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**Review**

# Reviewing the development and validation of analytical methods for different drugs utilizing uv spectroscopy

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## Abstract

UV-visible spectrophotometry refers to absorption spectroscopy. It provides fast and efficient analysis. It is used to quantify nucleic acid and protein content in biological samples and for quality control in drugs and food industries. It is based on the interaction between light and matter. It is used in the wavelength range of 190-900nm. Many drugs are analyzed by UV visible spectrophotometer. Fenofibrate is an oral medication of the fibrate class used to treat abnormal lipid levels. It works by increasing the natural substance that breaks down the fats in the blood. It is less commonly used when compared with statins because it treats a different type of cholesterol abnormality than statins. Ranolazine is an anti-anginal drug. It is used to treat chronic angina (cardiovascular illness). It is used concomitantly with angiotensin receptor β-blockers, and ACE inhibitors. Pantoprazole is an anti-ulcer (proton pump inhibitor). It irreversibly inhibits the gastric $H^+/K^+$-ATPase inhibitors. It is metabolized in the liver and excreted through urine.

**Keywords:** Fenofibrate, ranolazine, pantoprazole, UV-visible spectrophotometer.

## INTRODUCTION

**Fenofibrate**

Fenofibrate is used to regulate the lipid composition of the circulatory system. It belongs to the class of drugs known as fibrate, which have structural similarities to other fibrate. The IUPAC name of Fenofibrate is 2-{4-[4-chlorobenzoyl] phenoxy} (2-methyl propanoic acid 1-methyl ethyl ester). Its empirical formula is $C_{20}H_{21}ClO_4$, and its molecular weight is 360.83g/mol. It is a white yellowish crystalline powder that is soluble in organic solvents like ethanol and DMSO, but insoluble in water. Fenofibrate is currently used as an anti-hyperlipidemic drug that directly lowers blood levels of cholesterol, triglycerides, LDL (low-density lipids), and VLDL (very low-density lipids), while simultaneously increasing HDL (high-density lipids). It greatly reduces the levels of hypercholesterolemia and hypertriglyceridemia when administered with statins.

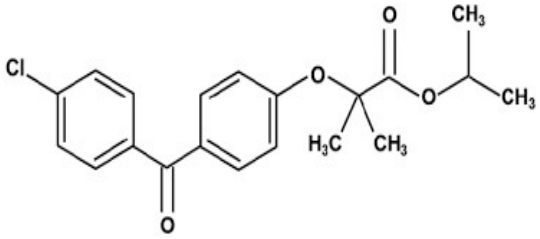

**Fig 1: Structure of fenofibrate**

**Ranolazine**

Ranolazine is an anti-anginal drug. Chemically, it is RS-N-(2,6-dimethylphenyl)-2-[4-hydroxy-3-(2-methoxyphenoxy)-propyl piperazin-1-yl] acetamide. A derivative of piperazine with amide-containing characteristics, ranolazine exhibits anti-anginal and possibly anti-neoplastic effects. It has the chemical formula ($C_{24}H_{33}N_3O_4$). Ranolazine anti-anginal and anti-ischemic effects occur regardless of a decrease in heart rate or blood pressure. Ranolazine is expected to decrease the late sodium current, which will reduce the amount of sodium that reaches the cells of the ischemic myocardium. Consequently, it has been proposed that Ranolazine could potentially reduce calcium absorption indirectly through the sodium/calcium exchanger.

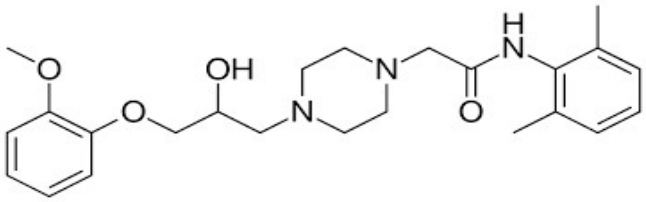

**Fig 2: Structure of ranolazine**

**Pantoprazole**

Pantoprazole is a proton pump inhibitor. Chemically, it is (difluoro methoxy) panthazol-2-[(3)4-dimethoxy pyridine–2–yl) methyl sulfonyl]-1H, 1-3 benzo diazole. They permanently block the stomach $H^+/K^+$-ATPase. The proton pump is the last fundamental system that secretes acid in reaction to any kind of stimulus. Since all proton pump inhibitors are acid labile, the tablet should be taken whole and without crushing. It has a 77% bioavailability and negligible first-pass metabolism. The Cytochrome P-450 system breaks down Pantoprazole substantially in the liver before excreting it in the urine.

