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HPLC METHOD FOR THE ASSAY DETERMINATION OF LANSOPRAZOLE PELLETS DOSAGE FORMS

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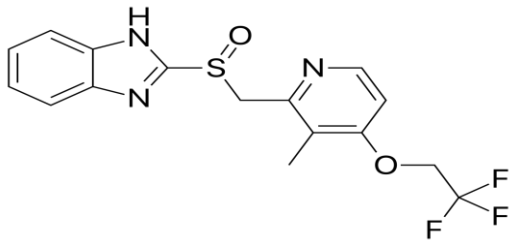
ABSTRACT
A simple and rapid High performance liquid chromate graphic method was developed for Assay determination of lansoprazole pellets dosage forms with U.V detection. The chromatographic system consisted of a Zodiac ODS 4.6mm×150mm column, an Isocratic mobile phase of 650ml phosphate buffer+350ml acetonitrile. The flow rate is 1ml/minute and effluent is monitored at 286nm.The lansoprazole was eluted at about 5.681 min with no interfering peak from excipients used for preparation of dosage form. The method was linear over the range of 10-150µg/ml lansoprazole.

KEYWORDS: High Performance Liquid Chromate Graphy, ASSAY, Isocratic, no Interfering Peak.

INTRODUCTION

Lansoprazole systematic 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) in the same pharmacologic class as omeprazole . Lansoprazole has been marketed for many years and is one of several PPIs available.[1] It is a racemic 1:1 mixture of the enantiomers Dexlansoprazole (Dexilant, formerly named Kapidex) and levo lansoprazole.[2] Dexlansoprazole is an enantiomerically pure active ingredient of a commercial drug as a result of the enantiomeric shift.

Structure of lansoprazole



Chemicals: KH_2PO_4, NaOH AR grade, Acetonitrile A.R grade.

Column: C18-150 mm× 4.6mm Zodiac.

Preparation of Buffer solution: 6.8 grams KH_2PO_4 +0.86 grams of NaOH dissolved in one liter of distilled water adjust the pH to 7.6

Mobile phase preparation: 650ml of 7.6 Buffer solution +350 ml of Aceto nitrile, make up to one liter.

Standard preparation for Assay: Accurately weighed 30 mg of working standard of lansoprazole transferred in to 100ml Volumetric flask add 20ml of 0.1N NaOH solution shake well and make up with the same up to the mark .Shake the flask for uniform concentration. From that solution take 5ml and transferred in to 50 ml volumetric flask make up with mobile phase .Pour in to the vials for HPLC analysis.

Sample solution or test solution: Take 30 mg equivalent Lansoprazole pellets transferred into 100ml volumetric flask with funnel add 20 ml 0.1 NaOH solutions, sonicate 10 to 15 minutes for dissolve, make up with the same up to the mark. Filter the solution, take 5ml of filtrate transferred in to 50 ml volumetric flask make up with mobile phase. Pour in the vials for HPLC analysis.

Chromatographic system: The liquid chromate graph is equipped with 286nm detector and 4.6mm×150 mm – Zodiac ODS column that contain 5-µm packing. The flow rate is about 1.0 ml per minute chromatograph the standard preparation and record the peak response as directed by the procedure, the relative standard deviation for replicate injection is not more than 2.0% Separately inject equal volumes (about 100 µl)of the standard solution and test solution in to the chromatograph, record

the chromatograms, and measure the responses for the major peak calculate the quantity in mg lansoprazole.

The results are tabulated as follows.

Semi formulation	S.NO	Label claim	Amount estimated %	% label claim	% deviation	S.D	RSD
Pellets	1	8.5%	8.49	99.88235	-0.11765	0.016	0.1880
	2		8.51	100.1176	0.117647		
	3		8.53	100.3529	0.352941		
	4		8.52	100.2353	0.235294		
	5		8.49	99.88235	-0.11765		
	6		8.51	100.1176	0.117647		

Calibration:100µl of the above working standard solutions are injected over a time interval of 15 minutes .Evolution is performed with U.V detector at 286nm. The retention time found to be around 5.681 minutes. Peak areas are recorded and the calibration graph is obtained by plotting peak area verses concentration,

Assay: 100 µl of standard and sample solution are injected in to an injector of liquid chromatography. 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 experiment was 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%.

System suitability test is applied to a representative chromatogram to check various parameters such as efficiency, resolution, and peak tailing. The results obtained are shown in table that is in concurrence with the USP requirements.

RESULT AND DISCUSSION

S. No	Parameters	Lansoprazole
1	Theoretical plates	7215
2	Tailing factor	1.192
3	RSD of 6 injections	0.1880

Linearity: The linearity of lansoprazole is established by plotting agraph of peak area of standard solutions versus concentration. The linearity is found to be between 10-150µg/ml.

Chromatography: The mobile phase of a mixture of 650 ml pH 7.6 buffer +350 ml acetonitrile found to be ideal for analysis of lansoprazole. The concentration of Lansoprazole found to be within limits and RSD values are reasonably low.

The precision of method is studied by making 5 injections of standard and very low RSD values indicating good precision.

The reproducibility and reliability of the method has been tested by performing recovery studies which showed good results.

CONCLUSION

The proposed method is very 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.