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Formulation and Evaluation of Chewable Tablets of Cefixime Trihydrate Solid Dispersion with Natural Polymer

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Abstract: Chewable tablets being a versatile dosage form which offer several advantages including oral drug delivery without the need for water, ease of swallowing, the stable solid dosage forms, and patient-centric drug delivery. Guar gum being a natural polymer with several interesting properties like biodegradability, biosafety, biocompatibility and sustainability presents a potential case for use in pharmaceutical formulations and drug release studies. Solid dispersion (SD) is one of the most effective and promising technique used to improve the solubility of poorly water soluble drugs. This technology is mainly applied to improve the solubility of Class II and Class IV drugs. Cefixime is an oral third generation cephalosporin antibiotic most widely used in the treatment of various infections, which has oral bioavailability of 40-50% and it belongs to the BCS Class IV. In the present study, an attempt was made to increase the solubility of Cefixime by preparing its solid dispersions using natural polymer i.e. guar gum. Solvent evaporation method was used for preparing Solid dispersions with different drug- polymer ratio. The prepared solid dispersions were evaluated for preformulation studies, percentage yield, *in vitro* dissolution studies, dissolution efficiency, FTIR, DSC etc. The result obtained from above studies showed that the solubility and dissolution profile of Cefixime solid dispersions were improved as compared to pure drug. The prepared chewable tablets were evaluated and found to exhibit satisfactory physico-chemical characteristic.

Keywords: Solid Dispersions, Cefixime, Solvent evaporation method, *In vitro* dissolution study

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Introduction

Chewable tablets are widely used as a solid dosage form for the delivery of many drugs. As a dosage form, chewable tablets have the advantages of conventional tablets in terms of manufacturability, dosing accuracy, portability, and long-term stability (Shital *et al.*, 2023). Additionally,

chewable tablets facilitate swallowing as the product is initially broken down into particles in the oral cavity. This is a useful patient-centric advantage for populations such as pediatrics for whom swallowing of conventional tablets is a concern. As water is not required for their administration, there is a benefit of convenience when dosing. The therapeutic efficacy of a drug product intended to be administered by the oral route mainly depends on its absorption by the gastrointestinal tract. However, for a drug substance to be absorbed, it needs to be solubilised. Solubility is a crucial and limiting step for oral drug bioavailability, particularly for drugs with low gastrointestinal solubility and low permeability. By improving the dissolution profile of these drugs, it is possible to enhance their bioavailability and reduce side effects. Solid dispersions (SDs) are one of the most successful strategies to improve dissolution rate of poorly soluble drugs. SDs can be defined as molecular mixtures of poorly water soluble drugs in hydrophilic carriers, which present a drug release profile that is driven by the polymer properties (Gennaro, 2000). Solid dispersion is a unique approach in which the drug is dispersed in extremely fine state in an inert water soluble carrier in solid state. Number of insoluble drugs has shown to improve their dissolution character when converted to solid dispersion. Solid dispersion technology is a well known process used to increase the dissolution kinetics and oral absorption of poorly water soluble drugs using water soluble inert carriers (Madhusudan *et al.*, 1999). A number of freely water soluble materials such as citric acid, succinic acid, bile acids, sterols and related compounds and polymers like polyvinyl pyrrolidone and poly ethylene glycols are used as carrier for solid dispersions. By this approach the dissolution rate and bioavaibility of poorly soluble drugs can be increased (Kamal *et al.*, 2006). The use of hydrophilic polymers as carriers for the dissolution enhancement of poorly water-soluble drug is increasing. Various hydrophilic carriers such as natural polymers viz. guar gum has been investigated for improvement of dissolution characteristics and bioavailability of poorly aqueous soluble drugs (Dehghan and Jafar, 2006). Cefixime is an oral third generation cephalosporin antibiotic which is used in the treatment of gonorrhea, tonsillitis and pharyngitis (Adam *et al.*, 1995; McMillan and Young, 2006). Cefixime is employed in the treatment of a variety of respiratory tract infections and otitis media (John and John, 2011). However, the low aqueous solubility and poor dissolution of this drug in gastric fluid affects its rate of absorption, resulting in a low and variable oral bioavailability. Hence, the present study was aimed to increase the solubility of Cefixime using natural polymer i.e. gaur gum by solid dispersions techniques and evaluate the formulated chewable tablets of Cefixime.

Materials and Methods

Preformulation Studies:

The drug was identified by organoleptic evaluation, UV Spectroscopy, FT-IR spectroscopy and Differential Scanning Calorimetry. The Flow properties were also determined by Carr's index, Hausner's ratio and angle of repose. Physical Characterization tests of Cefixime Trihydrate and excipients were carried out during Preformulation studies (Kathiresan *et al.*, 2010).

Preparation of Solid Dispersion:

Cefixime Trihydrate was mixed with natural polymer i.e. guar gum in ratio of 1:1, 1:2 and 1:3, later dissolved in an adequate amount of dichloromethane. To obtain solid dispersions (SDs) of Cefixime Trihydrate:Guar Gum, it was dried in oven for 50 min at 60 °C. The resultant SDs was scraped out with a spatula. Dispersions were pulverized in a mortar and pestle and passed through a sieve number # 60 before packing in an airtight container.

Evaluation of solid dispersions:

These solid dispersions (SDs) were evaluated for Percentage practical yield, IR spectra, DSC and dissolution studies (Patil *et al.*, 2017).

