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Pharmaceutical Characterization And Drug Studies Of Proton Pump Inhibitors: Dexlansoprazole Vs. Omeprazole

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Proton pump inhibitors (PPIs) such as Dexlansoprazole and Omeprazole are widely used for the management of gastroesophageal reflux disease (GERD) and peptic ulcer disorder. However, their acid-labile nature demands rational preformulation strategies to ensure stability, bioavailability, and product performance. The present study focuses on the comparative pharmaceutical characterization and drug–excipient compatibility assessment of Dexlansoprazole and Omeprazole to support the development of optimized gastro-resistant oral dosage forms. Physicochemical profiling including organoleptic evaluation, melting point, pKa, solubility, and partition coefficient was performed. Solid-state characterization using FTIR spectroscopy and UV–visible spectral analysis was carried out to establish structural integrity. The results demonstrated differential physicochemical behavior between both PPIs, with Dexlansoprazole showing improved stability and solubility in alkaline media, while Omeprazole exhibited greater sensitivity to environmental stressors. Compatibility studies revealed selective excipient suitability for preserving drug integrity. The findings provide critical preformulation insights that can aid in the rational design of stable, effective, and patient-compliant gastro-resistant PPI formulations.

Keywords: Dexlansoprazole; Omeprazole; Proton Pump Inhibitors; Preformulation Studies.

Introduction

Proton pump inhibitors (PPIs) are the most commonly prescribed class of drugs for the management of acid-related gastrointestinal disorders including gastroesophageal reflux disease (GERD), peptic ulcer disease, and Zollinger–Ellison syndrome[1]. They act by irreversibly inhibiting the H^+/K^+-ATPase enzyme located in the gastric parietal cells, resulting in profound suppression of gastric acid secretion[2]. Omeprazole was the first clinically approved PPI and has since become a standard therapy due to its proven efficacy and safety profile[3]. Dexlansoprazole, the R-enantiomer of lansoprazole, is a newer generation PPI developed to provide an extended duration of acid suppression with a dual delayed-release mechanism[4].

Despite their clinical importance, PPIs possess inherent limitations during formulation due to their acid-labile nature and susceptibility to degradation by light, moisture, and heat[5]. These

physicochemical challenges necessitate strategic formulation approaches such as enteric-coating or encapsulation to ensure drug stability throughout manufacturing, storage, and gastrointestinal transit[6]. Therefore, systematic preformulation studies are essential to elucidate physicochemical properties including solubility, melting behavior, pKa, hygroscopicity, and compatibility with excipients commonly used in gastro-resistant oral dosage forms[7].

Comparative characterization of Dexlansoprazole and Omeprazole can provide valuable insights into their differential stability profiles, solid-state behavior, and excipient interactions, thus guiding rational formulation design. Drug–excipient compatibility tools such as Fourier Transform Infrared (FTIR) spectroscopy and Differential Scanning Calorimetry (DSC) are widely utilized to detect potential physicochemical or chemical incompatibilities that could compromise product quality[8],[9]. Hence, the present study aims to evaluate and compare key preformulation parameters of Dexlansoprazole and Omeprazole to support the development of optimized gastro-resistant pharmaceutical products.

Material and Methods

Materials: Dexlansoprazole and Omeprazole were procured as gift samples from a certified pharmaceutical manufacturer. Methanol, ethanol, phosphate buffer salts, and hydrochloric acid were of analytical or HPLC grade. All chemicals used were compliant with pharmacopeial standards.

Organoleptic and Physicochemical Characterization: Initial characterization included assessment of colour, odour, and appearance under diffused daylight. Melting point was determined using a digital melting point apparatus (capillary method)[3]. The pKa values were determined by acid–base titration method and comparison with spectrophotometric profiles in variable pH conditions[10].

Solubility was investigated in different media such as distilled water, 0.1 N HCl, pH 6.8 phosphate buffer, and organic solvents at 25 ± 2 °C using shake-flask method[5]. **Partition coefficient (log P)** was evaluated using noctanol/water system as per OECD guidelines[10].

UV–Visible Spectroscopy: Standard stock solutions (100 µg/mL) of each drug were prepared in methanol. Working solutions were scanned between 200–400 nm using a UV–Vis spectrophotometer to determine λmax values[11]. Calibration curves were constructed at selected wavelengths to establish linearity.

