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# UV SPECTROPHOTOMETRIC METHOD FOR SIMULTANEOUS ESTIMATION OF ESOMEPRAZOLE MAGNESIUM AND DOMPERIDONE IN BULK AND PHARMACEUTICAL FORMULATION

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## ABSTRACT
A novel, simple, sensitive and speedy spectrophotometric technique has been developed for simultaneous estimation of esomeprazole magnesium and domperidone in pharmaceutical form. This technique was primarily based wholly on ultraviolet light Spectrophotometric determination of two medicines, using simultaneous equation technique. The method involved solving simultaneous equation based on measurement of absorbance of 2 totally different wavelengths 301 nm and 287 nm, of esomeprazole and domperidone severally. Beer's law was obeyed within the concentration range of 2-20 µg/ml and 2-20 µg/ml for esomeprazole and domperidone severally. The technique showed good reproducibility and recovery with % RSD. The method was found to express, accurate, and specific. The proposed technique was with success applied to estimation of esomeprazole and domperidone in combined dosage form. The technique was valid in the line with ICH guidelines.

**KEYWORDS:** Esomeprazole, Domperidone, Simultaneous equation method, ICH guideline.

## 1. INTRODUCTION
Esomeprazole magnesium trihydrate (ES), bis(5-me thoxy-2-[(S)-[(4-methoxy-3,5-dimethyl-2-pyridinyl) methyl]sulfinyl -1H-benzimidazole-1-yl) magnesium Trihydrate (fig 1a) is the S isomer of racemic omeprazole approved in February 2001 for use as a new pharmacological entity designed to improve the clinical outcome of available proton pump inhibitors in the managements of acid-related disorders.

Domperidone (DOM) is chemically 5-Chloro-1- [1-3(2-oxo-1, 3-dihydrobenzimidazole-1-yl]-4-piperidyl]-1,3-dihydrogen imidazole-2-one maleate. Domperidone acts as a gastroesophageal emptying (delayed adjunct and peristaltic stimulant). The gastroprokinetic property of domperidone is related to its peripheral dopamine receptor blocking properties.

This combination is used to treat acidity and heartburn or gastroesophageal reflux disease (GERD). A condition where the acid in the stomach flows back up into the food pipe (oesophagus). It is also used to treat gastric and duodenal ulcer. DOM helps to control vomiting by increasing the movement the gut, allowing the food to move more easily through the stomach.

The validation of method carried out as per ICH guideline. However, there are very few reported methods for simultaneous estimation of both drugs in combination. This paper present two simple, rapid, reproducible and economical method for the simultaneous estimation of both the drugs.

## 2. Experimental Condition
### *2.1 Instrument*
A Shimadzu UV-visible spectrophotometer (UV mini 1800, shimadzu corporation in Japan) was used for all absorbance measurements with matched quartz cells.

### *2.2 Materials and method*
Standard gift sample of Esomeprazole and Domperidone were procured from BDA Healthcare Pvt. Ltd. Nagpur and Aristo Pharmaceutical Pvt. Ltd. Mandideep. Combined dosage formulation containing Esomeprazole and Domperidone were purchase from local market. (IZRE*D 40).

### *2.3 Selection of Solvent*
Methanol: Acetonitrile (2:8) was selected as a suitable solvent for simultaneous estimation of Esomeprazole and Domperidone.

**Simultaneous equation method**

For the simultaneous equation method, 287 nm and 301 nm were selected as the two sampling wavelengths for Esomeprazole and Domperidone respectively. The Fig.2a represents the overlain UV spectra of Esomeprazole and Domperidone. The Esomeprazole and Domperidone exhibited linearity in the concentration range of 2-20 µg/ml and 2-20 µg/ml at their respective selected wavelengths respectively. Coefficients of correlation were found to be 0.9993 and 0.999 for Esomeprazole and Domperidone respectively. The optical characteristics and regression values for the calibration curves are presented in Table 2b and 2c. For simultaneous estimation of Esomeprazole and Domperidone.

The two equations were constructed based upon the fact that at $\lambda_1$ and $\lambda_2$ the absorbance of the mixture is the sum of individual absorbances of Esomeprazole and Domperidone.

At $\lambda_1$, $A_1 = ax_1bc_x + ay_1bc_y$…… (1)

At $\lambda_2$, $A_2 = ax_2bc_x + ay_2bc_y$…… (2)

Where, $A_1$ and $A_2$ are absorbances of mixed standard at 287 nm and 301 nm respectively.

