**Research Article**

# Development and Validation of Spectrophotometric Method for Simultaneous Estimation of Naproxen and Domperidone in Pure and Tablet Dosage Form

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**ABSTRACT**

The method for the simultaneous estimation of Naproxan and Domperidone in combined tablet dosage form have been developed, based on absorbance ratio method at two selected wavelengths 274.0nm (Iso-absorptive point) and 262.0nm (λmax of Naproxen). The linearity was obtained in the concentration range of 5-25µg/ml and 5-25µg/ml for Naproxen and Domperidone, respectively. These methods are simple, accurate and results of analysis have been validated statistically and by recovery studies.

**Keywords:** Naproxen, Domperidone, Absorbance ratio method.

## INTRODUCTION

Naproxen is well known non-steroidal anti-inflammatory drug which is clinically used in treatment of rheumatoid arthritis and other painful musculoskeletal disorders. It works by inhibiting both the COX-1 and COX-2 enzymes. It is a proprionic acid derivative related to the aryl acetic acid group of anti-inflammatory drugs.

Domperidone is a peripheral dopamine (D2) and (D3) receptor antagonist. It provides relief from nausea by blocking receptors at the chemo-receptor trigger zone (a location in the nervous system that registers nausea) at the floor of the fourth ventricle (a location near the brain).Few spectroscopic methods have been reported for determination of Naproxen as single drug or in combination with other drugs. Literature survey reveals, HPLC and HPTLC methods have also been reported for estimation of Naproxen in Pharmaceutical dosage forms. and also there are various methods such as UV spectrophotometry for Naproxen. Extensive literature survey reveals, none of the method is available that is based on estimation of Naproxan and Domperidone simultaneously by absorption ratio UV-spectrophotometric method. Aim of present work was to develop simple, precise, accurate and economical spectrophotometric methods for simultaneous determination of binary drug formulation. The proposed method was optimized and validated in accordance with International Conference on Harmonization (ICH) guidelines.[1,2,3]



**Naproxen**          **Domperidone**
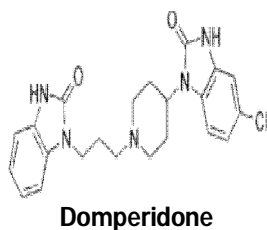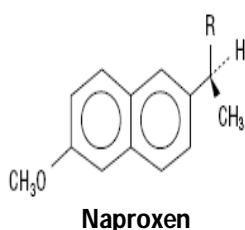
## MATERIALS AND METHODS

### Instrumentation

A double-beam Jasco UV- 2075; UV Visible spectrophotometer, spectral bandwidth of 2nm, wavelength accuracy ± 0.5nm and a pair of 1-cm matched quartz cells was used to measure absorbance of the resulting solution.

### Experimental[2,3,4]

Standard samples of Naproxen and Domperidone were taken. Combined dose Naproxen and Domperidone tablets (Naxdom-250 mg Naproxen & 10 mg Domperidone manufactured by Johnson & Johnson Pharmaceutical Pvt. Ltd.) taken.
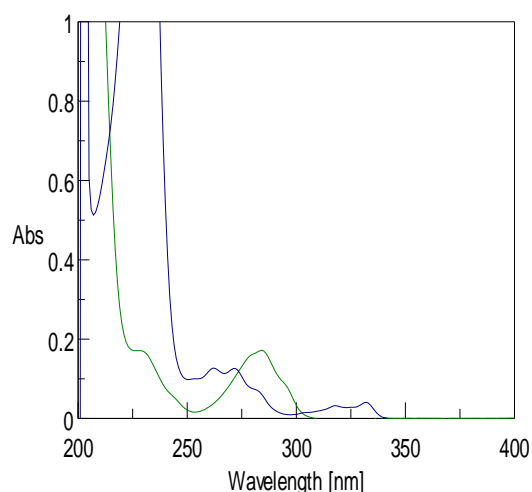


**Figure 1**: Overlain or Absorbance spectra for Naproxen & Domperidone.

### Solvent

Methanol selected as solvent for developing spectral characteristics of drug. The selection was made after assessing the solubility of both the drugs in different solvents.

## Preparation of Standard Stock Solutions[5,6,7]

Naproxen (NAX) and Domperidone (DOM) (10mg each) were accurately weighed and dissolved separately in100ml of methanol to give stock (100µg/ml). From the standard stock solution, 1ml each of NAX and DOM was taken in 10ml volumetric flask. Volume was made up to mark with methanol. Aliquot portion was appropriately diluted with distilled water to get final concentration of 5-25µg/ml (NAX) and 5-25 µg/ml (DOM) prepared respectively to give final concentrations and scanned between 200-400nm.

## Method

### Application of the Proposed Method for the Determination of NAX and DOM in Table Dosage Form

### Absorbance Ratio Method[6-9]

In the absorbance ratio method, from the overlain spectra of both drugs (Fig-1), wavelengths 274.0nm (Iso-absorptive point) and 262.0nm (λmax of Naproxen) were selected for analysis.