Fourier Transform Infrared (FTIR) Spectroscopy: FTIR analysis was performed using KBr pellet technique in the range of 4000–400 cm^{-1}[8]. Spectra of pure drugs, excipients, and drug–excipient physical mixtures were compared to detect potential chemical interactions via shift or disappearance of major peaks[12].

Results and Discussion

Preformulation studies are important component of the drug or therapeutics development. It ensures safety, effectiveness and stability of the developing formulation. In pre-formulation studies, physical pharmacists characterizes the developing therapeutics based on physical and chemical properties, along with the interaction of drug with excipients environment. Result obtains from characterization of Dexlansoprazole (DXZ) and Omeprazole (OMZ) is reported in Table 1.

Table 1: Organoleptic Properties of Dexlansoprazole (DXZ) and Omeprazole (OMZ)

Test	Observations	
	Dexlansoprazole (DXZ)	**Omeprazole (OMZ)**
Colour	White	White
Odor	Odorless	Characteristics
Taste	Bitter	Bitter

Solubility studies were conducted for determination of solvents that can facilitates the dissolution of API. The nature of solvent that can dissolve the API was also evaluated by the study. Volume of solvents required for dissolving Dexlansoprazole (DXZ) and Omeprazole (OMZ) completely is presented in Table 2. The melting point of the drug was recorded and was found and recorded (Table 3). The partition coefficient was assessed and recorded and was found to and recorded in table 4.

Table 2: Solubility Profile of Dexlansoprazole (DXZ) and Omeprazole (OMZ)

Solvents	Solubility	Solubility
	Dexlansoprazole (DXZ)	**Omeprazole (OMZ)**
MeOH	Soluble	Soluble
EtOH	Slightly Soluble	Soluble
$CHCl_3$	Soluble	Soluble
Ether	Soluble	Soluble
DW	Insoluble	Insoluble
PBS	Soluble	Soluble
DMSO	Soluble	soluble

Table 3: Melting Point of Dexlansoprazole (DXZ) and Omeprazole (OMZ)

Test	MP
Dexlansoprazole (DXZ)	138-140^{0}C
Omeprazole (OMZ)	155-156^{0}C

Table 4: Partition coefficient of Dexlansoprazole (DXZ) and Omeprazole (OMZ)

Test	PC
Dexlansoprazole (DXZ)	2.21
Omeprazole (OMZ)	2.32

Standard stock solution of Dexlansoprazole (DXZ) and Omeprazole (OMZ) with concentration of 10 micrograms per ml prepared in a methanol was scanned by employing UV-Vis spectrophotometer at 200 nm and 400 nm wavelengths. Maximum absorption was recorded at wavelength of 284 and 302 nm respectively as shown in Figure 1 and 2.