Percentage yield:

Percentage practical yield were calculated to know about per cent yield or efficiency of any method, thus it helps in selection of appropriate method of production. Solid dispersions were collected and weighed to determine practical yield (PY) from the following equation (Patil *et al.*, 2009):

$$PY = \frac{\text{Practical mass (SD)}}{\text{Theoritical mass (drug+carrier)}} \times 100$$

Calibration curve Alcoholic solution:

Accurately weighed solid dispersion of Cefixime Trihydrate (1:3) (100 mg) was dissolved in 100 ml of dichloromethane to get stock solution I (SS I) from which accurately measured 1 ml solution was withdrawn and diluted up to 100 ml with dichloromethane in volumetric flask to get SS II (100 µg/ml). The dilutions of 0.5, 1, 1.5, 2, 2.5 and 10 µg/ml were prepared. Absorbance of each solution was measured at 287 nm in triplicate by taking dichloromethane as a reference standard. The results were then plotted as a graph of Absorbance vs. Concentration (µg/ml).

Calibration curve Phosphate buffer pH 7.4:

Accurately weighed solid dispersion of Cefixime Trihydrate (1:3) (100 mg) was dissolved in 100 ml of PBS pH 7.4 to get stock solution I (SS I) from which accurately measured 1 ml solution was withdrawn and diluted up to100 ml with PBS pH 7.4 in volumetric flask to get SS II (100 µg/ml). The dilutions of 0.5, 1, 1.5, 2, 2.5 and 10 µg/ml were prepared. Absorbance of each solution was measured at 288 nm in triplicate by taking PBS pH 7.4 as a reference standard. The calibration curve was obtained by plotting Absorbance vs. concentration (µg/ml).

Fourier Transform Infra red spectroscopy (*FTIR*):

FTIR spectra were recorded on samples prepared in potassium bromide (KBr) disks using a Shimadzu Corporation (Koyto, Japan) facility (model - 8400S). Samples were prepared in KBr disks in a hydrostatic press at 6-8 tons pressure. The scanning range was 500 to 4000 cm (Rao *et al.*, 2008).

Differential Scanning Calorimetry of Cefixime Solid Dispersion (*1:3*):

The Differential Scanning Calorimetry (DSC) study was carried out for Cefixime solid dispersion (1:3) drug. The DSC pattern was recorded on a Mettler Toledo DSC. Thermograph was obtained by heating 1–5 mg sample in crimped aluminum pans at heating rate of 10 °C/min, from 40 °C to 220 °C, in a nitrogen atmosphere (flow rate 40 ml/min). Data was analyzed using STAR-SW 9.20 software.(Patil *et al.*, 2009).

In vitro dissolution studies:

Drug release profile of different drug: polymer ratio were obtained by using USP dissolution apparatus using phosphate buffer 7.4 (900 ml) as dissolution medium at 50 rpm. The samples were withdrawn at fixed intervals, diluted suitably with dissolution medium and analyzed spectrophotometrically at 287 nm. The dissolution was evaluated as dissolution efficiency at 180 min (Leuner and Dressman, 2000; Rawat and Jain, 2003). The dissolution efficiency (D. E.) of solid dispersion is the area under the dissolution curve of the rectangle described by 100% dissolution in the same time (Kumar *et al.*, 2003).

Preparation of Chewable Tablet by Wet Granulation:

Chewable tablets containing Cefixime Siold Dispersion (1:3) 114 mg were prepared with a total tablet weight of 325 mg by wet granulation method (Table 1). All excipients and drug were passed through the sive no.80 separately. Cefixime, mannitol, hydroxyl propyl cellulose, silicon dioxide, aspartame, and honey were mixed in mortal pestle with granulating liquid isopropyl alcohol. The wet powder blend was forced to pass through the sieve no. 25 to produce wet granules which were subsequently dried. After drying they are mixed with magnesium stearate and chewable tablets were punched by tablet punching machine (Kathiresan *et al.*, 2010).

Evaluation of chewable tablets:

Physical appearance:

Table 1: Formulation of Chewable Tablet

Ingredients	Quantity
Cefixime Siold Dispersion (1:3)	114.32 mg
Mannitol	179.77 mg
Hydroxyl Propyl Cellulose	9.75 mg
Silicon Dioxide	1.63 mg
Aspartame	4.90 mg
Honey	9.75 mg
Magnesium Stearate	4.88 mg
Total	**325 mg**

Prepared tablets were evaluated for various physical appearance tests (Allen *et al.*, 2005).

Weight variation:

The weight variation test was carried out in order to ensure uniformity in the weight of tablets in a batch. First the total weight of 20 tablets from each formulation was determined and the average was calculated. The individual weight of each tablet was also determined to find out the weight variation (Kuchekar *et al.*, 2003).

Hardness:

The hardness of tablet is an indication of its strength. Measuring the force required to break the tablet across tests it. The force is measured in kg and the hardness of about 3-5 kg/cm^2 is considered to be satisfactory for uncoated tablets. Hardness of the tablet was determined by Monsanto hardness tester, Pfizer hardness tester (Kuchekar *et al.*, 2003).

Friability test:

Friability is the loss of weight of tablet in the container due to removal of fine particles from the surface. Friability test is carried out to access the ability of the tablet to withstand abrasion in packaging, handling and transport. Roche friabilator is employed for finding the friability of the tablets. Weighed the 20 tablets from each batch and placed in Roche friabilator and rotated at 25 rpm for 4 min. Dedusted all tablets and weighed again. The percentage of friability was calculated (Kuchekar *et al.*, 2003).

Disintegration test:

The USP disintegration apparatus contains six glass tubes that are 3" long, open at the top, and held against 10" screen at the bottom end of the basket rack assembly. One tablet is placed in each tube and the basket rack is poisoned in 1 L beaker of distilled water at 37± 2 °C, such that the tablets remain below the surface of the liquid on their upward movement and descend not closer than 2.5 cm from the bottom of the beaker (Kuchekar *et al.*, 2003).

