*Available online at* www.derpharmachemica.com

Scholars Research Library

**Der Pharma Chemica, 2013, 5(2):67-74**
*(http://derpharmachemica.com/archive.html)*

**ISSN 0975-413X**
**CODEN (USA): PCHHAX**

# Simultaneous estimation of lansoprazole and naproxen by using UV spectrophotometer in tablet dosage form

**Nisha Choudhary, Inamullah Siddiqui, Jyoti Rai, Sunil Singh*, Sharma Surabhi and Hemendar Gautam**

*Department of Pharmaceutical Chemistry, Invertis Institute of Pharmacy, Invertis University Bareilly (U.P)*

---

**ABSTRACT**

*An accurate, specific and precise UV spectrophotometric method was developed for the simultaneous determination of lansoprazole and naproxen. The indicating proposed method was accurate and precise for simultaneous estimation of NAP and LAN in tablet dosage form by using Simultaneous Equation. Materials used were UV- - Visible Spectrometer (LAB INDIA 3200) with 1cm quartz cells. An analytical balance (Roy electronics – LCBCNS) was used for weighing the samples. Means, standard deviation (SD), relative standard deviation (RSD) and linear regression analysis were calculated using Microsoft Excel 2007. The maximum wavelength ($\lambda_{max}$) was found to be 284 nm for LAN and 271 nm for NAP. The linearity was found to be 10-35µg/ml ($r^2$ =0·999) for NAP and 5-30µg/ml ($r^2$=0·998) for LAN. Validation was performed as ICH guidelines for Linearity, accuracy, precision, LOD and LOQ. The limit of quantification of NAP was found to be 0·15µg/ml and for LAN was 1·7µg/ml. The limit of detection of NAP was found to be 0·04µg/ml and for LAN was 0·5µg/ml. The % recovery was found to be satisfactory. The proposed method is simple, sensitive and reproducible for simultaneous determination of UV Spectrophotometric method for lansoprazole and Naproxen in tablet dosage form.*

**Key words:** validation; simultaneous estimation; simultaneous equation.

---

## INTRODUCTION

Lansoprazole (Figure 1a) is a substituted benzimidazole[1]. Naproxen (Figure 1b) is capable of producing disturbances in the gastrointestinal tract [2]. The LAN in this medication helps reduce the risk of stomach ulcers in people who may be at risk for them while receiving treatment with an NSAID'S. On literature survey it was found that LAN and NAP was estimated independently or in combination with other drugs by several methods as HPTLC[3], LC-MS in human plasma[4], LC- electrospray Tandem Mass Spectrometry[5]. There was no UV- spectrophotometric method had been develop for the determination of LAN and NAP in combined dosage form.

## MATERIALS AND METHODS

*Drugs and chemicals*

Lansoprazole was procured from Lupin pharmaceuticals limited, India as a gift sample. Naproxen was procured from Glenmark Pharmaceuticalc Limited, India as a gift sample. Methanol was of analytical grade. All other chemicals used were of analytical grade. The pharmaceutical dosage form used in this study was junior lanzol-30 labelled to contain 30mg LAN and naprosyn labelled to contain 250mg of NAP.

*Apparatus*
Analysis was carried out on UV -Visible Spectrometer (LAB INDIA 3200) with 1cm quartz cells. An analytical balance (Roy electronics – LCBCNS) was used for weighing the samples.

*Preparation of standard stock solution*
The standard stock solutions of 1000µg/ml of LAN and NAP were prepared by accurately weighing 50mg drugs separately in methanol in 50ml volumetric flask. The working dilutions were in the range of 10-35 µg/ml for naproxen and 5-30 µg/ml for LAN respectively were prepared by further dilutions for calibration curves.

