International Journal of Pharmacy and Analytical Research (IJPAR)

IJPAR |Vol.14 | Issue 4 | Oct - Dec -2025

www.ijpar.com

ISSN: 2320-2831

DOI : https://doi.org/10.61096/ijpar.v14.iss4.2025.1111 -1127

Research

A VALIDATED RP-HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF ASPIRIN AND PRASUGREL IN BULK AND ITS PHARMACEUTICAL DOSAGE FORM

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Published on:

Published by:
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Abstract

A rapid and precise reverse phase high performance liquid chromatographic method has been developed for the validated of Aspirin and Prasugrel in its pure form as well as in tablet dosage form. Chromatography was carried out on a Symmetry C18 (4.6 x 150mm, 5µm) column using a mixture of Acetonitrile: Water (35:65) as the mobile phase at a flow rate of 1.0ml/min, the detection was carried out at 238nm. The retention time of the Aspirin and Prasugrel was 2.456, 4.312 ±0.02min respectively. The method produce linear responses in the concentration range of 50-250µg/ml of Aspirin and 5-25µg/ml of Prasugrel. The method precision for the determination of assay was below 2.0%RSD. The method is useful in the quality control of bulk and pharmaceutical formulations.

Keywords: Aspirin, Prasugrel, RP-HPLC, validation.

1. INTRODUCTION

1.1 Analytical chemistry[1]

Analytical chemistry is a scientific discipline used to study the chemical composition, structure and behaviour of matter. The purposes of chemical analysis are together and interpret chemical information that will be of value to society in a wide range of contexts. Quality control in manufacturing industries, the monitoring of clinical and environmental samples, the assaying of geological specimens, and the support of fundamental and applied research

are the principal applications. Analytical chemistry involves the application of a range of techniques and methodologies to obtain and assess qualitative, quantitative and structural information on the nature of matter.

- **Qualitative analysis** is the identification of elements, species and/or compounds present in sample.
- **Quantitative analysis** is the determination of the absolute or relative amounts of elements, species or compounds present in sample.

Structural analysis is the determination of the spatial arrangement of atoms in an element or molecule or the identification of characteristic groups of atoms (functional groups). An element, species or compound that is the subject of analysis is known as analyte. The remainder of the material or sample of which the analyte(s) form(s) a part is known as the matrix.

The gathering and interpretation of qualitative, quantitative and structural information is essential to many aspects of human endeavour, both terrestrial and extra-terrestrials. The maintenance of an improvement in the quality of life throughout the world and the management of resources heavily on the information provided by chemical analysis. Manufacturing industries use analytical data to monitor the quality of raw materials, intermediates and finished products. Progress and research in many areas is dependent on establishing the chemical composition of man-made or natural materials, and the monitoring of toxic substances in the environment is of ever increasing importance. Studies of biological and other complex systems are supported by the collection of large amounts of analytical data. Analytical data are required in a wide range of disciplines and situations that include not just chemistry and most other sciences, from biology to zoology, butte arts, such as painting and sculpture, and archaeology. Space exploration and clinical diagnosis are two quite desperate areas in which analytical data is vital. Important areas of application include the following.

Quality control (**QC**) in many manufacturing industries, the chemical composition of raw materials, intermediates and finished products needs to be monitored to ensure satisfactory quality and consistency. Virtually all consumer products from automobiles to clothing, pharmaceuticals and foodstuffs, electrical goods, sports equipment and horticultural products rely, in part, on chemical analysis. The food, pharmaceutical and water industries in particular have stringent requirements backed by legislation for major components and permitted levels of impurities or contaminants. The electronic industry needs analyses at ultra-trace levels (parts per billion) in relation to the manufacture of semi-conductor materials. Automated, computer-controlled procedures for process-stream analysis are employed in some industries.

Monitoring and control of pollutants The presence of toxic heavy metals (e.g., lead, cadmium and mercury), organic chemicals (e.g., polychlorinated biphenyls and detergents) and vehicle exhaust gases (oxides of carbon, nitrogen and sulphur, and hydrocarbons) in the environment are health hazards that need to be monitored by sensitive and accurate methods of analysis, and remedial action taken. Major sources of pollution are gaseous, solid and liquid wastes that are discharged or dumped from industrial sites, and vehicle exhaust gases.