In vitro dissolution test:

In vitro dissolution study was performed by using USP Type II Apparatus (Paddle type) at 50 rpm. Phosphate buffer pH 6.8, 900 ml was used as dissolution medium which maintained at 37±0.5°C. Withdraw aliquot of dissolution medium (5 ml) at specific time intervals and diluted 10 ml with buffer solution and filter. The amount of drug dissolved was determined by UV- analytical spectrometer technique (Jagdale *et al.*, 2010).

Results and Discussion

Preformulation Studies:

Cefixime Trihydrate is white to light yellow powder, odorless, bitter in nature and melting point about 218-220°C. Angle of repose of drug Cefixime was 22.93^0 and it is in the range of excellent flow property. The loose bulk density (LBD) of the drug was found to be 0.675 g/cc. The tapped bulk density (TBD) of the drug was found to be 0.757 g/cc. The Carr's compressibility index

Table 2: Physical Characteristics of CefiximeTrihydrate

Parameters	Observations
Colour	white to light yellow
Odour	Odourless
Taste	Bitter
Melting Point	218-220 ^{0}C
Angle Of Respose	22.93^0
Bulk Density	0.675 g/cc
Tapped Density	0.757 g/cc
Carr's compressibility index	12.56%
Hausner ratio	1.12

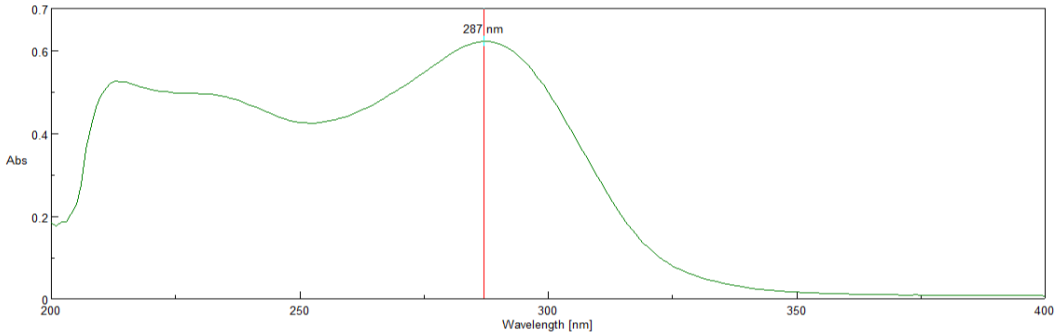

Fig. 1: UV ƛ max of Cefixime Trihydrate in phospate buffer pH 7.4 (287 nm).

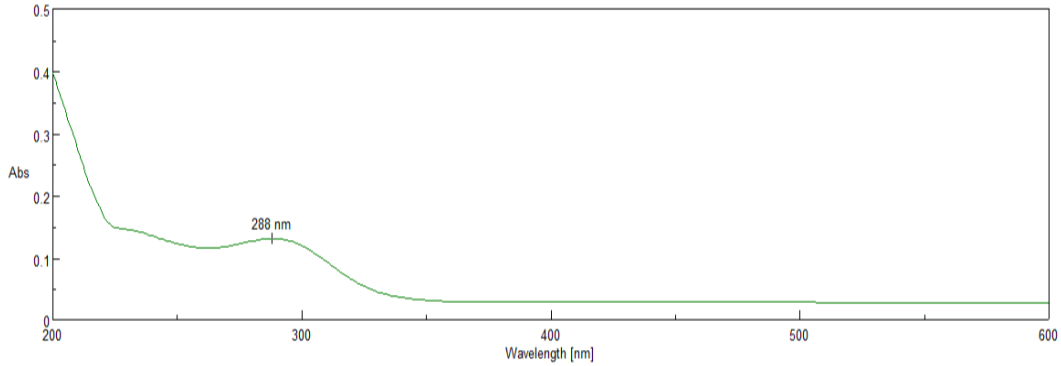

Fig. 2: UV ƛ max of Cefixime Trihydrate in Dichloromethane (288 nm).

was 12.56 and it is in the range of good flow property. The hausner ratio of the drug was found to be 1.12. The results of physical characterization of drug are summarized in Table 2.

Determination of Absorption Maximum (ƛ max):

The UV ƛ max of Cefixime Trihydrate in phospate buffer pH 7.4 (287 nm) and in Dichloromethane (288 nm) are shown in Figures 1 and 2, respectively.

Determination of Calibration curve:

(a) *Alcoholic solution*:

The standard calibration curves for Cefixime Trihydrate were dtermined in dichloromethane system, the calibration curve is depicted in Figure 3. The regression value of calibration curve in dichloromethane was found to be 0.993.

(b) *Phosphate buffer pH 7.4*:

The standard calibration curves for Cefixime Trihydrate were dtermined in phosphate buffer pH 7.4 system. The calibration curve is depicted in Figure 4. The regression value of calibration curve in phosphate buffer 7.4 was found to be 0.994.

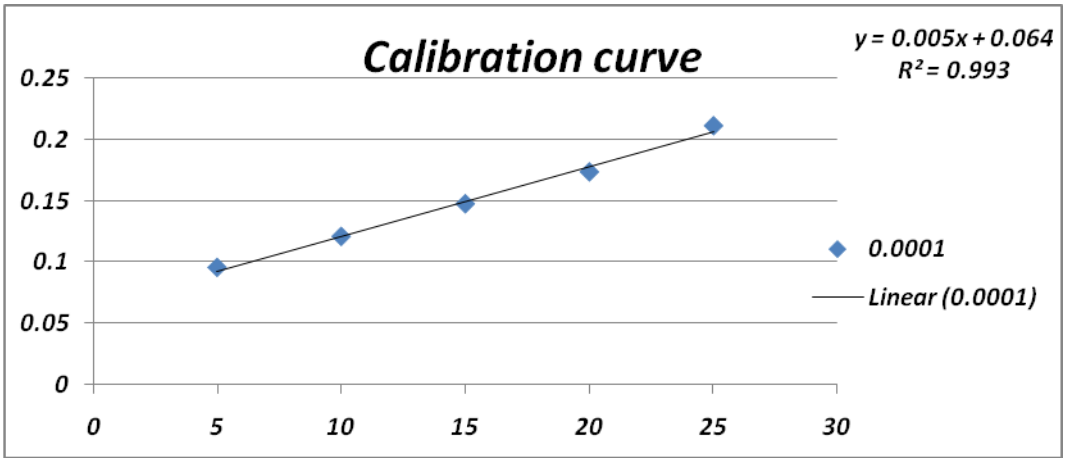

Fig. 3:Calibration curve of Cefixime Trihydrate in dichloromethane.

