

Selection of excipients for cefdinir floating tablets through drug excipient compatibility testing

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ARTICLE DETAILS

Article History

Published Online: 10 November 2018

Keywords

Cefdinir, FTIR, Eudragit, Hydroxy propyl methyl cellulose, gum karaya

ABSTRACT

Cefdinir is an expanded-spectrum, oral, third-generation cephalosporin antimicrobial agent active against Gram-positive and Gram-negative bacteria. It is used in the treatment of acute chronic bronchitis, rhino sinusitis, and pharyngitis and uncomplicated skin and skin structure infections in adults and adolescents, it is indicated for acute otitis media, acute sinusitis, and community-acquired pneumonia. Preformulation is the first step in the rational formulation of an active pharmaceutical ingredient (API). For any formulation interactions studies are very important. When there was no interaction between the chosen drug-excipient or excipient-excipient then the formulation will be an appropriate one. The selection of suitable study method to evaluate the interaction between the drug and the excipients is a prime most achievement in the pre-formulation study. Recently the thermal analytical techniques are applied to study the interaction study. The objective of the study was to study the compatibility of cefdinir drug substance with the excipients employed in the formulation of cefdinir floating tablets. Based on the FTIR results cefdinir was found to be compatible with excipients Eudragit, Hydroxy propyl methyl cellulose and gum karaya.

1. Introduction

Cefdinir is a third generation cephalosporin antibiotic having bactericidal activity by inhibition of cell wall synthesis and is used in the treatment of uncomplicated UTI, pharyngitis and tonsillitis, acute bronchitis and acute exacerbation of chronic bronchitis, uncomplicated gonorrhoea etc.¹ Preformulation is an investigation on the physical-chemical properties of the drug substance alone and in combination with excipients. Assessment of the possible incompatibilities between the drug and various excipients is an important part of the preformulation study of drug-excipient compatibility is an important process in the early development stage of stable dosage forms.² The successful formulation of a stable and effective dosage form depends on a careful selection of the excipients. However, no universally accepted protocol is available for evaluating the drug compatibility with different excipients.³ The aim of this work was to evaluate the compatibility between cefdinir and some pharmaceutical excipients, using thermo analytical techniques (DSC) and Fourier Transform Infrared Spectroscopy (FTIR).⁴

2. Materials and Method

2.1 Materials

Cefdinir were gift sample from Dr. Reddy's laboratories, Natural and synthetic polymers were purchased from AR chemicals.

2.2 Method

Drug-excipients compatibility study by FTIR^{5,6}

The FTIR spectra of sample were recorded on a FTIR equipped with spectrum 11.0.0.0449 software using KBr pellet method. The spectrum for each sample was recorded over than 1000 -3500 cm⁻¹.

3. Results and Discussion

Drug-excipients compatibility study by FTIR

The infrared (FT-IR) spectra were obtained in a KBr pellets using a Perkinelmer FTIR spectrometer spectrum one at resolution 4cm⁻¹ from 3500 to 500 cm⁻¹. A typical FT-IR spectra of novel Cefdinir showed absorption at the following wave number in cm⁻¹. 3290.87, 1616.26, 2999.09 and 1516.43. FTIR spectroscopy has been successfully used for exploring the differences in molecular conformations, crystal packing and hydrogen bonding arrangements for different solid state forms of an organic compound. Spectral variations originate due to alteration in bonds that exhibit characteristic vibrational frequencies, leading to frequency shifts and splitting in absorption peaks. The FTIR spectrum of samples showed characteristic absorption bands 10 which were comparable with absorption bands of individual sample. The results illustrated that, there were no chemical instabilities in drug-excipient combinations.