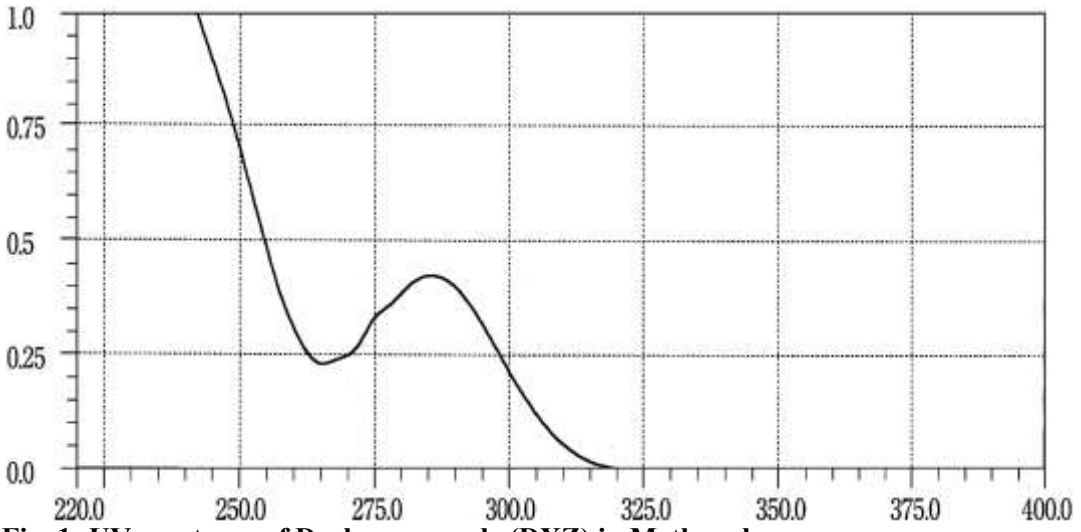

Fig. 1: UV spectrum of Dexlansoprazole (DXZ) in Methanol

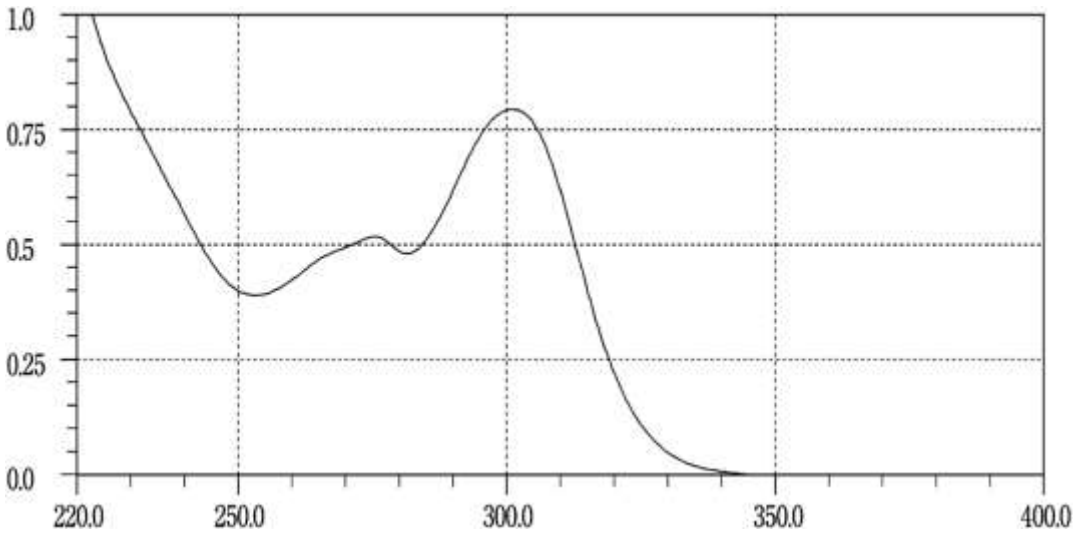

Fig. 2: UV spectrum of Omeprazole (OMZ) in Methanol

Table 5 and 6 contains the data for standard curve of Dexlansoprazole (DXZ) and Omeprazole (OMZ) and Figure 3 & 4 highlighting the standard curve. The R^2 value was found to be 0.983 and 0.995.

Table 5: Absorbance of Different Dilutions of Dexlansoprazole (DXZ)