Clinical and biological studies The levels of important nutrients, including trace metals (e.g., sodium, potassium, calcium and zinc), naturally produced chemicals, such as cholesterol, sugars and urea, and administered drugs in the body fluids of patients undergoing hospital treatment require monitoring. Speed of analysis is often a crucial factor and automated procedures have been designed for such analyses.

Geological assays The commercial value of ores and minerals are determined by the levels of particular metals, which must be accurately established. Highly accurate and reliable analytical procedures must be used for this purpose, and referee laboratories are sometimes employed where disputes arise.

Fundamental and applied research The chemical composition and structure of materials used in or developed during research programs in numerous disciplines can be of significance. Where new drugs or materials with potential commercial value are synthesized, a complete chemical characterization maybe required involving considerable analytical work. Combinatorial chemistry is an approach used in pharmaceutical research that generates very large numbers of new compounds requiring confirmation of identity and structure.

Analytical techniques There are numerous chemical or physico-chemical processes that can be used to provide analytical information. The processes are related to a wide range of atomic and molecular properties and phenomena that enable elements and compounds to be detected and/or quantitatively measured under controlled conditions. The underlying processes define the various *analytical techniques*. The more important of these are listed in Table.No.1 together with their suitability for qualitative, quantitative or structural analysis and the levels of analyte(s) in a sample that can be measured. *Atomic, molecular spectrometry* and *chromatography*, which together comprise the largest and most widely used groups of techniques, can be further subdivided according to their physico-chemical basis. *Spectrometric techniques* may involve either the *emission or absorption* of *electromagnetic radiation* over a very wide range of energies, and can provide qualitative, quantitative and structural information for analytes from major components of a sample down to ultra-trace levels. The most important atomic and molecular spectrometric techniques and their principal applications are listed in Table.No.2.

Chromatographic techniques provide the means of separating the components of mixtures and simultaneous qualitative and quantitative analysis, as required. The linking of chromatographic and spectrometric techniques, called *hyphenation*, provides a powerful means of separating and identifying unknown compounds.
Electrophoresis's another separation technique with similarities to chromatography that is particularly useful for this parathion of charged species. The principal separation techniques and their applications are listed in Table.No.3.

Analytical methods

An analytical method consists of a detailed, stepwise list of instructions to be followed in the qualitative, quantitative or structural analysis of a sample for one or more analytes and using a specified technique. It will include a summary and lists of chemicals and reagents to be used, laboratory apparatus and glassware, and appropriate instrumentation. The quality and sources of chemicals, including solvents, and the required performance characteristics of instruments will also be specified as will the procedure for obtaining a representative sample of the material to be analyzed. This is of crucial importance in obtaining meaningful results. The preparation or pre-treatment of the sample will be followed by any necessary standardization of reagents and/or calibration of instruments under specified conditions. Qualitative tests for the analyte(s) or quantitative measurements under the same conditions as those used for standards complete the practical part of the method. The remaining steps will be concerned with data processing, computational methods for quantitative analysis and the formatting of the analytical report. The statistical assessment of quantitative data is vital in establishing the reliability and value of the data, and the use of various statistical parameters and tests is widespread. Many *standard analytical methods* have been published as papers in analytical journals and other scientific literature, and in textbook form. Collections by trades associations representing, for example, the cosmetics, food, iron and steel, pharmaceutical, polymer plastics and paint, and water industries are available standards organizations and statutory authorities, instrument manufacturer's applications notes, the Royal Society of Chemistry and the US Environmental Protection Agency are also valuable sources of standard methods. Often, laboratories will develop their own *in-house methods* or adapt existing ones for specific purposes.

1.2 Chromatography [2]

1.2.1 Introduction

The chromatography was discovered by Russian Chemist and botanist *Micheal Tswett* (1872-1919) who first used the term chromatography (colour writing derived from Greek for colour – Chroma , and write – graphein) to describe his work on the separation of coloured plant pigments into bands on a column of chalk and other material such as polysaccharides, sucrose and insulin.

" *Chromatography is a method in which the components of a mixture are separated on an adsorbent column in a flowing system*".

