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Research Article

A new RP -HPLC method development and validation for simultaneous estimation of aspirin and omeprazole in bulk and pharmaceutical dosage forms

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ABSTRACT

A simple, accurate, precise method was developed for the simultaneous estimation of the Aspirin and Omeprazole in Tablet dosage form. Chromatogram was run through Discovery 250 x 4.6 mm, 5 μ . Mobile phase containing Buffer and Acetonitrile in the ratio of 70:30 v/v was pumped through column at a flow rate of 1 ml/min. Temperature was maintained at 30°C. Optimized wavelength for Aspirin and Omeprazole was 241 nm. Retention time of Aspirin and Omeprazole were found to be 2.454 min and 3.168 min %RSD of the Aspirin and Omeprazole were and found to be 1.1 and 0.8 respectively. Percentage recovery was obtained as 99.50% and 99.57% for Aspirin and Omeprazole. LOD, LOQ values were obtained from regression equations of Aspirin and Omeprazole were 0.26ppm, 0.80ppm and 0.06ppm, 0.17ppm respectively. Regression equation of Aspirin is $y = 3524x + 3853$, and of Omeprazole is $y = 10438x + 542.2$.

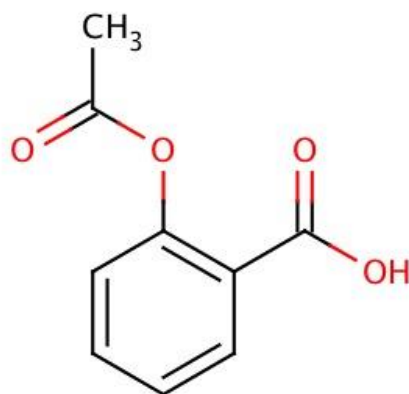
Keywords: Aspirin, Omeprazole, RP-HPLC

INTRODUCTION

Now a days combined dosage forms are mostly preferred when compared to single dosage forms. Aspirin and omeprazole are available in bulk and combined pharmaceutical dosage form The brand name is yosprala⁽¹⁾ used in the treatment of cardiovascular and cerebrovascular events, gastric

ulcers [1]. Literature survey reveals that various analytical methods have been reported for single dosage forms .The present paper aims to report a simple, accurate, precise, RP-HPLC method for estimation of Aspirin and omeprazole in combined dosage form.

STRUCTURE OF ASPIRIN [2]

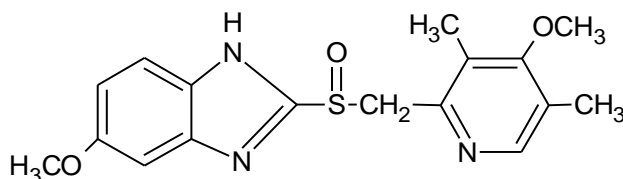


Aspirin it is a

2-(acetyloxy) benzoic acid CAS number is 50-78-2: and it is a prototypical analgesic used in the treatment of mild to moderate pain. It has anti-inflammatory and antipyretic properties it is a

Solid and it is Soluble in 100% ethanol (80mg/ml), DMSO (41mg/ml) or dimethyl formamide (30mg/ml); slightly soluble in PBS, pH 7.2 (2.7mg/ml).

Omeprazole [2]



Omeprazole it is a (RS)-5-methoxy-2-((4-methoxy-3, 5-dimethylpyridin 2-yl Methylsulfinyl)-1H-benzo[d]imidazole. It is used in the treatment of dyspepsia, peptic ulcer disease, gastroesophageal reflux disease, laryngopharyngeal reflux and Zollinger–ellison syndrome it is a white powder and Freely soluble in dichloro methane and chloroform.. Soluble in Ethanol (95%), methanol and water. It dissolves in Dilute solutions of alkali hydroxides.

Column temperature	: 30°C
Injection volume	: 10µL
Run time	: 6 min
Diluent	: Water and Acetonitrile in the ratio 50:50

MATERIALS AND METHODS

Optimised chromatographic method

Flow rate	: 1 ml/min
Column	: Discovery 250 x 4.6 mm, 5µ.
Detector wave length	: 241nm

Chemicals and Reagents

Materials

Aspirin and Omeprazole, Combination of Aspirin and Omeprazole tablet dosage forms, distilled water, acetonitrile, phosphate buffer, ammonium acetate buffer, glacial acetic acid, methanol, potassium dihydrogen phosphate buffer, tetra hydrofuran, tri ethyl amine, ortho-phosphoric acid etc.

