

Development and Validation of UV Spectrophotometric Method for Simultaneous Equation of Aspirin and Omeprazole in Tablet Dosage Form

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ABSTRACT

YOSPRALA is newly designed tablet which effective in cardiovascular as well as gastrointestinal protection due to its immediate release of Omeprazole (40 mg) and delayed release of Aspirin (81 mg) or (325 mg) dose strength. Yosprala was approved by USFDA in Sept 2016 for cardiovascular and cerebrovascular diseases.

Aspirin is an antiplatelet agent & Omeprazole is proton pump inhibitor therefore it is made to develop a new analytical method for Simultaneous estimation of Aspirin and Omeprazole using Mehtanol as a solvent on the basis of solubility. The maximum Absorption (λ_{max}) of Aspirin and Omeprazole was found at 276 and 301 respectively. Linearity range for aspirin was given at 10-50 $\mu\text{g/ml}$ with %RSD value 0.997 and Omeprazole was 2-10 $\mu\text{g/ml}$ with %RSD value 0.997. The method was validated for precision and % RSD was found less than 2.0 for both aspirin and omeprazole. The proposed method was statistically validated for standard deviation, relative standard deviation, coefficient of variance and the results were within the range. Hence the above method was simple, cheap, cost effective, economical, and robust.

Keywords: Yosprala; Aspirin; Omeprazole; UV spectroscopy; λ_{max}

INTRODUCTION

Aspirin is an antiplatelet agent while omeprazole is proton pump inhibitor used in combination for treatment of stroke and other cardiovascular disease. On extensive literature survey it was found that very few methods are reported for Simultaneous estimation of Aspirin and Omeprazole in combined dosage form by any analytical technique. These methods were developed on single Aspirin only or combination with other drugs by using UV spectroscopy in tablet dosage form, hence i was decided to develop a new method which having accurate, precise, economical, rapid and cost effective (Figure 1) [1].

Aspirin [2-(acetyloxy) benzoic acid], acts as an inhibitor of cyclooxygenase which results in the inhibition of the biosynthesis of prostaglandins. It also inhibits platelet aggregation and is used in the prevention of arterial and venous thrombosis (Figure 2) [2].

Omeprazole is a proton pump inhibitor used in the treatment of dyspepsia, peptic ulcer disease (PUD), Gastro esophageal reflux disease (GORD/GERD), Laryngopharyngeal reflux (LPR) and Zollinger–Ellison syndrome.

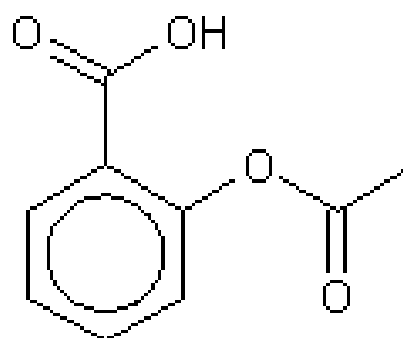


Figure 1: Aspirin.

Omeprazole is entirely metabolised by the hepatic cytochrome P-450 system (CYP), mainly in the liver. Identified metabolites in plasma are the sulfone, the sulfide and hydroxyomeprazole [3].

Simultaneous equation method is used where a sample contains two absorbing drugs (X and Y) each of this absorbance λ_{max} of each other, it may be possible to determine both the drugs by the technique of simultaneous equation method.

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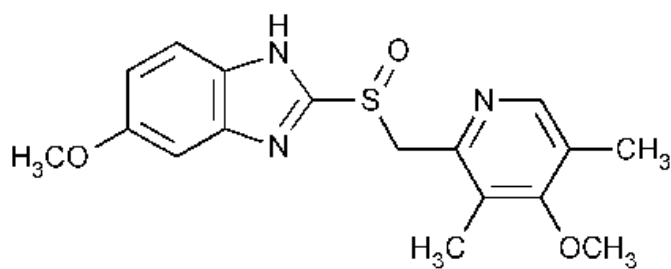


Figure 2: Omeprazole.

MATERIAL AND METHODS

Chemicals and reagents

The bulk drug of pure Aspirin powder was obtained from Alta laboratories, Mumbai and Omeprazole from Blue Cross Laboratories, Nasik. Yosprala tablets were procured from local market. All chemicals and reagents of analytical grade were purchase from Merck Chemical, Mumbai, INDIA

Instrument

A double beam Shimadzu UV-visible spectrophotometer model 1800 with UV probe software was used for absorption measurements.

