DOI: 10.22270/jmpas.V11I1.2227 ISSN NO. 2320–7418

International peer reviewed open access journal

Journal of Medical Pharmaceutical and Allied Sciences

Journal homepage: www.jmpas.com CODEN: JMPACO

Research article

A stability indicating method development and validation of esomeprazole in pharmaceutical dosage form by using RP-HPLC and *In Vitro* evaluation of nasogastric tube delivery of esomeprazole magnesium delayed-release capsules

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ABSTRACT

A simple, selective and well-defined stability indicating method was developed for the quantitative estimation of esomeprazole in tablet dosage form using XBridge BEH Shield RP18 (4.6 x 250 mm), 5µm with phosphate buffer pH 7.3 and acetonitrile (740:260 %v/v) as a mobile phase and successfully validated as per the ICH guideline. The method was found to be specific, linear, accurate, rugged, and robust. Stress degradation studies were performed by exposing the esomeprazole magnesium delayed release capsules into acidic, alkaline, oxidative, thermal, humidity and photolytic stress conditions as per ICH guidelines. In separate in-vitro experiments, esomeprazole pallets dispersion passed through feeding tubes using gentle syringe pressure to develop a clog-free dispersion-delivery method. Nasogastric tube (8-French [Fr]) and diluents (different pH of water used i.e. pH 5.5, 7.0 and 8.5) were tested. The results showed excellent delivery of esomeprazole pellets using water as a medium for tube delivery. Recovery of esomeprazole pallets dispersion in different pH of water i.e. pH 5.5, 7.0 and 8.5 at "0 and 15" minutes incubation time were nearly 100% in 8-Fr nasogastric tubes.

Keywords: Esomeprazole, Stress degradation, Stability indicating assay method, Nasogastric Tube.

Received - 21-10-2021, Accepted- 03-01-2022

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INTRODUCTION

Esomeprazole magnesium trihydrate [1], bis (5-methoxy-2-[(S)-[(4-methoxy-3, 5-dimethyl-2-pyridinyl) methyl] sulfinyl]-1-H-benzimidazole-1-yl) magnesium trihydrate [Fig. 1], is a compound that inhibits gastric acid secretion. Esomeprazole magnesium trihydrate is cost-effective in the treatment of gastric esophageal reflux diseases. Esomeprazole magnesium trihydrate is the S-isomer of omeprazole, the first single optical isomer proton pump inhibitor, generally provides better acid control than current racemic proton pump inhibitors and has a favorable pharmacokinetic profile relative to omeprazole [2]. Several methods have been used for the determination of esomeprazole magnesium trihydrate alone and combination with other drugs such as ultraviolet and RP-HPLC methods [3-11]. In the present work, we are therefore focused on to achieve the optimum chromatographic conditions for the estimation of esomeprazole magnesium trihydrate. The developed method could be applied to quality control of esomeprazole in drug product. To confirm the reproducibility and widespread applicability of the developed method, it was validated as per ICH guidelines.

Limited number of research work available for stability indicating RP-HPLC and its application in in- vitro evaluation of esomeprazole pallets (marketed drug product in India) dispersion delivery through enteral feeding tubes.

Figure 1: Chemical structure of esomeprazole

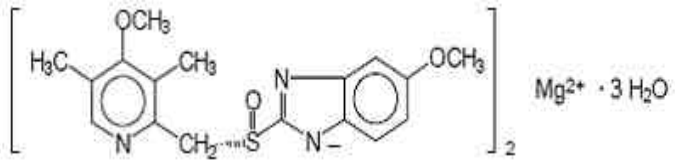


Table 1: Esomeprazole Summary

Category	proton pump inhibitors (PPIs)
Molecular formula	$C_{17}H_{19}N_3O_3S$
Molecular weight	345.42g/mole
Physicochemical Properties	Description: White to slightly colored crystalline powder
	Solubility: Very slightly soluble in water
	Melting point: 155 °C

Pallet dispersion of esomeprazole administered through a nasogastric tube may be beneficial in patients unable to swallow solid drug product. It is significant to evaluate whether formulations and/or methods of administration impact drug bioavailability and pharmacokinetic properties.

This paper presents analytical method development and

validation of stability indicating assay method for esomeprazole by using the RP-HPLC method as per ICH requirements as well as in-vitro evaluation of esomeprazole pallets dispersion delivery via enteral feeding tubes. These studies evaluated the recovery of esomeprazole pallets dispersion administered via nasogastric feeding tubes flushed with water (different pH i.e. pH 5.5, 7.0 and 8.5 water used) and esomeprazole was measured by a stability indicating validated assay RP-HPLC method.