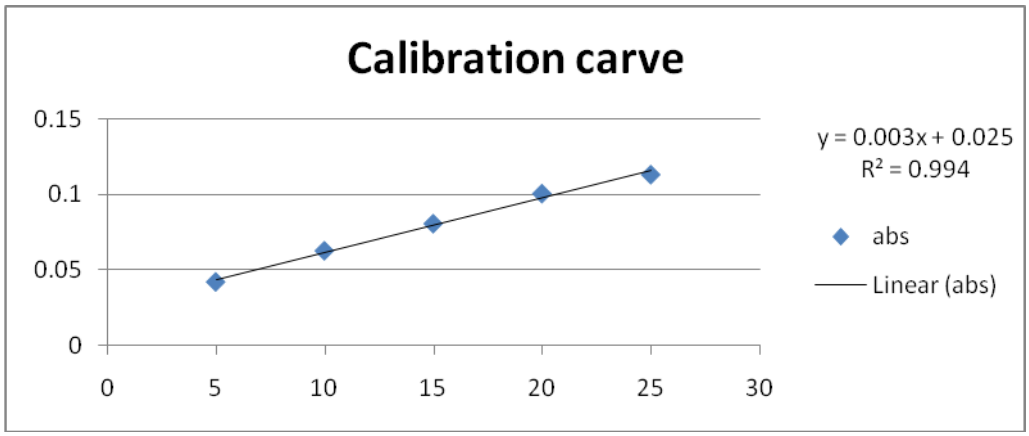

Fig. 4: Calibration curve of Cefixime Trihydrate phosphate buffer 7.4.

Table 3: IR spectra ranges of Cefixime Trihydrate

Functional group	Absorption range	Pure drug Peak	Type of Vibration
C=O Carbonyl	1670-1820 cm^{-1}	1760.69cm^{-1}	Stretch
NH2 Amine	3400-3500 cm^{-1}	3556.09 cm^{-1}	Stretch
C-N Amine	1080-1360 cm^{-1}	1069.94 cm^{-1}	Stretch
Alcohols (O-H)	3200-3600 cm^{-1}	3556.09 cm^{-1}	Stretch
C=C Alkenes	1640-1670 cm^{-1}	1668.12 cm^{-1}	Stretch

FTIR Analysis of Cefixime Trihydrate:

IR spectra of Cefixime and its solid dispersions are identical (Table 3; Fig. 5). The principal IR absorption peaks of Cefixime solid dispersions (1:3) were observed and found to be identical with the spectra of Cefixime pure drug. Thus, from the spectra it was understood that there was no interaction between Cefixime and the carriers used in the preparation of solid dispersions.

Differential Scanning Calorimetry of Cefixime Trihydrate:

The melting behaviour of pure Cefixime Trihydrate was studied using DSC; Mettler Teledo star system). The melting endotherm

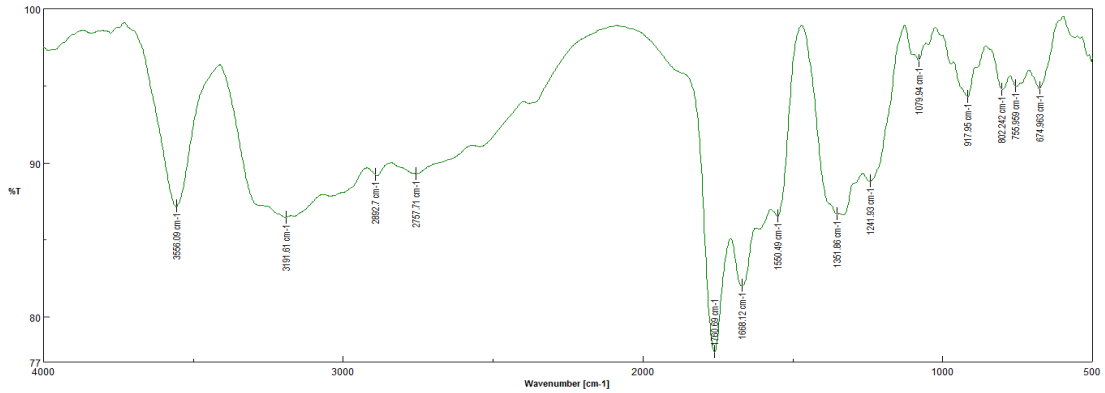

Fig. 5: IR spectra of CefiximeTrihydrate.

