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EVALUATION OF COMPATIBILITY BETWEEN DICLOFENAC SODIUM, ISOLATED NOVEL FICUS PALMATA MUCILAGE AND SOME OTHER PHARMACEUTICAL EXCIPIENTS

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ABSTRACT

The study was undertaken to evaluate the compatibility between diclofenac sodium, isolated novel plant mucilage, and some other pharmaceutical excipients, using physicochemical compatibility study and fourier transform infra red (FTIR) spectral study. Physicochemical compatibility study was carried out by observing any physical or chemical changes in the form of incompatibility in two combination mixtures in different storage conditions. All combinations, kept on glass vials, were stored at 4ºC, Room Temperature (RT) and 40ºC under observation. There were no characteristic changes shown by any of the mixture after every week intervals in different storage conditions. There were no sign of any incompatibility between diclofenac sodium, Ficus palmata mucilage and other excipients after FTIR spectral analysis. Therefore, such combinations can be best suitable in formulating any type of dosage forms for administration.

KEYWORDS

Diclofenac sodium, Ficus palmata, Compatibility, Excipients

INTRODUCTION

Excipients are the additives that convert active pharmaceutical ingredients into a specialized dosage form suitable for administration to patients. These are those chemical substances which affect the functionality, stability and drug release behaviour of any formulation. Excipients are chosen in formulation development based on its compatibility with the selected active pharmaceutical ingredient.[1, 2]

Preformulation is the primary step in the formulation of an active pharmaceutical ingredient. It is an investigation of the physicochemical properties of the drug substance, alone and in combination with other excipients.[3, 4]

During the preformulation study of any drug delivery systems, it is practically essential to have readily available knowledge of the physicochemical properties of the drug as well as the excipients to be used. Pharmaceuticals excipients are used in formulating dosage forms to provide administration and release the drug, as well as to protect it from the environment. The excipients are considered to be inert, but incompatibilities between drug and excipients can be possible in a formulation.[5-10]

Incompatibility between drug and excipient can cause alteration in stability and bioavailability of drugs which further affects its safety and efficacy. Study of drug-excipient compatibility is an important process that helps in the development of a stable solid dosage form after the selection a suitable excipient.[9, 11-14]

Plants are non-polluting resources for sustainable supply of economic pharmaceutical excipients or products. New and improved excipients continue to be developed to meet the requirements of drug delivery systems in general and that of tablet manufacturing in particular[1]. Gums and mucilage's obtained from plant are widely used natural material for conventional and novel drug delivery system. These natural materials have advantage over synthetic ones since they are chemically inert, nontoxic, less expensive, biodegradable and wider available. Various polymers have been investigated as either binder or release modifying agent each presenting a different approach to the matrix system.[15]

The aim of this study was to evaluate the compatibility between diclofenac sodium, isolated novel plant mucilage, and some other pharmaceutical excipients, using physicochemical compatibility study and fourier transform infra red (FTIR) spectral study.

MATERIALS AND METHODS

Materials

Diclofenac sodium was purchased from Yarrow Chem Products, Mumbai, India. Microcrystalline cellulose, magnesium stearate and talc were procured from Central Drug House, New Delhi, India. Ficus palmata whole plant was collected from nearby locality of

Dehradun, Uttarakhand. Plant sample was authenticated from Botanical Survey of India, Dehradun, Uttarakhand, India.

Isolation and Purification of Ficus palmata mucilage

Fresh leaves and stems of Ficus palmata were collected and washed with water to remove dirt and debris. The material was then partially crushed in grinder and soaked in water for 5-6 hr, boiled for 30 min, and allows standing so that all the mucilage was released into the water. The material was then squeezed from an eight fold muslin cloth to remove the marc from the solution. Following this, acetone was added to the filtrate to precipitate the mucilage. The mucilage was separated, dried in an oven at a temperature less than 50˚C, and the dried powder mucilage was passed through a sieve no. 80 and stored in a desiccator until required.

Methods

The compatibility between diclofenac sodium, isolated Ficus palmata mucilage and some other pharmaceutical excipients were evaluated using the following studies:

Physicochemical Compatibility Study

The pure drug i.e. diclofenac sodium, isolated Ficus palmata mucilage and other excipients e.g. microcrystalline cellulose, magnesium stearate and talc were subjected to physicochemical compatibility study and was carried out by observing any physical or chemical changes as incompatibility in two different combination mixtures. First mixture is of diclofenac sodium and Ficus palmata mucilage, while second combination consists of mixture containing diclofenac sodium, Ficus palmata mucilage and other excipients. All combinations were prepared and kept on glass vials which are stored at 4ºC, Room Temperature (RT) and 40ºC under observation. Observations were recorded after every week till one month.