Solubility

As per solubility studies it was found that both the drug sample are freely soluble in methanol.

Determination of λ max of individual component

An appropriate aliquot portion of ASP (0.5 mL) and OMZ (0.1 mL) were transferred to two separate 10 mL volumetric flasks, the volume was made up to the mark using 80% v/v methanol to obtain ASP (50 $\mu\text{g}/\text{mL}$) and OMZ (10 $\mu\text{g}/\text{mL}$). Drug solutions were scanned separately between 200 nm to 400 nm [4].

The overlain spectrum of both drugs having concentrations 130 $\mu\text{g}/\text{mL}$ ASP and 16 $\mu\text{g}/\text{mL}$ OMZ was recorded and two wavelengths 276.0 nm (λ max of ASP) and 301.0 nm (λ max of OMZ) were selected for further study [5].

Preparation of standard stock solutions of ASP and OMZ

A) Aspirin standard stock solution [A]: An accurately weighed quantity of ASP (10 mg) was taken in 10 mL volumetric flask and dissolved in methanol (8 mL) with the help of ultrasonication for about 10 min. Then the volume was made up to the mark using methanol to get Aspirin standard stock solution (1 mg / mL) [6].

B) Omeprazole standard stock solution [O]: An accurately weighed quantity of OMZ (10 mg) was taken in 10 mL volumetric flask and dissolved in methanol (8 mL) with the help of ultrasonication for about 10 min. Then the volume was made up to the mark using methanol to get Omeprazole standard stock solution (1 mg / mL) (Tables 1, 2 and Figures 3-6) [7-9].

RESULT AND DISCUSSION

Results of Standard Laboratory Mixture (API) and YOSPRALA Tablet by UV-Spectroscopic methods (Table 3).

Table 1: Linearity Study of ASP at 276 nm.

Sr. No.	Concentration of ASP in $\mu\text{g}/\text{mL}$	Absorbance Mean \pm S.D. [n=5]	% R.S.D.
1	10	0.073 \pm 0.0008	1.142
2	20	0.112 \pm 0.0007	0.631
3	30	0.165 \pm 0.0018	1.133
4	40	0.212 \pm 0.0011	0.536
5	50	0.265 \pm 0.0008	0.315

Table 2: Linearity Study of OMZ at 301 nm.

Sr. No.	Concentration of OMZ in $\mu\text{g}/\text{mL}$	Absorbance Mean \pm S.D. [n=5]	% R.S.D.
1	2	0.0588 \pm 0.0018	1.117
2	4	0.1052 \pm 0.0019	1.828
3	6	0.1622 \pm 0.0014	0.914
4	8	0.225 \pm 0.0012	0.544
5	10	0.2744 \pm 0.0018	0.662

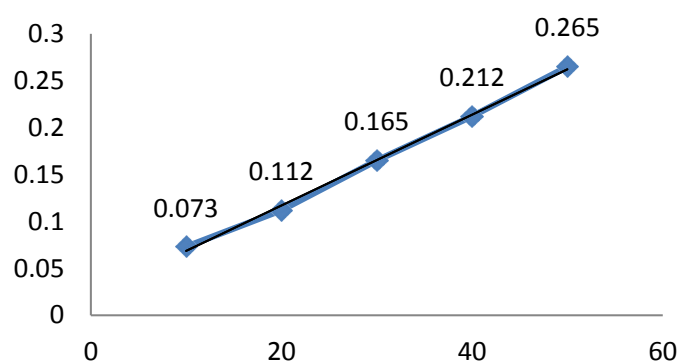


Figure 3: Calibration Curve of Aspirin at 276 nm.

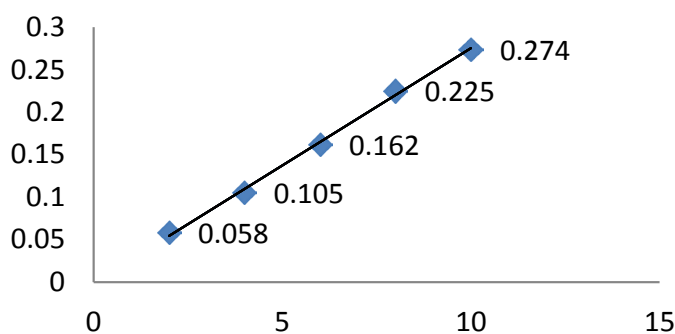


Figure 4: Calibration Curve of Omeprazole.