MATERIALS AND METHODS

Chemicals, Reagent and Materials

The acetonitrile and methanol were of HPLC grade while concentrated hydrochloric acid, disodium hydrogen phosphate, sodium borate, orthophosphoric acid, sodium hydroxide was of high purity analytical grades. All the chemicals purchased from the local franchise of sigma Aldrich. The medical grade nasogastric feeding tubes were procured from local market. The 0.45 µm membrane filters were procured from advanced micro devices pvt. ltd., Chandigarh, India. Commercially available tablets of esomeprazole (Nexium®contain 20 and 40 mg) were procured from local market and esomeprazole active pharmaceutical ingredient was obtained from an approved supplier. All excipients used were of pharmaceutical grade and obtained from loba chemie pvt. ltd., Mumbai, India.

Instrumentation

The shimadzu LC 2010 HPLC system supplied with a gradient pump connected to Ultra-violet detector and automatic injection facility was used. The column XBridge BEH Shield RP18 (4.6 x 250 mm), 5µm, lab solution software, shimadzu AY-120 balance, sonicator (Leela sonic) were used for this work. Thermal stability studies were conducted in an i-therm dry air oven.

Method Development and Optimization of Chromatographic Conditions

Development of chromatographic condition was conducted to achieve specific and robust method. As the drug is official in pharmacopeia [12], initial analytical method development was done with reference to the USP (revision bulletin, 2019) assay method chromatographic condition. However placebo interference was noted at the elution time of analyte (esomeprazole) and assay value was found on lower side due to incomplete drug extraction from dosage form.

Therefore, analytical method development was performed according to the nature of the drug, molecular weight, and solubility. The effect of various chromatographic parameters such as mobile phase pH, solvent strength, flow rate, solvent ratio and the nature of the stationary phase on the peak separation were studied to optimize the chromatographic conditions,.

Preparation of Standard Solution

Accurately weighed quantity of esomeprazole (50 mg) standard into a 250 ml volumetric flask, dissolved and diluted up to the mark and sonicated to get 0.2 mg/ml solution of esomeprazole (200µg/ml). Further dilutions were made as per the requirement by dissolving it in diluent and mix well.

Preparation of Sample Solution

Take the pallets equivalent to 100 mg esomeprazole into a 500 ml volumetric flask and add 20 ml of 0.1N sodium hydroxide and sonicate. Further add 20 mL of methanol and 350 mL of diluent and sonicate for 20 minutes and then make up the mark with diluent. This solution is filtered using a 0.45µ syringe filter in a glass vial. Dilute 5.0-mL of this solution to 10-mL volumetric flask with diluent and mix well (100µg/ml).

Assay of Marketed Formulation (Capsules)

Accurately weigh and transfer the pellets equivalent to 100 mg esomeprazole into a 500 mL volumetric flask. Add 20 mL of 0.1N sodium hydroxide and sonicate for 5 minutes with shaking. Add 20 mL of methanol and 350 mL of diluent and sonicate for 20 minutes with intermittent shaking after every 3 minutes (by maintaining temperature of water in sonicator temperature at controlled temperature (i.e. 2-8°C). Dilute to the volume with diluent and mix well. Filter this solution through 0.45 µm nylon syringe filter after discarding 2-3 mL of filtrate. Pipette out 5.0-mL of this solution to 10-mL volumetric flask and make up the volume up to the mark with diluent and mix well (concentration: esomeprazole 100µg/ml).

Stress Degradation Studies

In order to assess the interference from degradants, a forced degradation study was conducted by stressing simultaneously placebo and test under the following maximum stress conditions i.e. acidic, alkaline, oxidative, photolytic, humidity and thermal conditions[13-15].

Method Validation

The developed method was extensively validated in terms of specificity, linearity, accuracy, precision, precision at different levels, robustness, stability of analytical solutions and system suitability, filter interference as per guidelines of ICH Q2A and Q2B [16-18].

In Vitro Delivery of Esomeprazole Pallets Dispersion via Enteral Feeding Tubes [19-34]

As per the approved labeling for the reference listed drug product and FDA draft guidance on esomeprazole the product may be administered via a nasogastric tube. This study investigated the in vitro recovery of esomeprazole pallets dispersion in 50 mL water with different pH of water (e.g., pH 5.5, 7.0 and 8.5) after passage through PVC 8 French Nasogastric tube with “J” holding position. The recovery performed at ‘0’ minute and ‘15’ minutes incubation time.

Recovery Study for Sample Delivery through Syringe and Nasogastric Tube

An esomeprazole magnesium delayed-release capsule’s contents transferred to an oral syringe. Insert the syringe plunger and draw up

50-mL of water and shake vigorously for 15 seconds. Connect the syringe to the feeding tube (8 french nasogastric tubes). Using the syringe plunger push the pellets dispersion through the syringe and the feeding tube into the collection container.