*Determination of $\lambda_{max}$*
The standard solution of LAN and NAP were separately scanned at different concentration in the range of 200-400 nm and the $\lambda_{max}$ was determined. The overlain spectrum of both the drugs is also run. (Figure 2 and 3)

*Preparation of calibration curve*
For each drug appropriate aliquots were pipette out from standard stock solution into the series of 10 ml volumetric flask and the volume was made up to the mark with methanol to get concentration of 10-35 µg/ml of LAN ( Figure 4 ) and 5-30 µg/ml of NAP ( Figure 5 ). Solutions of different concentrations for each drug were analyzed at their respective wavelengths and absorbances were recorded. (Table 2)

***Method development***
*(Simultaneous equation method)*
Zero order overlain spectra (Figure 6) were carried out at 271nm and 284nm, the maximum absorbance wavelength of LAN and NAP respectively. Appropriate dilutions were prepared using methanol from the stock solution 1000µg/ml of LAN and NAP to get aliquots of the concentration of 10-35 µg/ml and 5-30 µg/ml for LAN and NAP respectively. The calibration curve was plotted from mean absorbance values of observation of the six replicate. The absorptivity values for both the drug were determined at their respective at their respective $\lambda_{max}$ by measuring absorbance values for working standard of LAN and NAP. The concentration of LAN and NAP were determined by solving the following equation:

$Cx= (A_1ay_2-A_2ay_1) / (ax_1ay_2-ax_2ay_1)$.....Eq (i)
$Cy= (ax_1A_2-ax_2A_1) / (ax_1ay_2-ax_2ay_1)$.....Eq (ii)

Where Cx and Cy are the concentration of LAN and NAP respectively.

*Analysis of commercial formulation*
Ten tablets of lansoprazole and naproxen were accurately weighed separately and its contents crushed to fine powder. Powder equivalent to 30mg of lansoprazole and 250mg of naproxen was weighed and dissolved in methanol, sonicate for 30min, mixed well and filtered through Whatman's filter paper no.41. After rejecting first few ml, different of tablets sample were prepared by serial dilution technique and analyzed at 271nm and 284nm. Then the absorbances were recorded at the respective wavelengths. (Table 1)

*Method validation*
The analytical method was validated with respect to parameters such as linearity, limit of detection (LOD), limit of quantitation (LOQ), precision, accuracy, robustness, and recovery (ICH Q2R1 2003).

*Accuracy*
To study the accuracy of the proposed methods, recovery studies were carried out by standard addition method at three different levels (80%, 100%, and 120% of the test concentrations as per ICH guidelines). A known amount of drug was added to per analyzed tablet powder and percentage recoveries were calculated. The results of recovery studies were satisfactory (Table 3).

*Linearity and range*
Linearity is established by least squares linear regression analysis of the calibration curve. The constructed calibration curve is linear over the constructed range 10-35µg/ml of naproxen (Table 2) and 5-30 µg/ml of lansoprazole respectively. Each concentration was repeated for 3 minutes.

*Precision*
The precision of the method, as intra-day repeatability was evaluated by performing six independent assays of the test sample preparation and calculating the RSD %. The intermediate (interday) precision of the method was checked by performing same procedure on different days by another person under the same experimental conditions. (Table 3)

*Robustness*
Robustness of proposed method was performed by changing the UV analyst and remaining condition was keeping constant (Table 3).

*LOD and LOQ*
The LOD and LOQ of lansoprazole and Naproxen are calculated by Mathematical equation.

LOD= 3.3×standard deviation ÷ slope
LOQ=10×standard deviation ÷ slope

The LOD of lansoprazole and Naproxen were found to be 0·04µg/ml and 0·5µg/ml and the LOQ of lansoprazole and Naproxen were found to be 0·15µg /ml and 1·7µg/ml (Table 3)

## RESULTS

The maximum wavelength ($\lambda_{max}$) was found to be 284 nm for LAN (Figure 2) and 271 nm for NAP (Figure 3) the linearity of the proposed method was investigated in the range of 5-30 µg/ml and 10-35 µg/ml for LAN, NAP respectively. Calibration curves show a linear relationship between the absorbance and concentration of LAN (Figure 4) and NAP (Figure 5). The overlain spectra (Figure 6) of LAN and NAP exhibit $\lambda_{max}$ of 284 nm and 271 nm respectively which are quite separated from each other. Analysis of commercial formulation absorbances were recorded at the respective wavelengths (Table 1). The optimum conditions for the analysis of the drug were established. The line equation for LAN y = 0.040x + 0.036 with $r^2$ of 0.998 and for NAP y = =0.022x - 0.022 with $r^2$ of 0.999 was obtained and linearity and range also shown in (Table 2). Validation was performed as ICH guidelines (Q2R1) (Table 3) accuracy, precision, LOD and LOQ. The LOD-0·525µg/ml, for LAN and 0·0455 for NAP and LOQ for LAN-0·151µg/ml and NAP-1·753µg/ml respectively.