Fourier Transform Infra Red (FTIR) Spectral Study

Fourier transform infra red (FTIR) spectrum of the pure drug i.e. diclofenac sodium, Ficus palmata mucilage and different combinations with other excipients were recorded using a Shimadzu spectrometer (FTIR-8700) over wave number range 4000 to 400 cm^{-1} using potassium bromide (KBr) discs prepared from powdered samples mixed with dry KBr.

RESULTS & DISCUSSION

Physicochemical compatibility study was carried out by observing any physical or chemical changes as incompatibility in two combination mixtures in different storage conditions and observations are shown in Table 1. There were no characteristic changes shown by any of the mixture after every week intervals in different storage conditions. Fourier transform infra red (FTIR) spectrum of diclofenac sodium (Figure 1), Ficus palmata mucilage (Figure 2), mixture of diclofenac sodium and Ficus palmata mucilage (Figure 3), mixture of diclofenac sodium and microcrystalline cellulose (Figure 4), mixture of diclofenac sodium and magnesium stearate (Figure 5), mixture of diclofenac sodium and talc (Figure 6) and mixture of diclofenac sodium, Ficus palmata mucilage and other excipients (Figure 7) were obtained and there were no sign of incompatibility between diclofenac sodium, Ficus palmata mucilage and other excipients after FTIR spectral analysis. Therefore, isolated plant mucilage from Ficus palmata and other pharmaceutical excipients were found to be compatible with diclofenac sodium.

Table 1: Physicochemical compatibility study

Combinations	Storage Conditions	Time Period			
		1st week	2nd week	3rd week	Last week
DS + FP mucilage	4°c	No Change	No Change	No Change	No Change
	RT	No Change	No Change	No Change	No Change
	40°c	No Change	No Change	No Change	No Change
DS + FP mucilage + Other Excipients	4°c	No Change	No Change	No Change	No Change
	RT	No Change	No Change	No Change	No Change
	40°c	No Change	No Change	No Change	No Change