The adsorbent material, or stationary phase, first described by Russian scientist named Tswett in 1906, has taken many forms over the years, including paper, thin layers of solids attached to glass plates, immobilized liquids, gels, and solid particles packed in columns. The flowing component of the system, or mobile phase, is either a liquid or a gas. Concurrent with development of the different adsorbent materials has been the development of methods more specific to particular classes of analytes. In general, however, the trend in development of chromatography has been toward faster, more efficient.

"In his early papers of Tswett (1906) stated that chromatography is a method in which the component of a mixture are separated on an adsorbent column in a flowing system. Chromatography has progressed considerably from Tswett's time and now includes a number of variations on the basic separation process".

"Chromatography is a physical method of separation in which the component to be separated are distributed between two phases of which in stationary while other moves in a definite direction (IUPAC)"

1.2.2. Chromatographic Process[4]

Chromatographic separations are based on a forced transport of the liquid (mobile phase) carrying the analyte mixture through the porous media and the differences in the interactions at analytes with the surface of this porous media resulting in different migration times for a mixture components. In the above definition the presence of two different phases is stated and consequently there is an interface between them. One of these phases provides the analyte transport and is usually referred to as the mobile phase, and the other phase is immobile and is typically referred to as the stationary phase. A mixture of components, usually called analytes, are dispersed in the mobile phase at the molecular level allowing for their uniform transport and interactions with the mobile and stationary phases. High surface area of the interface between mobile and stationary phases is essential for space discrimination of different components in the mixture. Analyte molecules undergo multiple phase transitions between mobile phase and adsorbent surface. Average residence time of the molecule on the stationary phase surface is dependent on the interaction energy. For different molecules with very small interaction energy difference the presence of significant

surface is critical since the higher the number of phase transitions that analyte molecules undergo while moving through the chromatographic column, the higher the difference in their retention. The nature of the stationary and the mobile phases, together with the mode of the transport through the column, is the basis for the classification of chromatographic methods.

EXPERIMENTAL WORK

INSTRUMENTS USED

Instruments And Glasswares	Model
HPLC WATERS, software:	Empower 2, Alliance 2695 separation module. 996 PDA detector.
pH meter	LabIndia
Weighing machine	Sartorius
Volumetric flasks	Borosil
Pipettes and Burettes	Borosil

CHEMICALS USED

Aspirin	Sura labs
Prasugrel	Sura labs
Water and Methanol for HPLC	LICHROSOLV (MERCK)
Acetonitrile for HPLC	Merck

RESULTS AND DISCUSSION

Optimized Chromatogram (Standard)

Mobile phase : Water: Acetonitrile (65:35)

Column : Symmetry C18 (4.6×150mm, 5.0 µm)

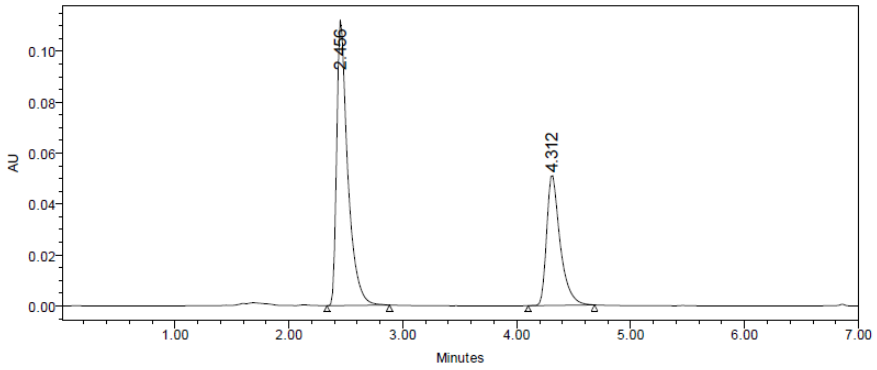
Flow rate : 1 ml/min

Wavelength : 238 nm

Column temp : 40ºC

Injection Volume : 10 µl

Run time : 7 minutes



Optimized Chromatogram

Table: - peak results for optimized

S. No	Peak name	R_t	Area	Height	USP Resolution	USP Tailing	USP plate count

1	Aspirin	2.456	600122	112157		1.6	5215
2	Prasugrel	4.312	422042	51068	3.2	1.5	5648

Observation: From the above chromatogram it was observed that the Aspirin and Prasugrel peaks are well separated and they shows proper retention time, resolution, peak tail and plate count. So it's optimized trial.