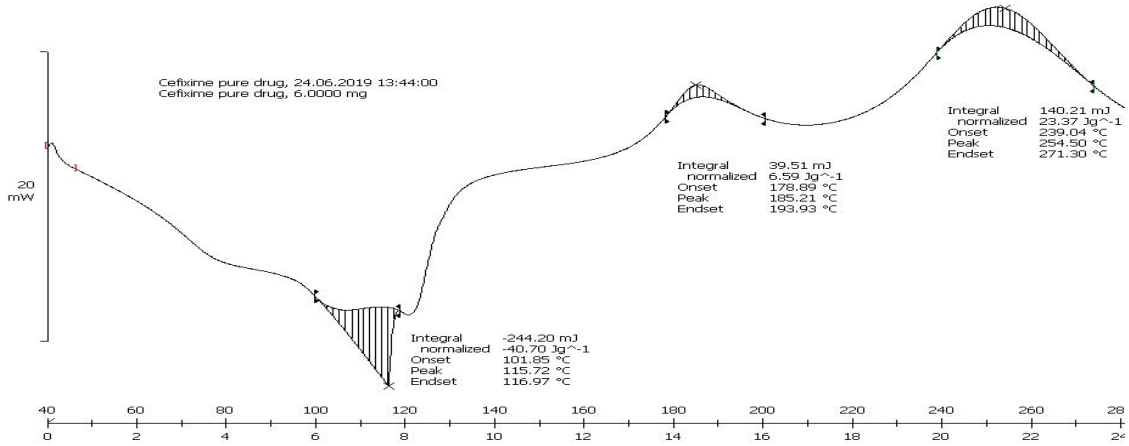

Fig. 6: Differential Scanning Calorimetry of Cefixime Trihydrate.

Table 4: Percentage yield of solid dispersions

Composition Ratio	Percentage yield
dispersion of CefiximeTrihydrate (1:1)	90%
dispersion of CefiximeTrihydrate (1:2)	88.33%
dispersion of CefiximeTrihydrate (1:3)	87.25%

was obtained and Cefixime showed sharp endothermic peak at 116.97 °C and exothermic peak at 254.50 °C as depicted in Figure 6. The melting point in the DCS is in the range of the reported melting point which was 216-220 °C, thus confirming purity of sample.

Evaluation of Solid dispersion:

Preparation and characterization of amorphous solid dispersion:

The appearance of the solid dispersion of Cefixime was amorphous in nature and light brown in colour.

Percentage yield:

Percentage yield of solid dispersion of Cefixime Trihydrate (1:1, 1:2, 1:3) is given in Table 4.

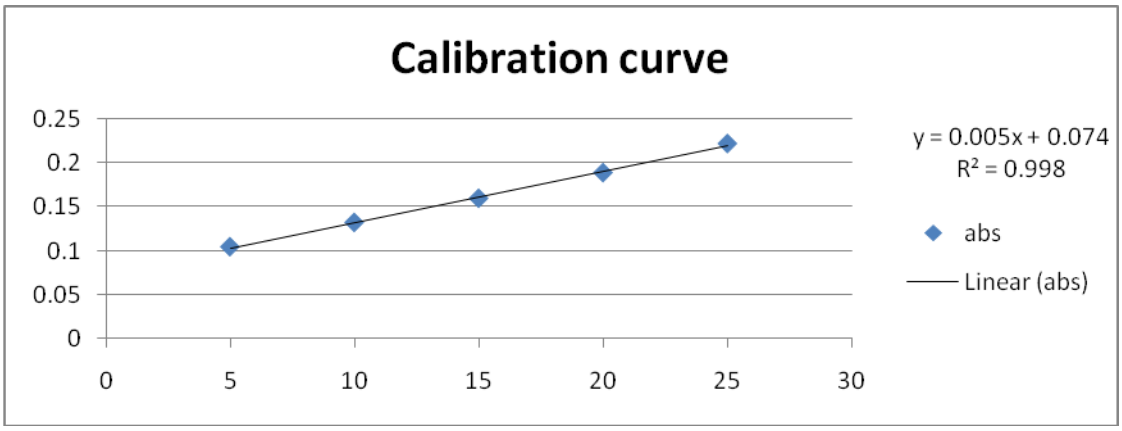

Fig. 7: Calibration Curve of SD (1:3) in Dichloromethane by UV spectrometer.

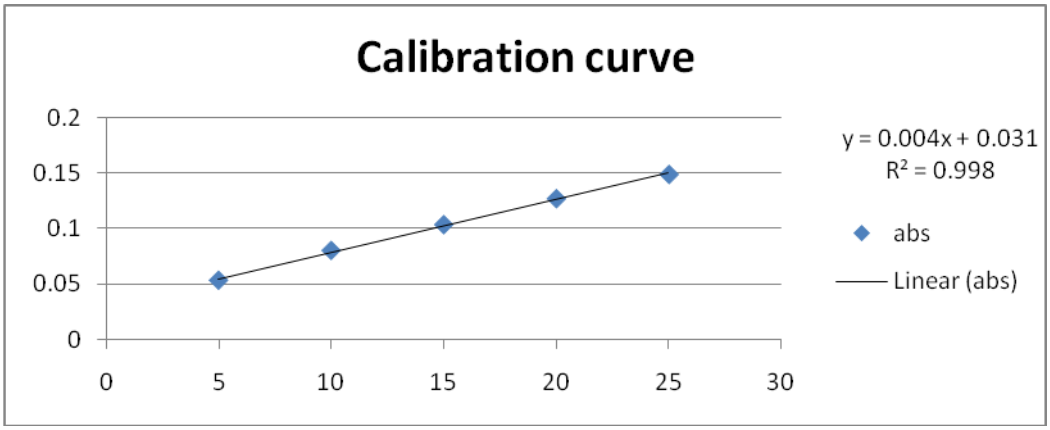

Fig. 8: Calibration Curve of SD (1:3) in Phosphate Buffer 7.4 by UV spectrometer.

Determination of Calibration curve:

(a) *Alcoholic solution*:

The standard calibration curves for Solid Dispersion Cefixime Trihydrate (1:3) were determined in dichloromethane system. The calibration curve is depicted in Figure 7. The regression value of calibration curve in dichloromethane was found to be 0.998.

