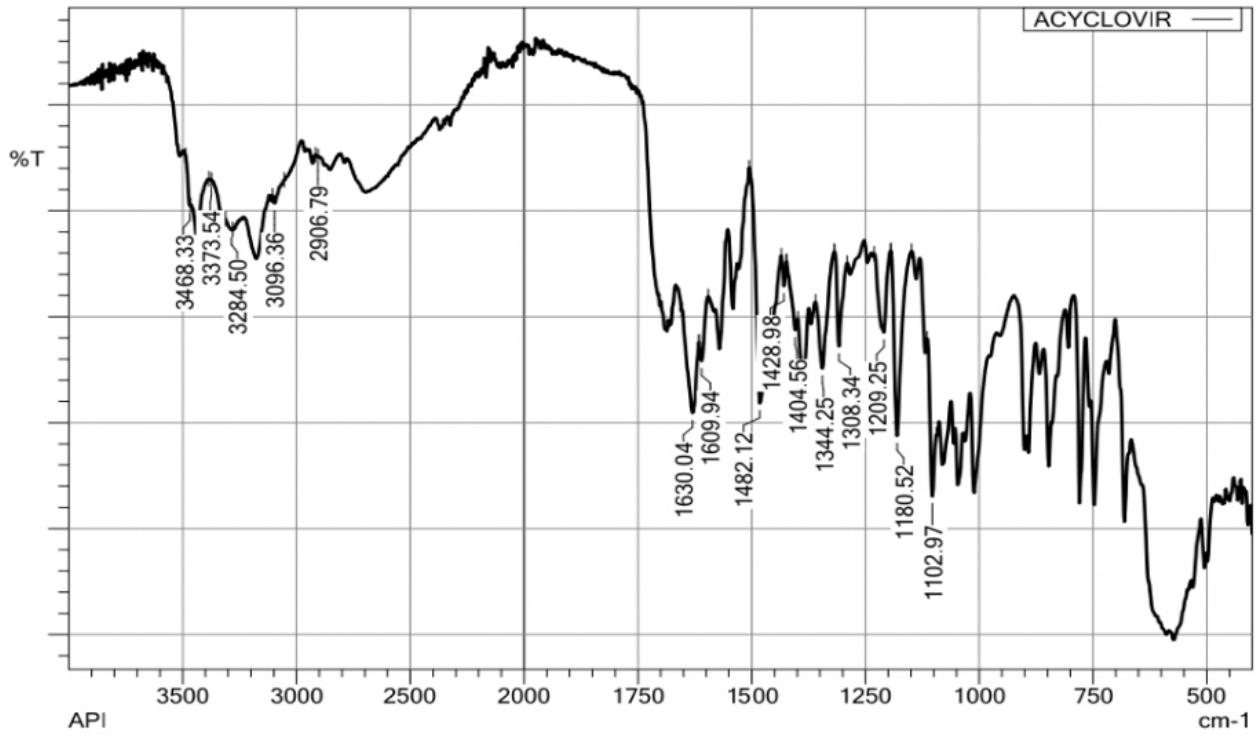


Figure 2. IR Spectra of Acyclovir API

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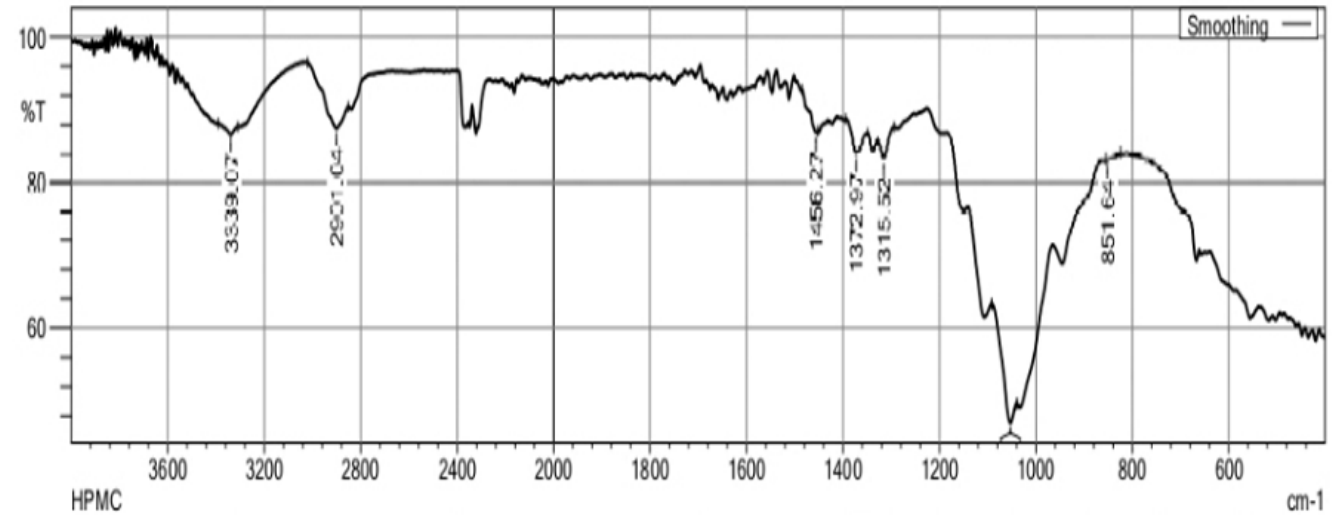


