A LOW-COST MULTIPARAMETRIC PAPER BASED DEVICE FOR SCREENING COUNTERFEIT GASTRIC TABLETS

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Introduction:

Counterfeit medicines pose a serious global public health challenge, particularly in low- and middle-income countries where nearly 10% of medicines are estimated to be falsified. Gastric tablets such as Pantoprazole, Domperidone, and Omeprazole are widely consumed for treating acidity and related disorders, making them highly vulnerable to counterfeiting. Conventional detection techniques like High Performance Liquid Chromatography (HPLC), Mass Spectrometry, and Nuclear Magnetic Resonance (NMR) are highly accurate but require sophisticated infrastructure, trained personnel, and are time-consuming.

To address these limitations, paper-based analytical devices (PADs) have emerged as a promising alternative due to their low cost, portability, and ease of use. These devices enable rapid, on-site detection through simple colorimetric reactions without the need for advanced instrumentation. However, current PADs are limited to single-parameter detection and are not widely applied for gastric medicines.

This project aims to develop a novel multiparametric PAD capable of simultaneously detecting multiple active pharmaceutical ingredients (APIs) and excipients such as lactose. The device is designed for rapid screening of counterfeit gastric tablets, especially in resource-limited settings, thereby contributing to improved drug safety and public health monitoring.

Objectives:

1. To develop a low-cost and portable paper-based analytical device for detecting counterfeit gastric tablets.
2. To establish a multiparametric detection system for identifying APIs such as pantoprazole, Domperidone, and omeprazole.
3. To optimize colorimetric reactions for rapid and visible detection.
4. To evaluate the device for field applicability, ease of use, and cost-effectiveness.

Methodology:

The project involves the development of a multiparametric PAD using colorimetric detection techniques. Initially, suitable reagents are selected and optimized for each API.

1. **Determination of pantoprazole:**

Pure pantoprazole tablet was taken and crushed until fine powder was obtained using mortar and pestle, from that 100mg of it was weighed and dissolved in 100ml distilled water in a volumetric flask, and filtered using Whatman filter paper. Different aliquots of this sample from 1-5ml were taken into different tubes along with a blank tube and made up with water. To these tubes 2ml of phosphoric acid and 1ml of KMnO4 were added and incubated for 15 minutes for the reaction to complete. Then the absorbance was observed at 400nm. (Syed *et al.*, 2008)

2. **Determination of Omeprazole**

Pure Omeprazole tablet was taken and crushed until fine powder was obtained using mortar and pestle, from that 100mg of it was weighed and dissolved in 10ml of methanol and mad upto 100 ml with distilled water in a volumetric flask, and filtered using Whatman filter paper. Different aliquots of this sample from 0.5-2.5ml were taken into different tubes along with a blank tube and made up with water. To all these tubes 3ml of Ferric Chloride and 3ml of Potassium ferricyanide were added and incubated for 15 minutes for the reaction to complete. Then the absorbance was observed at 575nm. (Moreno *et al.*, 2009)

3. **Fabrication of Paper based analytical device (PAD)**

Grade 1 Whatman filter paper was used for the paper fabrication and was cut into small squares. To this 1mL of 0.002M KMnO4 was coated kept for drying at dark condition. After it was dried in blank square 1mL of phosphoric acid was added, whereas for sample 1mL of 1mg/mL sample was added along with phosphoric acid and incubated for 15 minutes. (Jafari *et al.*, 2025)

Results:

1. **Determination of pantoprazole:**

Pantoprazole contains difluromethoxy-substituted pyridine ring linked by a sulfinyl group that acts as electron donors in presence of strong oxidizing agent like KMnO4, so during acidic condition these sulfur groups get protonated making it more reactive to transfer of manganese ion, which reduces the permanganate and causes the color change.