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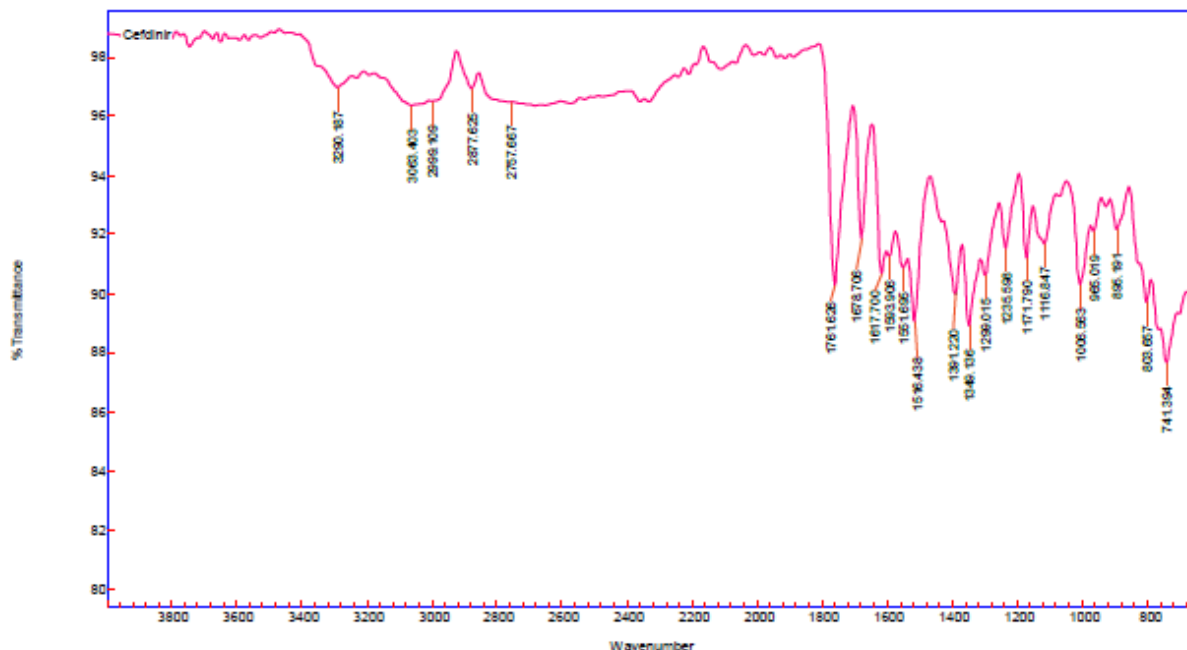
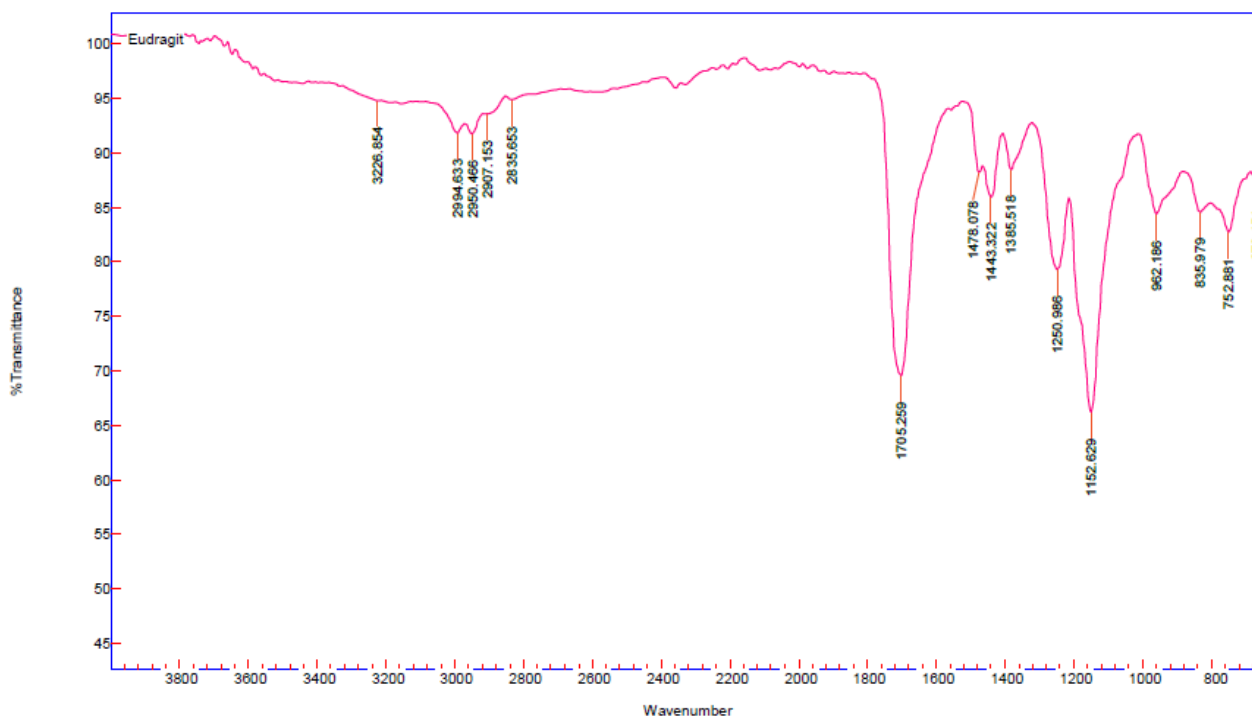