'0" minute incubation

The plunger was connected to the syringe and was gently mixed for about 30 seconds.

"15" minutes incubation

The plunger was connected to the syringe and was gently mixed and incubated for 15 minutes at room temperature. After incubation, the syringe was shaken gently for about 30 seconds.

Esomeprazole Pallets Dispersion Administration through Nasogastric Tubes

Nasogastric feeding tubes mounted to a board to mimic the position the tube would be in a patient. An oral syringe was connected with the feeding tube, the dispersion was allowed to pass through the tube via gravity, and the samples were collected into 100 mL volumetric flask after passing through the tube for estimation.

Quantification of Esomeprazole by Liquid Chromatography after Administration through Nasogastric Tubes:

All samples were labeled with a numerical code and add 1.0-mL 2N sodium hydroxide solution and sonicate for 20 minutes. Then add 30-mL diluent and sonicate for 5 minutes. Make up the volume with diluent and mix well. Filter through 0.45µ nylon syringe filter. Further dilute 5 mL to 20 mL with diluent (concentration: 100µg/ml).

Evaluation of Tube Delivery

The recovery study was repeated for 12 times each for Nexium samples.

RESULTS AND DISCUSSION

Method Development and Optimization of Chromatographic Conditions

Initially, to get better separation characteristics various chromatographic conditions were tried by changing mobile phase composition. The chromatogram of esomeprazole is shown in fig. 4 and final chromatographic conditions are mentioned in table 2.

Table 2: Optimized Chromatographic Conditions

Parameters	Details
Mobile phase	Disodium hydrogen phosphate buffer pH 7.3 and acetonitrile (740:260 %v/v)
Column	XBridge BEH Shield RP18 (4.6 x 250 mm), 5µm
Flow rate	0.9-ml / minute
Detection	280 nm
Injection volume	40-µL
Run time	18 min
Retention time	12.0 min
Diluent	Sodium borate buffer and acetonitrile in the ratio of 740:260 %v/v

Assay of Tablet Formulation

The value of mean % drug was found to be 98.5 % which is within acceptance criteria.

Table 3: Results of Assay of Esomeprazole

% Assay	Amount of drug estimated mean±SD*
98.6	98.5±0.40
98.8	
98.1	
98.9	
98.7	
97.9	

*The value is represented as a mean±SD of 6 observations.

Stress Degradation Studies

A forced degradation study was conducted to validate the ability of the HPLC method to separate the potential degradation products from the parent drug and establish the stability indicating characteristic of the developed method and identify the ability of the drug to withstand the different physical and chemical conditions. The assay of esomeprazole was calculated and reported under acid and alkaline hydrolysis, oxidation, thermal, humidity and photolytic stress conditions respectively in table 4.

Table 4: Forced Degradation Results of Esomeprazole

Degradation Conditions	% Degradation of Esomeprazole
Acid degradation (0.1 N Hydrochloric Acid, heated at room temperature)	No degradation
Alkali degradation (5N Sodium Hydroxide, heated at room temperature)	1.1
Oxidative degradation (30% Peroxide, heated at 40 °C)	5.2
Thermal degradation (60°C for 7 days)	1.6
Humidity degradation (40°C/75% RH for 7 days)	No degradation
Photolytic degradation (1.2 million lux hours and the light intensity not less than 200 watt-hours per sq. meter)	3.2

The degradation products were well separated from the parent drug, and no interference of the parent drug peak with those of the degradation products was observed. Therefore, the developed HPLC method was considered stability indicating and suitable for the proposed stability and enteric tubes delivery study of esomeprazole pallets dispersion.

Validation of the Method

The developed chromatographic method was validated as per ICH guidelines.

System Suitability

System suitability results obtained are shown in table 5.

Table 5: Results of System Suitability

System Suitability Parameter	Acceptance Criteria	Esomeprazole
Retention Time	About 12 minutes	12.247
Theoretical Plate Count	NLT 5000	10413
Tailing Factor	NMT 2.0	1.06
RSD	NMT 2.0	0.36

Specificity

The below figure 3 and 4 shows that the active ingredient was well separated from blank, placebo and impurities and there was no interference of placebo with the principal peak. Hence the method is specific.