Optimized Chromatogram (Sample)

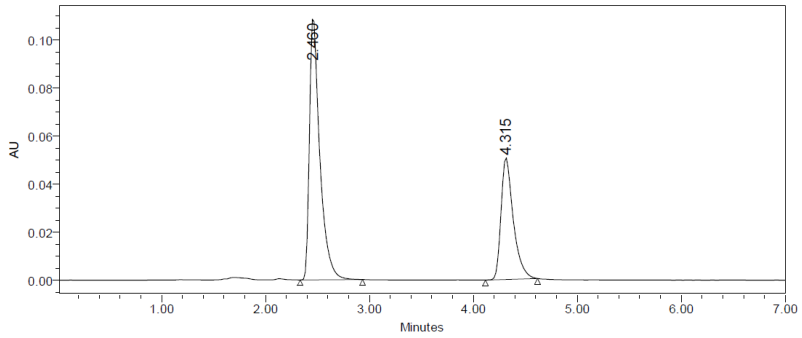


Figure: Optimized Chromatogram (Sample)

Table: Optimized Chromatogram (Sample)

S. No	Peak name	R_t	Area	Height	USP Resolution	USP Tailing	USP plate count
1	Aspirin	2.460	600123	112157		1.6	5011
2	Prasugrel	4.315	422041	51068	3.3	1.5	5947

Acceptance criteria:

- Resolution between two drugs must be not less than 2
- Theoretical plates must be not less than 2000
- Tailing factor must be not less than 0.9 and not more than 2.
- It was found from above data that all the system suitability parameters for developed method were within the limit.

VALIDATION

Blank:

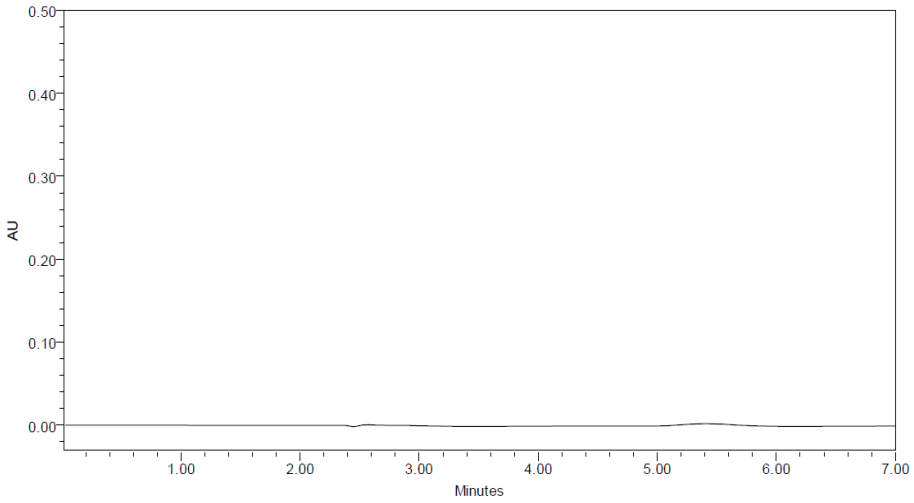


Fig: Chromatogram showing blank (mobile phase preparation)

System suitability:

Table: Results of system suitability for Aspirin

S no	Name	Rt	Area	Height	USP plate count	USP Tailing
1	Aspirin	2.459	602561	111160	5123	1.4
2	Aspirin	2.466	600543	53992	5023.2	1.4
3	Aspirin	2.472	601288	55420	5061.3	1.3
4	Aspirin	2.452	600776	112478	5147.3	1.6
5	Aspirin	2.450	600758	111779	5101.8	1.7
Mean			601185.2			
Std. Dev			816.3576			
% RSD			0.13			

Acceptance criteria:

- %RSD of five different sample solutions should not more than 2
- The %RSD obtained is within the limit, hence the method is suitable.

