International Journal of Technical Innovation in Modern Engineering & Science (IJTIMES)
Impact Factor: 5.22 (SJIF-2017), e-ISSN: 2455-2585
Volume 4, Issue 08, August-2018

DISSOLUTION TEST METHOD AND HPLC ANALYSIS FOR LANSOPRAZOLE PELLETS DOSAGE FORMS

Venkanna.R[1], Srinivasarao.Tumati[2], A.Revathi[3]

[123]*Assistant Professor, Department of chemistry,*
K.G Reddy Engineering College and Technology, Hyderabad-501504.

ABSTRACT: A Simple dissolution test procedure for Lansoprazole pellets dosages has been proposed and high performance liquid chromatography analytical method was developed for the measurement of Lansoprazole Pellets dosage forms with U.V detection. The chromatographic system consisted of a Zodiac ODS 4.6mm× 150mm column, an isocratic mobile phase of 650ml phosphate buffer+350ml acetonitrile. The flow rate is 1ml /minute and effluent is tested at 286nm, The lansoprazole was eluted at about 5.681min with no interfering peak from additives used for preparation dosage form. The method was linear over the range of 10-150µg/ml lansoprazole. The dissolution test was conducted in 500ml phosphate buffer pH7.6 with paddle stirring at 100 rotation per minute (RPM).Dissolution was found to be not less than 75% in 45 minutes. The proposed method was applied successfully for the measurement of Lansoprazole content in Pellets and for vitro dissolution studies.

Key words: Dissolution test, HPLC, Lansoprazole Pellets dosage forms, RPM, Mobile phase

1. INTRODUCTION

Lansoprazole IUPAC name is "2-([3-methyl-4-(2,2,2-trifluoroethoxy) pyridine-2-yl]mehylsulfinyl)-1H-benzo[d]imidazole". It is a proton-pump inhibitor (PPI). It is the same as pharmacologic class of anti ulcerative like omeprazole. Lansoprazole has been marketed for many years and is one of many PPIs available [1]. It is a 1:1 Racemic mixture of the Enantiomers Dexlansoprazole and levolansoprazole[2]. Dexlansoprazole is an enantiomerically pure active ingredient of a commercial drug as a result of the Enantiomeric shift.

Structure

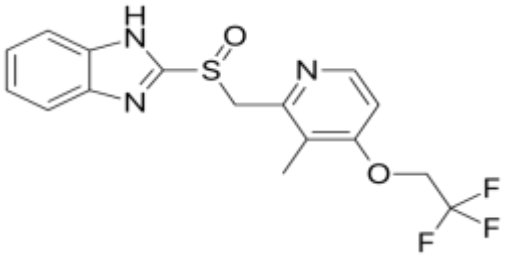

Figure1: Structure of Lansoprazole API

2. Materials and methods:

2.1. Instruments: Dissolution tester make Electro labs (India)(P) L.td, High performance liquid chromatograph shimadzu 2010 Rheodyne injector with 100µl loop ,L.C solutions computer based software is used. La

2.2 Chemicals: working standard Lansoprazole procured from M/S Metrochem, Acetonitrile, HPLC grade (make E-merck), KH_2PO_4, NaOH AR grade.

2.3 Drug release: Apparatus: USP-II (Paddle)
RPM: 100
Medium -1: 0.1N HCl (2 hours)
Medium-2: 7.6 phosphate buffer (45minutes)
Determination of the amount of lansoprazole released using the following method.

Media-: 1 8.5 ml of concentrated HCl dissolved in 1 liter of distilled water it's strength is 0.1 N HCl
Dissolution: Acid resistance: Dissolution is performed according to Paddle method with 100 RPM using 500 ml medium-1(0.1N HCl) at 37±0.5°C . Before starting the test immerse the Lansoprazole Pellets equivalent to 30 mg in to dissolution vessel, after 2 hours remove the medium without losing of any pellet, transfer the pellets in to 100 ml volumetric flask with funnel dissolved in 0.1N NaOH and make up with the same. Filter take the 5 ml of filtrate in to 50 ml volumetric flask make up with mobile phase. Take the sample in to vials for HPLC analysis.