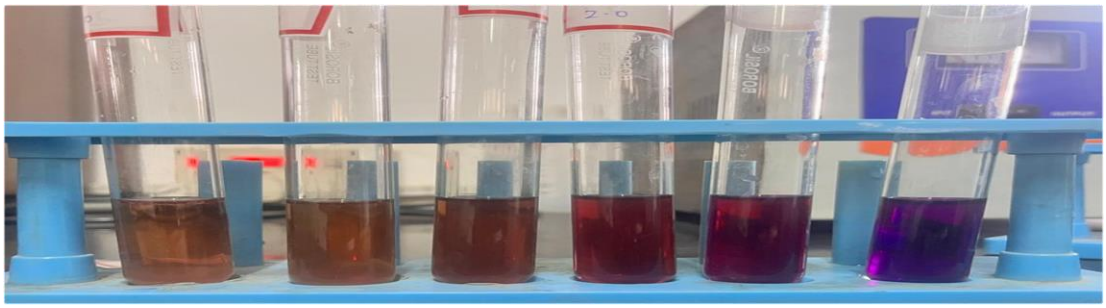


Figure 1: Right to left: Colorimetric reaction of pantoprazole with $KMnO_4$ under acidic conditions showing decrease in purple color intensity from blank to 1.0 mg/mL.

SL No	Concentration (mg/ml)	Mean Absorbance	SD	RSD%	Concentration found (mg/Ml)
B	0	0	0	0	0
1	0.2	0.14333	0.00577	4.025675	0.21806
2	0.4	0.27333	0.00577	2.111001	0.41584
3	0.6	0.41667	0.00577	1.384789	0.63391
4	0.8	0.51	0.01	1.960784	0.7759
5	1	0.65	0.01	1.538462	0.98889

Figure 2: Calibration curve of pantoprazole where X axis is concentration (mg/mL) and Y axis is absorbance using $KMnO_4$ method.

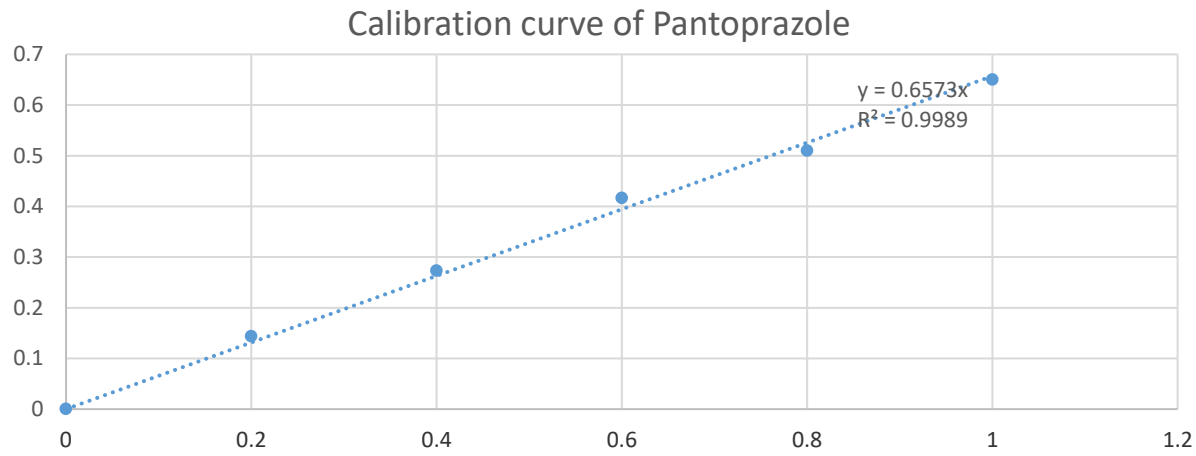
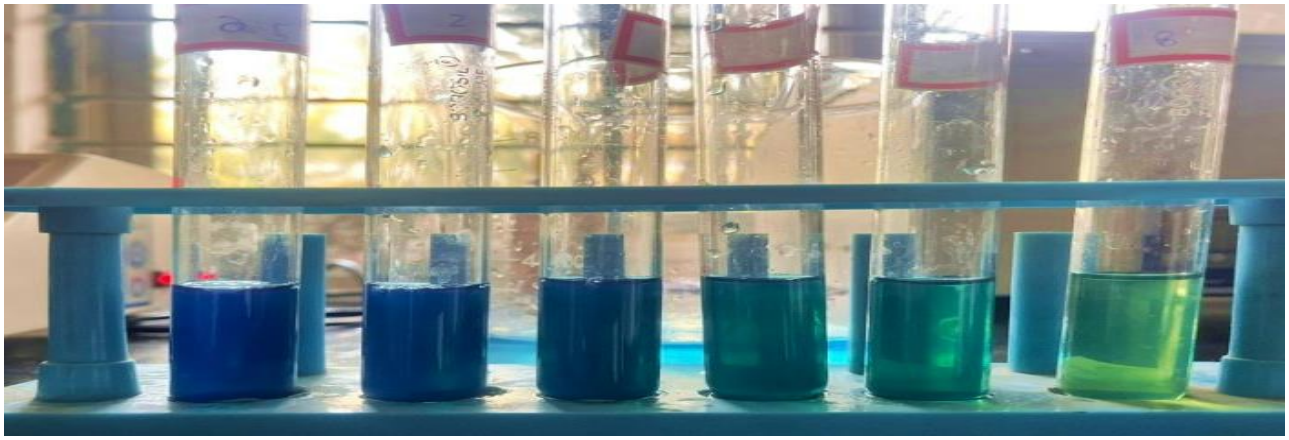