Table: Results of system suitability for Prasugrel

S no	Name	Rt	Area	Height	USP plate count	USP Tailing	USP Resolution
1	Prasugrel	4.322	422674	50988	5949	1.5	3.2
2	Prasugrel	4.323	424692	49813	5890.0	1.5	3.3
3	Prasugrel	4.342	421255	49826	5952.5	1.4	3.2

4	Prasugrel	4.300	415235	51804	5926.4	1.50	3.2
5	Prasugrel	4.295	416260	51274	5898.5	1.49	3.2
Mean			420023.2				
Std. Dev			724.7845				
% RSD			0.17				

Acceptance criteria:

- %RSD for sample should be NMT 2
- The %RSD for the standard solution is below 1, which is within the limits hence method is precise.

SPECIFICITY

The ICH documents define specificity as the ability to assess unequivocally the analyte in the presence of components that may be expected to be present, such as impurities, degradation products, and matrix components.

Analytical method was tested for specificity to measure accurately quantitate Aspirin and Prasugrel in drug product.

Assay (Standard):

Table: Peak results for assay standard

Sno	Name	Rt	Area	Height	USP Resolution	USP Tailing	USP plate count	Injection
1	Aspirin	2.456	600122	112157		1.5	5023	1
2	Prasugrel	4.312	420842	51068	3.3	1.4	5946	1
3	Aspirin	2.457	600205	112399		1.2	5149	2
4	Prasugrel	4.308	422034	51511	3.3	1.4	5848	2
5	Aspirin	2.456	600213	11201		1.5	5046	3
6	Prasugrel	4.312	420191	52014	3.2	1.5	5941	3

Assay (Sample):

Table: Peak results for Assay sample

Sno	Name	Rt	Area	Height	USP Resolution	USP Tailing	USP plate count	Injection
1	Aspirin	2.465	601812	110102		1.6	5028	1
2	Prasugrel	4.337	414764	49842	3.2	1.5	5949	1
3	Aspirin	2.474	600435	108333		1.6	5189	2

4	Prasugrel	4.356	418130	48360	3.3	1.5	5818	2
5	Aspirin	2.465	600212	112453		1.6	5061	3
6	Prasugrel	4.337	413645	48641	3.2	1.5	5812	3

$$\%ASSAY = \frac{\text{Sample area}}{\text{Standard area}} \times \frac{\text{Weight of standard}}{\text{Dilution of standard}} \times \frac{\text{Dilution of sample}}{\text{Weight of sample}} \times \frac{\text{Purity}}{100} \times \frac{\text{Weight of tablet}}{\text{Label claim}} \times 100$$

= 600819.7/600180×10/150×150/0.0265×99.7/100×0.2655/100×100

= 99.7%

The % purity of Aspirin and Prasugrel in pharmaceutical dosage form was found to be 99.7 %.

LINEARITY

CHROMATOGRAPHIC DATA FOR LINEARITY STUDY:

Aspirin:

Concentration Level (%)	Concentration µg/ml	Average Peak Area
33.3	50	215760
66.6	100	417001
100	150	600435
133.3	200	791969
166.6	250	974736

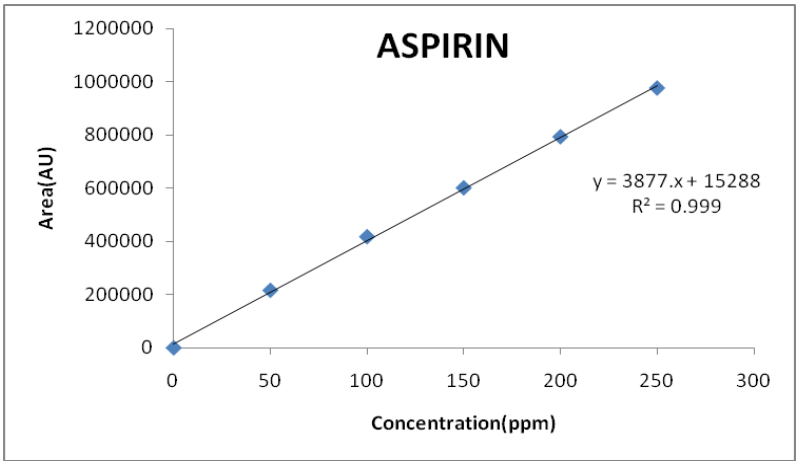


Figure 6.3.4 calibration graph for Aspirin

LINEARITY PLOT:

The plot of Concentration (x) versus the Average Peak Area (y) data of DRUG is a straight line.

