

ORIGINAL RESEARCH

**COMPARITIVE IN VITRO EVALUATION OF TWO COMMERCIALY AVAILABLE BRANDS OF PANTOPRAZOLE AND DOMPERIDONE CAPSULES.****Anupam Saha^{*}, Mayukh Jana, Ashmita Das**

Department of Pharmaceutics, Bharat Technology, Uluberia, Howrah,

Submitted on: 12.04.18; Revised on: 24.06.18; Accepted on: 05.07.18**ABSTRACT:**

Pantoprazole is a Proton Pump Inhibitor that decreases the amount of acid produced in the stomach. It is used to treat erosive esophagitis (damage to the esophagus from stomach acid), and other conditions involving excess stomach acid such as Zollinger-Ellison syndrome. Pantoprazole can be used in emergency treatment of hyper acidic condition. The present study is concerned to investigate and compare physico-chemical properties (thickness, hardness, weight variation, friability and disintegration), invitro dissolution of the drug along with drug content (assay) for different brands of tablets containing pantoprazole (40mg, 20mg) prepared by various pharmaceutical industries under different trade names.

KEY WORDS: Proton Pump Inhibitor, Drug Profile

Corresponding Author: Anupam Saha
Phone: +91-7278518763
E-Mail: sahaanupam05@gmail.com

Indian Research Journal of Pharmacy and Science; 17(2018)1500-1505;
Journal Home Page: <https://www.irjps.in>
DOI: 10.21276/irjps.2018.5.2.13

INTRODUCTION

A strong cylindrical shape in which the medication is encased in a hard or delicate dissolvable compartment, more often than not of a type of gelatin are called capsules. More precisely, a little case or holder, particularly a round or barrel shaped one which contains the medicament is known as Capsules. These are of two types ,

- Hard-shelled cases, which contain dry, powdered fixings or smaller than usual pellets made by e.g. procedures of expulsion or spherization. These are made in two parts: a littler breadth "body" that is filled and after that fixed utilizing a bigger measurement "top" ^[1].
- Soft-shelled cases, essentially utilized for oils and for dynamic fixings that are broken up or suspended in oil^[1].

Pantoprazole Sodium is chemically sodium 5-(difluoro methoxy)-2- [(3, 4-dimethoxy-2pyridyl) Methyl] sulphinyl] 1H- benzimidazole sesquihydrate 1 which has been widely used in the treatment of peptic ulcer. A wide varieties of Pantoprazole tablets are available in the market. Pantoprazole sodium comes under the class of proton pump inhibitor. ^[2]

The fundamental reason for an oral tablet is to convey a certain and characterized measure of medication to the human body through GI framework. Concentrates on bioavailability of

medications from a given report demonstrated that by and large tablets with same medication and medication content did not give a similar helpful reaction.^[3] Detailing added substances in the tablet, physical type of the medication utilized as a part of the tablet and assembling process shift from maker to producer, which is in charge of variety in the watched disintegration profile and restorative impact.

Here it's an endeavor to assess two possibly showcased tablet which are

- Pantocid DSR
- Pantosec DSR

Pantoprazole tablets are accessible in 40mg and 20mg measurements in the market. In the present investigation we are looking at 40mg and 20mg tablets of various brands accessible in the market. The physical parameters weight variety, thickness, hardness, friability, breaking down, disintegration and examine were considered amid the present investigation. Pantoprazole can be used in emergency treatment of hyper acidity, esophagitis ,etc.

MATERIALS :

Telescoping capsules are made principally of gelatin blends and may contain small amounts of certified dyes, opaquing agents, plasticizers and preservatives. Capsules have been made with methylcellulose, polyvinyl alcohols, and denatured gelatins to modify their solubility or to produce enteric effect.^[4]

Table 1: Chemicals used

CHEMICALS	MANUFACTURED BY
Pantoprazole(Drug)	Standard Pharmaceuticals Pvt. Ltd.
Hcl	Merck Specialities Pvt. Ltd.