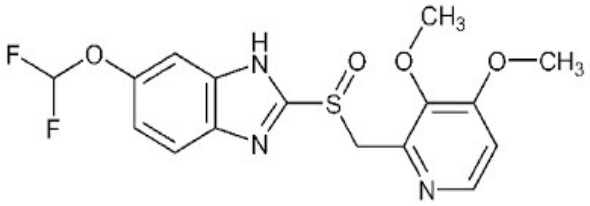

**Fig 3: Structure of pantoprazole**

**Table 1: Analytical methods**

| S.No | Author Name | Journal Name | Title Name | Analytical Conditions |
|---|---|---|---|---|
| 1 | Kutty et.al 2012[1] | International Journal of Pharmaceutical Sciences and Drug Research | Validated UV-Visible Spectrophotometric Method for the Estimation of Fenofibrate in Pure and Pharmaceutical Formulation Using MBTH Reagent | Solvent- Methanol<br>λmax (nm)-596<br>Linearity-2-5 µg /ml<br>Slope-0.101<br>Intercept-0.003<br>$r^2$-0.998<br>Accuracy-99.36 |

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|---|---|---|---|---|
| | | | | Precision<br>Reproducibility %RSD 1.7<br>repeatability %RSD 1.5 |
| 2 | P.H. Prathyusha et.al 2010[2] | International Journal of pharmacy & Technology | Spectrophotometric methods for the determination of fenofibrate | Solvent- Methanol<br>λmax (nm)-520<br>Beer's law-2.5-15µg/ml<br>Slope-0.0997<br>Intercept- 0.3624<br>$r^2$-0.9993<br>%RSD-0.88 |
| 3 | Krishna R. Guptha 2010[3] | Pelagia Research Library | Validated spectrophotometric determination of Fenofibrate in formulation | Solvent-Methanol<br>λmax (nm)-287.5<br>Linearity-10-60 µg/ml<br>$r^2$-0.9994<br>Regression Equation-<br>y = 0.044x + 0.05 |
| 4 | Sharma S 2012[4] | Journal of Drug Delivery & Therapeutics | Quantitative estimation of fenofibrate in bulk drug and tablets by UV-Visible spectroscopy | Solvent-4M Sodium acetate, 1.25M sodium citrate<br>λmax (nm)-296<br>Beers range-5-35 µg/ml<br>$r^2$-0.999<br>Regression Equation-<br>Y=0.059x+0.015<br>LOD-0.126 µg/ml<br>LOQ-0.406 µg/ml<br>Linearity-1-18 µg/ml |
| 5 | M.J Krishna 2014[5] | International journal of innovative pharmaceutical sciences and research, | Development and validation of a standard addition UV spectrophotometric method for simultaneous estimation of atorvastatin and fenofibrate in bulk and pharmaceutical dosage form | Solvent-Methanol<br>λmax (nm)-245<br>Linearity-4-20 µg/ml<br>%RSD-0.316<br>%Recovery-101.12 |
| 6 | R.R. Sevda 2011[6] | International Journal of ChemTech Research | UV spectrophotometric estimation of rosuvastatin calcium and fenofibrate in bulk drug and dosage form using simultaneous equation method | Solvent- Methanol<br>λmax (nm)-286<br>Beer's Law-2-20 µg/ml<br>$r^2$-0.999<br>Slope-0.049<br>Intercept-0.002 |
| 7 | G.G Raosaheb 2020[7] | World journal of Pharmaceutical and medical research, | Validated Spectrophotometric method for simultaneous estimation of fenofibrate and atorvastatin in synthetic mixture and in bulk tablet dosage form | Solvent- Methanol<br>λmax (nm)-287<br>Beer's Law-5-30 µg/ml<br>$r^2$-0.9984<br>Slope-0.0647<br>Intercept-0.0361<br>%RSD-0.6802<br>LOD-0.3017 µg/ml<br>LOQ-0.9144 µg/ml |
| 8 | D.Nagavalli 2011[8] | International journal of Pharmaceutical sciences review and research | Simultaneous estimation of atorvastatin calcium, ezetimibe and fenofibrate in pure and combined tablet dosage form by UV spectrophotometry | Solvent- Methanol<br>λmax (nm)-287<br>Beer's Law-5-30 µg/ml<br>%RSD-0.4193<br>%label claim-99.18 |
| 9 | Bhavan Patel 2013[9] | International journal of pharma research & review | Development and validation of a derivative spectroscopic method for the simultaneous estimation of Rosuvastatin calcium and Fenofibrate in tablets | Solvent- Methanol<br>λmax (nm)-224<br>Linearity-16-48 µg/ml<br>Slope-0.00096<br>Intercept-0.00176<br>$r^2$-0.9996<br>%recovery-100.92 |