Concentration (µg/ml)	**Absorbance (nm)**

2	0.119
4	0.212
5	0.328
6	0.485
8	0.591
10	0.719
12	0.881

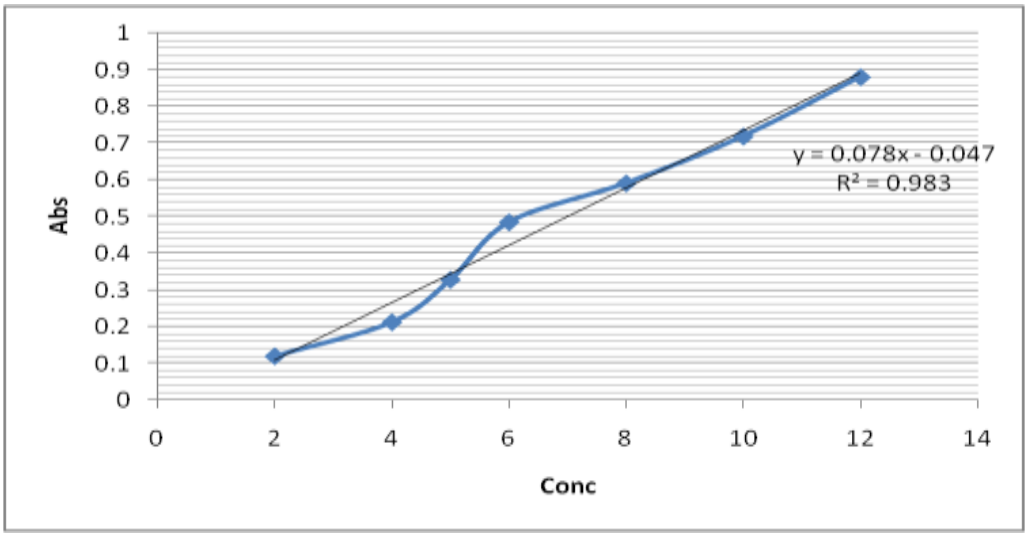

Fig. 3: Calibration Curve of Dexlansoprazole (DXZ)

Table 6: Absorbance of Different Dilutions of Omeprazole (OMZ)

Concentration (µg/ml)	Absorbance (nm)
2	0.101
4	0.222
5	0.301
6	0.352
8	0.513

10	0.61
12	0.711

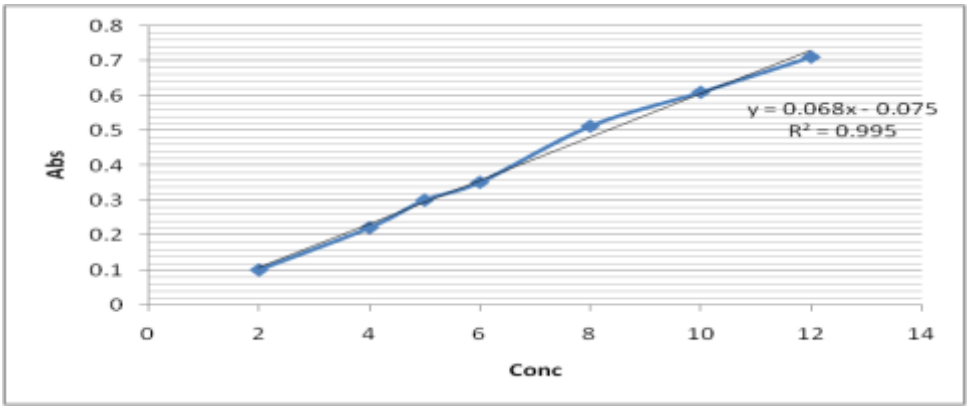

Fig. 4: Calibration Curve of Omeprazole (OMZ)

FTIR was done and spectra were recorded. An IR spectrum (KBr) showed characteristic bands of Dexlansoprazole (DXZ) (Figure 6.5)

Sulfoxide Group (S=O): Strong peaks in the 1300–1150 cm^{-1} region

Benzimidazole Ring (N–H and C=N): Broad **N–H stretch around** 3400 cm^{-1} **and C=N stretch near** 1600 cm^{-1}

Aromatic Systems: Several sharp peaks between 1600–1450 cm^{-1} and 850–750 cm^{-1}

Methoxy/Ether Groups (C–O–C): Strong absorptions in 1200–1000 cm^{-1}

Alkyl Groups: C–H stretching and bending around 2950 cm^{-1} **and** 1450 cm^{-1}