*RT= Room Temperature, DS= Diclofenac Sodium, FP= Ficus palmata

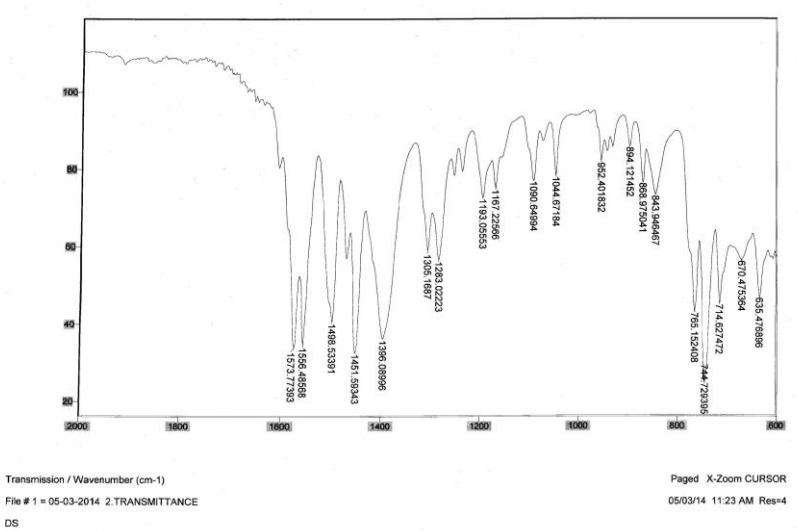

Figure 1: IR spectrum of Diclofenac sodium

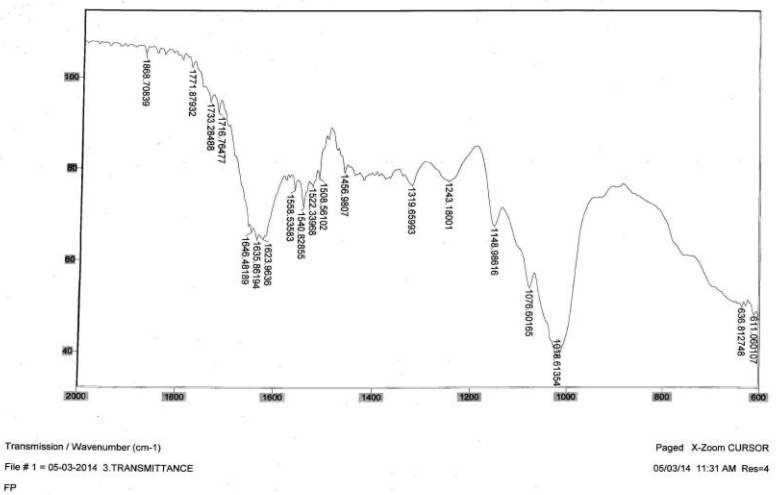

Figure 2: IR spectrum of Ficus palmata mucilage

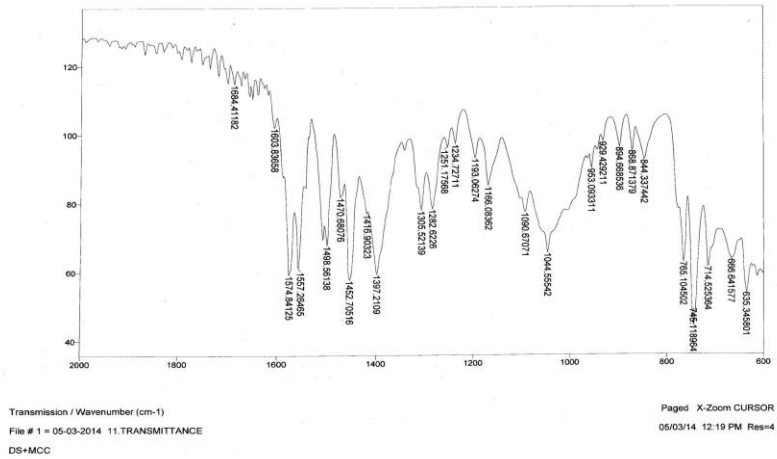

Figure 3: IR spectrum of Diclofenac sodium and Microcrystalline cellulose

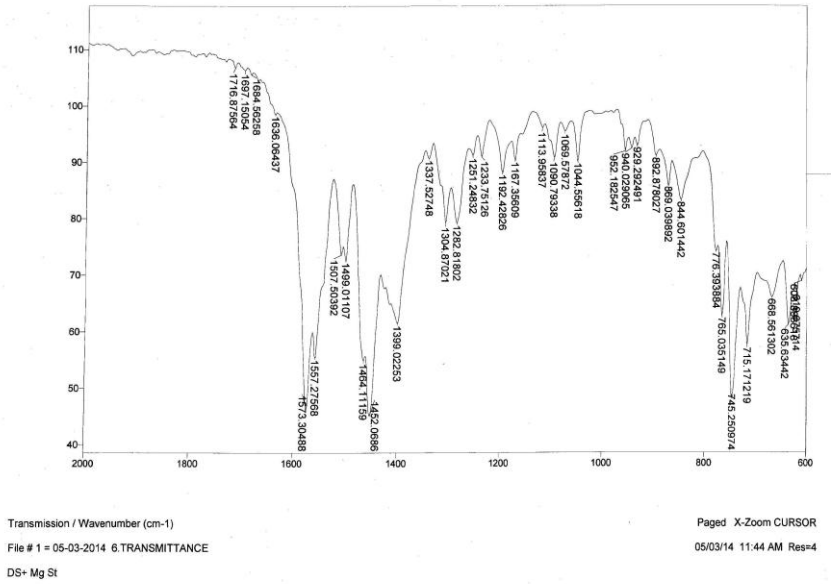

Figure 4: IR spectrum of Diclofenac sodium and Magnesium stearate

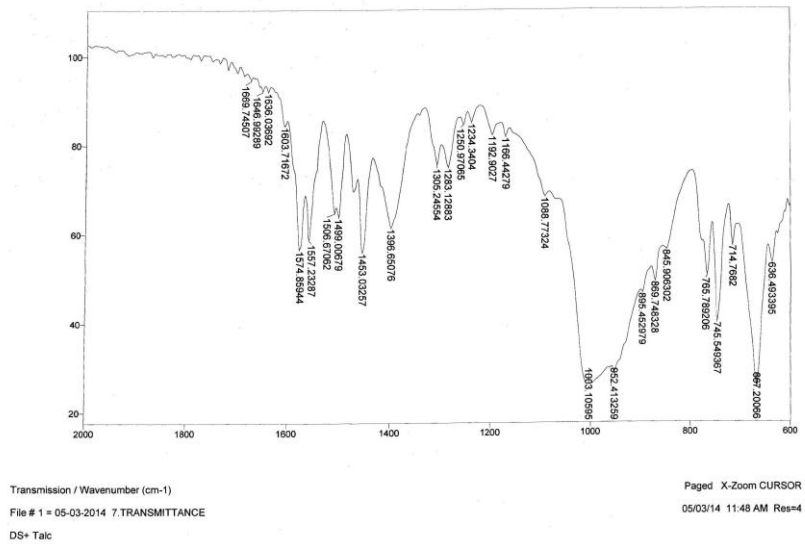

Figure 5: IR spectrum of Diclofenac sodium and Talc

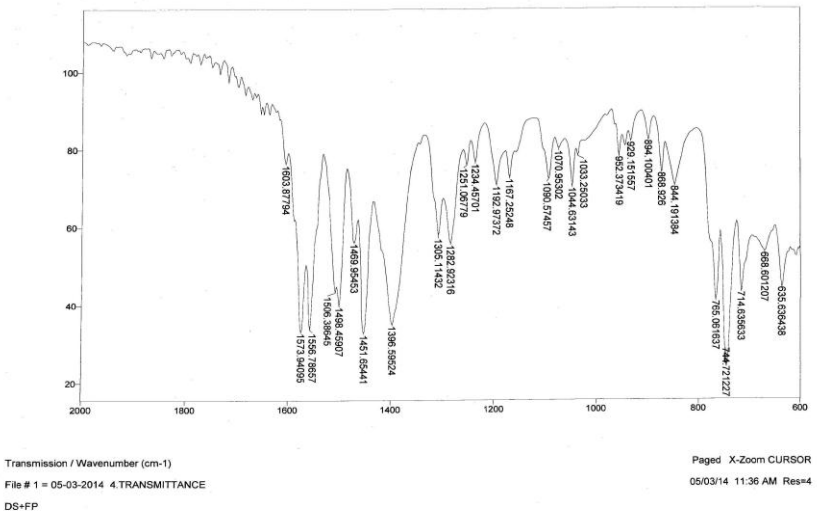

Figure 6: IR spectrum of Diclofenac sodium and Ficus palmata mucilage

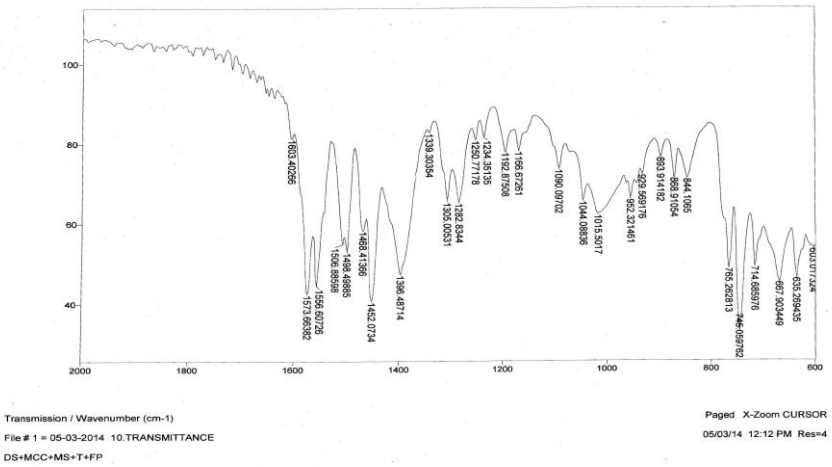

Figure 7: IR spectrum of Diclofenac sodium, Ficus palmata mucilage and Other Excipients

CONCLUSION

In this study, excipients, which were commonly used in solid drug formulations, were evaluated for interaction possibility with diclofenac sodium. Compatibility study showed no characteristic changes in the diclofenac sodium with isolated Ficus palmata mucilage and also with other excipients. There were no sign of incompatibility between diclofenac sodium, Ficus palmata mucilage and other excipients after FTIR spectral analysis. Therefore, such combinations can be best suitable in formulating any kind of pharmaceutical dosage forms.

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