ISSN: 0976-7126
Modi *et al.*, 12(8):20-26, 2021

International Journal of Pharmacy & Life Sciences
Open Access to Researcher

Stability Indicating Assay for Simultaneous Estimation of Aspirin and Omeprazole in Bulk by Validated RP-HPLC Method

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Article info

Received: 13/07/2021

Revised: 22/08/2021

Accepted: 28/08/2021

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Abstract

The aim of the present investigation is to study Stability Indicating Assay for Simultaneous Estimation of Aspirin and Omeprazole in Bulk by Validated RP-HPLC Method. The λ_{max} of the two ingredients i.e. Aspirin and Omeprazole, were found to be 240 nm and 270 nm respectively in mobile phase as solvent system. The isobestic point for the drugs was observed at 288 nm. 10 mg of Aspirin and Omeprazole was weighed accurately and transferred into 100 ml volumetric flask. About 10 ml versatile phases was inserted and sonicated to dissolution. The volume was made up to the mark with same solvent. The different HPLC conditions were employed to conclude out the optimum condition for superior extraction of drugs. Linearity range was observed as 0-60 µg/ml for Aspirin. The correlation coefficient was observed as 0.999, the slope was found to be 11904 and intercept was observed as 12043 for Aspirin. Linearity range was observed as 0-40 µg/ml for Omeprazole. The correlation coefficient was observed as 0.999, the slope was observed as 15639 and intercept was observed as 2119 for Omeprazole. The mean recoveries were observed as 100.41, 100.66 and 100.963% for Aspirin and 100.75, 100.59 and 100.05% for Omeprazole. As results are within the limit of 98-102%, the approach developed passes the test and hence can be reused. Based on spike purity results, acquired from the investigation of specimens utilizing depict approach, it can be finalized that due to lack of co-eluting spike along with the main spike of Aspirin & Omeprazole showed that the developed method is specific for the synchronal calculation of Aspirin & Omeprazole in the bulk.

Keywords: Stability Indicating Assay, Simultaneous Estimation, Aspirin and Omeprazole, Tablet Formulation, RP-HPLC Method

Introduction

Chromatography is approach use for the detachment of premixes. The mix is countermined in a very liquid known as the transportable stage, which flows through strongly bonded structure known as the still stage. According to their affinity towards still and transportable stage, they separate out at different speed. [1] High-performance liquid natural process (HPLC; once alluded to as high-weight fluid chromatography), may be a technique in instructive science used to isolated, recognize, and evaluate every part in a blend.

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It depends on drive to pass a pressurized fluid dissoluble containing the instance mix through a section loaded up with a powerful adsorbent. each section within the example connects marginally contrastingly with the adsorbent, inflicting distinctive stream rates for the varied segments and prompting the division of the parts as they stream out of the segment. [2] Review of literature for Aspirin and Omeprazole gave information related to its physical and chemical properties, various analytical approaches that were conducted alone. For development of appropriate RP-HPLC method for regular investigation of Aspirin and Omeprazole in formulations, attempts were taken to develop easy, exact and right investigational approach for estimation of Aspirin and Omeprazole and employed it for their ascertain men in formulation. Quantitative ascertainment of Aspirin and Omeprazole in bulk by the method development and validation of the developed RP-HPLC method. [3-5]

Material and Methods

RP-HPLC Method Development and its Validation for Aspirin and Omeprazole in Bulk

Selection of wavelength:

The λ_{max} of the two ingredients i.e. Aspirin and Omeprazole, were found to be 240 nm and 270 nm respectively in mobile phase as solvent system. The isobestic point for the drugs was observed at 288 nm. [6]

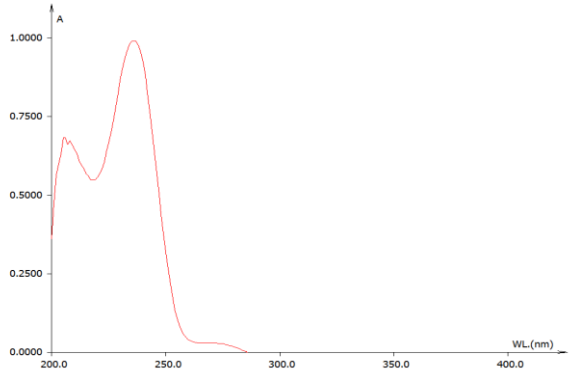

Fig-1: UV Spectrum for Aspirin (240nm)