$\lambda_1$ and $\lambda_2$ are wavelengths of Esomeprazole and Domperidone respectively,

$ax_1$ and $ax_2$ are absorptivity of Esomeprazole at $\lambda_1$ and $\lambda_2$, $ay_1$ and $ay_2$ are absorptivity of Domperidone at $\lambda_1$ and $\lambda_2$ respectively.

$c_x$ and $c_y$ are concentration of Esomeprazole and Domperidone respectively.

## RESULTS AND DISCUSSION

Under the experimental conditions represented, calibration curve, assay of tablets and recovery studies were performed. The developed strategies were valid as per ICH guidelines for linearity, repeatability, LOD, LOQ as shown in Table one. The mean deviation content of Esomeprazole and Domperidone in tablet formulation by the simultaneous equation technique was found to be 99.53 % and 99.88% respectively as shown in Table two. The mean % recoveries of Esomeprazole and Domperidone. were found to be 99.23% and 99.31% severally by simultaneous equation technique as shown in Table three.

**Table 1: Optical Characteristics and Validation Parameters of Esomeprazole and Domperidone.**

| Parameter | Esomeprazole | | Domperidone | |
|---|---|---|---|---|
| | Method I | Method II | Method I | Method II |
| λmax (nm) | 301 | 287 | 287 | 301 |
| Beer's law range (µg/ml ) | 2-20 | 2-20 | 2-20 | 2-20 |
| LOD (µg/ml) | 1.660 | 1.302 | 0.202 | 0.0399 |
| LOQ (µg/ml) | 5.030 | 3.94 | 0.612 | 0.121 |
| Regression Equation: | | | | |
| Y=mx+C | | | | |
| I. Slope | 0.1553 | 0.0978 | 0.0549 | 0.0239 |
| II. Intercep | 0.1661 | 0.0936 | 0.0101 | 0.002 |
| III. Regression Coefficient ($r^2$ ) | 0.9993 | 0.9988 | 0.9992 | 0.9988 |

**Table 2: Analysis of Pharmaceutical Dosage Form.**

| Drug | Method | Label Claim (mg/tab) | Amount Found (%) | S.D.* | C.V. |
|---|---|---|---|---|---|
| Esomeprazole | I | 40 | 99.53 | 0.070 | 0.071 |
| | II | | 99.63 | 0.615 | 0.614 |
| Domperidone | I | 30 | 99.88 | 0.0282 | 0.0283 |
| | II | | 99.86 | 0.367 | 0.369 |

**S.D.= Standard Deviation, Mean of six estimations.*

**Table 3: Statistical Analysis of Recovery Studies.**

| Level of recovery (%) | Method | %Recovery** | | C.V. | |
|---|---|---|---|---|---|
| | | Esomeprazole | Domperidone | Esomeprazole | Domperidone |
| 50 | I | 99.22 | 99.32 | 0.120 | 0.830 |
| | II | 99.23 | 99.31 | 0.121 | 0.833 |
| 100 | I | 100.45 | 100.07 | 0.439 | 1.997 |
| | II | 100.41 | 100.07 | 0.439 | 1.996 |
| 150 | I | 99.88 | 99.93 | 0.0347 | 0.1618 |
| | II | 99.86 | 99.91 | 0.0346 | 0.1623 |

