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Research Article

SIMULTANEOUS ESTIMATION OF ASPIRIN AND OMEPRAZOLE (YOSPRALA) IN BULK BY UV-SPECTROSCOPY

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ABSTRACT

In India, there are roughly 30 million heart patients and two Lac surgeries are being performed every year. YOSPRALA-a new emerging drug approved by USFDA in September 2016 to treat Ischemic stroke, prophylaxis and gastric ulcer prophylaxis. The active ingredients present are Aspirin and Omeprazole. Hence an attempt is made to develop a new analytical method for Simultaneous estimation of Aspirin and Omeprazole using methanol as solvent The Absorption maxima of Aspirin and Omeprazole was at 224nm and 251.8nm respectively. Linearity range for aspirin was 0.5-25µg/ml with regression co-efficient-099 and omeprazole was 1-8µg/ml with regression coefficient 0.992. The method was validated for precision and % RSD was less than 1.5% 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 limits. Hence the above method was simple, cost effective, robust and can be used for routine analysis in pharmaceutical preparations.

Keywords: Yosprala, Aspirin and Omeprazole, UV spectroscopy.

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INTRODUCTION

YOSPRALA is designed to support both cardio and gastro protection for at risk patients through proprietary intell-coat system, which is formulated to sequentially deliver immediate release of Omeprazole(40mg)followed by a delayed release ,enteric coated aspirin core either in (81mg) or 325mg dose strength.[1]Yosprala is approved by USFDA on September 1[4th] 2016 as a cardiovascular and cerebrovascular drug.[2]

An extensive literature survey reveals that there is no analytical method yet reported for simultaneous estimation of aspirin and omeprazole in combination by any analytical techniques. There are methods been developed for estimation of aspirin individually[3], in combination with other drugs by UV Spectroscophy in tablet dosage form [4-6], by RP-HPLC in bulk[7] and in tablet dosage form[8], by HPTLC in bulk and synthetic mixtiure[9]. Whereas methods been developed for estimation of Omeprazole capsules individually10[-11], bioanalysis of omeprazole by LC-MS/MS[12] in combination with other drugs by RP-HPLC in bulk and capsule [13-14], in tablet dosage dorm[15] , by NP-HPLC[16]. Hence an attempt was made to develop a simple and cost effective method for simultaneous estimation of aspirin and omeprazole and the proposed methods was validated according to ICH guidelines.

MATERIALS AND METHODS:

The reference standard of standard Aspirin (99%purity) and omeprazole (99%purity) were purchased from

yarrow Chem products (Mumbai, INDIA), DMF (99.0%potency), Acetone (99.0%potency), Ethanol (99%potency), Methanol (99.0% potency) was purchased from Finar Chemicals (Ahmadabad, Gujarat, INDIA).

1) Instrument employed: The instrument employed for the study was as follows.

Table 1: Instrument details

Instrument Employed	Double beam UV-VISIBLE spectrophotometer
Make	Systronics
Model no	2203
Detector	Photo Diode Array
Source of light	Sodium Vapour Lamp

2) Solubility studies: The solubility studies performed using various solvents are listed below.

Table 2: Solubility studies

Solvent	Aspirin	Omeprazole
Distilled water	Sparingly soluble	Freely soluble
0.1NNAOH	Sparingly soluble	Insoluble
0.1NHCL	Sparingly soluble	Freely soluble
DMF	Freely soluble	Freely soluble
Acetone	Insoluble	Sparingly soluble
Ethanol	Freely soluble	Freely soluble
Methanol	Freely soluble	Freely soluble

3) Mobile phase selection: Sharp peaks were obtained for Aspirin and Omeprazole when methanol was used as solvent.

Table 3: Mobile phase selection

SOLVENT	RESULT
Distilled water	Peak not Satisfactory
Acetone	Peak not Satisfactory
Ethanol	Better but not satisfactory
Methanol	Peak Satisfactory

4) Determination of λmax: UV Spectrums of Aspirin and Omeprazole were scanned throughout UV region and the lambda max obtained for aspirin was at 224.7nm and for Omeprazole was at 251.2nm.