Instrument

HPLC instrument used was of WATERS HPLC 2965 SYSTEM with Auto Injector and PDA Detector. Software used is Empower 2. UV-VIS spectrophotometer PG Instruments T60 with special bandwidth of 2nm and 10mm and matched quartz was be used for measuring absorbance for Aspirin and Omeprazole solutions.

Diluent

Based up on the solubility of the drugs, diluent was selected, Acetonitrile and Water taken in the ratio of 50:50.v\v

Preparation of Standard stock solutions

Accurately weighed 32.5mg of Aspirin 4 mg of Omeprazole and transferred to 10ml volumetric flask. and 3/4th of diluents was added and sonicated for 10 minutes. Flasks were made up with diluents and labeled as Standard stock solution (3250µg/ml of Aspirin and 400µg/ml of Omeprazole).

Assay calculations

S. No.	Aspirin %Assay	Omeprazole %Assay
1	98.26	100.02
2	98.34	100.92
3	98.73	101.04
4	98.58	99.29
5	100.60	99.41
6	100.67	99.36
AVG	99.20	100.00
STDEV	1.13	0.80
%RSD	1.13	0.80

Retention time of aspirin is 2.454mins and for omeprazole is 3.168 mins.

RESULTS

Parameters	Aspirin	Omeprazole
Calibration range (mcg / ml)	81.3-487.5ppm	10-60ppm
Optimized wavelength	241.0nm	241.0nm
Retention time	2.454	3.168
Regression equation (Y)	y = 3524x +3853	y = 10438x+542.2
Correlation coefficient(r^2)	0.999	0.999

Preparation of Standard working solutions (100% solution)

1ml from each stock solution was pipetted out and taken into a 10ml volumetric flask and made up with diluent. (325µg/ml Aspirin of and 40µg/ml of Omeprazole).

Preparation of Sample stock solutions

5 tablets were weighed and the average weight of each tablet was calculated, then the weight equivalent to 1 tablet was transferred into a 100) ml volumetric flask, 50ml of diluents was added and sonicated for 25 min, further the volume was made up with diluent and filtered by HPLC filters (3250µg/ml of Aspirin and 400µg/ml of Omeprazole).

Preparation of Sample working solutions (100% solution)

1ml of filtered sample stock solution was transferred to 10ml volumetric flask and made up with diluent. (325µg/ml of Aspirin and 40µg/ml of Omeprazole).

Precision (% RSD*)	1.1	0.8
% Recovery	99.50	99.57
Limit of Detection ($\mu\text{g}/\text{ml}$)	0.26	0.06
Limit of Quantitation ($\mu\text{g}/\text{ml}$)	0.80	0.17