Figure 2: Chromatogram of placebo

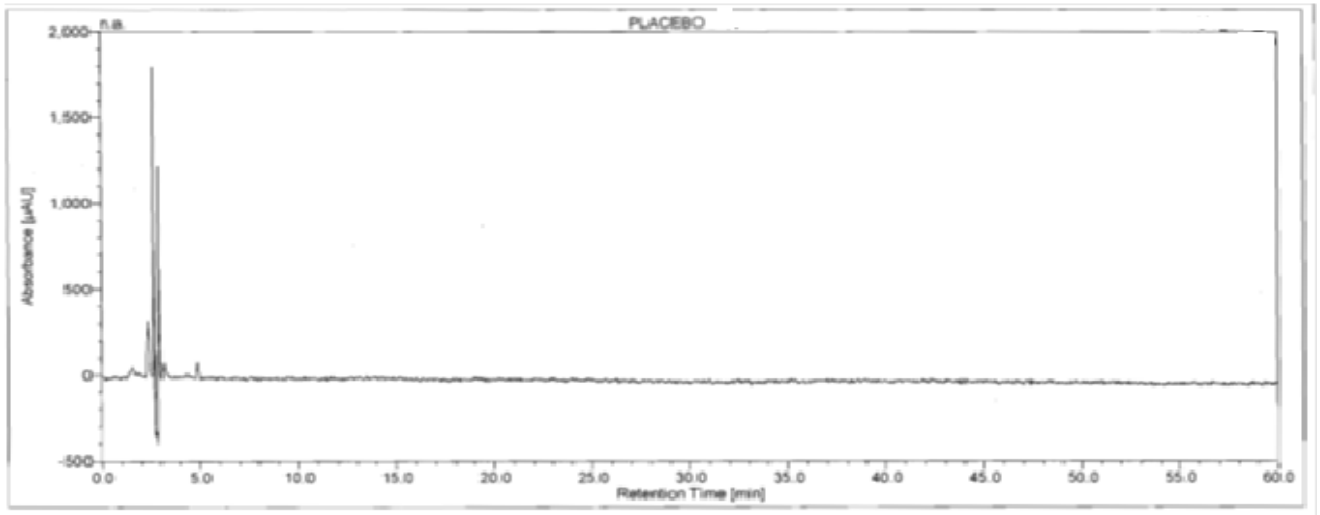


Figure 3: Chromatogram of sample

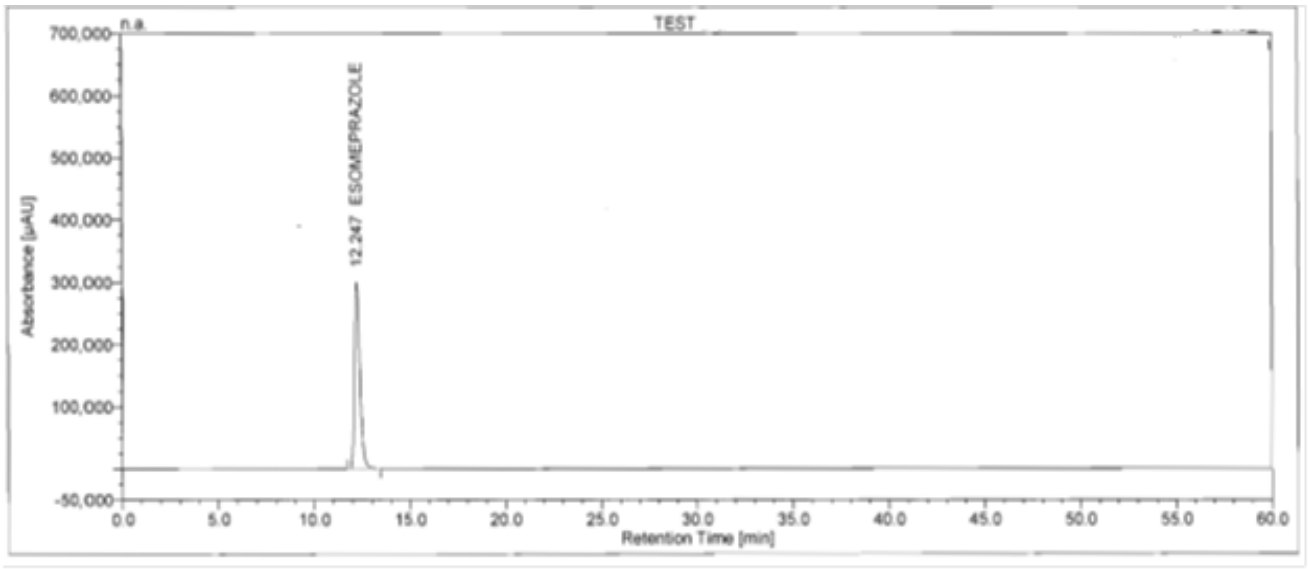
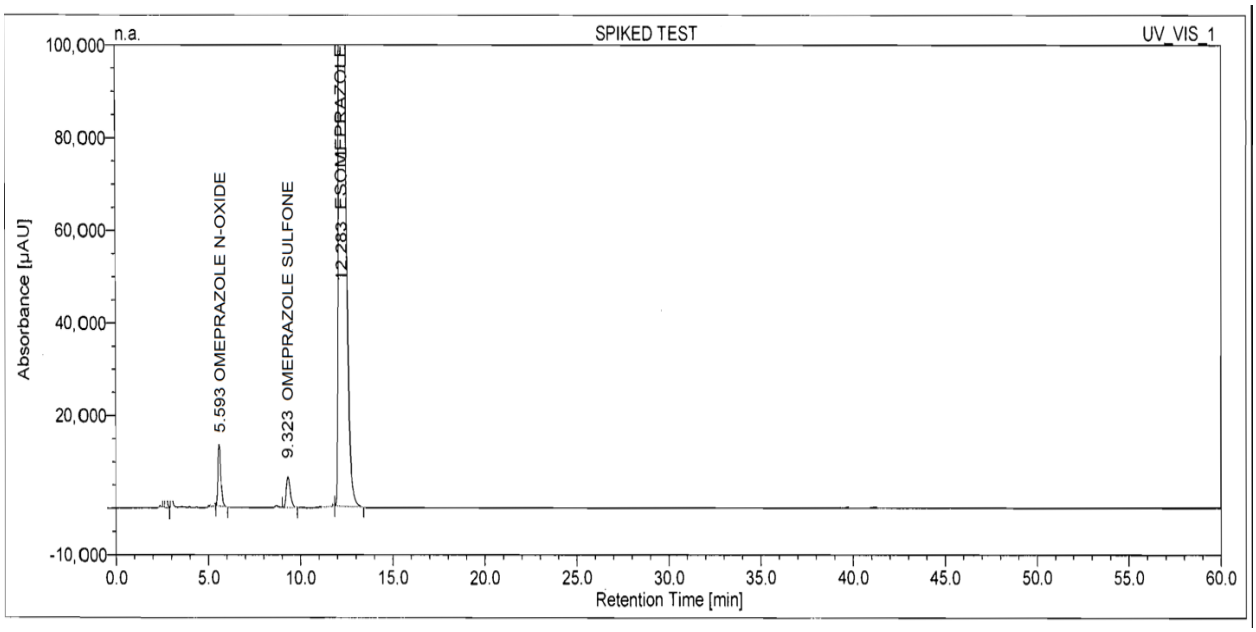


Figure 4: Chromatogram of spiked sample



Precision

The method and intermediate precision results are shown in table 6 and 7.

Table 6: Precision Results of Esomeprazole

Conc. (µg/ml)	Method Precision	Intermediate Precision
100	98.6	99.1
	98.8	98.8
	98.1	97.9
	98.9	99.8
	98.7	98.7
	97.9	99.8
Mean	98.5	99.0
% RSD	0.41	0.71
SD	0.40	0.71

Table 7: Precision at Different Levels Results of Esomeprazole