Standard preparation for medium-1(0.1N HCl): weigh accurately about 30 mg working stand of Lansoprazole transferred in to 100ml volumetric flask dissolved in 20 ml of 0.1N NaOH solution, make up with the same up to the mark. From this take 5 ml of the solution transfer in to 50 ml volumetric flask make up with mobile phase solution .Pour the stand samples in vials (HPLC)

Medium-2:- Preparation: 6.8 grams of KH_2PO_4 +0.86 grams of NaOH dissolved in 1 liter Demineralised water adjust the pH to 7.6.

Dissolution: pH 7.6 Phosphate Buffer: Dissolution is performed according to paddle method with a 100 RPM using 500ml medium-1(0.1N HCl) at37±0.5°C. Before starting the test immerse the 30 mg equivalent Lansoprazole Pellets in to dissolution vessel. After 2 hours replace all the test solution (0.1 N HCl) immediately by 500 ml of medium-2(Phosphate Buffer pH=7.6) previously warmed to 37±0.5°C .After starting the test exact 45 minutes take the 20ml test sample , filter directly pour in to the vials(HPLC)

Standard Preparation For medium-2(7.6 pH phosphate Buffer): Weigh accurately about 30 mg working standard of Lasoprazole transferred in to 100ml Volumetric flask , dissolved in 20 ml of pH 7.6 phosphate buffer, make up with the same up to the mark. From this take 5ml transferred in to 50 ml volumetric flask make up with mobile phase .Pour the stand samples in to vials (HPLC)

Calculation for acid Resistance:

$$\frac{Sample\ area}{standard\ area} \times \frac{Std\ weight}{sample\ weight} \times \frac{std\ dilution}{sample\ dilution} \times \frac{purity}{Assay} \times 100 = \%Acid\ resistanace$$

Calculation for Buffer release:

$$\frac{Sample\ area}{standard\ area} \times \frac{Std\ weight}{sample\ weight} \times \frac{std\ dilution}{sample\ dilution} \times \frac{purity}{Assay} \times 100 = \%\ of\ drug\ release$$

HPLC conditions:

Stationery phase: C18-150mm×4.6mm zodiac column
Mobile phase: prepare filtered and degassed solutions containing phosphate buffer pH 7.6 650 ml+350 ml Acetonitrile.
Chromatographic system: The liquid chromatography is equipped with a 286nm detector and 4.6mm×150 mm –C18 Zodiac column flow rate is about 1.0 ml per minute.
Procedure: Separately inject equal volumes (about 100µl) of the standard solution and test solution in to chromatograph, record the chromatograms and measure the peak responses, determine the amount of Lansoprazole dissolved.
Calibration: 100 µl of the above working standard solutions are injected at a time interval of 10 minutes, evaluation is performed with U.V detector at 286 nm. The retention time is found to be around 5.681 minutes Lansoprazole. Peak areas are recorded and the calibration graph is obtained by plotting peak area versus concentration.

3. Results and Discussion

Table 1: Dissolution results

Semi formulation	Medium	Bowl No'S	% release	Average	Limit	SD	RSD
P E L L E T S	pH 7.6 Phosphate Buffer-500ml	1 2 3 4 5 6	84.4 84.43 83.88 84.53 83.86 84.57	84.28	Not less than 75% release in 45 minutes	0.297	0.349

100µl of standard and sample solutions are injected in to an injector of liquid chromatograph .The amount of Lansoprazole calculated by comparing the peak ratio, with that of the standard.

Recovery studies: To study the linearity, accuracy and precision of proposed method, recovery experiments were carried out known quantities of standard at two different levels were added to the pre analyzed sample, the recovery was estimated to be more than 99%.

4. Conclusion: The proposed method is simple rapid and no where involves use of complicated sample preparation. High percentage of recovery shows that the method is free from interference of the excipients used in the semi formulations. Therefore method can be useful in routine quality control analysis.

5. Acknowledgement:

The authors wish to thank Principal, K.G. Reddy College of Engineering and Technology, Hyderabad for his encouragement and support. We also acknowledge the chairman of K.G Reddy College of Engineering and Technology K Krishna Reddy for financial support and providing lab space

6. References:

1. http;//www.patient.co.uk/showdoc/30002943/
2.”Pharmacy Benefit update” Retneved 2july 2014
3. ICH Guidelines
4. Dissolution test method for omeprazole pellets 8.5 %(high dissolution) optimization and Statistical analysis.Rasayana.j Vol.1,No.3(2008),618-619.
5. Dissolution profile of phenylephrine hydrochloride pellets, Journal of chemical and Pharmaceutical research, 2009, 1(1)257-260