Figure 3. IR Spectra of HPMC

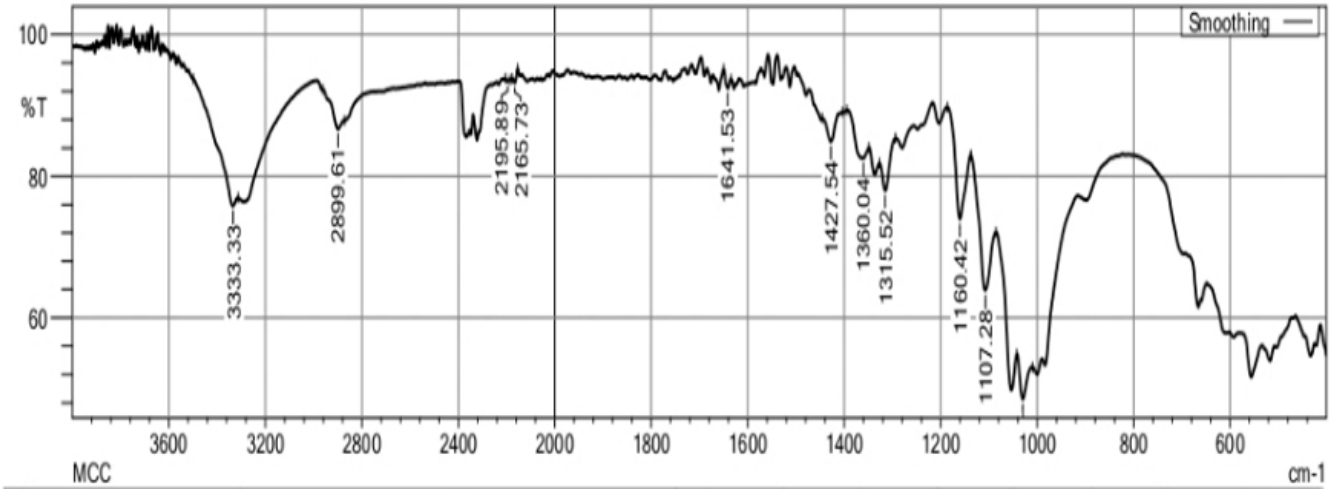


Figure 4. IR Spectra of MCC

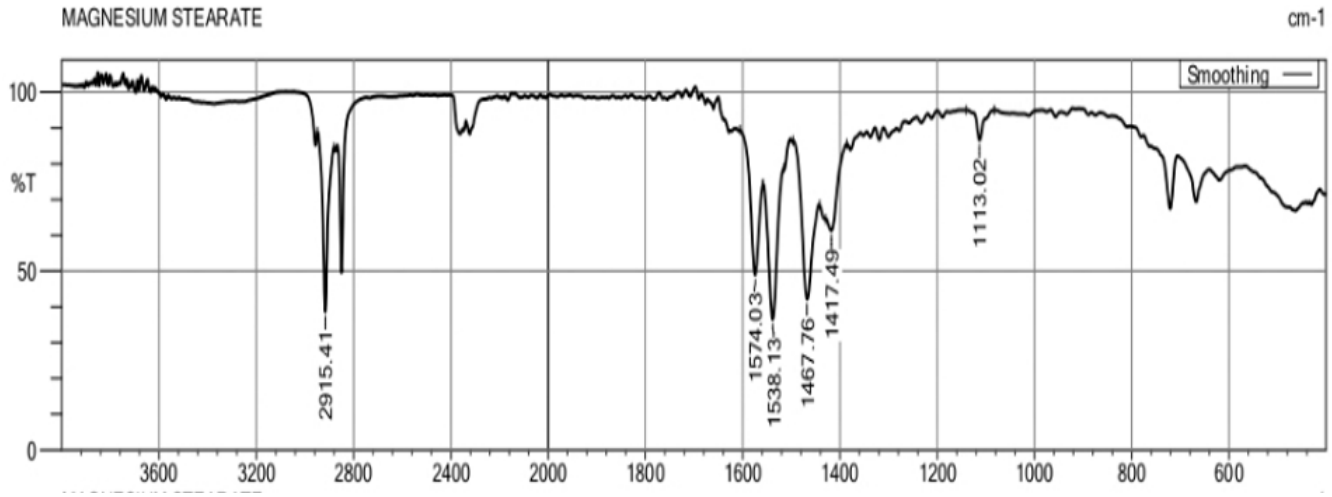