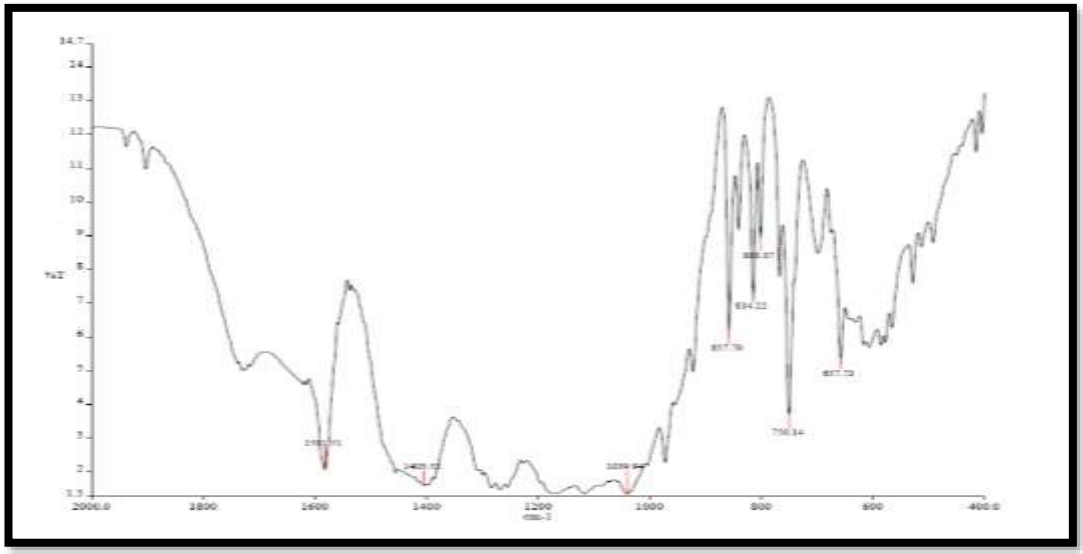

Fig. 5: FTIR Spectra of Dexlansoprazole (DXZ)

FTIR was done and spectra were recorded. An IR spectrum (KBr) showed characteristic bands of **Omeprazole (OMZ)** (Figure 6.6)

Sulfoxide Group (S=O): Strong, sharp peaks between 1300–1150 cm^{-1}

Benzimidazole Ring (C=N, N–H):

- **C=N stretch**: ~1600 cm^{-1}
- **N–H stretch**: ~3400 cm^{-1} (broad)

Methoxy Group (OCH_3): C–O–C stretching in the 1250–1050 cm^{-1} region

Aromatic Rings: Characteristic C=C stretching and bending in 1600–1450 cm^{-1}, and out-of-plane bending near 800 cm^{-1}

Alkyl Chains: CH_3/CH_2 stretching and bending around 2950 cm^{-1} and 1450 cm^{-1}

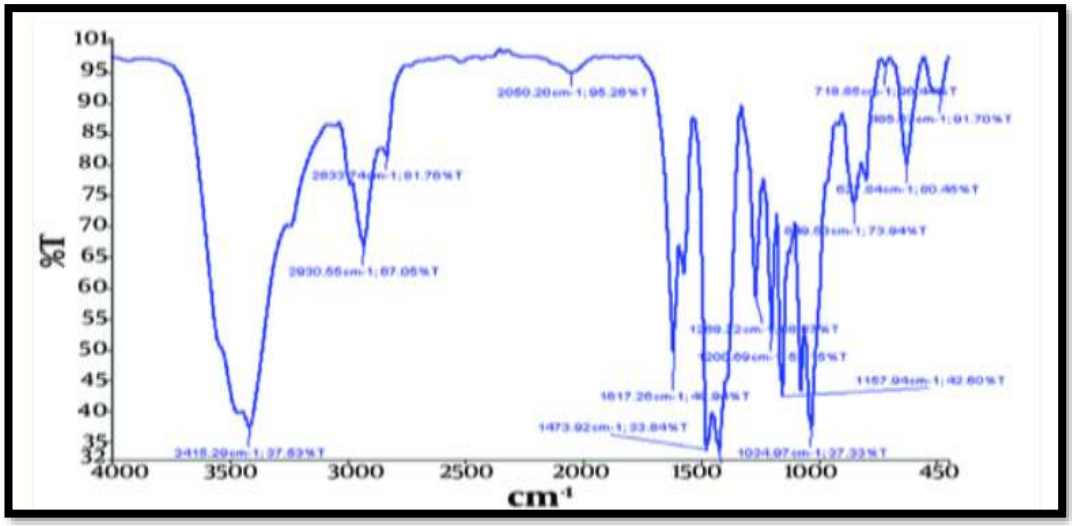

Fig. 6: FTIR Spectra of Omeprazole (OMZ)

Conclusion

The comparative preformulation evaluation of Dexlansoprazole and Omeprazole revealed that both drugs are highly acid-labile and require gastro-resistant formulation strategies to ensure stability and therapeutic efficacy. Dexlansoprazole demonstrated better solubility and stability in alkaline conditions, whereas Omeprazole exhibited greater sensitivity to degradation under stress. Drug–excipient compatibility studies indicated that HPMC and MCC are suitable carriers, while lactose and talc may lead to instability. Overall, these findings provide critical guidance for selecting appropriate formulation components to achieve optimal stability, performance, and patient compliance in PPI-based oral dosage forms.

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