Fig-1: FTIR Studies of Cefdinir

Table-1: Characteristic Peaks and frequency of cefdinir

S.No.	Characteristic Peaks	Frequency range (cm-1)	Frequency (cm-1)
1	OH stretching	3200-3400	3290.87
2	OH Bending	1800-1600	1616.26
3	C-H stretching	3000-2800	2999.09
4	C=O stretching	1600-1400	1516.43

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Name	
Eudragit	—

Fig-2: Characteristic Peaks and frequency of Eudragit

Table-2: Characteristic Peaks and frequency of Eudragit

S.No.	Characteristic Peaks	Frequency range (cm-1)	Frequency (cm-1)
1	OH stretching	3200-3400	3228.854
2	OH Bending	3000-2800	2994.833
3	C-H stretching	1200-1000	1152.429
4	C=O stretching	1800-1600	1705.250

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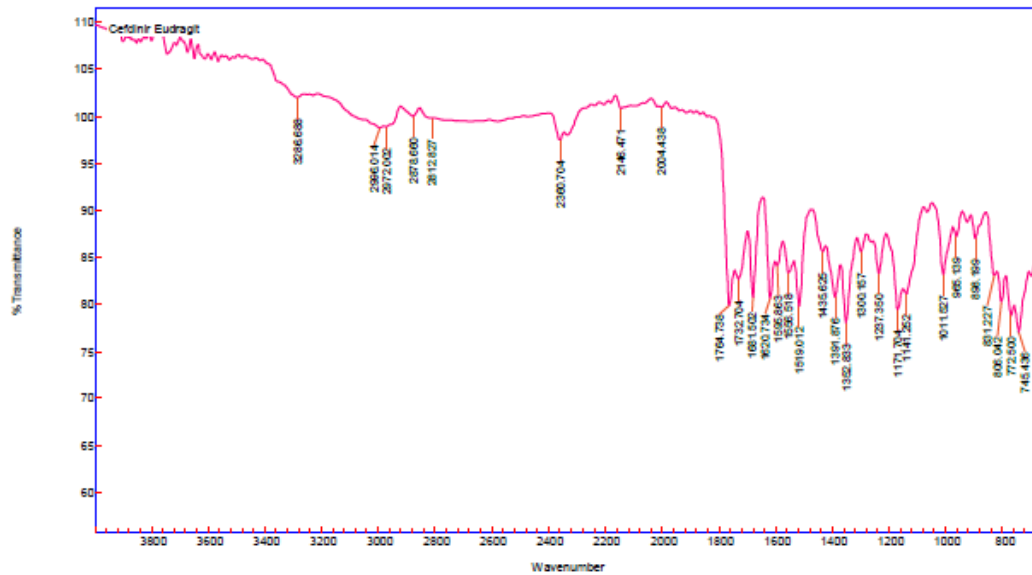
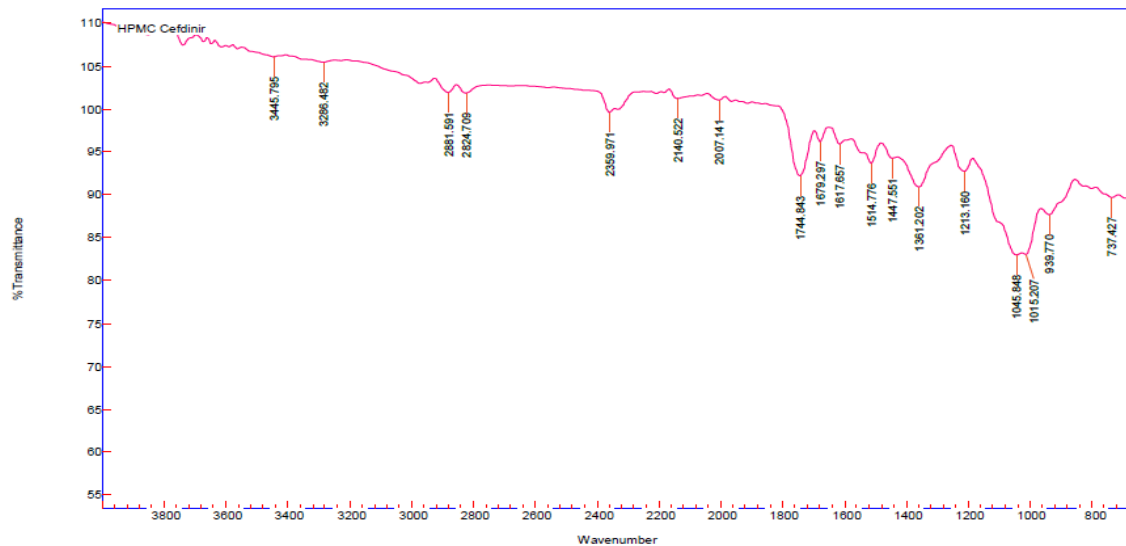


