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# Development And Validation Of HPLC Method For Simultaneous Estimations Of Ranitidine And Domperidone In Bulk And Tablet Dosage Form

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**Abstract-** A new HPLC method has been developed and validated with different parameters for Ranitidine and Domperidone in combine dosage form. The chromatograms were developed using a mobile phase of Acetonitrile: 0.05 % OPA (30:70) with a flow rate of 0.7 ml/min. C18 Column of 4.6 x 250 mm dimension was used as a stationary phase, particle size 5µm. The detection was carried out at 220 nm. The method was validated according to ICH guidelines for linearity, precision and Repeatability. The response was found to be linear in concentration range of 75-375 mcg/ml for Ranitidine and 5-25 mcg/ml for Domperidone. The stability studies were also done through exposure of analyte solution to five different stress conditions. The developed method was simple, precise, accurate and reproducible and therefore suitable for routine analysis of drugs in tablet dosage form.

**Index Terms**: HPLC; Ranitidine; Domperidone; Development; Validation.

## 1. INTRODUCTION

Ranitidine is a medication that decreases stomach acid production. Ranitidine is an $H_2$ histamine receptor antagonist that works by blocking histamine and thus decreasing the amount of acid released by cells of the stomach. It is commonly used in the treatment of peptic ulcer disease, gastro-esophageal reflux disease, Zollinger-Ellison syndrome. Common side effects are headache and pain or burning if given by injection. Domperidone is a peripherally selective dopamine $D_2$ receptor antagonist, it was developed by Janssen Pharmaceutica and is used as an antiemetic, gastroprokinetic agent, and galactagogue. It may be administered orally or rectally, and is available in the form of tablets, orally disintegrating tablets, suspension, and suppositories.

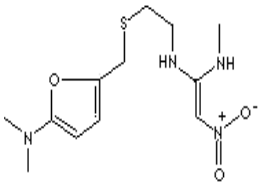

Fig. 1 Ranitidine

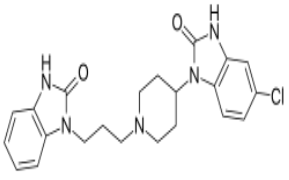

Fig. 2 Domperidone

## 2. MATERIAL AND METHOD

**Chromatographic conditions:**

The following chromatographic conditions were established by trial and error and were kept constant throughout the experimentation-

**Table No-1 CHROMATOGRAPHIC CONDITION:**

| | |
|---|---|
| HPLC | AGILENT (1100) Gradient System UV detector |
| Software | Chemstation |
| Column | id 4.6 x 250 mm length |
| Particle size packing | 5 µm |
| Stationary phase | C18 (AGILENT) |
| Mobile Phase | Acetonitrile : 0.05 % OPA (30:70) |
| Detection Wavelength | 220 nm |
| Flow rate | 0.7 ml/min |
| Temperature | Ambient |
| Sample size | 20 µl |

## 3. CHEMICALS AND REAGENTS:

Ranitidine, Domperidone and other chemicals obtained from pharmaceutical companies (J.B chemicals and other).

**Standard Stock solution:**

Take 75 mg Ranitidine and 5 mg Domperidone, dissolve in Methanol to make 10 ml. This makes 7500 µg/ml Ranitidine and 5000 µg/ml Domperidone. Then dilute this stock solution to make different concentrations.

## 4. RESULTS AND DISCUSSION:

***Method Development:***

The standard stock solution of Ranitidine and Domperidone was prepared and run through the column. The overlain spectra were scanned and isobestic wavelength was selected as 220 nm.

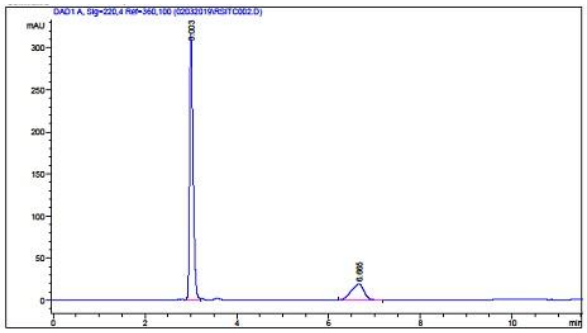

**Fig.3 Final developed graph of RANI and DOM**

***Method Validation:***

***Studies Of Calibration Plots:***

The mobile phase was allowed to equilibrRANI with stationary phase until steady baseline was obtained. Ranitidine and Domperidone solutions are made in a range of 75-375 µg/ml and 5-25 µg/ml respectively. The graphs were plotted as concentration versus peak area, shown in figure 1 & 2. Other details are given in table 2.

