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Characterizing of Cinnarizine & Dimenhydrinate: A preformulation framework for oral disintegrating tablet design

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Abstract
Introduction: Pre-formulation research serves as the foundational gatekeeper in pharmaceutical development, ensuring an active ingredient possesses the necessary physicochemical profile for viable commercialization.
Objective: To perform a comprehensive preformulation study of cinnarizine and dimenhydrinate, characterizing their key physicochemical properties to guide rational formulation design.
Methods: The physiochemical characteristics of both medications were examined. Additionally, solubility was assessed in a range of pH-varying solvents, and FTIR and absorption maxima were used to assess purity. A standard calibration curve was created to support more analytical research investigations. Finally, research on the compatibility of drugs and excipients were conducted.
Results: Organoleptic characteristics showed that both medications were odorless and nearly white in color. The partition coefficient and melting point were noted in range. The infrared spectra, which displayed distinctive peaks, and UV spectroscopy, which displayed maxima at 253 nm for cinnarizine and 276 nm for dimenhydrinate, were used to establish the drug's purity. The derived standard curve was linear, with an equation of y = 0.0788 + 0.069 and a correlation coefficient of R2 = 0.996 & 0.999. Drug samples showed no discernible alterations in terms of coloring, liquefaction, or odor, indicating that there were no drug excipient interactions.
Conclusion: The powder blend in question was pure, had good physiochemical properties that suggested it could be used to make new drugs, including mouth dissolving tablets, using a variety of methods, and was stable with the chosen excipient at the reported ratio for four weeks at 40°C and 75% relative humidity.

Keywords: Pre-formulation, cinnarizine, dimenhydrinate, excipients, flow property, FTIR

Introduction

To show a better and more desirable action at the right site, a potential novel API must be converted into the appropriate dosage form after it has been synthesized and produced. Mouth dissolving tablets are a novel way to distribute medications since they dissolve and break down quickly, releasing the drug's active ingredients [1, 2]. The basic process used to make these tablets is the use of superdisintegrants such carboxy methyl cellulose (Croscarmellose), cross-linked poly-vinyl pyrrolidone or crospovidone (Polyplasdone), sodium starch glycolate (Primogel, Explotab), etc [3]. The process of creating a new medication entails lengthy, expensive, and time-consuming research with a low success rate [4]. To reduce this, it is essential to understand the physicochemical properties of the biological components or pharmacological content that are candidates [5].

The study of a drug's chemical and physical properties before the compounding process is known as pre-formulation. The initial stage in creating dosage forms for any pharmacological ingredient is pre-formulation research [1, 6].

Pre-formulation studies serve as a crucial criterion for comprehending the possible pharmaco-kinetics of a drug substance in both humans and animals, as well as the advantages and disadvantages of changing the procedure as the product's production scales up [6, 7].

Prior to beginning the actual formulation and development of the dosage form, these studies are carried out following the conclusion of preclinical and clinical trials. The purpose of these investigations was to ascertain how the physicochemical qualities of drug substances and excipients affected the pharmacokinetic-biopharmaceutical properties of the final product, the manufacturing process, and the formulation properties of the dosage form [6, 8]. Pre-formulation studies are used to determine whether a medicine is compatible with all excipients [9]. It helps researcher to choose appropriate form of a drug substance to enhance bioavailability [10].

Cinnarizine is a first-generation H1 receptor antagonist. It blocks histamine H1 receptors, which contributes to its use as an anti-emetic (anti-nausea and vomiting) agent and in treating allergic conditions like chronic urticarial [12, 13]. Similarly Dimenhydrinate is a salt combination of diphenhydramine & 8-chlorotheophylline. Its effects are mainly due to the diphenhydramine component, which acts as a histamine H_1-receptor antagonist with central anticholinergic properties [14, 15].

In order to achieve this objective characterization of both the drugwas done by calculatephysiochemical parameters [16]. Solubility of drugs in various solvents of having different pH was determined. Infrared spectrum was done to determine purity of drug and UV Spectra was developed which will help in further analytical studies [17]. Finally drug-excipients compatibility studies were carried out to determine drug – excipient interactions [18].