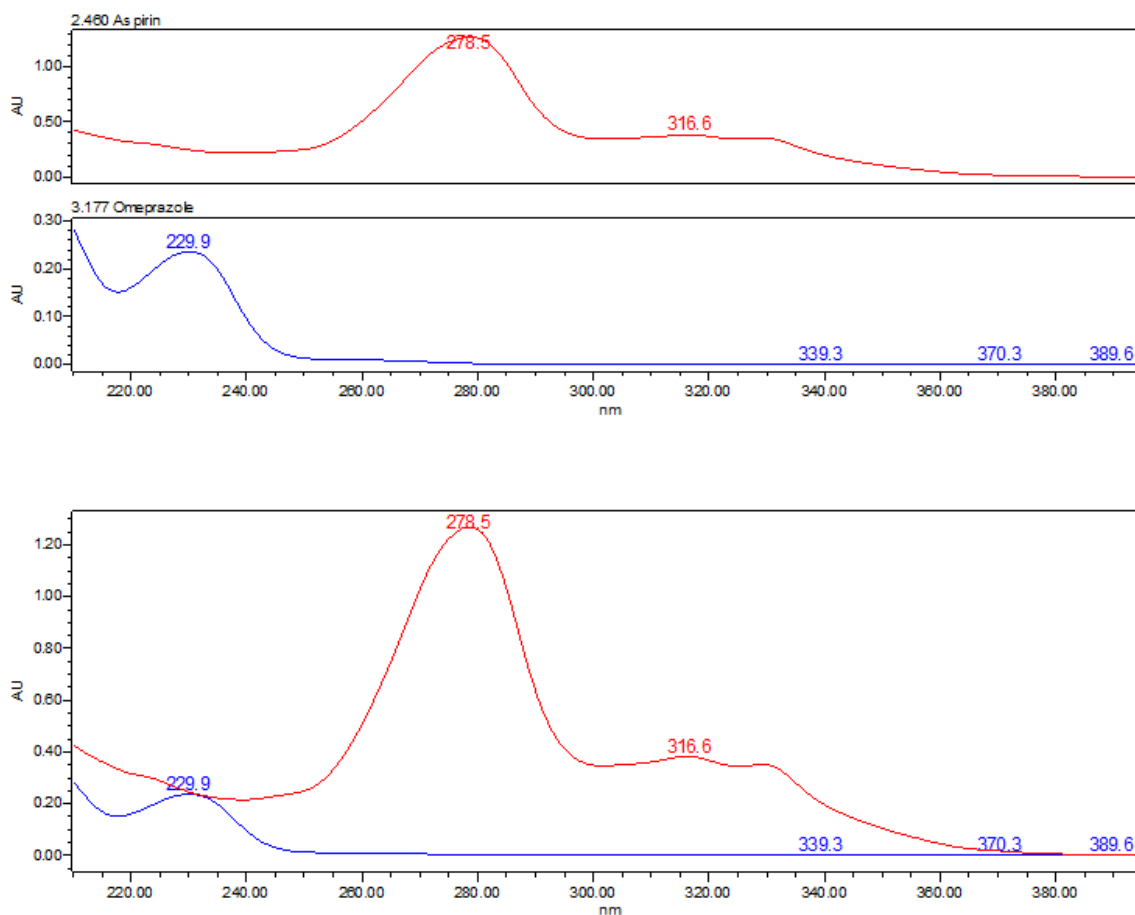
DISCUSSION

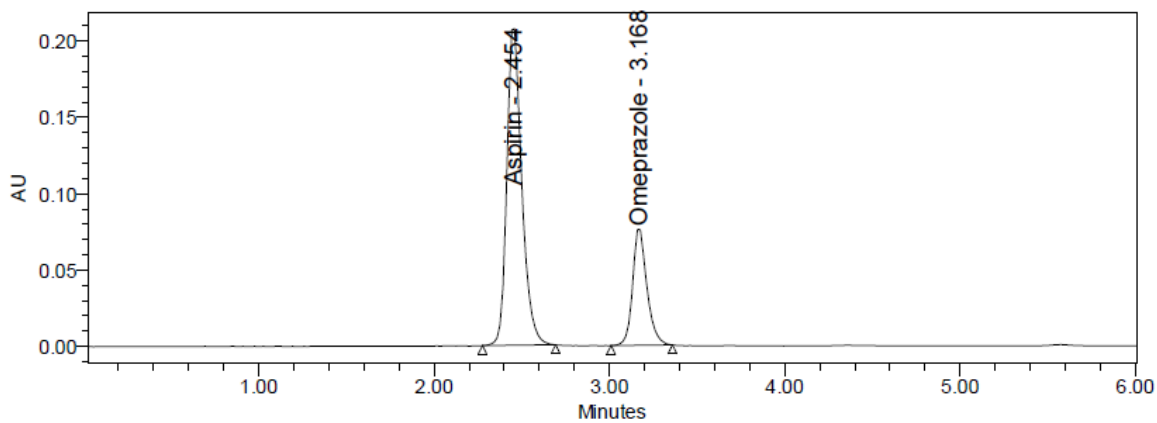
A simple, Accurate, precise method was developed for the simultaneous estimation of the Aspirin and Omeprazole in Tablet dosage form. Retention time of Aspirin and Omeprazole were found to be 2.454 min and 3.168 min. %RSD of the Aspirin and Omeprazole were and found to be 1.1 and 0.8 respectively. %Recover was Obtained as 99.50% and 99.57% for Aspirin and Omeprazole.

LOD, LOQ values were obtained from regression equations of Aspirin and Omeprazole were 0.26ppm, 0.80ppm and 0.06ppm, 0.17ppm respectively. Regression equation of Aspirin is $y = 3524x + 3853$, and of Omeprazole is $y = 10438x + 542.2$. Retention times are decreased and that run time was decreased so the method developed was simple and economical that can be adopted in regular Quality control test in Industries.