## DISCUSSION

The present research works discuss the development of a UV Spectrophotometric method for the estimation of LAN and NAP in tablet dosages form. The proposed method is simple, sensitive and reproducible and hence it can be used in routine analysis for simultaneous determination of UV Spectrophotometric method for lansoprazole and Naproxen in pharmaceutical preparation. Statistical analysis of the results has been carried out revealing high accuracy and good precision.

**Table 1: Analysis of commercial formulation:**

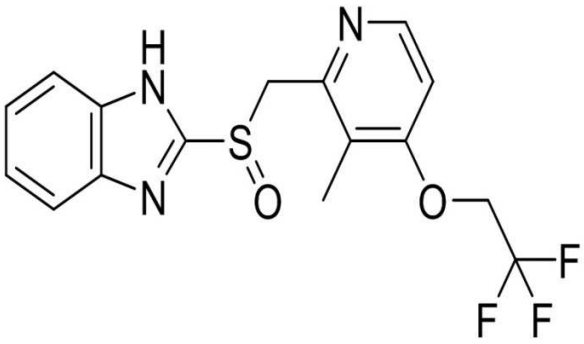
| Formulation | Drug | Label claim | % Label claim ( mean ± SD) |
|---|---|---|---|
| Tablet | Lansoprazole | 30mg | 100·13 ± 0·000985 |
| | naproxen | 250mg | 100·16 ± 0·012757 |

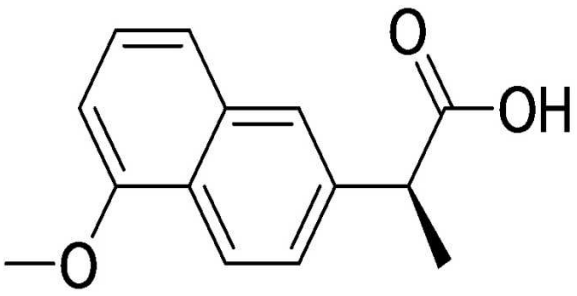
**Table 2: UV analysis (Callibration Curve):**