Principal Areas of Pre-formulation

Organoleptic properties: [9, 10]

- **Color:** A small quantity of drug was taken in butter paper and viewed in well-illuminated place.

- **Taste and odour:** Very less quantity of drug was used to get taste with the help of tongue as well as smelled to get the odor.

Melting point: Melting point was determined by capillary fusion method [19].

Partition coefficient ($P_{o/w}$): The partition coefficient of Drugwas determined in n-octanol/distilled water at room temperature (25± 2ºC) [20].

$P_{o/w} = (C_{octanol} / C_{aqueous})$

Characterization of Cinnarizine and Dimenhydrinate: [21, 22]

The drug substance was characterized for following parameters.

Determination of Solubility

It is an essential and extensively utilized pre-formulation parameter [23]. The solubility of drugsweredetermined as per BCS classification system. The solubility was checked in 250 ml different medium and water. The solubility of both the drugsin different solvents likewater, 0.1N HCl, and phosphate buffer pH 6.8 were determined by using standard procedure.

Infrared Spectrum

The infrared spectrum of Cinnarizine and Dimenhydrinatepure drug andwith excipients was carried out using potassium bromide disk method. The samples were prepared on KBr-press and over wave number range of 4000 to 400cm $^{-1}$ it was scanned.

Differential Scanning Calorimetry: Samples were prepared by placing 5 mg of the drug substance into an aluminium pan, which covered and crimped for analysis. Samples were desiccated over calcium chloride for 24 hours prior to assay in an effort to remove surface absorbed water. Thermograph was analyzed qualitatively by examining both the peak temperature and the endothermic transition contour. The nitrogen flow rate was 20ml/min and the heating rate was 5°C/min over the range of 40 to 2500C.

UV Spectral Analysis

An accurately weighed amount (10mg) of both drugs separatelywas transferred to 100 ml volumetric flask. The drug was dissolved in methanol and volume was made up to 100 ml with the same solvent (Methanol) to obtain a stock solution of 100mg/ml. From the standard stock solution, 1 ml was taken out in 10 ml volumetric flask and volume was made up to 10 ml with PBS pH 7.5. The resulting solution containing 10mg/ml was scanned over complete UV range (i.e. 200–400 nm)[19] using Shimadzu UV–Visible spectrophotometer for determination of λ_{max} of the drugs. This stock solution was diluted with PBS pH 7.5 to give concentrations in the range of 5µg/ml-30µg /ml.

Drug Excipients compatibility study

The study was designed with different ratio for drug and excipients as per their functionality. The weighed amount of API was mixed well with a proposed proportion of individual excipients (Table 5). Blend was filled and sealed in 5 ml glass vials. Vials were subjected to 40°C ± 2°C/75% ± 5% RH and 25°C/60% RH for 4 weeks conditions. The initial samples were analyzed immediately and used as control. The samples were observed for physical changes like discoloration, liquefaction.

Results and discussion

Physiochemical Characterization of Dimenhydrinate and Cinnarizine

Organoleptic characteristics revealed that both medications were odorless and nearly white in color. The melting points of dimenhydrinate and cinnarizine were found to be 105.2 ºC and 122.5 ºC, respectively. For Cinnarizine, the partition coefficient value log P was found to be too high at 5.72±0.15 and for Dimen at 0.63±0.012. The observations are recorded in table 1.

Table 1: Results of Physiochemical properties of the Drugs

Properties	Cinnarizine	Dimenhydrinate
Colour	White powder	Crystalline white powder
Odor	odorless	Almost odorless
Melting Point	122.5^{0}C	105.2^{0}C
Partition Coefficient	5.72±0.15	0.63±0.012

Solubility Study

Cinnarizine is essentially insoluble in water but easily soluble in dichloromethane, soluble in acetone, and somewhat soluble in 95% ethanol and methanol. Dimenhydrinate is very soluble in chloroform, freely soluble in ethanol (95), and slightly soluble in water and in diethyl ether. The amount of drug (s) dissolved was determined using UV spectrophotometeric method the observations are given in table 2.