(b) *Phosphate buffer pH 7.4*:

The standard calibration curves for Solid dispersion (1:3) Cefixime Trihydrate were dtermined in phosphate buffer pH 7.4 system. The calibration curve is Depicted in Figure 8. The regression value of calibration curve in phosphate buffer 7.4 was found to be 0.998.

FTIR of solid dispersion Cefixime (1:3):

Compatibility study solid dispersion Cefixime Trihydrate (1:3) ratio carried out with polymer guar gum to determine possibility of any drug interaction (Table 5; Fig. 9). FTIR spectro-scopy shows no evidence of any interaction between drug and interaction. In FTIR spectra result, solid dispersion Cefixime Trihydrate (1:3) ratio if it is stabilized, then offers many fold increase in solubility.

Differential Scanning Calorimetry of Cefixime Solid Dispersion (1:3):

The solid dispersion 1:3 Cefixime prepared with polymer (gaur gum), was subjected for DSC studies, where in solid dispersion 1:3 of Cefixime started melting at 84°C and completed at 257°C (Fig. 10). This wide range of melting process suggests that formulation is a product of physical mixture of the polymer (gaur gum) mentioned

Table 5: IR spectra ranges of solid dispersion Cefixime (1:3)

Functional group	Absorption range	Cefixime with gaur gum (1:3) Peak	Type of Vibration
C=O Carbonyl	1670-1820 cm^{-1}	1760.69cm^{-1}	Stretch
NH2 Amine	3400-3500 cm^{-1}	3550.31cm^{-1}	Stretch
C-N Amine	1080-1360 cm^{-1}	1037.52cm^{-1}	Stretch
Alcohols (O-H)	3200-3600 cm^{-1}	3550.31cm^{-1}	Stretch
C=C Alkenes	1640-1670 cm^{-1}	1664.27cm^{-1}	Stretch

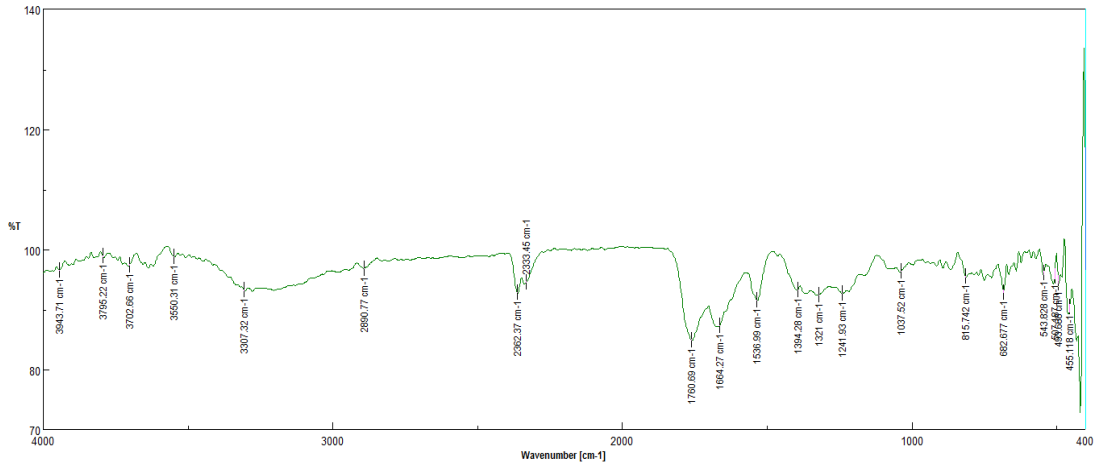

Fig. 9: FTIR of solid dispersion Cefixime (1:3).

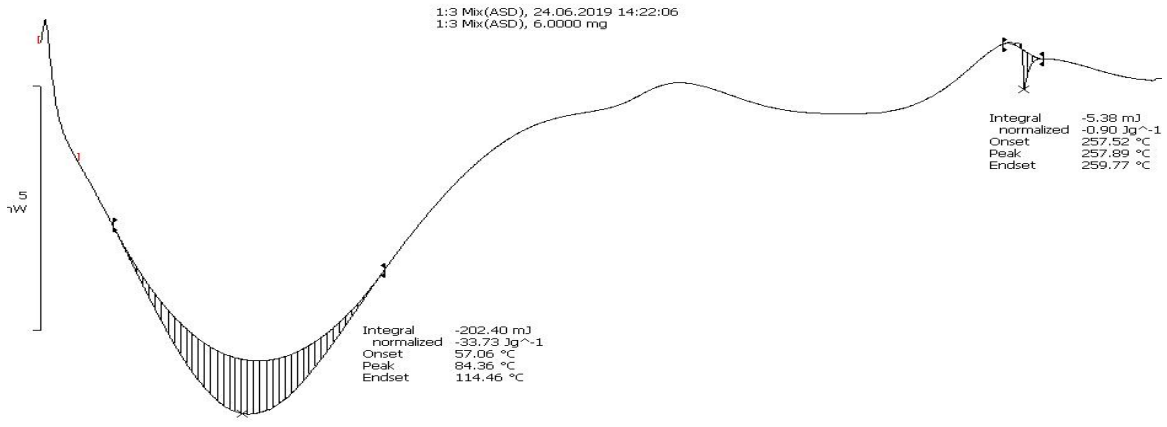

Fig. 10: Differential Scanning Calorimetry of Cefixime Solid Dispersion (1:3).