Preparation of standard Solutions of Aspirin and Omeprazole:

10 mg of Aspirin and Omeprazole was weighed accurately and transferred into 100 ml volumetric flask. About 10 ml versatile phases was inserted and sonicated to dissolution. The volume was made up to the mark with same solvent. The final solution contained about 100µg/mland 100 µg/mlof Aspirin and Omeprazole respectively. [7]

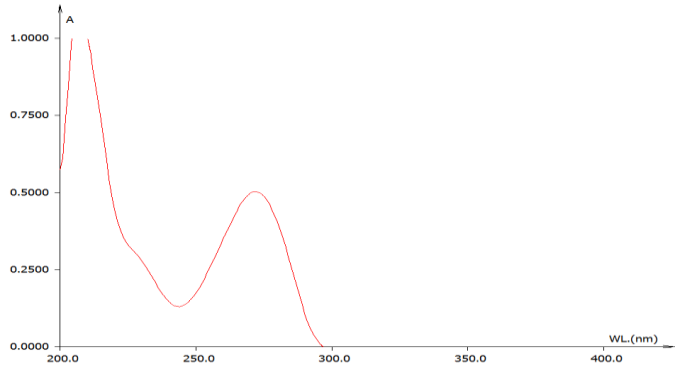

Fig-2: UV Spectrum for Omeprazole (270nm)

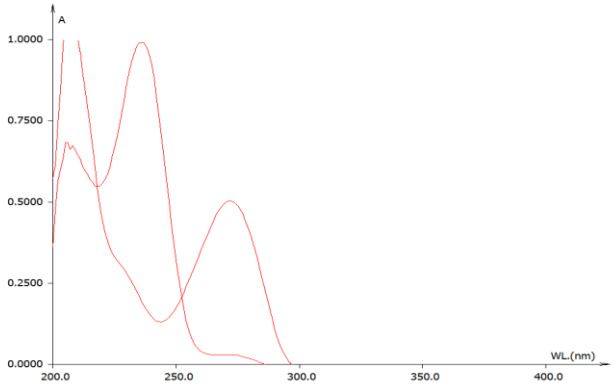

Fig-3: Isosbestic Point (256nm)

Initialization of the instrument

The HPLC instrument was switched on. The column was washed with HPLC water for 45 minutes. The column was then saturated with versatile phase for 45 minute. The versatile phase was run to find the spikes. After 20 minutes the standard drug solution was injected in HPLC. [8]

Different chromatographic environments used and their Optimizations

The different HPLC conditions were employed to conclude out the optimum condition for superior extraction of drugs.

Table-1: Results of Trial-1

S. No.	Drug Name	RT	Peak Area	Tailing Factor	Theoretical Plates
1	Aspirin	3.250	685478	0.99	2586
2	Omeprazole	7.300	365897	1.06	3235

ISSN: 0976-7126
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Table-2: Results of Trial-2

S. No.	Drug Name	RT	Peak Area	Tailing Factor	Theoretical Plates
1	Aspirin	2.120	485787	0.95	2967
2	Omeprazole	4.916	865874	0.91	3968

Table-3: Results of Trial-3

S. No.	Drug Name	RT	Peak Area	Tailing Factor	Theoretical Plates
1	Aspirin	3.223	568247	0.98	2867
2	Omeprazole	5.857	469857	0.96	3857

Table-4: Results of Trial-4

S. No.	Drug Name	RT	Peak Area	Tailing Factor	Theoretical Plates
1	Aspirin	1.249	536857	0.99	2698
2	Omeprazole	3.343	356854	0.93	3365

Table-5: Results of Trial-5

S. No.	Drug Name	RT	Peak Area	Tailing Factor	Theoretical Plates
1	Aspirin	3.254	5124415	1.20	6358
2	Omeprazole	5.424	4846243	1.12	5687

The best environment acquired from research can be outlined as below:

Table-6: Summary of Optimised Chromatographic Conditions

Mobile phase	Methanol :Di-potassium Phosphate buffer (0.1 M) =70:30(pH 3).
Column	Develosil ODS HG-5 RP C_{18}, 5µm, 15cmx4.6mm i.d.
Column Temperature	Ambient
Detection Wavelength	256 nm
Flow rate	1.0 ml/ min.
Run time	07 min.
Temperature of Auto sampler	Ambient
Diluent	Mobile Phase
Injection Volume	10µl
Type of Elution	Isocratic

