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## Spectrophotometric method for the estimation of domperidone in bulk and pharmaceutical formulations

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### ABSTRACT

A simple and sensitive spectrophotometric method has been developed for the estimation of domperidone in bulk and pharmaceutical formulations. The estimation of domperidone was carried out on a UV/VIS spectrophotometer (Analytical technologies) using 1 cm quartz cell. Domperidone obeyed Beer's law in a concentration range of 10 to 150 µg/ml exhibiting maximum absorption at 284 nm. This method is extended to pharmaceutical additive and diluent. The results have been validated statistically and recovery studies confirmed the accuracy of proposed method.

**Keywords:** Spectrophotometry, Domperidone, Pharmaceutical formulations.

### INTRODUCTION

Domperidone is an antiemetic and antinauseant and acts on dopamine receptor system as an antagonist. Chemically it is 5-chloro-1-[1-(2,3-dihydro-2-oxo-1H-benzimidazole-1-yl)propyl]-4-piperidyl]-2,3-dihydro-1H-benzimidazol-2-one<sup>1</sup>. The recommended dosage for Domperidone is 10 mg per day. It is official in British Pharmacopoeia and European Pharmacopoeia where non-aqueous titration is the official method of assay<sup>(2,3)</sup>. Literature survey reveals that several methods like Spectrophotometry, HPLC, HPTLC and LC-MS were reported for the determination of Domperidone in combination with other drugs as well as in biological fluids<sup>(4-19)</sup>. These methods are too expensive and time consuming. An attempt has been made to develop a simple, economical, precise, accurate and reproducible spectrophotometric method for estimation of Domperidone in bulk as well as pharmaceutical formulations.

### MATERIALS AND METHODS:

Pure Domperidone was obtained from Dr.Reddy's labs, Hyderabad, India. The commercial fixed dose tablet formulations Domstal and Vomistop both containing 10 mg Domperidone were procured from the local market. All other reagents used were of AR grade. Distilled water was used during the experiment. Spectral and absorbance measurements were made on Analytical technologies spectrophotometer with 1 cm matched quartz cells.

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#### Preparation of standard stock solution:

Accurately weighed 25 mg of Domperidone was dissolved in 25 ml of 0.1N Hcl to get a concentration of 1 mg/ml. The stock solution is further diluted suitably with 0.1N Hcl to obtain working standard solutions of 10, 100 and 150 µg/ml.

#### Assay procedure for Domperidone:

Aliquots of solution 0.5 to 3.0 ml were transferred into a series of 10 ml volumetric flasks and the volume was made up to 10 ml with 0.1 N Hcl. The absorbance of the prepared solutions was measured at 284 nm for Domperidone against 0.1N Hcl as blank. The amount of Domperidone present in the sample solution was computed from its calibration curve.

#### Analysis of commercial formulations:

#### Preparation of standard stock solution:

Twenty tablets of each brand were accurately weighed and finely powdered. The powder equivalent to 25 mg of domperidone was transferred into 25 ml volumetric flask and dissolved in 0.1 N Hcl. Then the solution was filtered using Whatmann (Grade-I) filter paper and further diluted with 0.1 N Hcl to obtain working standard solutions of 10, 100 and 150 µg/ml.

### RESULTS AND DISCUSSION:

The Beer's law limit, Sandall's sensitivity, Molar extinction coefficient, Regression equation, Percent relative standard deviation are calculated and shown in table no:1. The absorbance was mea-

**Table No: 1.Optical Characteristics and precision of proposed method**

Parameter	Bulk Drug	Vomistop	Domstal
$\lambda_{max}$ (nm)	284	284	284
Beer's range ( $\mu\text{g/ml}$ )	10-150	10-150	10-150
Sandell's sensitivity ( $\mu\text{g/cm}^2$ )	9.1652 (10 $\mu\text{g}$ ) 9.0357 (100 $\mu\text{g}$ ) 8.0795 (150 $\mu\text{g}$ )	12.8960(10 $\mu\text{g}$ ) 11.4242(100 $\mu\text{g}$ ) 9.3345(150 $\mu\text{g}$ )	13.6201 (10 $\mu\text{g}$ ) 10.7904 (100 $\mu\text{g}$ ) 9.6218 (150 $\mu\text{g}$ )
Molar extinction coefficient	9165.24(10 $\mu\text{g}$ ) 9035.77(100 $\mu\text{g}$ ) 8079.50 (150 $\mu\text{g}$ )	12896.08(10 $\mu\text{g}$ ) 11424.19 (100 $\mu\text{g}$ ) 9334.46 (150 $\mu\text{g}$ )	13620.10(10 $\mu\text{g}$ ) 10796.42 (100 $\mu\text{g}$ ) 9621.80 (150 $\mu\text{g}$ )
Correlation coefficient (r)	0.9959	0.98606	0.9962
Regression equation ( $y=mx+c$ ) <sup>*</sup>			
Slope (m)	0.0191	0.02193	0.0222
Intercept (c)	0.0722	0.1903	0.1555
Percent relative standard(%) deviation <sup>**</sup>	64.22	61.61	62.14

\* $y=mx+c$ ,  $c=$  Intercept,  $m=$  Slope,  $x=$  Concentration in  $\mu\text{g/ml}$ \*\* Average of six determinations.

sured at 284 nm for domperidone and the quantity was determined from the standard curve graph.

**Recovery studies:**

The recovery studies were carried out at the different concentrations by spiking a known concentration of standard drug to the pre analysed sample and contents were reanalysed by proposed methods. The results of marketed formulation analysis and recovery studies are depicted in table no:1. The proposed method for the determination of domperidone in bulk and pharmaceutical dosage forms was found to be simple,rapid,accurate and economical and is applicable to the determination of domperidone in pure and pharmaceutical formulations.

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