Y = mx + c

Slope (m) = 3877

Intercept (c) = 15288

Correlation Coefficient (r) = 0.999

VALIDATION CRITERIA: The response linearity is verified if the Correlation Coefficient is 0.99 or greater.

CONCLUSION: Correlation Coefficient (r) is 0.99, and the intercept is 15288. These values meet the validation criteria.

Prasugrel

Concentration Level (%)	Concentration µg/ml	Average Peak Area
33	5	145474
66	10	279372
100	15	421045
133	20	562151
166	25	721671

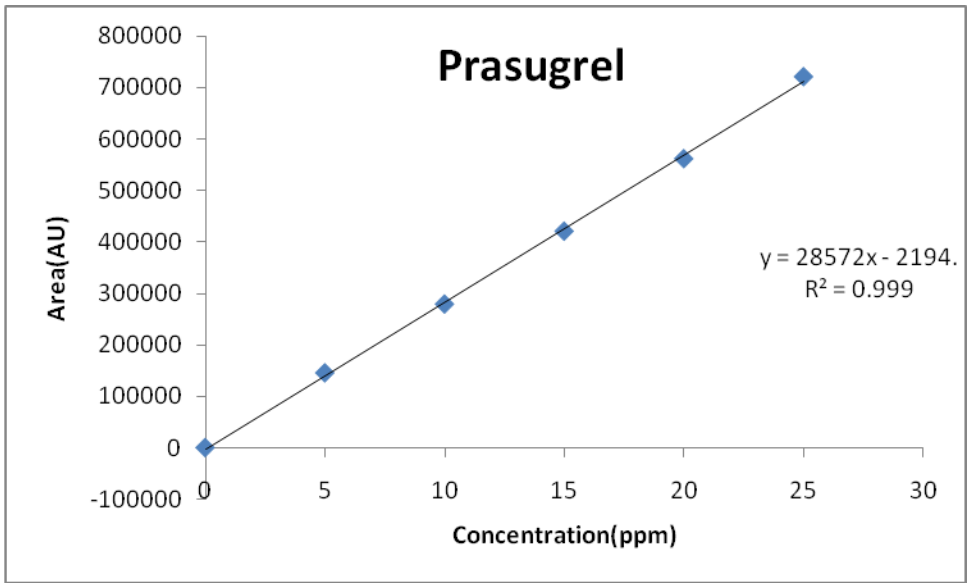


Figure 6.3.4 calibration graph for Prasugrel

LINEARITY PLOT:

The plot of Concentration (x) versus the Average Peak Area (y) data of DRUG is a straight

line.

Y = mx + c

Slope (m) = 28572

Intercept (c) = 2194

Correlation Coefficient (r) = 0.999

VALIDATION CRITERIA: The response linearity is verified if the Correlation Coefficient is 0.99 or greater.

CONCLUSION: Correlation Coefficient (r) is 0.99, and the intercept is 2194. These values meet the validation criteria.

Precision:

The precision of 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.

REPEATABILITY

Obtained Five (5) replicates of 100% accuracy solution as per experimental conditions. Recorded the peak areas and calculated % RSD.

Table: Results of repeatability for Aspirin:

S no	Name	Rt	Area	Height	USP plate count	USP Tailing
1	Aspirin	2.453	603403	112688	5881.3	1.4
2	Aspirin	2.455	608107	113637	5844.1	1.3
3	Aspirin	2.453	607266	112849	5918.1	1.3
4	Aspirin	2.452	608776	112478	5847.3	1.4
5	Aspirin	2.450	609758	111779	5801.8	1.5
Mean			607462			
Std. Dev			2445.82			
% RSD			0.40			

Acceptance criteria:

- %RSD for sample should be NMT 2
- The %RSD for the standard solution is below 1, which is within the limits hence method is precise.

Table: Results of method precession for Prasugrel:

S.No	Name	Rt	Area	Height	USP plate count	USP Tailing	USP Resolution
1	Prasugrel	4.289	429183	52411	5050.9	1.49	3.2

2	Prasugrel	4.309	416643	52475	5084.8	1.5	3.2
3	Prasugrel	4.306	424052	51841	5000.1	1.4	3.2
4	Prasugrel	4.300	425235	51804	5026.4	1.51	3.2
5	Prasugrel	4.295	416260	51274	5098.5	1.51	3.2
Mean			422274.6				
Std. Dev			5646.668				
% RSD			1.3				

Acceptance criteria:

- %RSD for sample should be NMT 2
- The %RSD for the standard solution is below 1, which is within the limits hence method is precise.