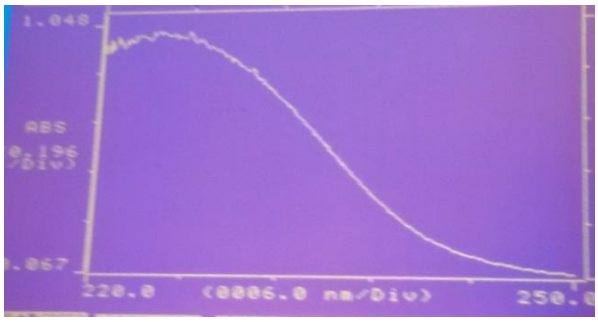

Figure 1: UV-spectrum of Aspirin (224.7nm)

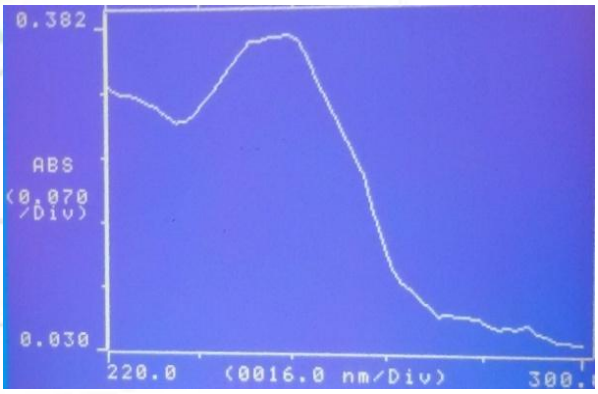

Figure 2: UV-spectrum of Omeprazole (251.2nm)

5) Preparation of Stock solution

5.1. Stock solution of Aspirin

50mg of Aspirin standard was dissolved in 50ml of methanol in 50 ml of volumetric flask which gives 1000µg/ml.

10ml of above solution is taken and made up to 100ml with Methanol in 100ml standard flask which gives 100µg/ml.

5.2. Stock solution of Omeprazole

50mg of Omeprazole standard was dissolved in 50 ml of methanol in 50ml standard flask which gives 1000µg/ml.

10ml of above solution is taken and made up to with Methanol in 100ml standard flask which gives 100µg/ml.

6) Sample preparation

6.1. Sample preparation of Aspirin 0.5ml of above Aspirin stock solution is made up to 10ml with methanol in 10ml standard flask which gives 5µg/ml.

6.2. Sample preparation of omeprazole

0.1ml of above Omeprazole stock solution is made up to 10ml with methanol in 10ml standard flask which gives 1µg/ml.

RESULTS & DISCUSSION:

1) System suitability parameters:

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

Table 4: System suitability parameters of Aspirin and Omeprazole:

Sr.no	Parameters	Aspirin	Omeprazole
1	ƛmax	224.7nm	251.2nm
2	Slope	0.091	0.288
3	Regression co-efficient(r^2)	0.99	0.992
4	LOD(µg/ml)	1.08µg/ml	1.126µg/ml
5	LOQ(µg/ml)	3.27 µg/ml	3.00µg/ml
6	Linearity range	0.5-25µg/ml	1-8µg/ml
7	Regression Equation	Y=0.091x+0.194	Y=0.288x+0.128

2) Validation of proposed method:

2.1) Linearity: It is an analytical procedure is its ability (within a given range) to obtain test results which are directly proportional to the concentration (amount) of analyte in the sample.

2.1.1: For Aspirin:

Table 5: Linerity results of Aspirin

S/NO	Conc. (µg/ml)	Absorbance (nm)
1	0	0
2	0.5	0.276
3	1	0.372
4	5	0.699
5	10	1.169
6	15	1.568
7	20	1.998
8	25	2.448

2.1.2: For Omeprazole:

Table 6: Linearity results of Omeprazole

S/NO	Conc. (µg/ml)	Absorbance (nm)
1	0	0
2	1	0.484
3	2	0.749
4	3	0.997
5	4	1.283
6	5	1.626
7	6	1.896
8	7	2.167
9	8	2.329

According to ICH guidelines Acceptance criteria- the regression co-efficient should NLT 0.99

2.2) Precision: An analytical procedure expresses the closeness of agreement (degree of scatter) between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed conditions.