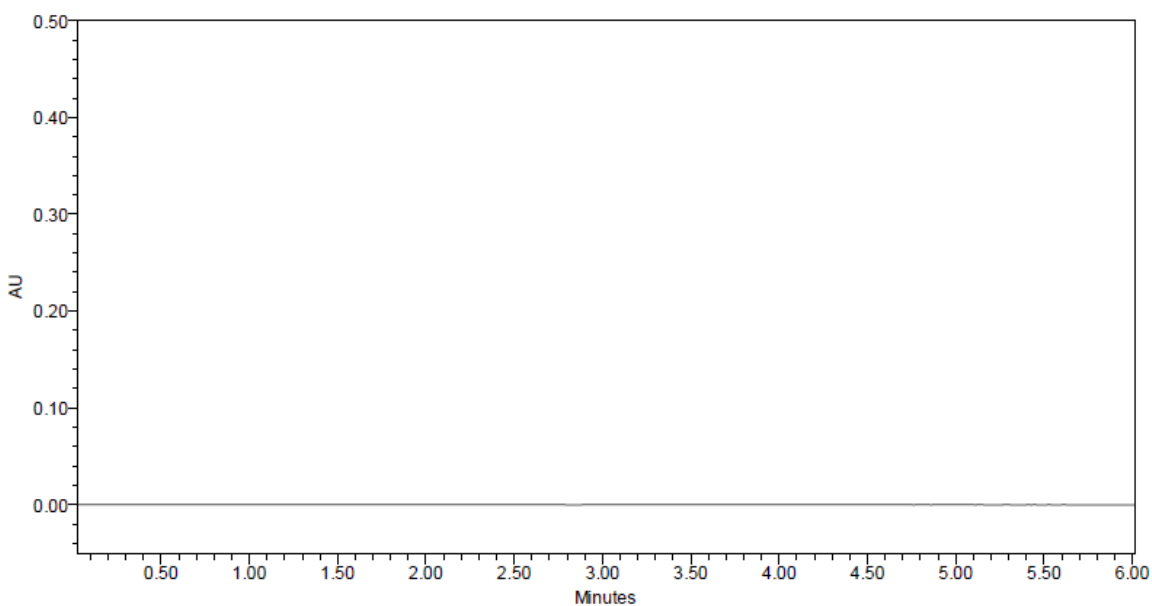
TABLES /FIGURES

Overlay spectrum

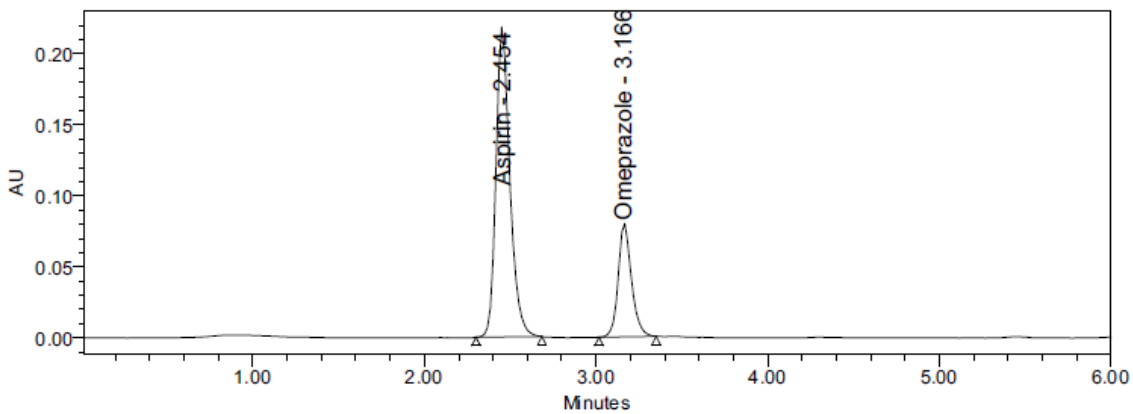




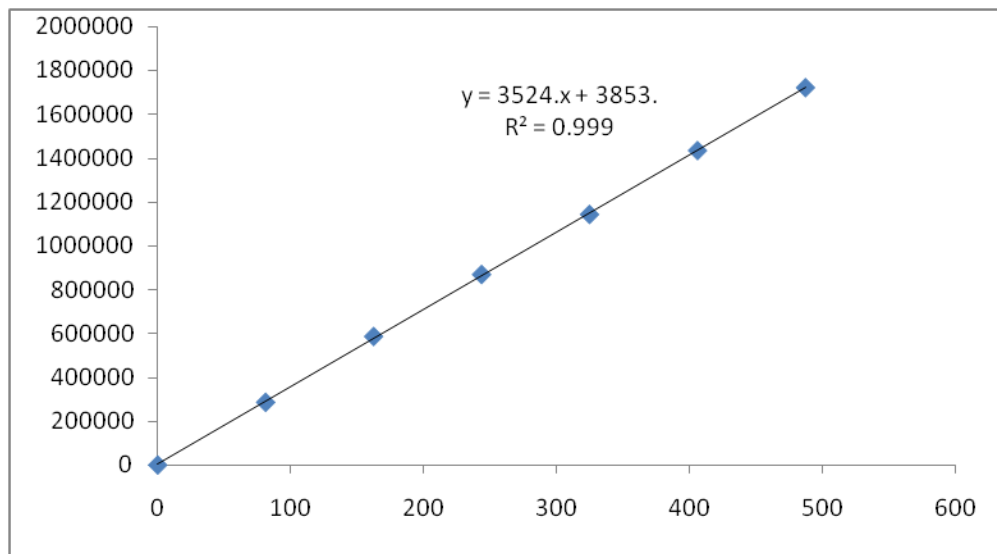
Standard chromatogram of Aspirin and Omeprazole



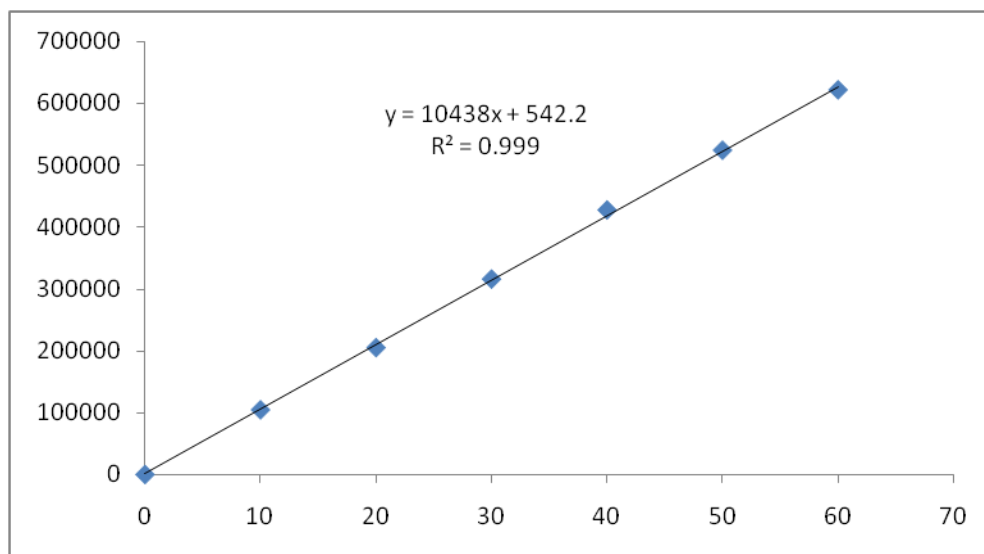
Chromatogram of blank



Sample chromatogram of Aspirin and Omeprazole



Calibration curve of Aspirin



Calibration curve of Omeprazole

REFERENCES

- [1]. www.yosprala.com
- [2]. WWW.DRUGS.COM/ingredient
- [3]. Rajaa F. Hussein et al., a validated Reversed Phase HPLC assay for the determination of omeprazole in human Plasma. *ejpmr*, 3(6), 2016, 26-30
- [4]. Foram Jaysukhlal Chodvadiya, et al., simultaneous estimation of aspirin and lansoprazole by rp-hplc method. *International Journal of Recent Scientific Research* 6(4), 2015, 3385-3390.
- [5]. Dipali Patelet et al., Development and Validation of RP-HPLC Method for Simultaneous Estimation of Aspirin and Eesomeprazole Magnesium in Tablet Dosage Form. *Journal of Chemistry* Article ID 751940, 2013, 5.
- [6]. Kalakonda Sri Nataraj et al., Development and validation of RP-HPLC method for the estimation of omeprazole in bulk and capsule dosage forms. Nataraj et al., *International Current Pharmaceutical Journal* 1(11), 2012, 366-369.
- [7]. ICH Tripartite Guidelines Q2R1 validation of analytical procedures: Text and methodology, ICH, Geneva, Switzerland, 2005.