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| | | | | %RSD-0.42 |
| 10 | V. Niraimathi 2015[10] | International journal of pharma sciences and research | UV Spectrophotometric Determination of Fenofibric Acid By Using Hydrotropy | 2M Urea & 1M Sodium citrate used as solubilizing agent.<br>λmax (nm)- 299<br>Beer's law limit-5-30 µg/ml<br>$r^2$-0.9996<br>%recovery-99.30-100.99 |
| 11 | Apeksha Funde 2020[11] | International journal of Chemistry research | Validated stability indicating UV-spectrophotometric simultaneous estimation of rosuvastatin calcium and fenofibrate in bulk and pharmaceutical formulation | Solvent- Methanol, NaOH, HCl , 30%$H_2O_2$<br>λmax (nm)-287<br>concentration range- 4-24 µg/ml<br>$r^2$-0.999<br>Intercept-0.053<br>Slope-0.054<br>%RSD-0.314<br>%RSD(interday)-0.05 µg/ml<br>%RSD(intraday)-0.03 µg/ml |
| 12 | Geetha Rajput 2021[12] | Pharmaspire | Simultaneous estimation of simvastatin and fenofibrate from their combined dosage form by ultraviolet-visible spectroscopy using the simultaneous equation method | Solvent- Methanol<br>λmax (nm)-287<br>Beer's law limit- 4.35-26.10 µg/ml<br>$r^2$-0.9984<br>slope-0.0239<br>intercept-0.0126<br>LOD-1.19 µg/ml<br>LOQ-3.16 µg/ml |
| 13 | Shaikh Nasima Khatun 2020[13] | World journal of pharmaceutical sciences | Estimation of Atorvastatin Calcium and Fenofibrate in Human Plasma by UV Spectrophotometric Method | Solvent-Methanol, Acetonitrile<br>λmax (nm)-286<br>concentrationrange-1-5 µg/ml<br>$r^2$-0.99978<br>slope- 0.00197<br>intercept- 0.00108<br>%recovery- 100.2-100.4%<br>%RSD-less than 2 |
| 14 | Narender 2024[14] | Asian journal of pharmaceutical research and development | Development and Validation of Fenofibrate in Bulk and Tablets using UV-Spectroscopy: An Anti-Hypercholesterolemic Agent | Solvent- DMF<br>λmax (nm)-290<br>$r^2$-0.999<br>LOD-0.243 µg/ml<br>LOQ-0.738 µg/ml<br>%RSD(interday)-0.284<br>%RSD(intraday)-0.07 |
| 15 | Ramesh Jet al, 2013[15] | Annals of Pharma Research | Method development and validation for the estimation of ranolazine in bulk and in pharmaceutical dosage form by UV-Spectrophotometry | Solvent- Methanol, Water<br>λmax -263nm, 282nm<br>Linearity-10-35 mcg/ml<br>Correlation coefficient-0.9992<br>LOD-0.0072µg/ml<br>LOQ-0.021µg/ml |
| 16 | Noon A. A. Kamilet al, 2022[16] | Hacettepe University Journal of the Faculty of Pharmacy | Derivative Spectrophotometric Methods for the Analysis and Stability Studies of Ranolazine in Bulk and Dosage Forms | Solvent- Methanol<br>λmax -283nm, 278nm<br>LOD- 24.0,17.8 µg/ml<br>LOQ- 73.0,53.6 µg/ml |
| 17 | Jayprakash B. Ugale et al, 2015[17] | World Journal of Pharmaceutical Research | Development and validation of UV-Spectrophotometric area under curve method for quantitative estimation of ranolazine in API and tablet formulation | Solvent- Methanol, Water<br>λmax -261 to 281 nm<br>Linearity-75-200µg/ml.<br>LOD- 10.77 µg/ml<br>LOQ- 32.63 µg/ml<br>$r^2$- 0.998 |