Validation of proposed method

The Proposed method was validated as per the ICH guidelines.

Accuracy [recovery study]

Accuracy of proposed method was ascertained on the basis of recovery study performed by standard addition method (Tables 4).

Precision

According to ICH guidelines acceptance criteria for precision the %RSD should NMT 2% (Table 5).

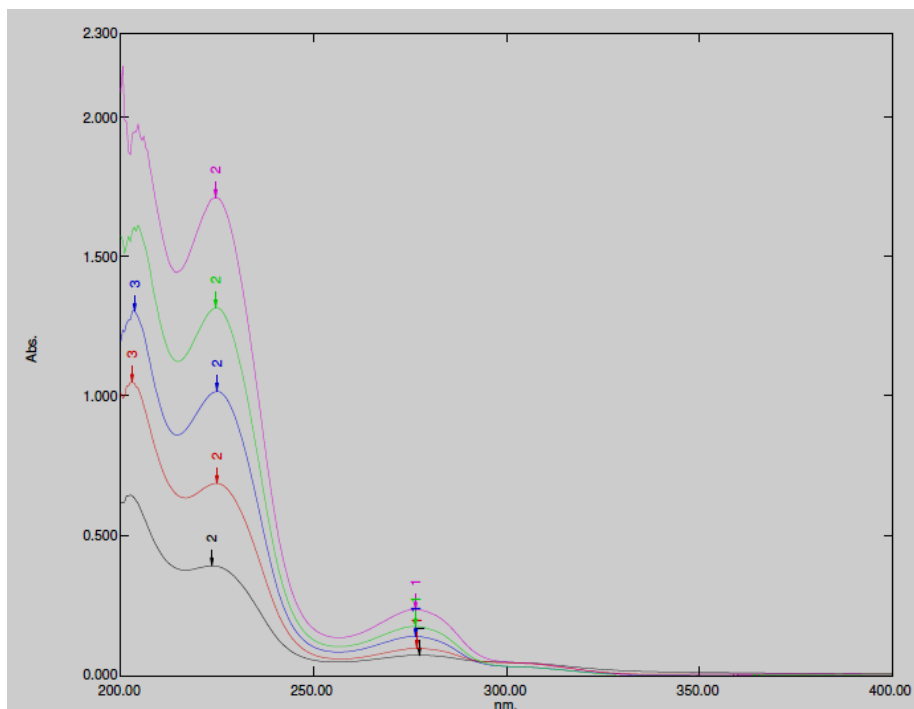


Figure 5: Overlay Spectra of ASP at 276 nm.

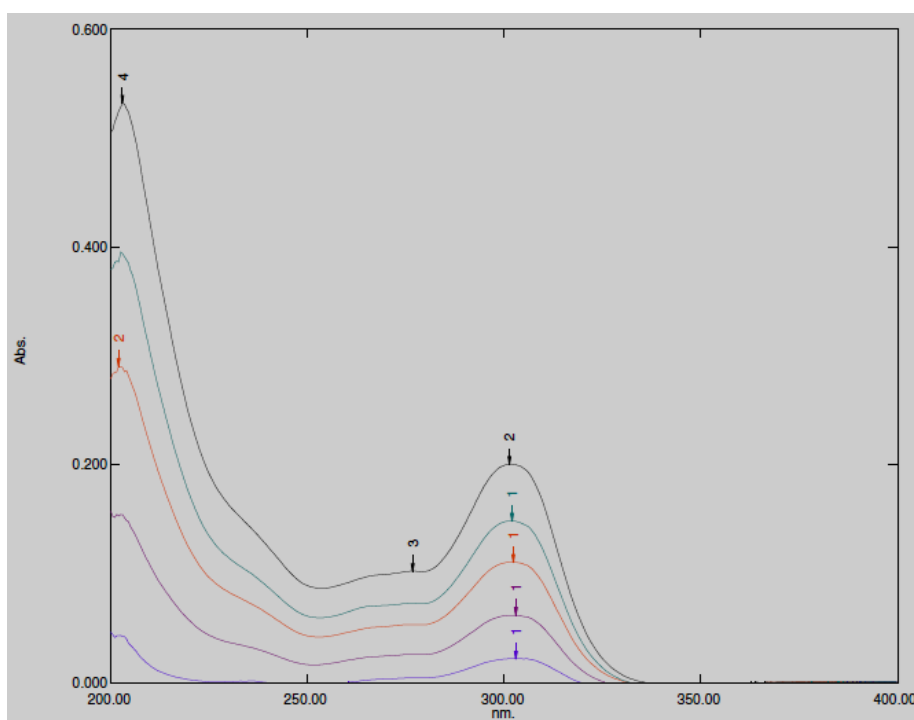


Figure 6: Overlay Spectra of OMZ at 301 nm.