The calibration curves for Naproxen and Domperidone were plotted in the concentration range of 5-25µg/ml and 5-25µg/ml at both the wavelengths respectively. The absorptivities values were determined for both the drugs at both the wavelengths. From the following set of equations the concentration of each component in sample was calculated,

$$Cx = \frac{Qm-Qy}{Qx-Qy} \times \frac{A_1}{ax_1} \qquad (1) \text{ and}$$

$$Cy = \frac{Qm-Qx}{Qy-Qx} \times \frac{A_1}{ay_1} \qquad (2)$$

Where

Cx=concentration of Naproxen,

Cy=concentration of Domperidone,

$A_1$=absorbance of sample at wavelength 262.0nm,

$A_2$=absorbance of sample at wavelength 274.0nm,

$ax_1$= absorbtivity of Naproxen at 262nm,

### Results of Analysis of Tablet Formulation

$ay_1$=absorbtivity of Domperidone at 284nm,

Qm=ratio of absorbance of sample solution at 274nm and 262nm resp.,

Qx=ratio of absorbtivities of Naproxen at 274nm and 262nm and

Qy=ratio of absorbtivities of Domperidone at 274nm and 284nm.

## Validation Parameter[8,10]

### Linearity

The linearity was obtained in the concentration range of 5-25µg/ml and 5-25µg/ml for Naproxen & Domperidone respectively in both methods which obeys Beer-Lambert's law. The results of the same are shown in Fig 2 and Fig 3.
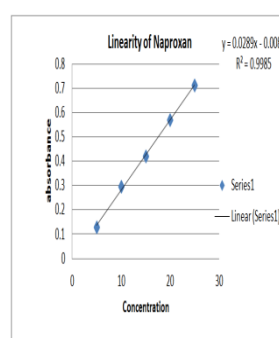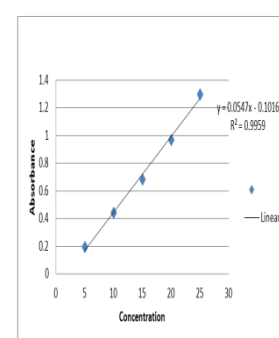


**Figure 2:** Linearity of Naproxen.



**Figure 3:** Linearity of Domperidone.

### Accuracy

To ascertain the accuracy of the proposed methods, recovery studies were carried out by standard addition method at Table 1.

### Limit of Detection (LOD) and Limit of Quantitation (LOQ)

The LOD and LOQ by proposed methods were determined using calibration standards. LOD and LOQ were calculated as 3.3s/S and 10s/S, respectively, where S is the slope of the calibration curve and s is the standard deviation of response. The results of the same are shown in Table 1.

**Table 1:** Absorbance Ratio Method

| Drug | Label Claim (µg/ml) | Amount Taken (mg/tab) | Amount Found (mg) | % Recovery | S.D | S.E | C.V | LOD (µg/ml) | LOQ (µg/ml) |
|------|------|------|------|------|------|------|------|------|------|
| NAX | 250 | 10 | 9.98 | 99.8 | 0.252 | 0.1453 | 0.24 | 0.8310 | 0.250 |
| | | | 9.91 | 99.1 | | | | | |
| | | | 9.93 | 99.3 | | | | | |
| DOM | 10 | 0.4 | 0.396 | 99 | 0.2 | 0.1156 | 0.23 | 0.6606 | 0.2 |
| | | | 0.395 | 98.8 | | | | | |
| | | | 0.396 | 99.2 | | | | | |

**S.D:** Standard Deviation, **S.E:** Standard Error, **C.V:** Coefficient Variation

## RESULTS AND DISCUSSION

From the proposed research, it was found that Naproxen and Domperidone obeys linearity within the concentration range 5-25 ppm & 5-25 ppm respectively.

Percentage label claim for Naproxen and Domperidone in tablet, by absorption ratio methods was found in the range of 99.1% to 99.8% and 98.8% to 99.2% respectively.

For coefficient of variation (CV) were calculated, which was found to be less than 2% indicating the both method has good reproducibility.

Accuracy of proposed methods was ascertained by recovery studies & results are expressed as % recovery. Percent recovery for Naproxen & Domperidone by absorption ratio method was found in range of 99.1 to 99.8 and 98.8 to 99.2 respectively, values of standard deviation, standard error and coefficient of variation for range of 0.2 to 0.252, 0.1156 to 0.1453, 0.23 to 0.24 respectively indicating the accuracy of proposed method.

## CONCLUSION

Based on the results obtained, it is found that the proposed methods are accurate, precise, reproducible and economical and can be employed for routine quality control of Naproxen and Domperidone in combined dose tablet formulation.

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**Source of Support:** Nil, **Conflict of Interest:** None.

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