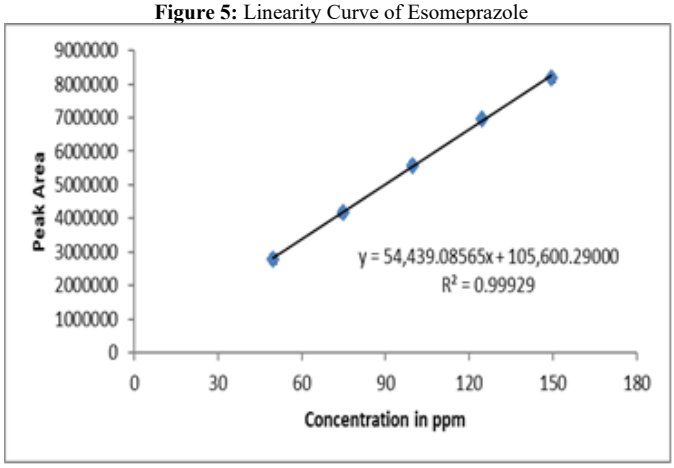
Esomeprazole Concentration (µg/ml)			
50 µg/ml		100 µg/ml	150 µg/ml
2831821		5635323	8396632
2824300		5620358	8374333
2812867		5597605	8340431
2813247		5598362	8341559
2802762		5577497	8310470
2807669		5587262	8325021
Mean	2815444	5602734	8348074
% RSD	0.38	0.38	0.38

Linearity and Range

The calibration curve (figure 5) was linear over the concentration range of 50-150 µg/ml for esomeprazole. The linearity was represented by a linear regression equation as follows:

Y = 54,439.08565conc. + 105,600.29000 (r^2 = 0.99929), Where, Y is the area under curve and r2 is the correlation coefficient.