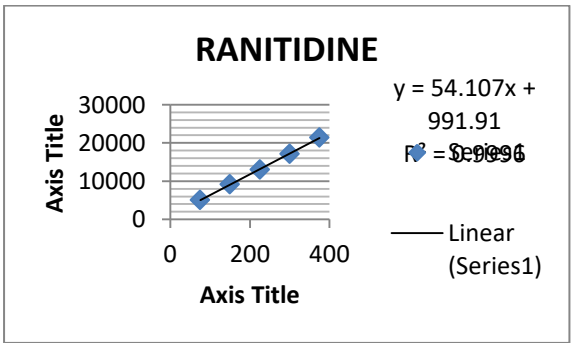


Fig.4 Calibration curve of Ranitidine

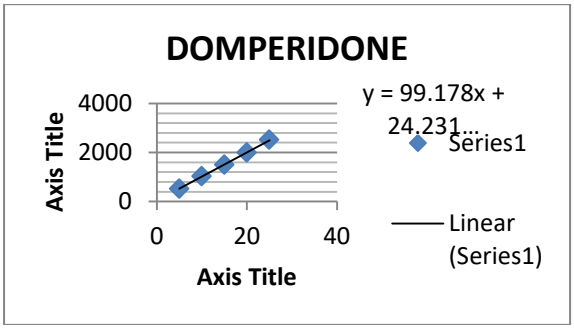


Fig.5 Calibration curve of Domperidone

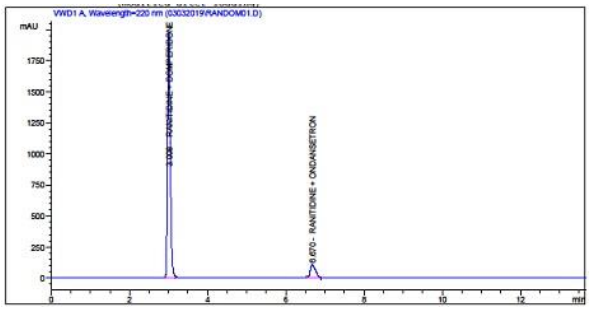

Fig.6 Linearity graph

Table 2: Linearity Data of RANI and DOM

| Ranitidine | | | | | | |
|---|---|---|---|---|---|---|
| Sr No | Conc | Area I | Area II | Mean | SD | %RSD |
| 1 | 75 | 5055.64 | 5056.33 | 5055.98 | 1.90 | 0.04 |
| 2 | 150 | 9227.08 | 9229.36 | 9228.22 | 1.61 | 0.02 |
| 3 | 225 | 13028.3 | 13036.9 | 13032.6 | 6.12 | 0.05 |
| 4 | 300 | 17104 | 17110.2 | 17107.1 | 4.41 | 0.03 |
| 5 | 375 | 21403.4 | 21410.2 | 21406.8 | 4.83 | 0.02 |
| Domperidone | | | | | | |
| 1 | 5 | 512.8 | 522.24 | 517.52 | 6.68 | 1.29 |
| 2 | 10 | 1030.08 | 1031.52 | 1030.80 | 1.02 | 0.10 |
| 3 | 15 | 1499.35 | 1501.23 | 1500.29 | 1.33 | 0.09 |
| 4 | 20 | 1996.91 | 1997.23 | 1997.07 | 0.23 | 0.01 |
| 5 | 25 | 2513.67 | 2514.01 | 2513.84 | 0.24 | 0.01 |

**PRECISION:**

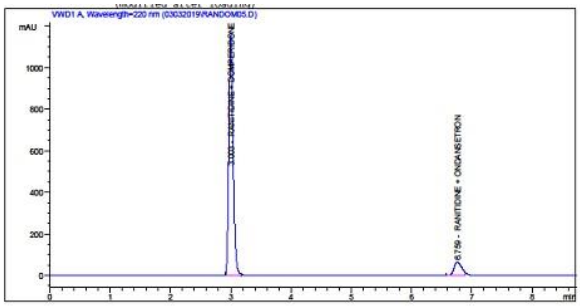

Fig.7 Precision graph

Table 3: Intraday Precision

| RANITIDINE | Sr No. | 1 | 2 | DOMPERIDONE | 1 | 2 |
|---|---|---|---|---|---|---|
| | Conc. | 75 | 225 | | 5 | 15 |
| | Area I | 5044.3 | 13068 | | 515.37 | 1508.4 |
| | Area II | 5062.7 | 13098 | | 518.36 | 1502.3 |
| | Mean | 5053 | 13083 | | 516.87 | 1505.4 |
| | Amt Fnd | 75.07 | 223.55 | | 4.96 | 14.9 |
| | % Amt Found | 100.1 | 99.33 | | 99.2 | 99.36 |
| | SD | 12.96 | 21.07 | | 2.11 | 4.32 |
| | %RSD | 0.26 | 0.16 | | 0.89 | 0.29 |