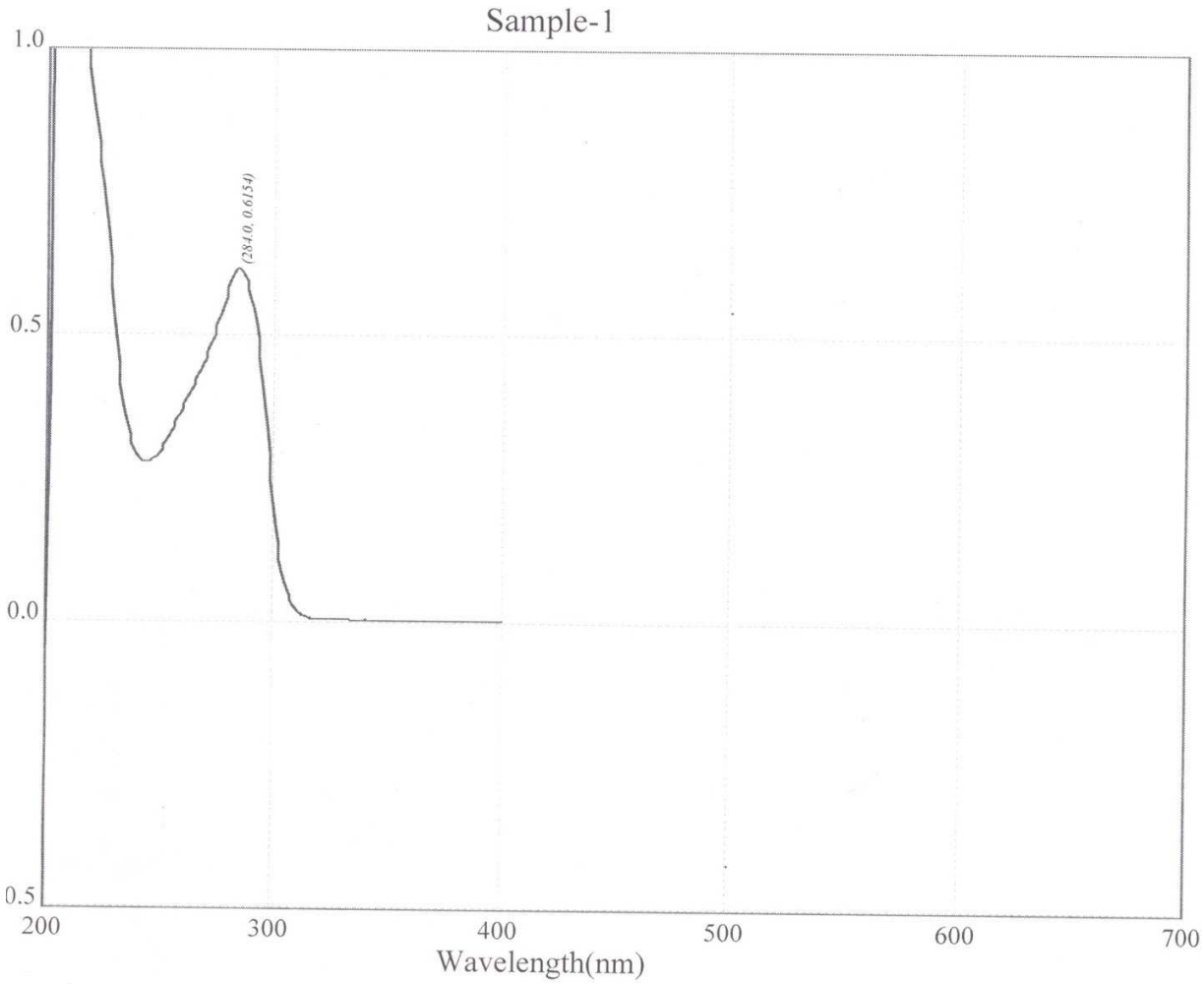
| S.NO. | Parameter (units) | Lansoprazole | Naproxen |
|---|---|---|---|
| **i.** | Linearity range (µg/ml) | 5-30 µg/ml | 10-35µg/ml |
| **ii.** | Correlation coefficient ($r^2$) | 0.998 | 0.999 |
| **iii.** | Slope | 0.040 | 0.054 |
| **iv.** | Intercept | 0.022 | 0.022 |