Table 2: Instruments used

INSTRUMENTS	MANUFACTURED BY
Digital Weight Balance	Accurate Weighing Balance
Digital Dissolution Rate Test Apparatus	Test Master
Pipette	Borosil
Funnel	Borosil
Measuring Cylinder	Borosil
Volumetric Flask	Borosil
Filter Paper	Indica
Glass Rod	Borosil
Beaker	Borosil

Materials & Reagents: The Pantoprazole Capsules sample were bought from Medicine Centre Shop, Sapuipara, Belur. Both brands were obtained from that retail pharmacy. All the others facilities were obtained at Pharmaceutical Technology Lab 1, Bharat Technology College, Uluberia, Howrah.

EVALUATION PARAMETERS OF PANTOPRAZOLE CAPSULES

Empty hard capsules :

According to Japanese Pharmacopoeia, the test called 'purity' uses five capsules which are tested individually. Each is placed in a 100 ml conical flask and shaken vigorously after adding 50 ml of water 37°C throughout the test. The capsule passes the test if it completely dissolves within 10 mins giving odorless, neutral (or slightly acidic).

Weight variation :

Accurately weigh 10 capsules. By suitable means the contents of each capsules are removed. The weights of emptied shells are recorded individually. The

difference of both the weights will yield the net weight of the contents

Disintegration time :

5 capsules of each brand were taken and performed the disintegration time.

Dissolution time :

5 capsules of each brand were taken and performed in vitro dissolution test by using USP dissolution apparatus and the percentage of drug release were calculated at different time intervals. Percentage of drug release versus time was noted.

RESULT AND DISCUSSION

Pantoprazole 100 mg was dissolved in 100ml of Distilled Water. From the stock solution, with concentration ranging from 5-25 µg/ml were prepared by transferring appropriate volume of stock solution to 25 ml volumetric flask. The volume was then adjusted with 0.1N HCl. The absorbance between 296 nm was calculated. B1 here is Pantocid DSR and B2 is Pantosec DSR.

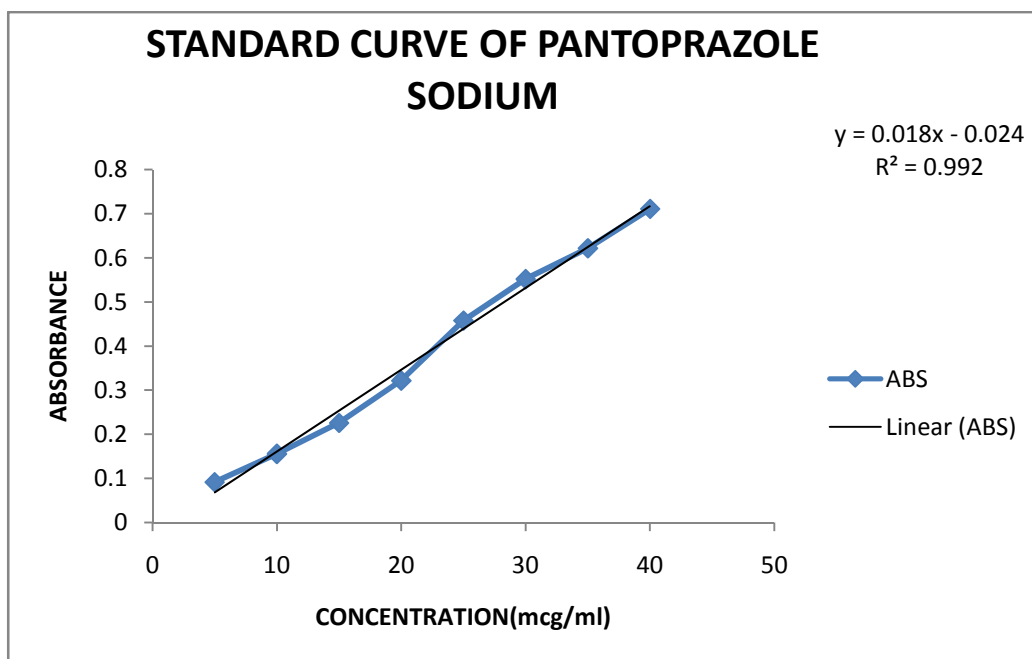


Fig 1: Standard Curve Of Pantoprazole Sodium

EVALUATION PARAMETERS OF PANTOPRAZOLE CAPSULES:**Table 3: Empty Hard Capsule , Weight Variation, Disintegration and Dissolution**

