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Short communication

In-vitro study for evaluating compatibility of using Omeprazole ready-to-use oral solution though enteral feeding tubes

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Introduction

Administration of oral medicinal products through enteral feeding tubes (EFTs) is an essential component of therapy for patients who are unable to swallow conventional solid dosage forms due to neurological disorders, critical illness, congenital conditions, or age-related physiological limitations (Wright et al., 2019). The use of EFTs is particularly prevalent in neonates, infants, and pediatric patients with chronic disease, where enteral access is often indispensable for both nutrition and pharmacotherapy. However, despite its widespread clinical use, administration of medicines via EFTs remains a complex and largely unlicensed practice, associated with an increased risk of medication errors, tube obstruction, altered dose delivery, and reduced therapeutic efficacy (Hu et al., 2025; Wright et al., 2019).

The complexity of enteral drug administration arises from the interplay between formulation characteristics, tube-related factors, and administration techniques. Enteral feeding tubes differ substantially in terms of diameter, length, material composition, and design, all of which may influence drug transit, adsorption to tube walls, sedimentation, and dose recovery. Inappropriate preparation practices, such as crushing modified-release or enteric-coated dosage forms, insufficient flushing, or mixing of multiple medicines, have been associated with clinically significant adverse outcomes, including therapeutic failure and tube occlusion (Williams, 2008). Liquid formulations may reduce the risk of tube obstruction compared with solid dosage forms.

From a pharmaceutical development and regulatory perspective, most oral drug products currently on the market were not originally designed or evaluated for administration through EFTs. Consequently, robust clinical data supporting this route of administration are frequently lacking. Regulatory authorities therefore recognise *in-vitro* testing as a scientifically justified, risk-based approach to evaluate the feasibility of administration via EFTs, particularly when clinical studies are not feasible or ethically appropriate (EMA, 2013; FDA, 2021).

The aim of this study was to assess the applicability, compatibility and feasibility of administration of Omeprazole 10 mg/15 mL and 20 mg/15 mL oral solution through enteral feeding tubes, possibility of causing tube blocking and for the assay and dose recovery without product modification.

Materials and methods

An *in-vitro* compatibility study was conducted using two omeprazole oral solutions: 10 mg/15 mL and 20 mg/15 mL (Alkaloid AD Skopje).

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Administration was evaluated through commonly used polyurethane enteral feeding tubes including nasogastric (NG)/nasointestinal (NI) and gastrostomy tubes of different internal diameters (6-15 cm) and lengths (60-120cm). A single therapeutic dose (15 mL) was administered by gravity. Tube patency, dose retention, and dose recovery were assessed. The c hemical stability of omeprazole after exposure to simulated gastric fluid and after dilution with water was evaluated using a validated HPLC method.

Results and discussion

Administration of omeprazole oral solution through all tested polyurethane enteral feeding tubes was feasible without tube obstruction. Increased dose retention was observed in longer and narrower tubes (~10% of API). However, this was substantially reduced by appropriate post-administration flushing, in line with clinical best-practice guidance (Wright et al., 2019). Dose recovery exceeded 95 % for all tube types and strengths when recommended flushing volumes were applied. Larger volume of tubes requires at least 20 mL flush volume as for the smallest volume of tubes a smaller flush volume of 3 mL may be used to support the use in very young children where fluid intake restriction may be of relevance.

Knowing the nature of the API and the stability of the Omeprazole oral solution (pH dependent), stability of the drug product was evaluated when mixed with water (administered for flushing the tubes) and average quantity of gastric fluid (pH 1.6) simulating empty stomach environment. Omeprazole remained chemically stable for a clinically relevant period following its period of usage after preparation. Maximum retained dose spanning from 0.3-3% was observed for both applied strengths in all evaluated feeding tubes.

Conclusion

The present *in-vitro* data demonstrate that omeprazole oral solution is compatible with commonly used polyurethane enteral feeding tubes when appropriate administration techniques are applied. Adequate tube flushing, consideration of tube diameter and placement, and timely administration after preparation are essential to ensure optimal dose delivery and minimize drug loss or degradation. These findings provide scientifically justified support for safe and effective enteral administration of omeprazole and contribute to improved clinical practice and patient outcomes.

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