***Mean of three estimations*

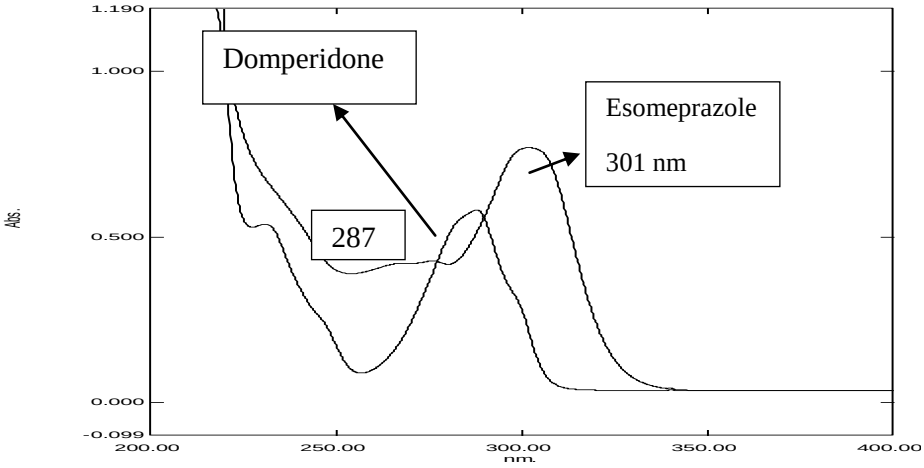


**Fig 1: Overlain spectra of Esomeprazole (10 µg/ml) and Domperidone (10 µg/ml).**

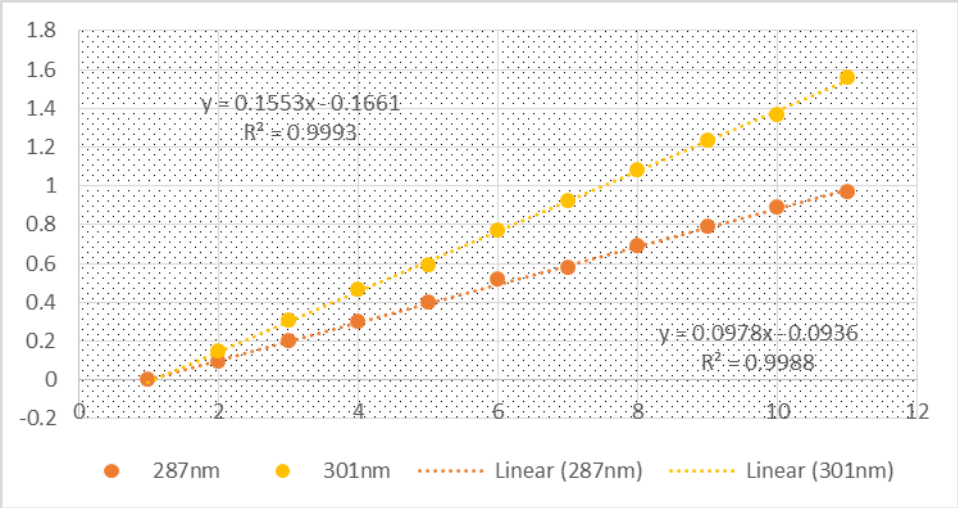


**Fig 2: Calibration curve of Esomeprazole.**

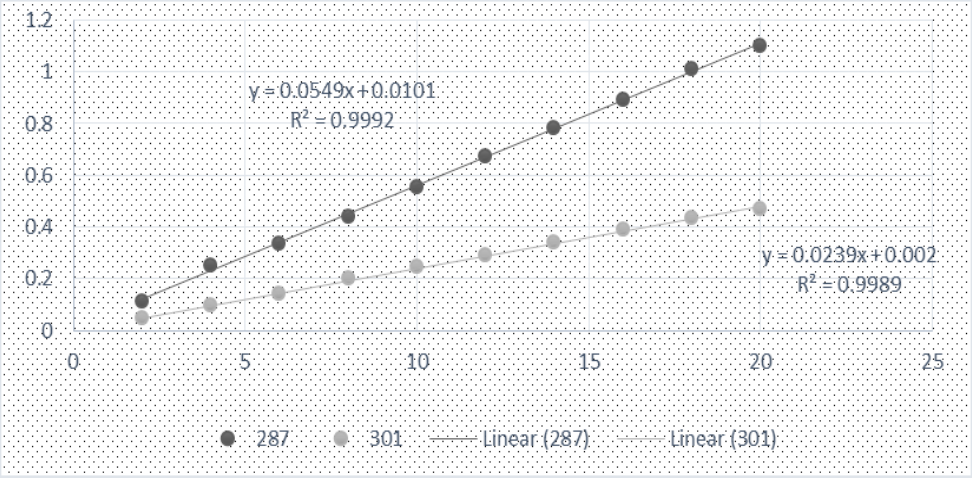


**Fig 3: Calibration Curve of Domperidone.**

## 4. CONCLUSION

The results of statistical parameters demonstrate that the planned ultraviolet spectrophotometric technique is simple, rapid, specific, correct and precise. Therefore, this technique may be used for the determination of esomeprazole and domperidone either in bulk or within the dose formulations while not interference with normally used excipients and connected substances.

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