Table 7: Precision results of Apirin and Omeprazole

S/NO	Aspirin	Absorbance's		Absorptivity		Omeprazole	Absorbance's		Absorptivity	
	Conc. (µg/ml)	224.7λ_1 Nm	251.2λ_2 Nm	224.7 λ_1 nm(ax_1)	251.2 λ_2 nm(ax_2)	Conc. (µg/ml)	224.7 λ_1 nm	251.2 λ_2 nm	224.7 λ_1 nm(ay_1)	251.2 λ_2 nm(ay_2)
1	5	0.724	0.150	72.4	1.5	1	0.021	0.603	2.1	60.3
2	5	0.724	0.151	72.4	1.51	1	0.019	0.603	1.9	60.3
3	5	0.715	0.149	71.5	1.49	1	0.020	0.601	2.0	60.1
4	5	0.721	0.150	72.1	1.50	1	0.021	0.599	2.1	59.9
5	5	0.723	0.151	72.3	1.51	1	0.023	0.600	2.3	60.0
			Mean	72.14	15.02			Mean	2.08	60.12
			SD	0.228	0.126			SD	0.0632	0.1897
			%RSD	0.31%	0.83%			%RSD	0.03%	0.31%

According to ICH guidelines acceptance criteria for precision the %RSD should NMT 2%

2.3) Statistical validation: The proposed method was statistically validated for the following parameters and was within the Acceptance criteria as per ICH guidelines.

Table 8: Statistical data of method

S/NO	1		2	
Drug	Aspirin		Omeprazole	
Conc.(µg/ml)	5		1	
E=A/g per 100ml	ax_1	ax_2	ay_1	ay_2
Absorptivity	72.14	15.02	2.08	60.3
SD	0.228	0.126	0.0632	0.1897
SE	0.0268	0.0325	0.0438	0.0244
RSD	0.0031	0.0083	0.0303	0.0031
%RSD	0.31%	0.83%	0.03%	0.31%
C.V.	0.316%	0.838%	0.038%	0.315%

2.4) Ruggedness and Robustness: An analytical procedure is a measure of its capacity to remain unaffected by small, deliberate variations in method parameters and provides an indication of its reliability during normal usage.

2.4.1: Ruggedness:

Table 9: Ruggedness result

S/No	Drug (n=3)	Conc. (µg/ml)	Instrument Employed			
			Systronics		Shimadzu	
			ax_1	ax_2	ax_1	ax_2
1	Aspirin	2.5	36.56	0.746	36.53	0.75
		SD	0.081	0.047	0.080	0.054
			ay_1	ay_2	ay_1	ay_2
2	Omeprazole	1	2	60.23	2.01	60.21
		SD	0.230	0.077	0.054	0.189

2.4.2: Robustness:

Table 10: Robustness result

S/NO	Drug (n=3)	Conc. (µg/ml)	Temperature			
			0^0c		24^0c	
			ax_1	ax_2	ay_1	ay_2
1	Aspirin	2.5	36.56	0.746	36.57	0.745
		SD	0.081	0.047	0.083	0.048
			ay1	ay2	ay1	ay2
2	Omeprazole	1	2	60.23	2.1	60.25
		SD	0.230	0.077	0.231	0.079

CONCLUSION:

An attempt was made to develop an analytical method for simultaneous estimation of Aspirin and Omeprazole by UV Spectrosopy. The developed method was validated for linearity, precision, ruggestness, robustness and results were within the limits according to ICH guidelines. The proposed method was cost effective, simple, Precise and robust. This is the first report on the simultaneous estimation of aspirin and omeprazole in bulk by UV-spectrophotometric method. The above method can be used for routine analysis of Aspirin and Omeprazole in bulk and Tablet Dosage Form.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest regarding the manuscript and experimentation done.

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