Table 2: Results of Solubility of the Drugs in different media

S. No	Solvents	Amount of Di-menhydrinate dissolved	Amount of Cinnarizine dissolved
1	Water	<1 mg/ml	0.054 mg/ml
2	0.1N HCl pH1.2	0.084 mg/ml	0.355 mg/ml
3	PBS pH6.8	0.8 mg/ml	0.4 mg/ml

Fourier Transform infrared (FTIR) spectral studies

While comparing the obtained FTIR spectra with the official spectra given in Indian Pharmacopoeia (2010), no differences were witnessed in the absorption peak pattern, which indicated the purity of the drug.

Only significant bands were found among the many bands found in the cinnarizinespectrum. An infrared band at 1592.25 corresponds to a C=C stretch, while 3095.5 is associated with an aromatic C-H group stretch, 1685.6 assigned to stretching of aliphatic C-N Stretching, 3128.3 assigned to N-H Stretching Table 3.

Table 3: Interpretation of FTIR spectra of Cinnarizine

Stretching type	Spectra range cm^{-1}	Observed peak cm^{-1}
N-H	3700-3250	3128.3
C=C	1650-1570	1592.25
C-H aromatic	3100-3000	3095.5
C-H aliphatic	2950-2800	2815.35
C-N	1700–1600	1685.6