Figure 3: Right to left: Color development in omeprazole samples using Ferric Chloride and Potassium Ferricyanide showing formation of Prussian blue complex with increasing concentration from blank to 1.0 mg/mL.

2. Determination of Omeprazole:

Omeprazole contains electron-rich methoxy groups on its benzimidazole and pyridine rings which acts as reducing agent and facilitates the reduction of ferric ions to ferrous ions that reacts with potassium ferricyanide to form measurable Prussian blue color complex.

Table 1: Analytical validation data for pantoprazole using $KMnO_4$ method showing mean absorbance, standard deviation (SD), relative standard deviation (RSD%), and calculated concentration (mg/mL).



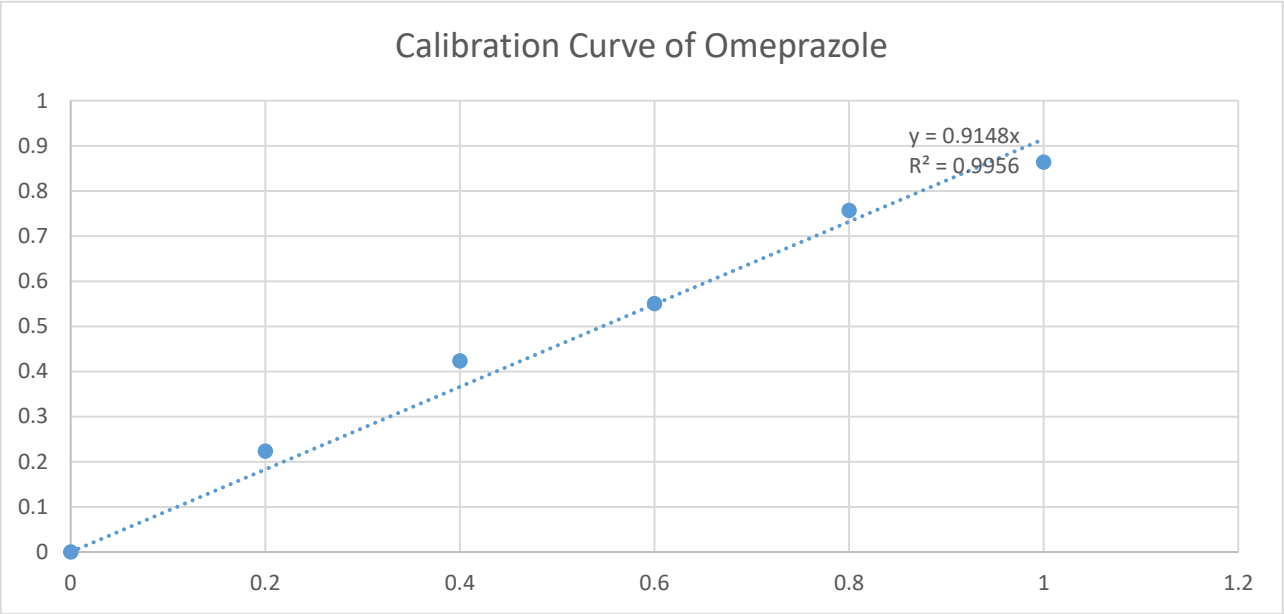


Figure 4: Calibration curve of omeprazole where X axis is concentration (mg/mL) and Y axis is absorbance using Ferric Chloride and Potassium Ferricyanide colorimetric method.

SL No	Concentration (mg/ml)	Mean	SD	RSD%	Concentration found (mg/mL)
B	0	0	0	0	0
0.5	0.2	0.22333	0.00577	2.58515	0.244267
1	0.4	0.42333	0.05277	1.36382	0.463014
1.5	0.6	0.55	0.01	1.818182	0.601553
2	0.8	0.75667	0.00577	0.763018	0.827591
2.5	1	0.8633	0.01528	1.769334	0.944256

Table 2: Analytical validation data for omeprazole using Ferric Chloride and Potassium Ferricyanide colorimetric method showing mean absorbance, standard deviation (SD), relative standard deviation (RSD%), and calculated concentration (mg/mL).

3. Fabrication of Paper based analytical device (PAD):

Whatman filter paper has cellulose and when it reacts with KMnO4 and forms MnO2 (Manganese dioxide) which has brown color, but when it is kept for long term in dark condition it becomes colorless due to deposition of Mn(II). Upon adding the sample and phosphoric acid, a selective redox-complexation occurs, where Pantoprazole triggers the formation of a measurable brown chromogen proportional to its concentration.

Figure 5: Blank paper which is impregnated with potassium permanganate ($KMnO_4$) and dried under dark conditions. 1mLof phosphoric acid was added and incubated for 15 minutes.