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| 18 | Patil Shubham Pet al, 2018[18] | American Journal of PharmTech Research | Development and Validation of UV Spectroscopic Method for Estimation of Ranolazine in Tablet Dosage Form | Solvent- Methanol<br>λmax-235 nm<br>Linearity-2-12 µg/ml<br>Correlation coefficient-0.999<br>Melting point- 120-122˚C |
| 19 | Ashish Sharmaet al, 2010[19] | International Journal of Chem Tech Research | Development and Validation of UV Spectrophotometric Method for the Estimation of Ranolazine in Bulk Drug and Pharmaceutical Formulation | Solvent- Methanol<br>λmax-272 nm<br>Linearity-10-100 µg / ml<br>LOD- 0.27µg / ml<br>LOQ- 0.82µg / ml |
| 20 | Ramanaiah Ganjiet al, 2012[20] | American Journal of Pharm Tech Research | Development and Validation of UV Spectroscopy method for Estimation of Ranalozine in bulk and its Pharmaceutical Formulation | Solvent- Methanol, distilled water, Acetonitrile<br>λmax -230nm<br>Linearity-12-40µg/ml<br>Correlation coefficient-0.999<br>%Recovery-100.2% |
| 21 | DVS Roopa Sirisha Doppaet al, 2019[21] | Research Journal of Pharmacy and Technology | Development and Validation of UV Spectroscopic Method for the Determination of Ranolazine in Bulk and Formulation | Solvent- Methanol, distilled water, orthophosphoric acid<br>λ-max- 271nm<br>Linearity-10-100µg/ml<br>LOD-0.807 µg/ml<br>LOQ-2.4460µg/ml<br>Correlation coefficient-0.999<br>%Recovery-97.25-97.75% |
| 22 | Vishakha D. Patel et al, 2016[22] | Asian Journal of Pharmaceutical Analysis | Second Derivative Spectroscopic Method for Simultaneous estimation<br>of Amiodarone Hydrochloride and Ranolazine in synthetic mixture | Solvent- Synthetic mixture<br>λmax - 249 nm<br>Linearity- 10-200 µg/ml<br>LOD-0.271µg/ml<br>LOQ-0.823µg/ml<br>Correlation coefficient-0.9996 |
| 23 | Vishal Rathod et al, 2023[23] | Journal of Emerging Technologies and Innovative Research | Development and validation of indicating instrumental method for estimation of ranolazine in bulk and tablet dosage form | Solvent- Methanol<br>λmax-274nm<br>Linearity- 10-60 µg/ml<br>LOD-0.68µg/ml<br>LOQ-2.15µg/ml<br>Correlation coefficient-0.999 |
| 24 | Magesh AR et al, 2021[24] | DerPharmaChemica | Development of Visible Spectrophotometric Methods for the Determination | Solvent- Methanol<br>λmax-432nm<br>Linearity range-25-125µg/ml<br>LOD - 0.81 µg/ml<br>LOQ- 2.23 µg/ml<br>Correlation coefficient-0.9996 |
| 25 | Krupa Vyas et al, 2022[25] | Journal of Drug Delivery & Therapeutics | Development of a UV visible spectrophotometric method for simultaneous estimation of Ranolazine and Metoprolol | Solvent- 0.1N HCl<br>λmax- 272nm<br>Linearity range-7.5-37.5ppm<br>LOD- 0.17069ppm<br>LOQ- 0.51724ppm |
| 26 | Jitesha Patel et al, 2020[26] | The Pharma Innovation Journal | Novel UV-spectrophotometric & RP-HPLC method development and validation of simultaneous estimation of ranolazine and metformin HCL: A statistical analysis | Solvent- Methanol<br>λmax-237nm<br>LOD- 0.09 µg/mL<br>LOQ- 0.28 µg/mL<br>Accuracy- 98.41% to 100.02%<br>Correlation coefficient-0.989 |
| 27 | Rakesh Kumar Singh et al, 2011[27] | International Journal of Pharmaceutical Sciences and Research | Nanodrop spectrophotometric method development and validation for estimation of ranolazine in their bulk | Solvent- Distilled water<br>λmax-272nm<br>Correlation coefficient-0.9995<br>Linearity-12.5-2000ppm<br>% RSD less than 2 |