Table 3: Summary of Results for UV-spectroscopic methods.

Sr. No	Sample	Statistical data	%Label Claim	
			ASP	OMZ
1.	Standard Laboratory Mixture (API)	Mean	99.85	99.80
		S.D.	0.0764	0.0697
		% R.S.D	0.0766	0.0699
2.	YOSPRALA Tablet	Mean	99.87	99.85
		S.D.	0.0702	0.0465
		% R.S.D	0.0703	0.0466

Table 4: Recovery Study.

Sr. No.	Quantity Tablet Powder Taken	Percentage %	Amount of Pure Drug Added (mg)		Total Amount of Drug Recovered (mg) ± S.D. (n=3)		% of Drug Recovered (n=3)	
			ASP	OMZ	ASP	OMZ	ASP	OMZ
1.	478	80	260	32	583.3 ± 1.08	71.64 ± 0.06	99.70	99.50
2.	478	100	325	40	649.6 ± 1.17	79.91 ± 0.05	99.95	99.88
3.	478	120	390	48	714.7 ± 1.43	87.95 ± 0.02	99.90	99.94
						Mean	99.85	99.77
						SD	0.1322	0.2386
						% RSD	0.1324	0.2388

Table 5: Precision study.

	Conc. [µg/mL]	Intra-day Amount Found		Inter-day Amount Found	
		Mean ± S.D. [n=5]	% R.S.D.	Mean ± S.D. [n=5]	% R.S.D.
ASP	10	9.94 0.064	0.6462	9.92 ± 0.1013	1.0213
	20	19.89 0.1814	0.9121	19.86 ± 0.2309	1.1622
	30	29.79 0.272	0.9156	29.75 ± 0.3614	1.2147
OMZ	2	1.97 ± 0.081	0.5452	1.95 ± 0.0151	0.7753
	4	3.92 0.0336	0.856	3.91 ± 0.0420	1.0737
	6	5.87 0.0342	0.5819	5.83 ± 0.0707	1.2128

Table 6: Ruggedness study.

Parameters	ASP 325 µg/mL		OMZ 40 µg/mL	
	Amount Found in µg/mL Mean ± S.D. (n=3)	% RSD	Amount Found in µg/mL Mean ± S.D.(n=3)	% RSD
Analyst I	324.46 ± 0.3614	0.1113	39.78 ± 0.1484	0.3730
Analyst II	324.95 ± 0.3968	0.1221	39.82 ± 0.1569	0.3940
Day-I	324.29 ± 0.6340	0.1955	39.77 ± 0.1861	0.4678
Day-II	325.06 ± 0.6562	0.2019	39.80 ± 0.1908	0.4795
Instrument I	324.21 ± 0.7379	0.2276	39.73 ± 0.2753	0.6930
Instrument II	324.89 ± 0.8580	0.2641	39.70 ± 0.2662	0.6707

Table 7: System suitability parameters.

Sr.no	Parameters	Aspirin	Omeprazole
1	λ _{max}	276 nm	301 nm
2	Regression co-efficient (r ²)	0.997	0.997
3	LOD (µg/ml)	0.2528	0.2307
4	LOQ (µg/ml)	1.766	1.954
5	Linearity range	10-50 µg/ml	2-10 µg/ml

Ruggedness

LOD: Limit of detection of Aspirin and Omeprazole were found to be 0.2528 µg/mL and 0.2307 µg/mL respectively (Table 6).

LOQ: Limit of Quantitation of Aspirin and Omeprazole were found to be 1.766 µg/mL and 1.954 µg/mL respectively.

System suitability parameters

The following parameters are system suitability parameters for the analytical method developed according to ICH guidelines (Table 7).

CONCLUSION

It was through to develop an analytical method for simultaneous equation method for estimation of Aspirin and Omeprazole by using UV Spectroscopy. The developed method was validated for linearity, Accuracy, precision, ruggedness and results were within the limits according to ICH guidelines. The proposed method was cost effective, simple, rapid, economic, cheap, precise and robust. The above method can be used for routine analysis of Aspirin and Omeprazole in bulk and Tablet Dosage Form

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