Intermediate precision:

Day 1:

Table: Results of Intermediate precision for Aspirin

S no	Name	Rt	Area	Height	USP plate count	USP Tailing
1	Aspirin	2.465	602386	111226	5075.9	1.5
2	Aspirin	2.472	608118	112497	5043.2	1.3
3	Aspirin	2.467	605566	110347	5029.9	1.5
4	Aspirin	2.466	608543	53992	5023.2	1.4
5	Aspirin	2.472	609288	55420	5061.3	1.4
6	Aspirin	3.424	607315	54154	5078.4	1.3
Mean			606869.3			
Std. Dev			2538.025			
% RSD			0.41			

Acceptance criteria:

- %RSD of five different sample solutions should not more than 2

Table: Results of Intermediate precision for Prasugrel

S no	Name	Rt	Area	Height	USP plate count	USP Tailing	USP Resolution
1	Prasugrel	4.323	422252	50991	5886.2	1.6	3.2
2	Prasugrel	4.343	418090	50664	5947.5	1.5	3.2

3	Prasugrel	4.324	424361	50295	5907.8	1.55	3.2
4	Prasugrel	4.323	424692	49813	5890.0	1.50	3.2
5	Prasugrel	4.342	411255	49826	5852.5	1.49	3.2
6	Prasugrel	4.323	422252	50991	5756.8	1.50	3.2
Mean			420483.7				
Std. Dev			5096.974				
% RSD			1.2				

Acceptance criteria:

- %RSD of five different sample solutions should not more than 2
- The %RSD obtained is within the limit, hence the method is rugged.

Day 2:

Table: Results of Intermediate precision Day 2 for Aspirin

S no	Name	Rt	Area	Height	USP plate count	USP Tailing
1	Aspirin	2.456	602581	112175	5013	1.7
2	Aspirin	2.457	600985	112422	5007	1.7
3	Aspirin	2.456	600145	114513	5198	1.8
4	Aspirin	2.459	600332	111580	5246	1.7
5	Aspirin	2.467	600566	110347	5096	1.8
6	Aspirin	2.459	600332	111580	5178	1.8
Mean			600823.5			
Std. Dev			908.2622			
% RSD			0.15			

Acceptance criteria:

- %RSD of five different sample solutions should not more than 2

Table: Results of Intermediate precision for Prasugrel

S no	Name	Rt	Area	Height	USP plate count	USP Tailing	USP Resolution

1	Prasugrel	4.312	425263	50936	5981	1.5	3.2
2	Prasugrel	4.308	427069	51400	5887	1.49	3.2
3	Prasugrel	4.312	424231	51236	5928	1.5	3.2
4	Prasugrel	4.322	423569	51084	5898	1.50	3.2
5	Prasugrel	4.324	414361	50295	5887	1.5	3.2
6	Prasugrel	4.322	413569	51084	5940	1.5	3.2
Mean			421343.7				
Std. Dev			5841.789				
% RSD			1.38				

Acceptance criteria:

- %RSD of five different sample solutions should not more than 2
- The %RSD obtained is within the limit, hence the method is rugged.

ACCURACY:

Accuracy at different concentrations (50%, 100%, and 150%) were prepared and the % recovery was calculated.

The accuracy results for Aspirin

%Concentration (at specification Level)	Area	Amount Added (ppm)	Amount Found (ppm)	% Recovery	Mean Recovery
50%	308408	75	75.5	100.6	100.3%
100%	600619	150	150	100	
150%	894293	225	226	100.4	

The accuracy results for Prasugrel

%Concentration (at specification Level)	Area	Amount Added (ppm)	Amount Found (ppm)	% Recovery	Mean Recovery

50%	216092	7.5	7.55	100	99.7%
100%	423626	15	14.95	99.6	
150%	634469.7	22.5	22.4	99.5	

Acceptance Criteria:

- The percentage recovery was found to be within the limit (98-102%).

The results obtained for recovery at 50%, 100%, 150% are within the limits. Hence method is accurate.