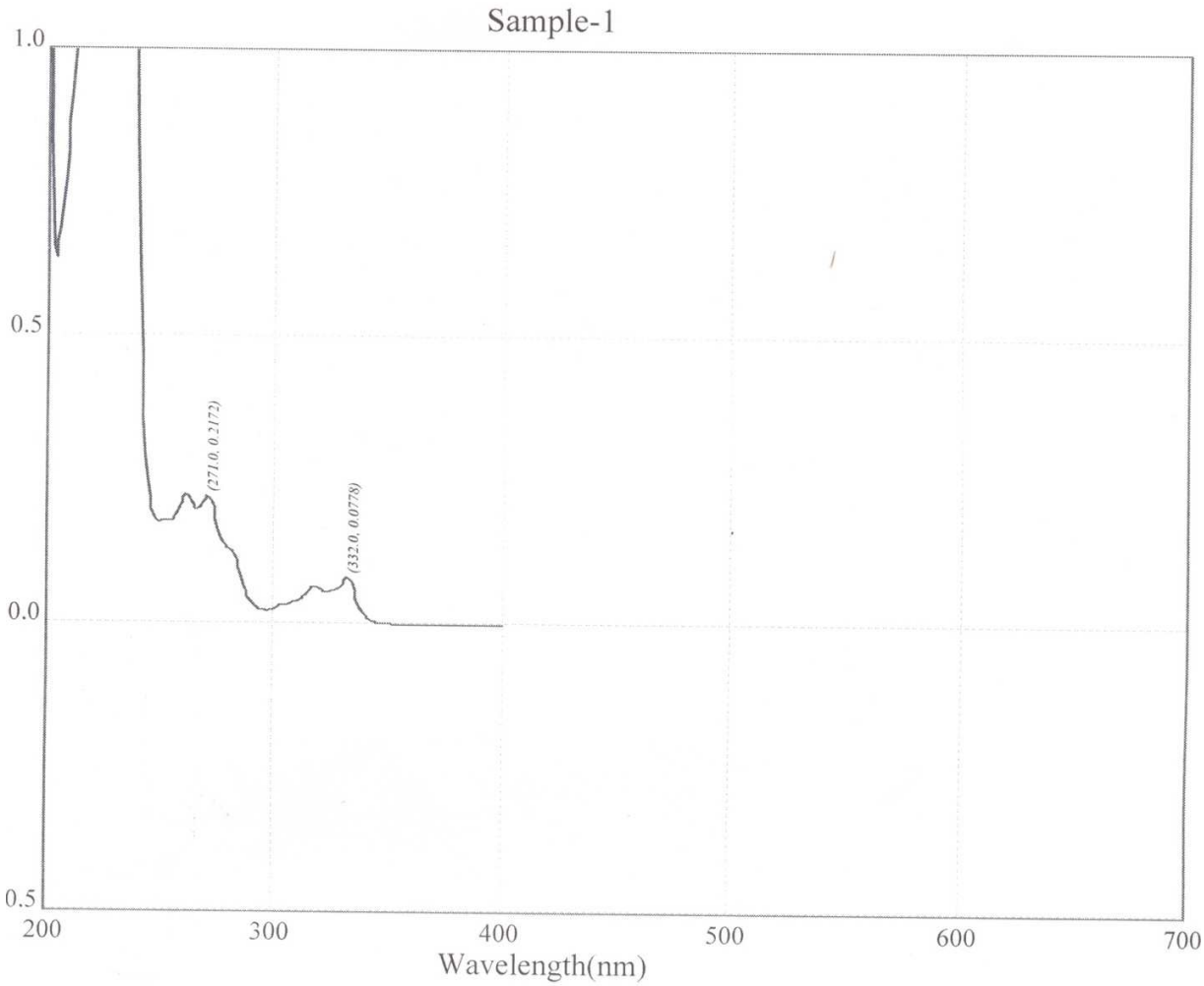
**Table 3: Validation parameter:**

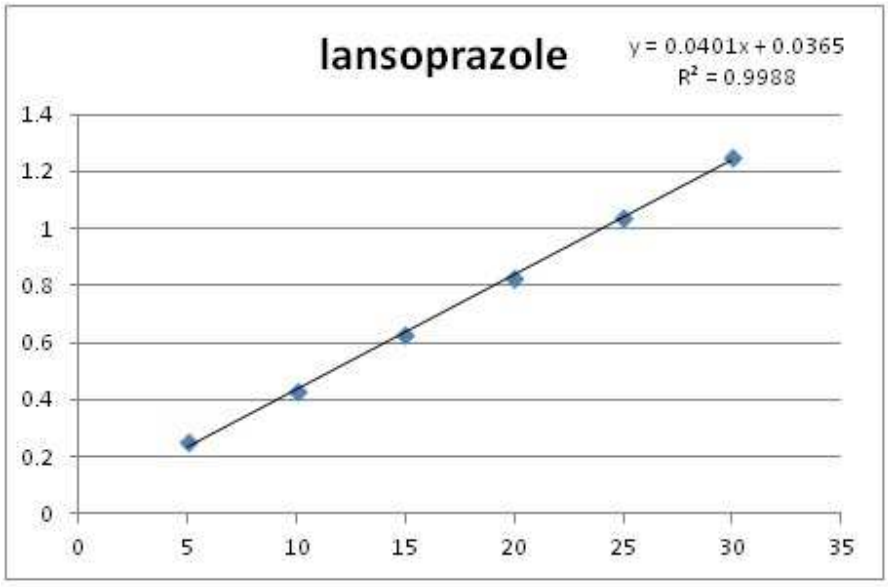
| | | | |
|---|---|---|---|
| **i.** | **Interday Precision** | **Lansoprazole** | **Naproxen** |
| | (1st d) | 159%±0·0016686 | 101%±0·0018626 |
| | (2nd d) | 95%±0·000842 | 97%±0·0014136 |
| | (3rd d) | 96%±0·0044293 | 97%±0·000375 |
| | **Intraday precision** | | |
| | (1st h) | 93%±0·002339 | 98%±0·001002 |
| | (2nd h) | 93%±0·000321 | 96%±0·002631 |
| | (3rd h) | 94%±0·002346 | 98%±0·000608 |
| **ii.** | | **Recovery** | |
| | 80% | 96%±0·06247 | 107%±0·003912 |
| | 100% | 95%±0·064849 | 120%±0·0025485 |
| | 120% | 99%±0·004732 | 115%±0·00928 |
| **iii.** | **LOD (mg/ ml)** | 0·525mg/ ml | 0·0455mg/ ml |
| **iv.** | **LOQ (mg/ ml)** | 0·151mg/ ml | 1·753mg/ ml |
| **v.** | **Robustness** | 86%±0·001201 | 126%±0·003889 |