Figure 5: Linearity Curve of Esomeprazole



Accuracy

The accuracy data of the proposed method is summarized in table 8.

Table 8: Results of Accuracy

% Level	Esomeprazole % Recovery
50	99.2
100	99.2
150	99.7
Mean	99.4
SD	0.29

Mean+SD (n=3)

Stability of Analytical Solution

The changes in response with respect to initial are calculated and data reported in table 9.

Table 9: Stability Results of Esomeprazole

Time in Hours	Standard		Test	
	Area Response	% Deviation from Initial	Area Response	% Deviation from Initial
Initial	5561831	Not applicable	5618626	Not applicable
12	5555421	0.12	5615763	0.05
18	5560097	0.03	5624804	-0.11
24	5566642	-0.09	5620226	-0.03
30	5568756	-0.12	5618479	0.00
36	5568299	-0.12	5623025	-0.08
42	5571584	-0.18	5622705	-0.07
51	5583890	-0.40	5624733	-0.11

Robustness

Results of analysis were summarized in table 10 and found to be within acceptance criteria which showed the reliability of the method.

Table 10: Robustness Data of Esomeprazole

Parameter Name	% RSD
Flow rate: +10%	0.32
Flow rate: -10%	0.21
Wavelength: +3 nm	0.27
Wavelength: -3 nm	0.21
Column temperature: +5°C	0.11
Column temperature: -5°C	0.43
Mobile phase ratio change: +2 % absolute (acetonitrile)	0.51
Mobile phase ratio change: -2 % absolute (acetonitrile)	0.32
Mobile phase buffer pH: +0.2 unit	0.52
Mobile phase buffer pH: - 0.2 unit	0.41

In Vitro Delivery of Esomeprazole Pallets Dispersion via Enteral Feeding Tubes

The recovery results of esomeprazole pallets dispersion are presented in table 11. After the dispersion traversed the tubes completely, the tubes were visually inspected for the presence of any residual fluid and none of the tubes exhibited any signs of blockage. To ensure a complete delivery of drug dosage, water flush could be used to rinse the residual volume of dispersion through the tube. After medication administration, tubes are typically flushed with 10 mL of water. The mean recovery of esomeprazole in the prepared dispersion in water with different pH values (e.g., pH 5.5, 7.0 and 8.5) was found to be about 100%.

Figure 6: Photograph of 8F PVC Nasogastric Tube

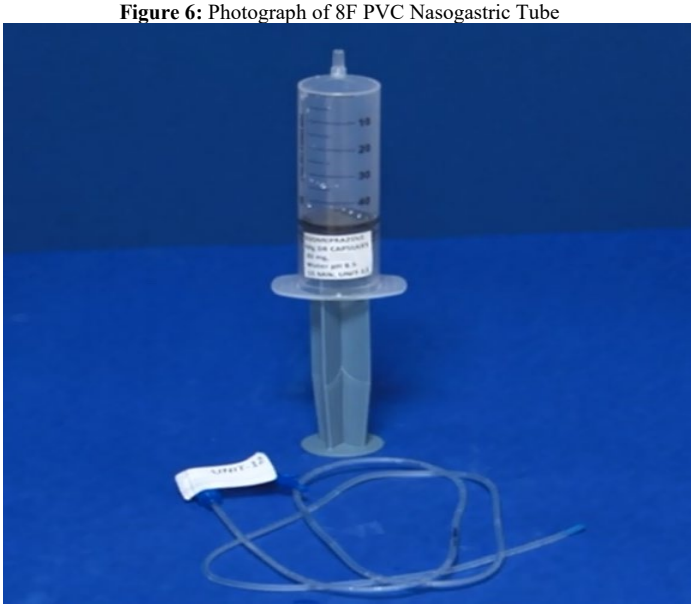


Table 11: Mean Recovery (%) of Esomeprazole in the Prepared Dispersion after Passing through Enteric Feeding Tubes

Esomeprazole Recovery, Mean (%)					
Strength/Label Claim		20 mg		40 mg	
Tube Type	pH of Water	Incubation Time			
		"0" minute	"15" minutes	"0" minute	"15" minutes
PVC, 8 Fr, Nasogastric Tubes	pH 5.5	99.3± 1.19	97.2± 1.26	98.8± 1.65	98.6± 1.21
	pH 7.0	97.5± 2.27	96.9± 2.04	97.4± 2.36	97.5± 1.00
	pH 8.5	96.7± 2.74	96.6± 1.13	96.3± 4.08	97.6± 1.11

The mean esomeprazole content in each set expressed as a percentage of the dose administered (target dose).