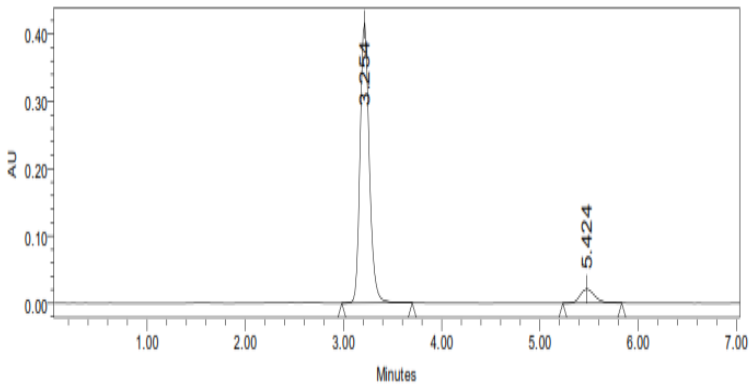

Fig-4: Chromatogram of Aspirin and Omeprazole in Optimized Chromatographic Condition

ISSN: 0976-7126
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Method Validation

Linearity and Range

Method: Different concentrations of 0-60 & 0-40 ppm of Aspirin & Omeprazole were prepared. [9]

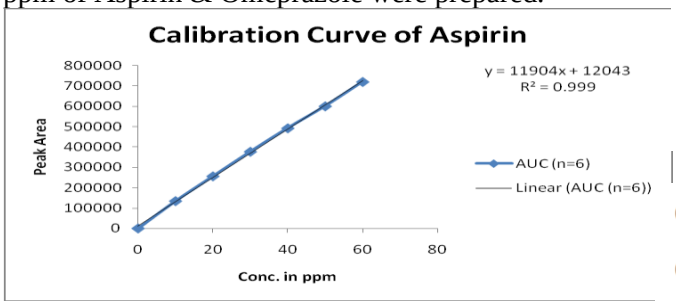

Fig-5: Standard Curve for Aspirin

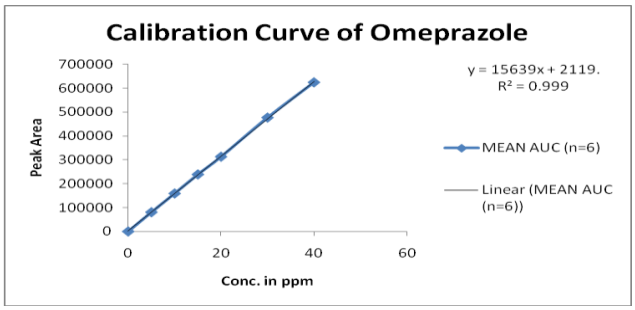

Fig-6: Standard curve for Omeprazole

Results and Discussion

Linearity range was observed as 0-60 µg/ml for Aspirin. The correlation coefficient was observed as 0.999, the slope was found to be 11904 and intercept was observed as 12043 for Aspirin. Linearity range was observed as 0-40 µg/ml for Omeprazole. The correlation coefficient was observed as 0.999, the slope was observed as 15639 and intercept was observed as 2119 for Omeprazole. [10-12]