Figure 6: Sample paper which is impregnated with potassium permanganate ($KMnO_4$) and dried under dark conditions. 1mLof phosphoric acid along with 1ML of 1mg/ml sample was added and

Conclusion:

In conclusion, the developed paper-based analytical device (PAD) successfully demonstrated the capability for rapid and reliable detection of pantoprazole through colorimetric analysis. The study confirmed that pantoprazole and omeprazole can be effectively identified based on their specific redox reactions, producing distinct and concentration-dependent color changes. The calibration curves and analytical validation data showed good linearity, reproducibility, and acceptable relative standard deviation, indicating the reliability of the method.

The fabrication of the PAD using Whatman filter paper proved to be simple, cost-effective, and suitable for controlled reagent interaction. The observed color transitions on the paper device validated its potential for visual as well as semi-quantitative analysis. Additionally, this method eliminates the need for sophisticated instrumentation, making it highly applicable for on-site and resource-limited settings

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Future Scope:

The future scope of this project includes:

1. The device can be upgraded into a multiparametric PAD by integrating multiple reaction zones for simultaneous detection of pantoprazole, omeprazole, and domperidone on a single paper platform.
2. Sensitivity and accuracy can be improved through smartphone-based quantitative analysis, enabling precise concentration determination and automated counterfeit detection.
3. Further studies can focus on stability and shelf-life optimization of reagent-coated paper to ensure long-term usability under different environmental conditions.
4. The system can be validated using real market samples and extended to other pharmaceutical drugs, making it a versatile and scalable tool for large-scale drug quality monitoring.