Table 6: Dissolution efficiency of pure drug and solid dispersion Cefixime Trihydrate

Time in min	% dissolution efficiency For Compositions			
	Pure Drug	1:1	1:2	1:3
00	00	00	00	00
5	34.74	44.52	55.37	78.59
10	34.89	44.64	56.08	79.76
15	35.44	44.91	56.44	80.43
20	36.65	45.40	56.60	81.68
25	37.58	46.57	57.87	82.54
30	38.22	47.71	59.63	83.40
45	39.28	48.40	61.56	86.12
60	41.39	51.12	64.19	87.31
120	43.05	55.07	65.96	89.56
180	44.06	56.52	68.99	91.98

herein, if it is a reaction product which might have formed during the formulation, it would give rise to short range of melting process, which has not happened in this case. This confirms the drug used in the formulation is in the free state rather than in the chemically reacted form. Drug is freely available to the system whenever administered. It can be concluded that during the process of formulation, drug and polymer have not undergone any chemical reaction.

In vitro dissolution profile and dissolution efficiency:

In vitro release studies revealed that there was marked increase in the dissolution rate of drug from all the SDs when compared to pure drug itself. The dissolution efficiency was found to 91.98% with 1:3 ratio composition after 180 min (Table 6). The drug release profile is depicted in Figure 11 confirmed that solubility was enhanced in the drug: polymer ratio of 1:3 as it has higher dissolution rate compared to pure drug. All the SDs followed first order kinetics and 'r' values suggested that all the SDs followed Higuchi matrix model.

Evaluation of chewable tablets:

The results of various parameters for evaluation of tablets are depicted in Table 7.

In vitro dissolution efficiency of chewable tablet:

Drug release profile of different chewable tablet of solid dispersion Cefixime with honey and chewable tablet of pure Cefixime without honey were obtained by using USP dissolution apparatus using phosphate buffer 6.8 (900 ml) as dissolution medium at 50 rpm (Fig. 12). The samples were withdrawn at fixed intervals, diluted suitably with dissolution medium and analyzed spectrophotometrically at 287 nm.

DSC of chewable tablet:

The chewable tablet of Cefixime formulation prepared with honey and other ingredients were subjected for DSC studies, wherein formulation product started melting at 163°C and completed at 240 °C (Fig. 13). This wide range of melting process suggests that formulation is a product of physical mixture of all the constituents mentioned therein, this confirmed that the drug used in the formulation is in the free state rather than in the

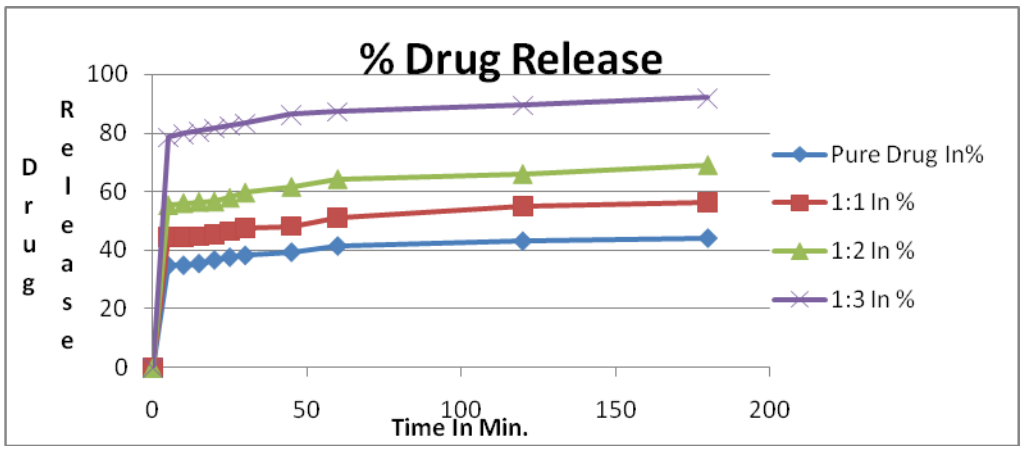

Fig. 11: % of drug release of drug and different (SDs).

Table 7: Physical Evaluation of chewable tablets

Parameter	Obervation
Colour	Yellowish brown
Shape	Round Circular Shape
Tablet Size	7mm
Thickness	2 mm
Avg Weight	326 mg
Hardness	4.1 kg/cm^2
Friability	4.92 %
Disintegration time	19 sec

