

FAST PANTOPRAZOLE MEASUREMENT IN PILLS

Dieter Trau and Raj Bairoliya, Tip Biosystems Pte Ltd, Singapore and Dawai Dost Pharmacies, India

- Photopette® enables quantitative Pantoprazole measurements in tablets within 10 min.
- Ideal for quick checks and quality control at the pharmacy or at the manufacturer.

OBJECTIVE

Here we demonstrate a method to measure the pantoprazole content in tablets within 10 minutes. There are no reagents necessary. By using the Photopette® handheld spectrophotometer [1, 2] only minimal training is required. The method is easy and fast performed in two steps 1) Calibration and 2) Measurement. The method can be performed at any location and does not require a lab.

INTRODUCTION

Pantoprazole is a medication used for the treatment of stomach ulcers, short-term treatment of erosive esophagitis due to gastroesophageal reflux disease, maintenance of healing of erosive esophagitis, and pathological hypersecretory conditions. It is available as tablet or injection. Pantoprazole is a proton pump inhibitor that decreases gastric acid secretion. It works by inactivating (H⁺/K⁺)-ATPase function in the stomach. It is available as a generic medication and on the WHO list of essential medicines [3].

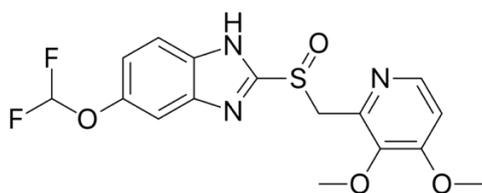


Figure 1: Structure of Pantoprazole.

Pantoprazole has very good solubility in water and an absorbance maxima at 290 nm. The drug can be quantified at its absorbance maxima or at a wavelength close to it; here we use 280 nm. We compared the spectrum from pure

pantoprazole with pantoprazole extracted from tablets; the spectrum was identical confirming that there are no interfering substances present.

MATERIALS AND APPARATUS

Instrument:

- Photopette® with 280 nm wavelength

Reagents:

- Pantoprazole standards of 20, 40 and 80 mg/L in water.

Materials:

- 1 liter measurement cylinder (plastic).
- 1 liter bottle (glass or plastic).
- Glass or metal rod (30 cm long).

METHOD

The method requires an initial calibration using the “Method Maker” in the Photopette app. This calibration only needs to be performed once; after, the created method can be called and measurements are performed on the spot. The initial calibration needs a Pantoprazole standard solution.

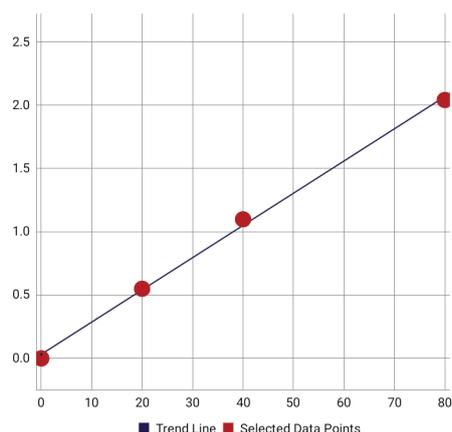
INITIAL CALIBRATION WITH THE METHOD MAKER

This process is performed in two steps. First, the Photopette’s normal measurement function is used to generate the calibration data. Second, the “Method Maker” is opened and the calibration data is loaded to create the new Method. The calibration can be performed by using a Pantoprazole standard from Tip Biosystems Pte Ltd or by using a self-prepared standard.

Self-preparation of the standard: Weight 80 mg of pantoprazole and transfer it to a 100 mL glass measurement flask. Fill up half with water, shake and dissolve the Pantoprazole. Fill up to the mark. Dilute the standard by 10, 20 and 40 fold to generate calibration solutions of 80, 40 and 20 mg/L.