CONCLUSIONS

A simple, accurate, specific, precise, robust, rugged and rapid reversed phase high performance liquid chromatographic (HPLC) method for the analysis of esomeprazole has been developed and validated. Method validation was conducted inline to ICH requirements, and all the parameters were acceptable. The method validation proved the stability indicating characteristics of the developed method. Thus, this method can be used for analysis and to check the stability testing of esomeprazole formulation. The developed method could be employed to distinguish batches with suboptimal product quality for delivery through nasogastric tubes.

The aim of this publication was to develop a stability indicating method and provides additional information on utility of esomeprazole for individuals with swallowing difficulties. Unlike previous studies that have measured proton pump inhibitor delivery by counting drug particles, our study measured proton pump inhibitor delivery using HPLC techniques [39].

A dispersion of esomeprazole in different pH of water (e.g., pH 5.5, 7.0 and 8.5) were identified as suitable for administration via enteral feeding tubes. The recovery of esomeprazole after passing through the selected enteric feeding tubes was found to be within acceptable range (±10%) of the label claim, indicating absence of any physical/chemical interactions of esomeprazole with the tubes and a successful delivery of esomeprazole dosage via enteric feeding tubes. The study presents a convenient procedure for the preparation of a stable dispersion of esomeprazole pallets using nexium tablets, for administration via enteral feeding tubes.

A limitation of these evaluations is that they were not performed in patients with feeding tubes. Clogging of the nasogastric tube was not observed regardless of incubation or type of water used to disperse the drug (Fig. 6). Notably, in this study, one type of nasogastric tube was investigated. However, additional parameters such as the material and design of the nasogastric tube could be investigated in the future. The methods developed in this study could be used to evaluate in vitro equivalence and to assess the potential risks of delivering oral drug products through enteral feeding tubes after esomeprazole pallets dispersion in water with different pH values (e.g., pH 5.5, 7.0 and 8.5).

CONFLICT OF INTERESTS

There is no conflict of interest regarding the publication of this article.

REFERENCES

1. Andersson T, Hassan-Alin M, Hasselgren G,et al, 2001. Pharmacokinetic studies with esomeprazole, the (S)-isomer of omeprazole. Clin Pharmacol. 40, 411–26.
2. Scott LJ, Dunn CJ, Mallarkey G, et al, 2002. Esomeprazole- a review of its use in the management of acid-related disorders. Drugs. 62, 1503–38.
3. Hultman I, Stenhoff H, Liljeblad M, 2007. Determination of esomeprazole and its two main metabolites in human, rat and dog plasma by liquid chromatography with tandem mass spectrometry. J Chromatogr B. 848, 317-22.
4. Johnson DA, Roach AC, Carlsson AS,et al, 2003. Stability of esomeprazole capsule contents after *in vitro* suspension in common soft foods and beverages. Pharmacotherapy. 23, 731-4.
5. Li XQ, Anderson TB, Ahlstrom M,et al, 2004. Comparison of inhibitory effects of the proton pump-inhibiting drugs omeprazole, esomeprazole, lansoprazole, pantoprazole and rabeprazole on human cytochrome P450 activities. Drug Metab Dispos. 32, 821–7.
6. Shetty R, Subramanian G, Kumar RA,et al, 2005. Estimation of esomeprazole in human plasma by reverse phase high performance liquid chromatography. Indian Drugs. 42, 158-61.
7. Magesh AR, Vijayalakshmi R, Satyavati D,et al, 2010. Validated spectrophotometric estimation of esomeprazole using hydrotrophic solubilisation technique. Orie J Chem. 26, 1191-3.
8. Onal A, Oztunc A, 2006. Development and validation of high performance liquid chromatographic method for the determination of esomeprazole in tablets. J Food Drug Anal. 14, 12-8.
9. Prabu SL, Shirwaikar A, Shirwaikar A, et al, 2008. Simultaneous estimation of esomeprazole and domperidone by UV spectrophotometric method. Indian J Pharm Sci. 70, 128-31.
10. Patel BH, Suhagia BN, Patel MM, et al, 2007. Determination of pantoprazole, rabeprazole, esomeprazole, domperidone and itopride in pharmaceutical products by reverse phase liquid chromatography using single mobile phase. Chromatographia. 65, 743-8.
11. Zanitti L, Ferretti R, Gallinella B, et al, 2010. Direct HPLC enantioseparation of omeprazole and its chiral impurities: Application to the determination of enantiomeric purity of esomeprazole magnesium trihydrate. J Pharm Biomed Anal. 52, 665-71.
12. "The United States Pharmacopeia. The National Formulary." Rockville, Md.: United States Pharmacopeial Convention, Inc., 2019
13. USP 32 – NF 27, 2009. General Chapter 1226, Verification of Compendial Methods.
14. Reynolds DW, Facchine KL, Mullaney JF,et al, 2002. Available guidance and best practices for conducting forced degradation studies. Pharmaceutical Technology. 26(2), 48-54.
15. Reynolds DW, 2004. Forced degradation of pharmaceuticals. American Pharmaceutical Review. 7(3), 56-61.
16. ICH harmonized tripartite guidelines, 1996. Validation of analytical procedures methodology. 1-8.
17. ICH, 1996. Topic Q2A, Validation of Analytical Procedures. Methodology.
18. ICH Harmonized Tripartite Guideline. Validation of Analytical Procedures: Text and Methodology Q2 (R1).