Formulation	Empty hard capsules	Weight variation	Disintegration time
B₁	7min	70.03mg – 69.98mg = 0.05mg	1min 51sec
B₂	5min	70.02mg – 69.98mg = 0.04mg	1min 22sec

In-Vitro Dissolution Profile of Pantoprazole Sublingual Tablet :**Table 4: Zero Order Release kinetics:**

Time (min)	B₁	B₂
0	0	0
10	29 ± 0.44	29 ± 0.80
20	56.3 ± 0.81	58.7 ± 0.77
30	69.25 ± 0.38	71.75 ± 0.78
40	84.95 ± 0.78	88.22 ± 0.18
50	94 ± 0.11	95.22 ± 0.21

Both the brands showed great disintegrating test, which is required for fast remedial impact. Brand 2 (B2) showed low disintegrating time contrasted with Brand 1 (B1). Both the brands of capsules breezed through the U.S.P breaking down test demonstrating that they will totally disintegrate in the digestive tract inside 1 hour 30 minutes , however no crumbling happens in the stomach.

The empty shell weighted 0.04mg (B1) and 0.03mg (B2). It could be said the net content are approximately uniform.

As indicated by USP, if the cases are uniform in weight, it is likely that the shells will be uniform in

medicate content moreover. Subsequently, USP recommends just weight variety test on the promoted containers when the medication frames the real main part of the cases. As both the brands finished the discharge hard shell test, it is presumed that every one of the tablets are uniform in medicate content moreover.

Both the Brands of Pantoprazole tablets breezed through the disintegration test as endorsed by U.S.P. Despite the fact that all brands breezed through the disintegration test as recommended by U.S.P., there was variety in Pantoprazole disintegration rate from brand to mark.