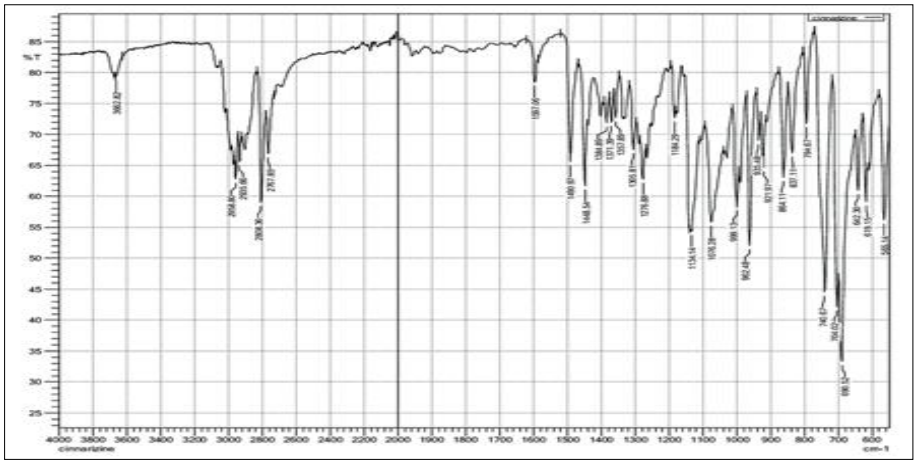

Fig 1: Official FTIR of Pure Cinnarizine

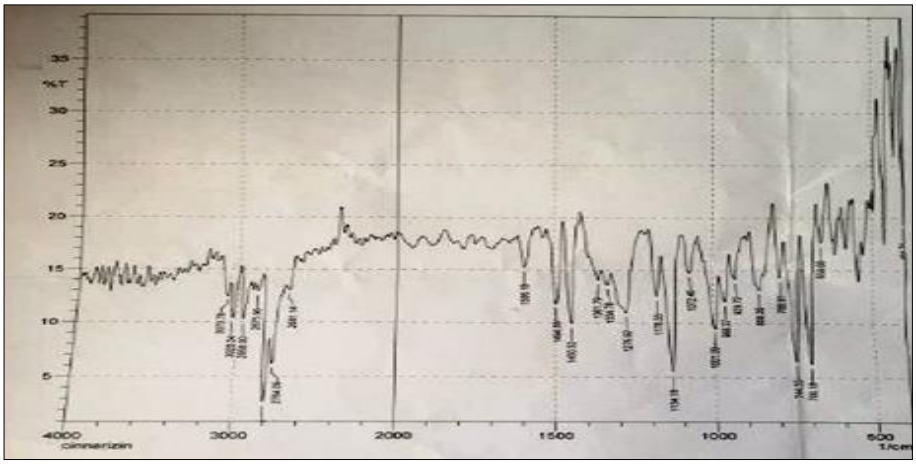

Fig 2: Observed spectra of Cinnarizine

Table 4: Interpretation of FTIR spectra of Dimenhydrinate

Stretching type	Spectra range cm^{-1}	Observed peak cm^{-1}
C-HStretching	3300-2800	3164.8
C-O-C Stretching	1300-1000	1132
C-N Stretching	1750–1600	1645.1
C-H aromatic	3100-3000	3031.4
C-H bending	1750-1400	1488.7