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| 28 | Naveen Kumar GS et al, 2014[28] | Unique Research Journal of Chemistry | Spectrophotometric Method For The Estimation Of Ranolazine In Bulk And Pharmaceutical Formulations | Solvent- Distilled water<br>λmax- 447nm<br>Correlation coefficient-0.9997<br>Linearity range- 5-25µg/ml |
| 29 | Rahul H. Khiste et al, 2019[29] | International Journal of Pharmaceutical & Biological Archives | Simultaneous Equation and Area Under the Curve Spectrophotometric Methods for Estimation of Ranolazine Hydrochloride Presence of its Base-induced Degradation Product: A Comparative Study | Solvent- Methanol<br>λmax- 249nm, 272nm<br>Linearity range- 5-30µg/ml<br>LOD- 0.246µg/ml, 0.358µg/ml<br>LOQ- 0.9256µg/ml, 0.974µg/ml |
| 30 | V. Shirisha et al.2018[30] | International Journal of pharmacy and Analytical Research | Analytical Method Development and validation of pantoprazole in tablet dosage form by using UV Spectroscopic method as per ICH Guidelines | Solvent- Water<br>λ max-290nm<br>%recovery 92-102%<br>LOD - 0.1583(µg/ml)<br>LOQ - 0.3333(µg/ml)<br>Linearity range-10-60(µg/ml)<br>Correlation Coefficient NLT-0.999<br>Robustness- 0.174<br>Precision - 0.055<br>Intermediate Precision-0.14 |
| 31 | Shamkant S. Patil et al. 2008[31] | International Journal of Chemical Sciences | Spectrophotometric Estimation of pantoprazole in tablet dosage form | Solvent- Methanol<br>λmax - 290, 282, 286-296nm<br>Beers-Lambert's range (µg/mL) 5-35 10-100 5-40<br>Coefficient of correlation - 0.999934, 0.999973, 0.99996<br>LOD- 0.15,0.35,0.1<br>LOQ- 0.45,1.05,0.30 |
| 32 | P. Ravi Kumar et al. 2006[32] | E-Journal of Chemistry | Simultaneous Estimation of Domperidone and Pantoprazole in Solid Dosage Form by UV Spectrophotometry | Solvent- Methanol<br>λ max-216nm, 287nm, 290nm<br>Linearity- 0-50 mcg/mL |
| 33 | B. Shrestha et al. 2019[33] | Research of Journal of Life Sciences, Bioinformatics, Pharmaceutical Sciences | A Novel Difference Spectrophotometric Method or the determination of Pantoprazole in tablet Dosage form | Solvent- Methanol<br>λ max-284nm,295nm<br>Linearity- 5-50 µg/mL<br>Accuracy- 98.3-102.4% |
| 34 | Rajnish Kumar et al. 2011[34] | Journal of Chemical and Pharmaceutical Research | Development of UV Spectrophotometric method for estimation of Pantoprazole in pharmaceutical dosage forms | Solvent-Water<br>λ max - 292nm<br>Beer's law limit- 5-70 µg /mL<br>Molar absorptivity, L $mol^{-1}$ $cm^{-1}$ 1.52x104<br>Regression equation<br>Slope (m) 0.399<br>Intercept (c) 0.01547<br>Correlation coefficient 0.9998 |
| 35 | Basavaiah et al. 2009[35] | Iranian Journal of chemical and Engineering | Spectrophotometric Determination of Pantoprazole Sodium in pharmaceuticals using N- Bromo succinimide Methyl Orange and Indigo Carmine as Reagents | Solvent- Water<br>λ max- 520-610nm<br>Beer's law limits, µg mL-1 0.1 - 2.0, 0.5 - 6.0<br>Sandell sensitivity, µg $cm^{-2}$ 0.003 - 0.01<br>LOD - 0.02- 0.06µg/ml<br>LOQ - 0.07 -0.19 µg/ml |
| 36 | Gaur A et al. 2018[36] | International Journal of Pharmaceutical Quality Assurance | Development and Validation of UV Spectroscopic Method for Simultaneous Estimation of | Solvent- Distilled water<br>λmax-289 nm, 267.2 nm |