Figure 5. IR Spectra of Magnesium Stearate

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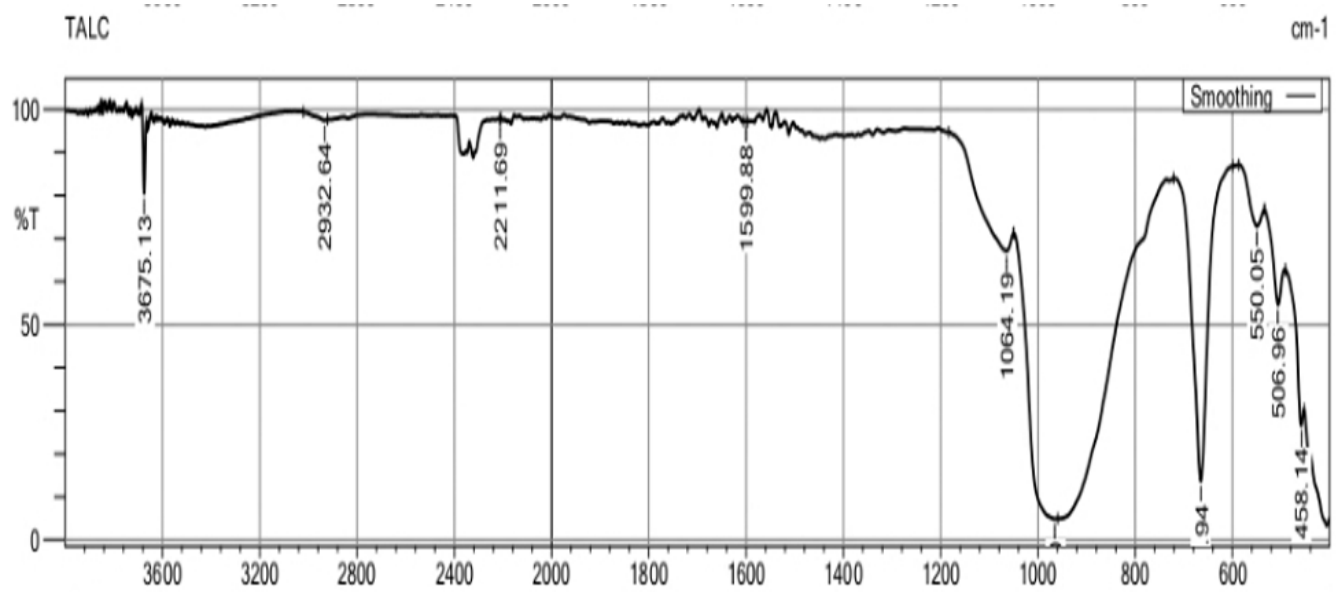