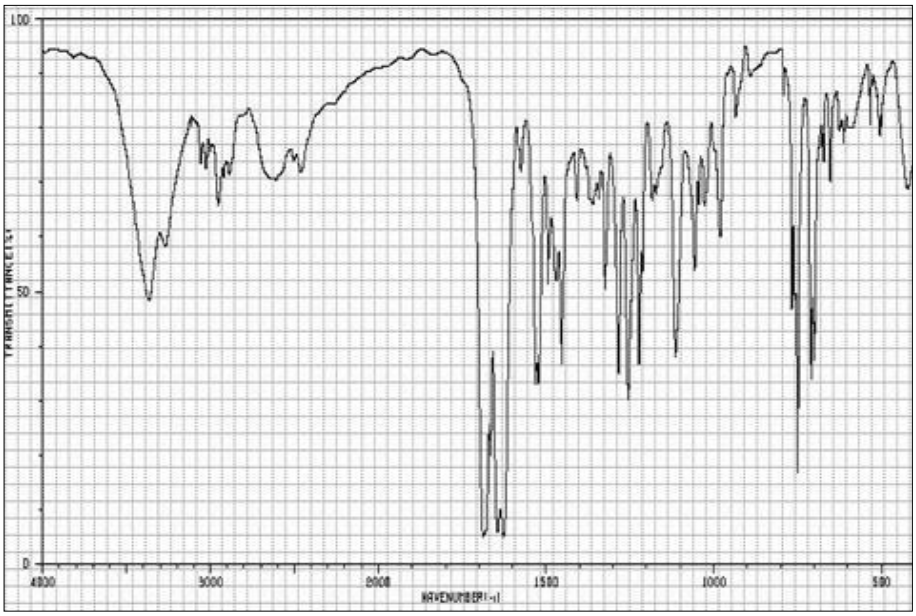

Fig 3: Official FTIR of Pure Dimenhydrinate

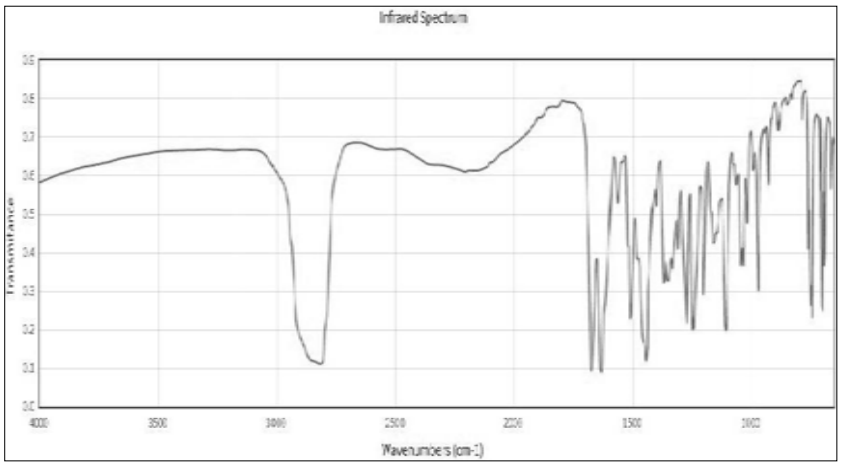

Fig 4: Observed spectra of Dimenhydrinate

Spectrophotometric Analysis

A solution of known concentration in HCl Buffer pH 1.2 was tested for ultraviolet absorption in the 200–400 nm range. The absorption maxima (λmax) of cinnarizine in this solution was determined to be 253 nm (Fig. 6.1), which is nearly identical to maxima reported in official monographs and literature. To create the calibration curve, the produced stock solution was subjected to spectrophotometric analysis at253 nm.

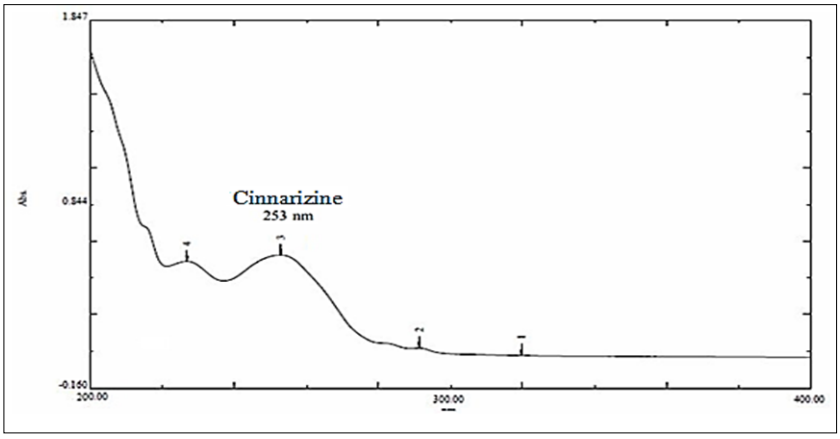

Fig 5: UV scanning of Cinnarizineshowing absorption maxima (λ_{max}) at 253nm

Table 5: Calibration curve data of Cinnarizinein 0.1N HCl pH 1.2

Concentration (µg/ml)	Absorbance 0.1 N HCl pH 1.2
5	0.482
10	0.821
15	1.246
20	1.675
25	2.043
30	2.421

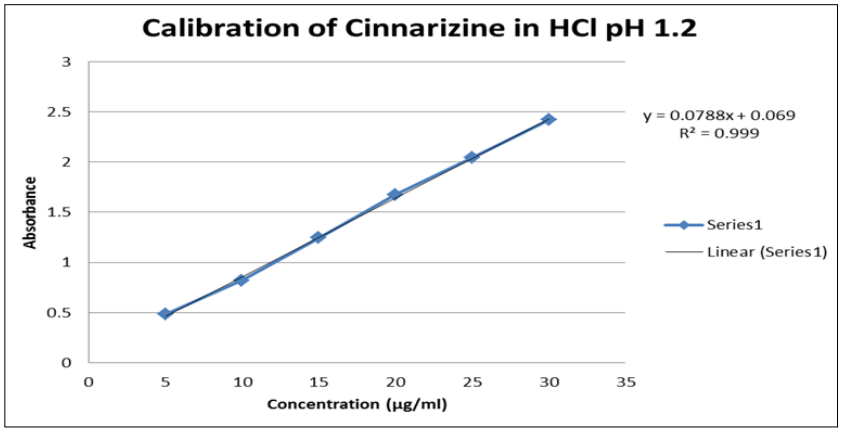

Fig 6: Calibration curve of Cinnarizinein HCl Buffer pH 1.2

Concentration versus Absorbance reading of Dimenhydrinate in HCl Buffer pH 1.2

Concentration (µg/ml)	Absorbance in 0.1 N HCl buffer pH 1.2
5	0.268
10	0.352
15	0.441
20	0.539
25	0.625
30	0.711