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| | | | Pantoprazole and Cinitapride in Bulk and in Capsule Dosage Form | Beer's law Concentration 13-65µg/ml and 1-5 µg/ml<br>Accuracy- 101.32 %,98.9 %<br>Accuracy (% Recovery) 100.153 99.25<br>Repeatability (% RSD) 1.417 1.003<br>Intraday analysis (% RSD) 0.360 0.243<br>Intraday analysis (% RSD) 0.305 0.300<br>LOD (µg/ml) - 0.0820 0.1092<br>LOQ (µg/ml) - 0.247 0.331 |
| 37 | Kaveri Chandrakant Dulange et al. 2019[37] | Asian Journal of Pharmaceutical Analysis and Medicinal Chemistry | Development and Validation of UV Spectrophotometric Method for Simultaneous Estimation of Domperidone and Pantoprazole Sodium in bulk and pharmaceutical dosage form | Solvent- Methanol<br>λmax -288nm,291nm<br>Beer's Law limit - 5-25 µg/ml, 5-25 µg/ml<br>LOD (µg/ml)- 0.045, 0.01<br>LOQ (µg/ml)- 0.122 0.059<br>Robustness (%RSD)- 0.13, 0.191<br>Ruggedness(%RSD)- 0.137, 0.1<br>Accuracy - 99-100%, 98-99% |
| 38 | Barri Swathi et al. 2019[38] | Indo American Journal of Pharmaceutical Research | Development and validation of new Analytical method for the Simultaneous Estimation Pantoprazole and Domperidone by UV Spectrophotometry | Solvent- Methanol<br>λmax-290nm,287nm<br>Linearity- 1-15 µg/ml, 1-50 µg/ml<br>Recovery- 99 -103% |
| 39 | Incilay Suslu et al. 2004[39] | Fabad Journal of Pharmaceutical Sciences | Determination of pantoprazole in tablet dosage forms by two different spectrophotometric methods | Solvent- Methanol<br>λmax-295-305nm<br>Correlation coefficient (r) 0.999 0.999<br>LOQ- 2.31 0.5 µg/ml<br>LOD- 0.69 0.15 µg/ml<br>Linearity range (µg mL-1) 2.50 - 80.00 ,0.5 – 70 |
| 40 | Nejal M. Bhatt et al. 2014[40] | The Scientific World Journal | Manipulating Ratio Spectra for the Spectrophotometric Analysis of Diclofenac Sodium and Pantoprazole Sodium in Laboratory Mixtures and Tablet Formulation | Solvent- Methanol<br>λmax-251-318<br>Linearity- 2.0–24.0 µg/mL, 2.0–20.0 µg/mL<br>Accuracy-99.25%<br>Precision-101.05% |
| 41 | Dimal A. Shah et al.2013[41] | Hindawi Publishing Corporation | Simultaneous Estimation of Pantoprazole Sodium and Levosulpiride in Capsule Dosage Form by Simultaneous Equation Spectrophotometric Method | Solvent- Methanol<br>λmax- 290 ,232 nm<br>Linearity- 4–12 µg/mL, 8–20 µg/mL<br>% recovery-100.23–100.99%,100.51–100.94%<br>Robustness 98.45–100.48% 99.12–100.65% |
| 42 | Jigar Pandya et al.2012[42] | Journal of Pharmaceutical Science and Bioscientific Research | Development and Validation of Differential Spectrophotometric method for Determination of Pantoprazole in Tablet Dosage Form | Solvent- Water<br>λmax- 296 ,319 nm<br>Linearity- 5-25 µg/ml<br>Precision (RSD)%- 0.5-0.9<br>LOD- 0.0954<br>LOQ 0.2891<br>Correlation Coefficient- 0.997<br>% Recovery- 99.06% |

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| 43 | Suresha D. N et.al. 2002[43] | European Journal of Pharmaceutical and Medical Research | A Novel Method Development and Validation of Pantoprazole in Pure and Capsule Dosage Forms by using UV- Spectrophotometric Method | Solvent- 0.1N NaOH<br>λmax- 288- 298nm<br>Linearity- 3-18 µg/ml<br>correlation coefficient- 0.9999<br>regression equation- Y=0.031x+0.0025<br>Sandell's Sensitivity 0.0023<br>%Recovery - 99.29% - 99.92% |
| 44 | Smita Mujbaile et al.2012[44] | IOSR Journal of Pharmacy and Biological Sciences | Simultaneous Estimation of Ondansetron and Pantoprazole in Solid Dosage Form by First Derivative Spectroscopy Method | Solvent- Water<br>λmax- 288.5- 310 nm<br>concentration range-0.5-2.5ug/ml, 5-25ug/ml<br>Regression equation- y=0.001x-0.0011, y=0.0118x+0.0117. |
| 45 | Abdel-Aziz M. Wahbi et al. 2002[45] | Journal of Pharmaceutical and Biomedical Analysis | Spectrophotometric determination of omeprazole, lansoprazole and pantoprazole in pharmaceutical formulations | Solvent- NaOH<br>λmax- 306.2, 292.4, 295.4nm<br>Linearity-0.5 / 3.5 mg/ml $^{-1}$<br>Repeatability-0.3-0.5% |

## CONCLUSION

Spectrophotometric methods are being used for the analysis of fenofibrate in single and combined formulations. The majority of the techniques use UV absorbance detection because it provides the highest levels of precision, reliability, and simplicity. Additionally, it is a rapid and robust quantitative analytical method.

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