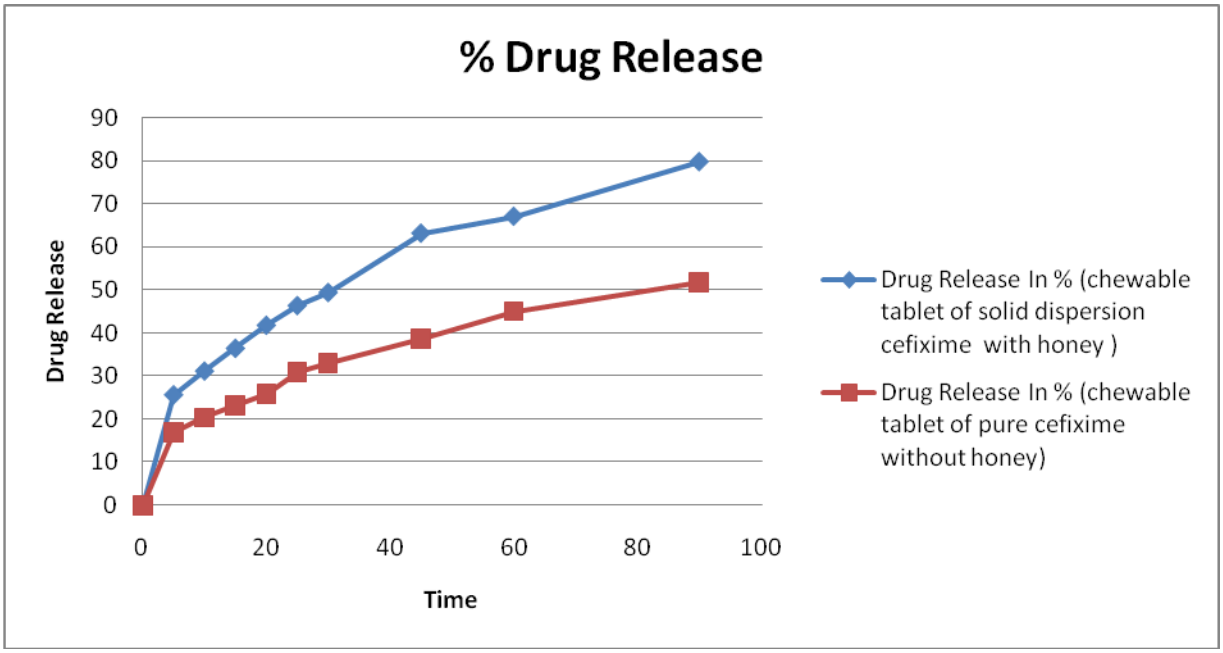

Fig. 12: % Drug Release profile of chewable tablet of solid dispersion Cefixime with honey and chewable tablet of pure Cefixime without honey.

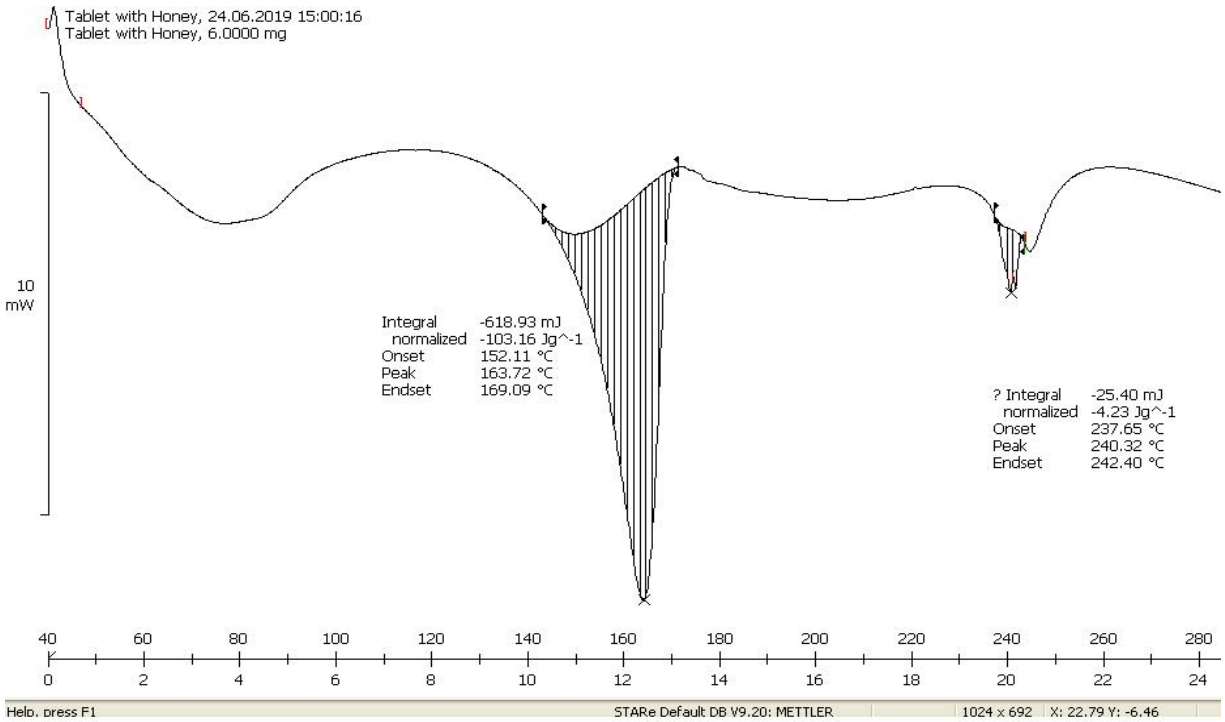

Fig. 13: DSC of chewable tablet of solid dispersion Cefixime with honey.

chemically reacted form. Drug is freely available to the system whenever administered. It is concluded that during the process of formulation in this case, drug and constituents have not undergone any chemical reaction.

Conclusion

In the present study an attempt was made to formulate Cefixime Trihydrate chewable tablet with honey. Preformulation study of Cefixime Trihydrate was performed which include physical characterization, U.V, FTIR, solubility, flow properties, angle of repose, bulk density, compressibility index, hausener ratio, and find out the absorption maximum, calibration curve and DSC study. The calibration curve was taken in dichloromethane at 287 nm and phosphate buffer 7.4 at 288 nm by UV spectrophotometer for the determination of solubility concentration. Solid dispersion was prepared by solvent evaporation method of drug with natural polymer (gaur gum). After the solubility enhancement the dissolution efficiency test was done and 1:3 solid dispersions were selected for formulation of chewable tablets. The main objective of present study was to formulate and evaluate chewable tablet of Cefixime Trihydrate solid dispersions. Tablet's physical appearance, weight variation, hardness, disintegration test, uniformity of dispersion, *in vitro* dissolution test and drug excipients compatibility study by DSC exhibited satisfactory physico-chemical characteristics.

Ethical Statement

No animal or microbes have been used or sacrificed for this study, hence Ethical Approval not required.

Author Contributions

Each author has contributed equally to the writing, and editing the manuscript. They collaborated in designing the research, conducting thorough analysis, drafting the manuscript, and refining its content. All authors have read and agreed to the published version of the manuscript.

Acknowledgements

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providing gift sample of Cefixime.

Conflict of Interest

The authors declare no conflicts of interest.

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