19. Holcombe B, Koda-Kimble M, Young L, 2001. Applied Therapeutics: The Clinical Use of Drugs. Vol. 34, Philadelphia, PA: Lippincott Williams & Wilkins; pp. 1-34.
20. Williams NT, 2008. Medication administration through enteral feeding tubes. Am J Health Syst Pharm. 65(24), 2347-2357.
21. Clarke S, 2008. Drug administration via nasogastric tube. Paediatr Nurs. 20(7), 32-32.
22. FDA, 2018. Draft Guidance on Esomeprazole Magnesium, Food and Drug Administration, Rockville, MD.
23. Pickering K, 2003. The administration of drugs via enteral feeding tubes. Nurs Times. 99(46), 46-49.
24. Grissinger M, 2013. Preventing errors when drugs are given via enteral feeding tubes. P T. 38(10), 575-576.
25. Devlin JW, Bakshi A, Bungay K, et al, 2006. An in vitro comparison of different providers to deliver four proton pump inhibitor products through a feeding tube. Aliment Pharmacol Ther. 24(11-12), 1603-1611.
26. Dunn A, White CM, Reddy P, et al, 1999. Delivery of omeprazole and lansoprazole granules through a nasogastric tube in vitro. Am J Health Syst Pharm. 56(22), 2327-2330.
27. Messaouik D, Sautou-Miranda V, Bagel-Boithias S, et al, 2005. Comparative study and optimisation of the administration mode of three proton pump inhibitors by nasogastric tube. Int J Pharm. 299(1-2), 65-72.
28. Ponrouch MP, Sautou-Miranda V, Boyer A, et al, 2010. Proton pump inhibitor administration via nasogastric tube in pediatric practice: comparative analysis with protocol optimization. Int J Pharm. 390(2), 160-164.
29. Ruzsikova A, Souckova L, Suk P, et al, 2015. Quantitative analysis of drug losses administered via nasogastric tube-in vitro study. Int J Pharm. 478(1), 368-371.
30.
31. Shah SA, Sander S, Coleman CI, White CM, 2006. Delivery of esomeprazole magnesium through nasogastric and gastrostomy tubes using an oral liquid vehicle as a suspending agent in vitro. Am J Health Syst Pharm. 63(19), 1882-1887.
32. Da Silva MJS, Meireles Cava CE, Pedroso PK, et al, 2011. Evaluation of the profile of drug therapy administered through enteral feeding tube in a general hospital in Rio de Janeiro. Braz J Pharm Sci. 47, 331-337.
33. Stewart P, Dayneka N, Grenier S, et al, 2009. In vitro study of esomeprazole sachet suspension administered via enteral feeding tubes. Can J Hosp Pharm. 62(1), 48-49.
34. White C, Kalus J, Quercia R, et al, 2002. Delivery of esomeprazole magnesium enteric-coated pellets through small caliber and standard nasogastric tubes and gastrostomy tubes in vitro. Am J Health Syst Pharm. 59(21), 2085-2088.
35. White CM, Kalus JS, Quercia R, et al, 2002. Delivery of esomeprazole magnesium enteric-coated pellets through small caliber and standard nasogastric tubes and gastrostomy tubes in vitro. Am J Health Syst Pharm. 59, 2085-8.

How to cite this article

Rajendra Singh Rajput, Narendra Lariya, 2022. A stability indicating method development and validation of esomeprazole in pharmaceutical dosage form by using RP-HPLC and In Vitro evaluation of nasogastric tube delivery of esomeprazole magnesium delayed-release capsules. J. Med. P'ceutical Allied Sci. V 11 - I 1, Pages - 4375 - 4381 doi: 10.22270/ jmpas.V11I1.2227.