Table No-3 displayed the study of Intraday Precision of RANI and DOM. For this, RANI was used in a concentration of 75 µgm/ml and 225 µgm/ml. The % of amount found for these concentrations were 100.1, and 99.33 respectively. The %RSD for these concentrations was 0.26, and 0.16. DOM was used in a concentration of 5 µgm/ml and 15 µgm/ml. The % of amount found for these concentrations were 99.2 9 and 99.36 respectively. The %RSD for these concentrations was 0.89 and 0.29.

***Repeatbility:***

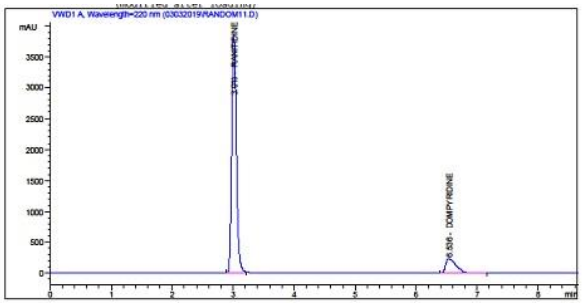

Fig.8 Repeatability

Table 4: Repeatability

| RANITIDINE | Sr No. | 1 | DOMPERIDONE | 1 |
|---|---|---|---|---|
| | Conc. | 375 | | 25 |
| | Area I | 21398.80 | | 2554.6 |
| | Area II | 21410.23 | | 2535.63 |
| | Mean | 21404.52 | | 2545.12 |
| | Amt Fnd | 377.31 | | 25.28 |
| | % Amt Found | 100.62 | | 101.12 |
| | SD | 8.08 | | 13.41 |
| | %RSD | 0.04 | | 0.53 |

Table No- 4 displayed the system suitability test (Repeatability) study of RANI and DOM. The mean areas found were 21404.52 and 2545.12 for RANI and DOM respectively. The % amount recovered was 100.62 and 101.12 for RANI and DOM respectively.

## 5. ASSAY OF MARKETED FORMULATION:

***Tablet Solution Preparation:***

Twenty tablets (Each Tab. contains 75 mg RANI and 5 mg DOM) were taken from market, and equiv. weight of tablet was determined (130mg). This quantity was dissolved in 10 ml Methanol to make 7500 µg/ml RANI and 500 µg/ml DOM. (Tablet stock solution). 0.2 ml is pipette out from tablet stock solution and makes up volume upto 10 ml with mobile phase. It contains 10 µg/ml DOM and 150 µg/ml RANI.

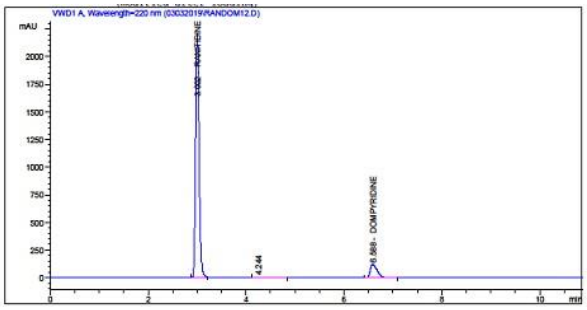

Fig.9 Assay of Marketed formulation of RANI and DOM

Table-5 Assay of RANI and DOM:

| Ranitidine | | | |
|---|---|---|---|
| Conc. | Area | Amt Found | % Label Claim |
| 150.00 | 9216.3 | 152.02 | 101.35 |
| 150.00 | 9219.39 | 152.07 | 101.38 |
| Mean | 9217.85 | 39.67 | 101.36 |
| SD | 2.18 | 0.04 | 0.01 |
| %RSD | 0.02 | 0.09 | 0.01 |
| Domperidone | | | |
| 10.00 | 1035.78 | 10.19 | 101.94 |
| 10.00 | 1031.42 | 10.15 | 101.50 |
| Mean | 1033.60 | 39.67 | 101.72 |
| SD | 3.08 | 0.03 | 0.07 |
| %RSD | 0.30 | 0.07 | 0.07 |

Table No- 5 displayed the assay of marketed formulation of RANI and DOM. 10 µg/ml DOM and 150 µg/ml RANI were taken to determine % label claim of tablet. The mean area was found to be 9217.85 and 1033.60 for RANI and DOM

respectively. The mean of % amount recovered was 101.36 and 101.72 for RANI and DOM respectively.

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