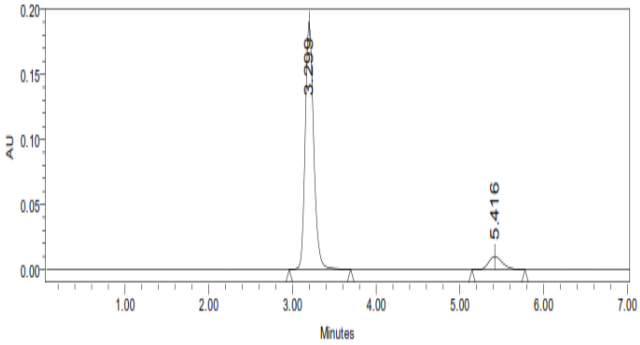

Fig-7: Chromatogram for linearity-1

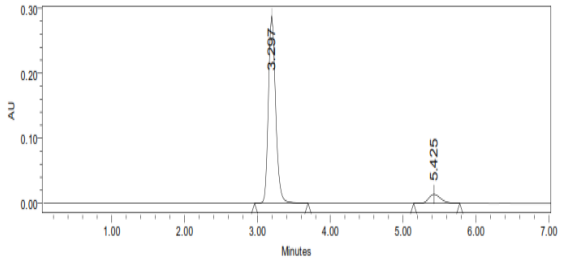

Fig-8: Chromatogram for linearity-2

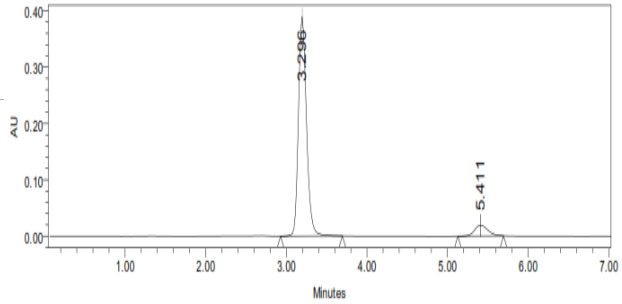

Fig-9: Chromatogram for linearity-3

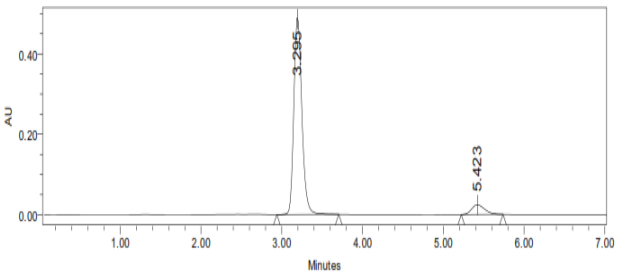

Fig-10: Chromatogram for linearity-4

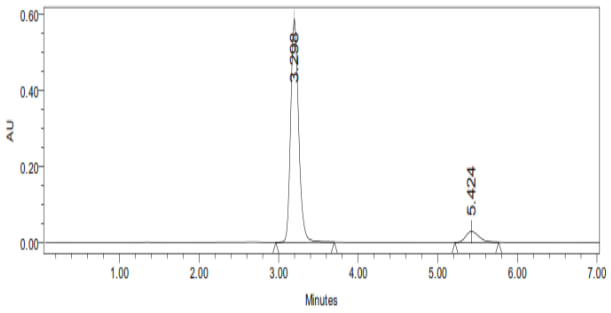

Fig-11: Chromatogram for linearity-5

Table-7: Results of Linearity-6

S. No.	Drug Name	RT	Peak Area	Theoretical Plates	Tailing Factor
1	Aspirin	3.212	721010	3896	1.23
2	Omeprazole	5.482	623852	2352	1.29

Accuracy:

Recovery study: For Aspirin

From that proportion recovery values were computed. The results were shown in Table-8.

Table-8: Accuracy Readings for Aspirin

Sample ID	Concentration (µg/ml)			%Recovery of Pure drug	Statistical Analysis
	Conc. Found	Conc. Recovered	Peak Area		
S_1 : 80 %	40	39.947	487574	99.867	Mean= 100.4113 % S.D. = 0.473694 % R.S.D.= 0.471754
S_2 : 80 %	40	40.255	491241	100.637	
S_3 : 80 %	40	40.292	491685	100.73	
S_4 : 100 %	50	49.705	603735	99.41	Mean= 100.6647 % S.D. = 1.166369 % R.S.D.= 1.158668
S_5 : 100 %	50	50.434	612421	100.868	
S_6 : 100 %	50	50.858	617459	101.716	
S_7 : 120 %	60	59.927	725421	99.878	Mean= 100.4637 % S.D. = 0.511543 % R.S.D. = 0.509182
S_8 : 120 %	60	60.414	731214	100.69	
S_9 : 120 %	60	60.494	732165	100.823	

Recovery study: Omeprazole

From that rate recuperation esteems were figured. The outcomes were appeared in Table-9.