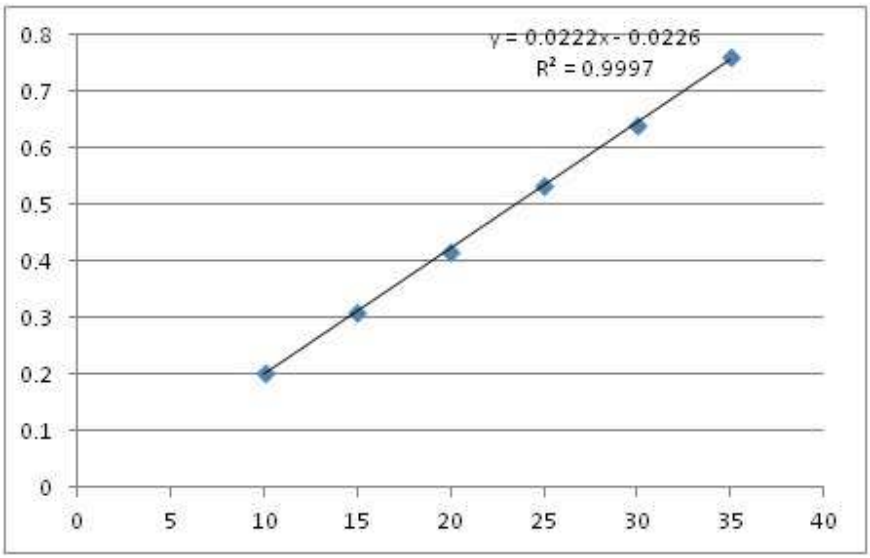


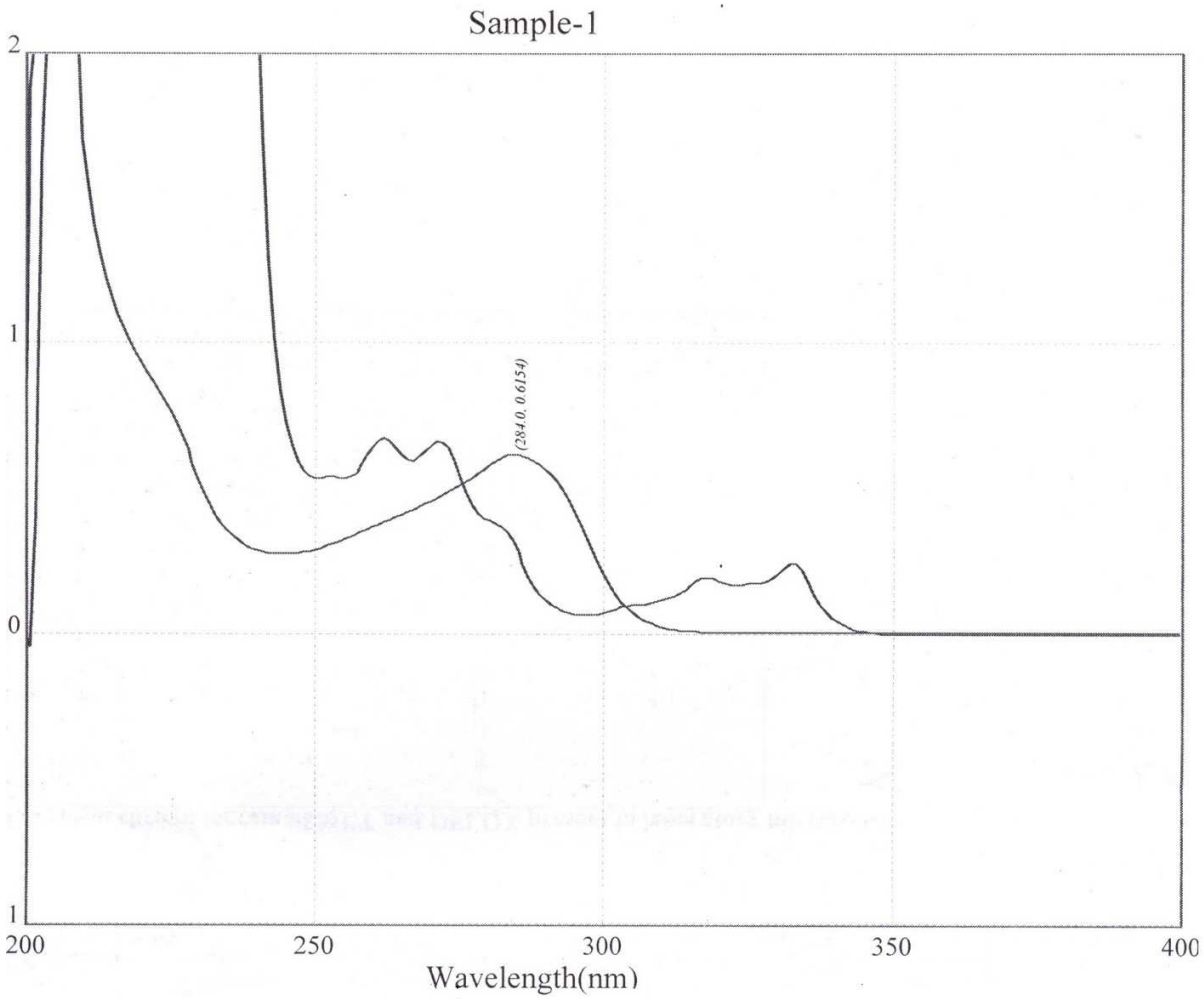




Sample-1
1.0
0.5
0.0
0.5
(284.0, 0.615)
200
300
400
500
600
700
Wavelength(nm)


Sample-1
1.0
0.5
0.0
0.5
(271.0, 0.2172)
(332.0, 0.0778)
200
300
400
500
600
700
Wavelength(nm)


lansoprazole
y = 0.0401x + 0.0365
R² = 0.9988
1.4
1.2
1
0.8
0.6
0.4
0.2
0
0
5
10
15
20
25
30
35


y = 0.0222x - 0.0226
R² = 0.9997
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
0
5
10
15
20
25
30
35
40


Sample-1
2
1
0
1
(284.0, 0.6154)
200
250
300
350
400
Wavelength(nm)

**Acknowledgement**
The authors are thankful to Lupin pharmaceuticals limited, India. For providing gift sample of Lansoprazole and Glenmark Pharmaceuticalc Limited, India for providing gift sample of Naproxen and also thankful to Invertis institute of pharmacy for providing research facilities in laboratory and constant encouragement.