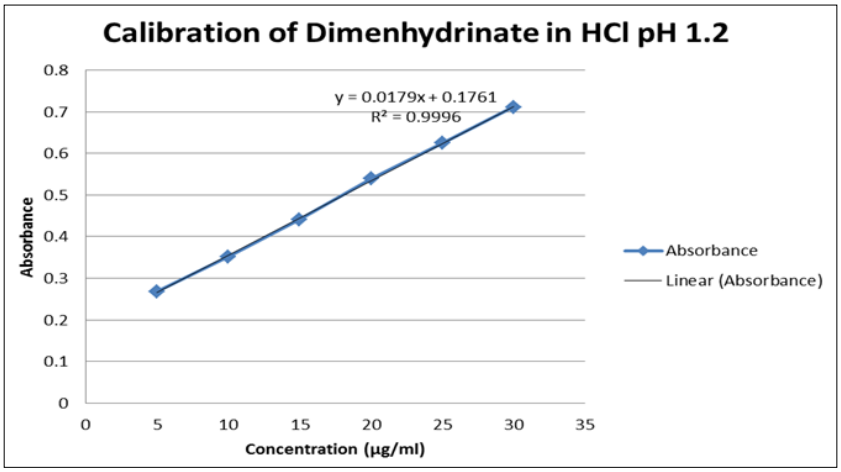

Fig 7: Calibration curve of Dimenhydrinatein HCl Buffer pH 1.2

Drug-Excipients Compatibility Study

The one-month stability study confirmed the compatibility of the selected excipients with both active ingredients. No alterations in the physical characteristics of the individual components or their mixtures were observed under the defined storage conditions. The observations are recorded in table 6.5.

Table 6: Observations of Drug-Excipient Interaction Studies

S. No	Drug-Excipients Blend	Initial Physical State	Observation at Different Storage Conditions							
			25˚C				40˚C			
			Duration (weeks)							
			1	2	3	4	1	2	3	4
1	Dimenhydrinate	WP*	N#	N	N	N	N	N	N	N
2	Cinnarizine	WP*	N	N	N	N	N	N	N	N
3	DRUG +PEG6000	WP	N	N	N	N	N	N	N	N
4	DRUG +PVPK30	WP	N	N	N	N	N	N	N	N
5	DRUG + sodium starch glycolate	WP	N	N	N	N	N	N	N	N
6	DRUG + crospovidone	WP	N	N	N	N	N	N	N	N
7	DRUG+Mannitol+MagnesiumStearate+Talc+AvicelPH102	WP	N	N	N	N	N	N	N	N
8	DRUG+PEG6000+Mannitol+MagnesiumStearate+Talc+AvicelPH102+Lactose	WP	N	N	N	N	N	N	N	N
9	DRUG+PVPK30+Mannitol+MagnesiumStearate+Talc+AvicelPH102+Lactose	WP	N	N	N	N	N	N	N	N

***WP:** white powder #**N:** No change

Conclusion

The preformulation study of the antihistaminic medications dimenhydrinate and cinnarizine was completed in the current work. The most crucial stage in creating a dosage form that is stable, safe, and effective is pre-formulation analysis. The results of these investigations have a significant influence on how the final dosage form is developed. The Indian Pharmacopeia is compliant with the organoleptic feature. Research on the drug's physical attributes revealed that it had good physiochemical qualities. It was discovered that the drug's solubility increased when pH rose. The drug's purity was verified by UV spectroscopy, which revealed maxima at 253 and 276 nm, and the infrared spectrum, which displayed distinctive peaks. The resulting standard curve had a correlation value of 0.999 and was linear. When exposed to varying temperatures and humidity levels, the potential excipients cross-povidone, Sodium Starch Glycolate, Crospovidone, Lactose, Mannitol, Mg Stearate, and talc—all of which we plan to use in the formulation of a mouth-dispersing drug delivery system—were found to be compatible with the combination of both medications. We came to the conclusion that the medicine was appropriate for the formulation choice based on the study's excellent results for every characterization.

Conflict of interest

No conflicts of interest are mentioned by the researchers. The composition and writing of the document are the sole responsibility of the writer.

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