Figure 6. IR Spectra of Talc

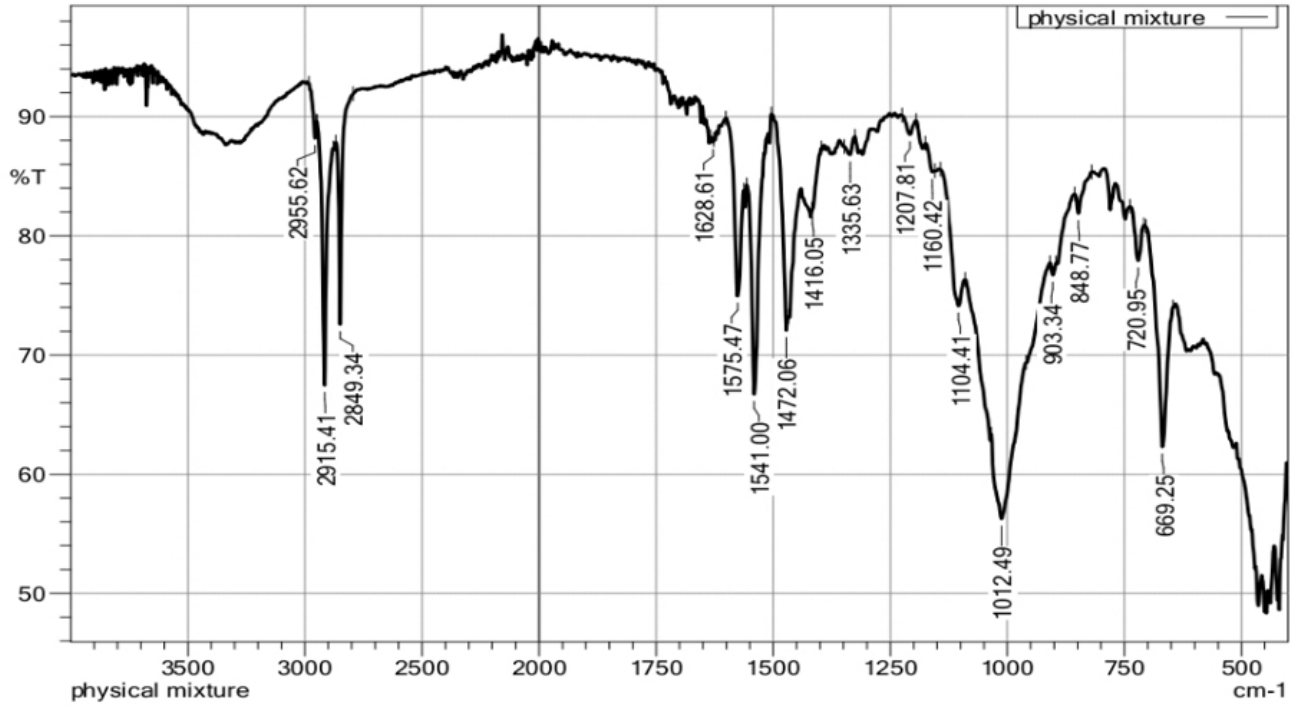


Figure 7. Physical Mixture of API With Other Excipients

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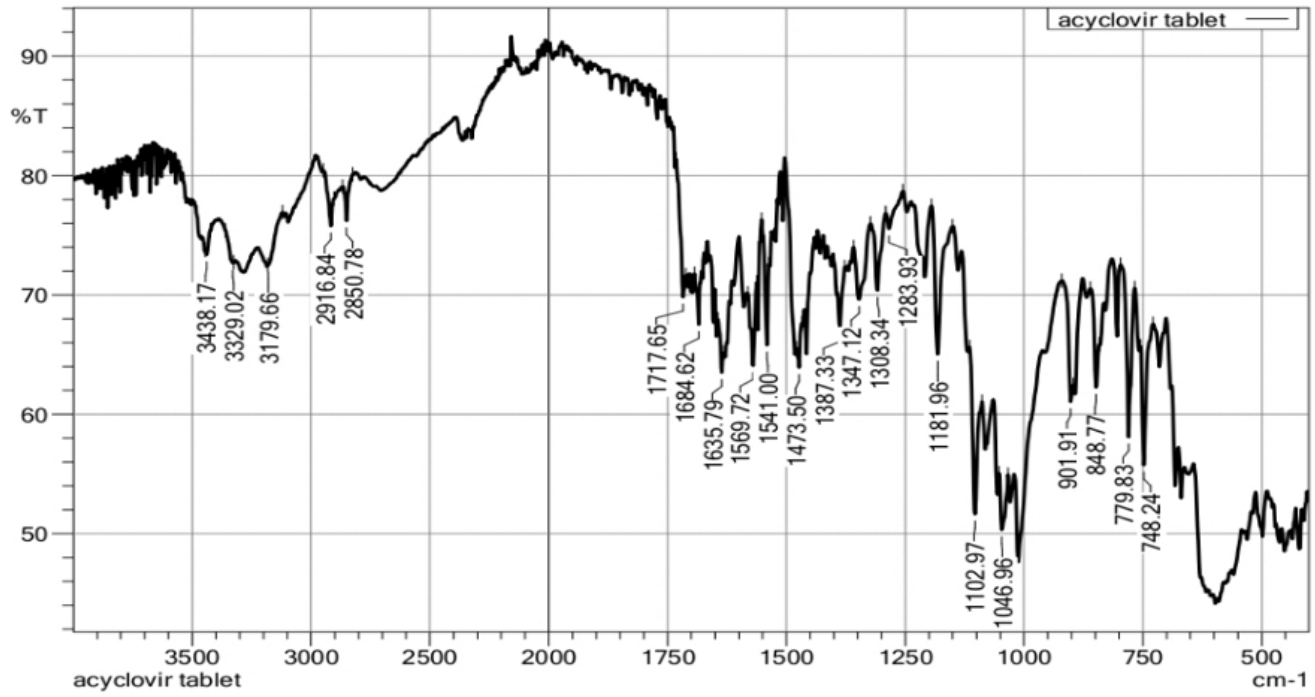


Figure 8. Acyclovir tablet (API with all excipients)

4. DISCUSSION

From the result we identify and confirm the Acyclovir API has the N-H and O-H stretching in 3373.54 and with the excipients 3329.02, similarly, C=O stretching of acyclovir API in 1630.04 and with other excipients it is 1635.79 and C=C stretching of API at 1550.92 and with excipients it is 1541.73 and CH2 bending of API at 1404.56 and with excipients it is 1413.79. Similarly, C-N and C-O stretching of API are at 1102.01 and 1180.52, respectively and with excipients it is 1102.97 and 1181.96, respectively and it also has aromatic C-H bending of API at 750.12 and along with excipients it is seen 748.24.

Here, we identify and confirm the presence of Acyclovir and its associated excipients in the tablet formulation based on their characteristic functional group peaks in the FTIR spectrum confirms that the Sample is Acyclovir (API), Microcrystalline Cellulose (MCC), Talc, Hydroxypropyl Methylcellulose (HPMC), Magnesium Stearate.

5. CONCLUSION

The compatibility studies of physical mixtures of Acyclovir API with different excipients such as HPMC, MCC, Magnesium Stearate, Talc were investigated by FTIR it was detected that there was no variation or no minor deviation in the characteristic peaks in FTIR spectroscopy. The Acyclovir tablet's FTIR spectrum shows all of the distinctive peaks that correspond to:

Acyclovir: Confirmed by O–H, N–H, C=O, aromatic ring, and amine-related peaks.

MCC and HPMC: Identified via O–H broad stretches, C–O–C, and C-H bending vibrations.

Magnesium Stearate: Verified by COO^- stretching and alkyl C–H stretches.

Talc: Confirmed through Si–O stretches and weak O–H stretches. FTIR provides information on chemical reactions taking place between the API and the excipient. In order to encourage the creation of more stable blends, this process alerts formulation experts on which chemical groups in the excipients should be avoided. All incompatibilities could occur in a covert or visible way. Usually, inadequate solubility, changes in viscosity, colour, clarity, etc., lead to visual or obvious incompatibilities. It could be tricky to find hidden incompatibilities that are not immediately apparent. Stress and Preformulation studies do not always predict drug-excipient interactions, and they can take a long time to show up in traditional stability testing programmes. They may complicate and compromise a commercial product's viability or a development program [29]

Understanding the chemical and physical properties of excipients, their associated impurities or residues, and how they might interact with other materials or other substances alerts the pharmaceutical technologist to potential unfavourable outcomes. The IR spectrum confirms the presence and compatibility of both the API and excipients in the formulation [30].

DECLARATIONS

Conflict of Interest: Authors Declare no conflict of interest.

Acknowledgement: None

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