Fig-3: FTIR Spectra of Cefdinir + Eudragit

Table-3: Characteristic Peaks and frequency of Cefdinir + Eudragit

S.No.	Characteristic Peaks	Frequency range (cm-1)	Frequency (cm-1)
1	OH stretching	3400-3200	3286.636
2	OH Bending	1800-1600	1601.800
3	C-H stretching	2400-2200	2300.704
4	C=O stretching	1200-1000	1140.253

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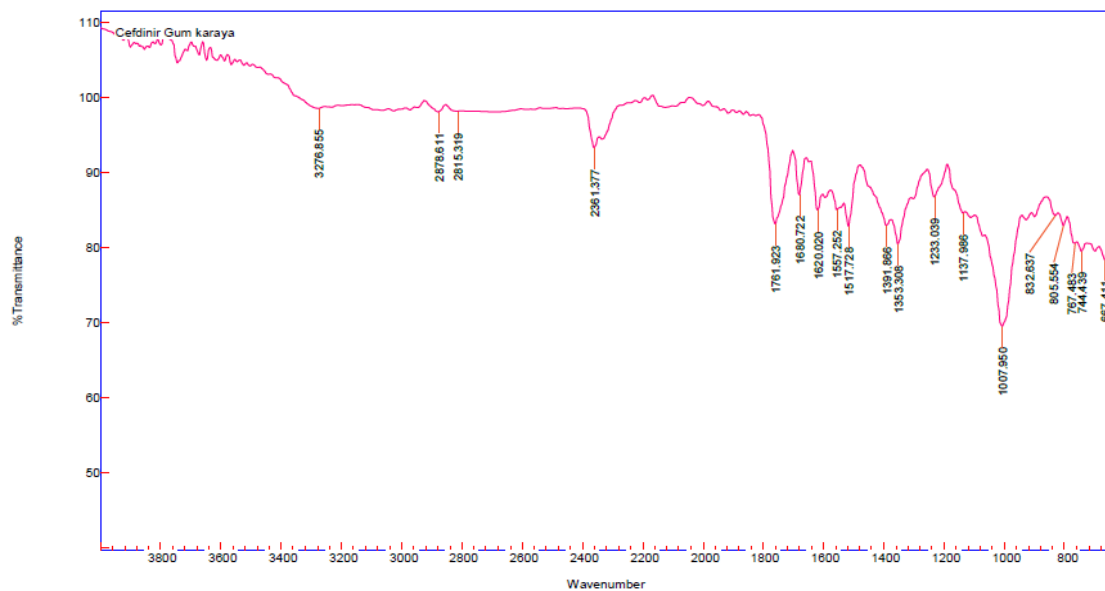
Name	HPMC Cefdinir
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Fig-4: Characteristic Peaks and frequency of Cefdinir + HPMC

Table-4: Characteristic Peaks and frequency of Cefdinir + HPMC

S.No.	Characteristic Peaks	Frequency range (cm-1)	Frequency (cm-1)
1	OH stretching	3600-3400	3445.785
2	OH Bending	3000-2800	2881.591
3	C-H stretching	2200-2000	2140.522
4	C=O stretching	1200-1000	1045.848

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Name
Cefdinir Gum karaya

Fig-5: Characteristic Peaks and frequency of Cefdinir + Gum karaya

Table-5: Characteristic Peaks and frequency of Cefdinir + Gumkaraya

S.No.	Characteristic Peaks	Frequency range (cm-1)	Frequency (cm-1)
1	OH stretching	3400-3200	3278.855
2	OH Bending	3000-2800	2878.611
3	C-H stretching	2400-2000	2361.377
4	C=O stretching	1200-1000	1007.950

4. Conclusion

From the results of FTIR studies, it is proven that FTIR as fast screening tools to check compatibility in early stages of a preformulation process. Based on our results, all mentioned

excipients were found to be fully compatible with. It is conclude that the selected excipients can be further used for preparing cefdinir floating tablets.

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