LIMIT OF DETECTION

The detection limit of an individual analytical procedure is the lowest amount of analyte in a sample which can be detected but not necessarily quantitated as an exact value.

LOD= 3.3 × σ / s

Where

σ = Standard deviation of the response

S = Slope of the calibration curve

Result:

Aspirin:

=3.3 × 5590.256/38776

=4.75µg/ml

Prasugrel:

=3.3 × 8274.935/57144

=0.95µg/ml

LIMIT OF QUANTITATION

The quantitation limit of an individual analytical procedure is the lowest amount of analyte in a sample which can be quantitatively determined.

LOQ=10×σ/S

Where

σ = Standard deviation of the response

S = Slope of the calibration curve

Result:

Aspirin:

=10×5590.256/38776

= 14.4µg/ml

Prasugrel:

=10 × 8274.935/57144

= 2.89µg/ml

Robustness

Table: Results for Robustness

Aspirin:

Parameter used for sample analysis	Peak Area	Retention Time	Theoretical plates	Tailing factor
Actual Flow rate of 1.0 mL/min	600122	2.456	5215	1.8
Less Flow rate of 0.9 mL/min	651206	2.741	5199	1.79
More Flow rate of 1.1 mL/min	546820	2.270	5234	1.8
Less organic phase	586420	3.266	5298	1.8
More organic phase	542813	2.147	5287	1.76

Acceptance criteria:

The tailing factor should be less than 2.0 and the number of theoretical plates (N) should be more than 2000.

Prasugrel:

Parameter used for sample analysis	Peak Area	Retention Time	Theoretical plates	Tailing factor
Actual Flow rate of 1.0 mL/min	422042	4.312	5648	1.5
Less Flow rate of 0.9 mL/min	453012	4.830	5687	1.6
More Flow rate of 1.1 mL/min	398654	3.979	5602	1.5
Less organic phase	445983	3.266	5643	1.55
More organic phase	402315	2.147	5699	1.51

Acceptance criteria:

The tailing factor should be less than 2.0 and the number of theoretical plates (N) should be more than 2000.

SUMMARY

The analytical method was developed by studying different parameters.

First of all, maximum absorbance was found to be at 238nm and the peak purity was excellent.

Injection volume was selected to be 10µl which gave a good peak area.

The column used for study was Symmetry C_{18} because it was giving good peak.

40ºC temperature was found to be suitable for the nature of drug solution. The flow rate was fixed at 1.0ml/min because of good peak area and satisfactory retention time.

Mobile phase is Acetonitrile: water (35:65% v/v)was fixed due to good symmetrical peak. So this mobile phase was used for the proposed study.

Run time was selected to be 7min because analyze gave peak around 2.456, 4.312 ±0.02min respectively and also to reduce the total run time.

The percent recovery was found to be 98.0-102 was linear and precise over the same range. Both system and method precision was found to be accurate and well within range.

The analytical method was found linearity over the range 50-250µg/ml of Aspirin and 5-25 µg/ml of Prasugrel of the target concentration.

The analytical passed both robustness and ruggedness tests. On both cases, relative standard deviation was well satisfactory.

CONCLUSION

In the present investigation, a simple, sensitive, precise and accurate RP-HPLC method was developed for the quantitative estimation of Aspirin and Prasugrel in bulk drug and pharmaceutical dosage forms.

This method was simple, since diluted samples are directly used without any preliminary chemical derivatisation or purification steps.

Aspirin and Prasugrel was freely soluble in ethanol, methanol and sparingly soluble in water.

Acetonitrile: water (35:65% v/v) was chosen as the mobile phase. The solvent system used in this method was economical.

The %RSD values were within 2 and the method was found to be precise.

The results expressed in Tables for RP-HPLC method was promising. The RP-HPLC method is more sensitive, accurate and precise compared to the Spectrophotometric methods.

This method can be used for the routine determination of Aspirin and Prasugrel in bulk drug and in Pharmaceutical dosage forms.

ACKNOWLEDGEMENT

The Authors are thankful to the Management and Principal, Princeton College of Pharmacy, Narapally, Ghatkesar, Telangana, for extending support to carry out the research work. Finally, the authors express their gratitude to the Sura Pharma Labs, Dilsukhnagar, Hyderabad, for providing research equipment and facilities.

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