## REFERENCES

[1] Yeniceli D, Dogrukol DA, Tuncel M. *J. Pharm. Biomed. Anal*. **2004**; 36:145–48.
[2] Haque T, Talukder MU, Laila S, Fatima K. *Pak. J. Pharm. Sci.* **2010**;23(4):379-83.
[3] Aanandhi VM, Thiyagarajan N, Koilraj M, Shanmugasundaram P, Sujatha M. *Rasayan. J. Chem.* **2009**;1:15-7.
[4] Saudaya RB, Saraf S. *Indian Drugs*. **2006**;43(5):388-92.
[5] ICH, Stability Testing of New Drug Substances and Products Q1A (R2), *International Conference on Harmonization*, IFPMA, Geneva, **2003**.
[6] Anonymus *British pharmacopoeia* (BP), British Pharmacopoeial Commission, London 2009.
[7] Anonymous *The United States Pharmacopeial Convention* (29th Edn), Rockville, MD, **2007** pp 1485.
[8] Katsuki H, Hamada A, Nakamura C, Arimori K, Nakano M. *J. of Chromatography B* **2001**;757:127–33.
[9] Moustafa AAM. *J Pharm Biomed Anal*. **2000**;22:45-58.
[10] Wahbi AAM, Razak AO, Mahgoub H, Azza A, Moneeb MS. *J Pharma. Biomed Anal*. **2002**;30:1133-42.
[11] Pandey M, Chawla P, Saraf AS. *Asian J. Pharm. Clin. Res.* **2012**;5(3):176-78.
[12] Mehta P, Sharma SC, Nikam D, Ranawat MS. *Int. J. Pharma. Sci. and Drug Res.* **2012**;4(1):63-69.
[13] Reddy SP, Sait S, Vasudevmurthy G, Vishwanath B, Prasad V, Reddy J. *Der Pharma Chemica*. **2011**;3(6):553-64.
[14] Pawar MS, Patil SB, Patil YR. *Eurasian J Anal Chem.* **2010**;5(3):284-92.
[15] Mondal S, Haque A, Islam S, Islam A. *J. App. Pharma. Sci.* **2011;**01(07):145-48.
[16] Patel B, Dedanta Z, Dedanta R, Ramolla C, Sagar GV, Mehta RS. *Asian J. Research Chem.* **2009**;2(2):210-12.
[17] Janardhanan VS, Manavalan R, Valliappan K. *Int. J. Drug Dev. & Res.* **2011**;3(4):323-35.
[18] Reddy BP, Jayaprakash M, Sivaji K, Kumar GTJ, Reddy ECS, Reddy BR. *Int. J. App. Bio. and Pharma. Tech.* **2010;** 1(2):683-88.
[19] Kumar SM, Kumar DS, Rajkumar T, Kumar EU, Geetha AS, Diwedi D. *J. Chem. Pharm. Res.* **2010**;2(6):291-95.
[20] Singh S, Patel K, Agarwal VK, Chaturvedi S. *Int. J. Pharm. and Pharma. Sci.* **2012**;4(4):468-71.
[21] Singh S, Patel K, Agarwal VK, Chaturvedi S. *Scholar Research Library, Der Pharmacia letter*. **2002**;4 (3):897-05.
[22] Singh S, Yadav AK, Gautam H. *Bull. Pharm. Res.* **2012**;2(2):83-6.
[23] Singh S, Dubey N, Jain DK. *Int. J. Pharm. Biomed. Sci*. **2011**; 5(1):57-60.
[24] Patel K, Singh S, Sahu P, Trivedi P. *Scholar Research Library, Der Pharmacia Lettre*, **2011**;3(6):102-07.
[25] Singh S, Yadav AK, Gautam H. *Bull. Pharm. Res.* **2011**;1(3):10-2.
[26] Singh S, Dubey N, Jain DK. *Asian J. Research Chem.* **2010**;3(4):885-87.
[27] Inamullah, Singh S, Sharma S, Yadav AK, Gautam H. *Scholar Research Library, Der Pharmacia letter*. **2012**; 4 (6):1837-1842.