Generating the calibration data: Connect the Photopette device to a smart device and open the Photopette App. Click on “Measurement type” and select 280 nm. Place a CuveTip® firmly onto the Photopette® device and insert into DI water as BLANK sample to perform auto-zero. Ensure that there is no air-bubble trapped in the CuveTip® cavity. A guide to use the CuveTip® correct is available as download [2]. Use the same CuveTip® to take 3 more measurements in the water sample (this is the 0 mg/tablet measurement). Remove any water trapped in the CuveTip cavity by touching a clean paper wipe. Take 3 measurements in the standard labeled “20 mg/tablet”, clean the tip and take 3 measurements in the standard labeled “40 and 80 mg/tablet”. This completed the data generation.

Creating a method with Method Maker: Click on “Method Maker” in the menu at the button of the app. Click on “Dataset” and load the dataset that contains the calibration data.



X-Axis	Unit (mg per tablet)
Y-Axis	Absorbance (A) (280 nm)
R Square Value	0.9982
Equation	$y = 0.0255x + 0.0295$

Figure 2: Calibration curve from “Method Maker” showing perfect linearity and large measurement range.

Click on “Unit” and chose “User-defined”, type “mg/tablet”. Click on “Calibration Type” and chose “Linear Fit”. Click “Next”. Fill in the corresponding concentrations 80, 40, 20 and 0 into the table. Click “Next”. You will now see the calibration curve on the screen including its equation and R Square value. Click on “Method Name” and name the method “Pantoprazole Measurement”. If you wish, add instructions about the method and its creator and references if any. Click “next”, this creates the new method.

Linear range

The calibration curve of Figure 2 shows a linear range up to 80 mg/tablet and a high R Square. The accuracy calculated from repeated measurements is 1 mg/tablet.

Recalibration

Recalibration is recommended every week or if the environment is changing (e.g. different temperature). Highest accuracy is achieved if the calibration is performed directly before the measurement.

DETERMINING THE PANTOPRAZOLE CONCENTRATION IN TABLETS

Sample preparation: Transfer one Pantoprazole tablet in a 1 litre bottle. Use a clean glass or metal rod to crush the tablet to a powder. Fill 1 litre clean water (DI water if available or bottled water) into the 1 litre measurement cylinder. Transfer some water from the measurement cylinder into the bottle and flush the rod. Remove the rod and transfer the rest of the water from the cylinder into the bottle. Close the bottle and gentle shake for 5 min. Let the bottle rest for 5 min to allow any particles to sediment.

Measurement: Open the Photopette App, connect to the Photopette device, click on “Measurement type” and select “Pantoprazole Measurement”. Click on “Start Measurement” and follow the instructions.

Pantoprazole Tablets	Result (mg/tablet)
Generic brand A	44
Generic brand B	45
Generic brand C	42

Table 1: Results of pantoprazole measurements in generic medicines (average of 3 repeats).

Place a CuveTip[®] firmly onto the Photopette[®] device and insert into the same water used to dissolve the tablet to perform Autozero. Measure the Pantoprazole sample prepared above by using the same CuveTip. The result is displayed in mg/tablet Pantoprazole with a resolution of 0.1 mg.

Errors

The error of the volume measurement is max 5 mL or less than 0.5% and therefore negligible. The error of the photometric measurement is smaller than 0.01 AU or about 1% at an AU corresponding to 40 mg Pantoprazole per tablet. With the same error made at the calibration, the total error of the method is smaller than 3% or about plus/minus 1 mg/tablet pantoprazole.

SUMMARY

With Photopette the concentration of pantoprazole in tablets can be measured at any location in less than 15 min. Almost no training is required. The accuracy of ± 1 mg/tablet is sufficient to test drug specifications. Photopette is ideal for quick checks, troubleshooting and quality control.

REFERENCES

- [1] Tip Biosystems Pte Ltd, "Photopette User Manual V1.0.0" Singapore, 2017.
- [2] Tip Biosystems Pte Ltd, Technical Note "How to use Photopette's CuveTip correctly".
- [3] Wikipedia; Keyword "Pantoprazole".

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