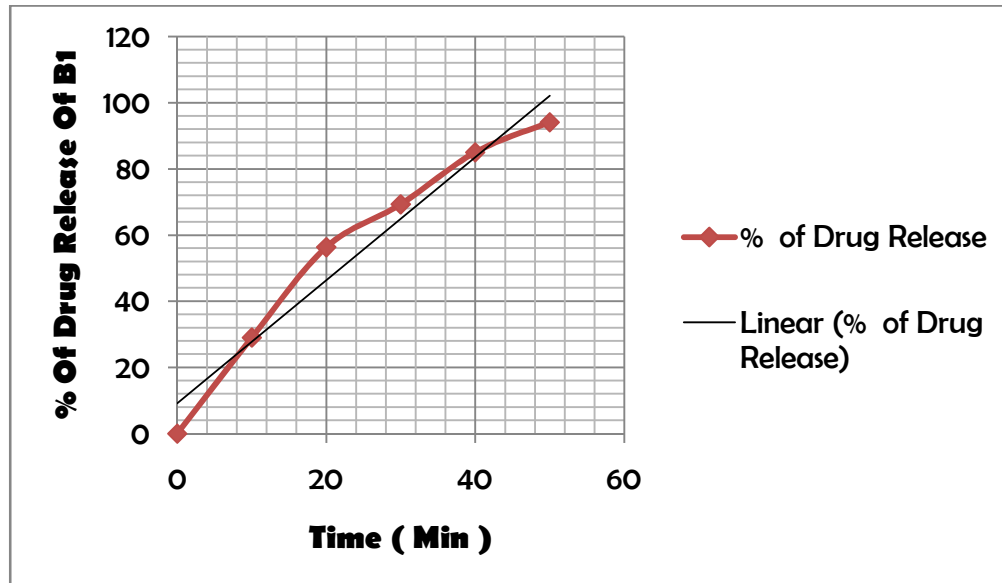


Fig 2: Zero order release kinetics of B1

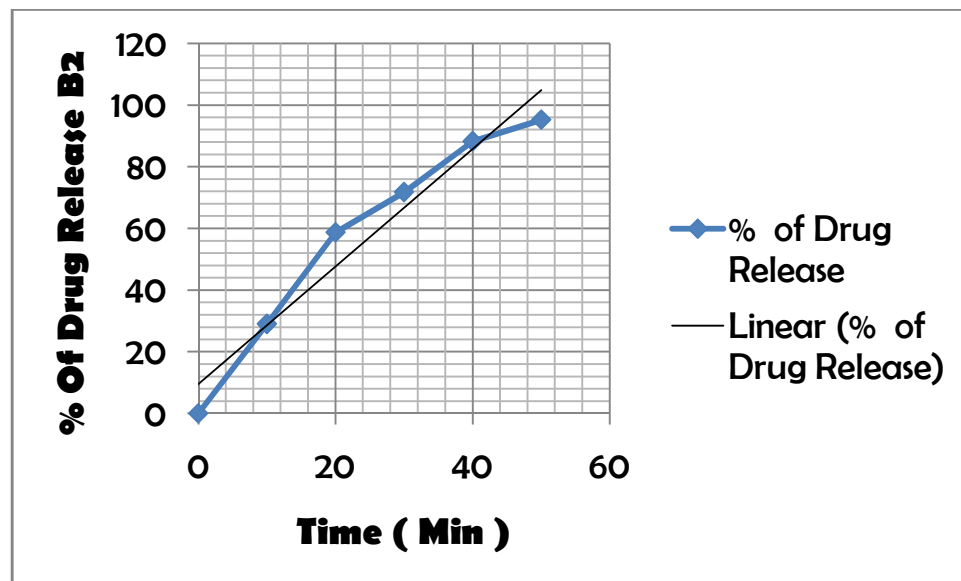


Fig 3: Zero order release kinetics of B2

CONCLUSION:

In this work, the promoted Pantoprazole capsules were chosen and subjected to assessment for discharge hard case test, weight variety, disintegration time and in vitro dissolution profile.

Pantoprazole is a Proton Pump Inhibitor that controls the amount of excessive acid produced in the stomach. It is used to treat erosive esophagitis which is the damage to the esophagus from stomach acid, and other conditions involving excess stomach acid.

such as Zollinger-Ellison syndrome.^[5] The two brands have finished all the official tests endorsed by USP. Plan added substances in the capsules, physical type of the medication utilized as a part of the capsule and assembling forms fluctuate from producer to maker which is in charge of the variety in the watched disintegration profiles.^[6] In this case study the observations recorded favors the B2. Its disintegration time is low which means fast

therapeutic effect compared to B1. The dissolution test also shows better result in B2. However the results are very close and it is hard to claim B2 is much better than B1. It is an other option to decide Pantoprazole sodium in the pharmaceutical measurements shapes that contain it as one of a kind dynamic standard with very tasteful outcomes for the particular motivations behind its outline.

REFERENCE:

1. Capsule Details - <https://en.wikipedia.org/wiki/Capsule> (pharmacy)
2. Rani T. Neelima, Kumari Ch. T. Lalitha , Reddy B. Mallikarjun , Reddy D.R. Brahma , Comparative in vitro evaluation of different commercially available brands of Pantoprazole tablets , IJPSR 2012; 3(4) : 1108- 1111.
3. Naisarg D Pujara, Ramesh B Parmar. Formulation and Evaluation of Hard Gelatin Capsule of Losartan Potassium. Inventi Rapid: Pharm Tech, 2013(2): 1-4.
4. Lachman Leon, Liberman Herbert A.The theory and practice of industrial pharmacy, ed. Speacial Indian Edition 2009 Pg– 374.
5. Protonix Details - <https://www.webmd.com/drugs/2/drug-18142/protonix-oral/details>.
6. Ramana B.V., Reddy P Venkateshwar., Triveni.C. , Chandrasekhar U. , G.Nagarajan, Murthy T.E.G.K., Formulation and in-vitro dissolution studies of Domperidone Floating tablets, World Journal Of Pharmacy And Pharmaceutical Sciences.,2013; 2(6): 5396 – 5411.

CONFLICT OF INTEREST REPORTED: NIL ;

SOURCE OF FUNDING: NIL