Table-9: Accuracy Results for Omeprazole

Sample ID	Concentration (µg/ml)			%Recovery of Pure drug	Statistical Analysis
	Conc. Found	Conc. Recovered	Peak Area		
S_1 : 80 %	32	32.195	505624	100.609	Mean= 100.7527 % S.D. = 1.097575 % R.S.D.= 1.089375
S_2 : 80 %	32	31.915	501243	99.734	
S_3 : 80 %	32	32.613	512164	101.915	
S_4 : 100 %	40	40.668	638137	101.67	Mean= 100.5967 % S.D. = 1.172714 % R.S.D.= 1.165758
S_5 : 100 %	40	39.738	623584	99.345	
S_6 : 100 %	40	40.310	632541	100.775	
S_7 : 120 %	48	48.181	755635	100.377	Mean= 100.0547 % S.D. = 0.397865 % R.S.D. = 0.397647
S_8 : 120 %	48	48.085	754124	100.177	
S_9 : 120 %	48	47.813	749878	99.610	

The mean recoveries were observed as 100.41, 100.66 and 100.963% for Aspirin and 100.75, 100.59 and 100.05% for Omeprazole. As results are within the limit of 98-102%, the approach developed passes the test and hence can be reused. [13]

Repeatability

The percent relative standard deviations were calculated for Aspirin & Omeprazole are presented in the Table-10.

Table-10: Data showing repeatability analysis for Aspirin & Omeprazole

HPLC Injection Replicates	AUC for Aspirin	AUC for Omeprazole
Replicate – 1	613568	645214
Replicate – 2	613241	635241
Replicate – 3	625408	635424
Replicate – 4	617412	635987
Replicate – 5	612541	635216
Average	**616434**	**637416.4**
Standard Deviation	**5363.157**	**4370.055**
% RSD	**0.870029**	**0.685589**

The repeatability study which was conducted on the solution having the concentration of about 50µg/ml for Aspirin and 40µg/ml for Omeprazole (n =5) showed a RSD of 0.870029% for Aspirin and 0.685589% for Omeprazole. It was concluded that the analytical technique showed good repeatability. [14]

Intermediate precision

Information was subjected to factual treatment for the assessment of SD and RSD. The information is appeared in Table 11 and 12.

Table-11: Data for Aspirin Analysis

Conc. OfAspirin (API) (µg/ml)	Observed Conc. Of Aspirin (µg/ml) by the designed method			
	Intra-Day		Inter-Day	
	Mean (n=3)	% RSD	Mean (n=3)	% RSD
40	40.05	0.85	40.02	0.87
50	49.84	0.32	50.06	0.34
60	59.98	0.13	59.96	0.17

Table-12:Data for Omeprazole Analysis

Conc. Of Omeprazole (API) (µg/ml)	Observed Conc. of Omeprazole (µg/ml) by the designed method			
	Intra-Day		Inter-Day	
	Mean (n=3)	% RSD	Mean (n=3)	% RSD
32	31.95	1.11	32.01	0.32
40	40.07	0.55	40.052	0.48
48	48.89	0.72	47.97	0.15

Intraday and interday ponders demonstrate that the mean RSD (%) was observed to be inside acknowledgment restrict (≤2%), so it was presumed that there was no critical distinction for the test, which was tried inside day and between days. Thus, strategy at chose wavelength was observed to be exact.

Limit of detection and limit of quantification

The detection limit (LOD) and quantization limit (LOQ) may be expressed as:

L.O.D. = 3.3(SD/S). L.O.Q. = 10(SD/S)

Where, SD = Standard deviation of the response

S = Slope of the calibration curve

The LOD was observed as 0.35µg/ml and 1.47µg/ml and LOQ was observed as0.98µg/ml and 2.39µg/ml for Aspirin & Omeprazole respectively which represents that sensitiveness of the method is high. [14]

Conclusion

A sensitive & selective RP-HPLC approach has been established & validated for the investigation of Aspirin & Omeprazole in bulk. Based on spike purity results, acquired from the investigation of specimens utilizing depict approach, it can be finalized that due to lack of co-eluting spike along with the main spike of Aspirin & Omeprazole showed that the developed method is specific for the synchronal calculation of Aspirin & Omeprazole in the bulk.

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Cite this article as:
Modi P., Jain N.K., Bairagee D. and Gokhale N. (2021). Stability Indicating Assay for Simultaneous Estimation of Aspirin and Omeprazole in Bulk by Validated RP-HPLC Method, *Int. J. of Pharm. & Life Sci.*, 12(8):20-26.

Source of Support: Nil
Conflict of Interest: Not declared
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