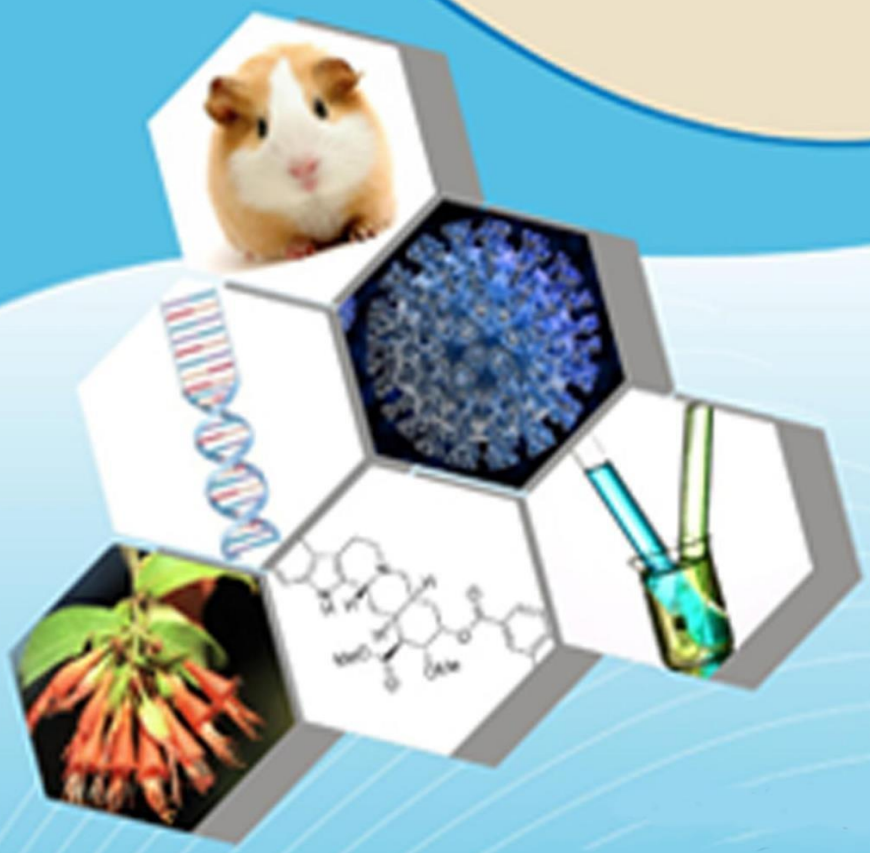
ISSN : 2347-2251

Indo-American Journal of Pharma and Bio Sciences



iajpb.editor@gmail.com
editor@iajpb.com

www.iajpb.com

Indo-American Journal of Pharma and Bio Sciences

Vol. 22, Issue 2, 2024

METHOD DEVELOPMENT AND VALIDATION FOR TRIPROLIDINE AND PHENYLEPHERINE IN BULK AND ITS PHARMACEUTICAL DOSAGE FORMS BY USING RP-HPLC

DR. P. GOPAL RAO[1]*, PAISA, B.SINDH, G.YASHWANTH, G.SHIVANI, K.SUPRAJA,P.AKHILA

DEPARTMENT OF PHARMACEUTICAL ANALYSIS, HOD SVS SCHOOL OF PHARMACY, BHEEMARAM, TELANGANA, INDIA.

Corresponding Author: Dr.P.Gopal Rao.Paisa

Email.id: dra,gopaal7207124124@gmail.com

Contact no: 720124124

The Phosphate support was pH 4.5 was improved with cushion blended degree of PH 4.5(20:80 v/v). Kromosil C18 Fragment (250mm x 4.6mm)5µg or indistinct misleadingly associated. The finder at 254 nm. The potential increases method. Triprolidine %RSD 0.2

and Phenylephrine %RSD 0.6. Generally engaging precision for Triprolidine %RSD 0.2 and Phenylephrine %RSD 0.1 The of Triprolidine and Phenylephrine seen as inside limit. The framework was viewed as having research office serious and precision.

KEYWORDS: Kromosil C_{18} , Triprolidine and Phenylephrine, RP-HPLC

Indo-American Journal of Pharma and Bio Sciences

Vol. 22, Issue 2, 2024

INTRODUCTION

CHROMATOGRAPHY

The term ' Chromatography' covers those processes aimed at the separation of the various species of a mixture on the basis of their distribution characteristics between a stationary and a mobile phase.

Modes of Chromatography:

Modes of chromatography are defined essentially according to the nature of the interactions between the solute and the stationary phase, which may arise from hydrogen bonding, Vander walls forces, electrostatic forces or hydrophobic forces or basing on the size of the particles (e.g. Size exclusion chromatography).

Different modes of chromatography are as follows:

- Normal Phase Chromatography
- Reversed Phase Chromatography
- Reversed Phase – ion pair Chromatography
- Ion Chromatography
- Ion-Exchange Chromatography
- Affinity Chromatography
- Size Exclusion Chromatography

Reversed Phase Chromatography:

Since 1960' s chromatographers started modifying the polar nature of silanol group by chemically reacting silica with organic silanes. The objective was to make less polar or non polar so that polar solvents can be used to separate water-soluble polar compounds. Since the ionic nature of the chemically modified silica is now reversed i.e. it is non-polar or the nature of the phase is reversed. The chromatographic separation carried out with such silica is referred to as reversed-phase chromatography.

Indo-American Journal of Pharma and Bio Sciences

Vol. 22, Issue 2, 2024

A large number of chemically bonded stationary phases based on silica are available commercially. Silica based stationary phases are still most popular in reversed phase chromatography however other absorbents based on polymer (styrene-di-vinyl benzene copolymer) are slowly gaining ground.

The retention decreases in the following order: aliphatics > induced dipoles (i.e. CCl_4) > permanent dipoles (e.g.CHC_{l3}) > weak Lewis bases (ethers, aldehydes, ketones) > strong Lewis bases (amines) > weak Lewis acids (alcohols, phenols) > strong Lewis acids (carboxylic acids). Also the retention increases as the number of carbon atoms increases.

As a general rule the retention increases with increasing contact area between sample molecule and stationary phase i.e. with increasing number of water molecules, which are released during the adsorption of a compound. Branched chain compounds are eluted more rapidly than their corresponding normal isomers.

In reversed phase systems the strong attractive forces between water molecules arising from the 3-dimentional inter molecular hydrogen bonded network, from a structure of water that must be distorted or disrupted when a solute is dissolved. Only higher polar or ionic solutes can interact with the water structure. Non- polar solutes are squeezed out of the mobile phase and are relatively insoluble in it but with the hydrocarbon moieties of the stationary phase.

Chemically bonded octadecyl silane (ODS) an alkaline with 18 carbon atoms is the most popular stationary phase used in pharmaceutical industry. Since most pharmaceutical compounds are polar and water soluble, the majority of HPLC methods used for quality assurance, decomposition studies, quantitative analysis of both bulk drugs and their formulations use ODS HPLC columns. The solvent strength in reversed phase chromatography is reversed from that of adsorption chromatography (silica gel) as stated earlier. Water interacts strongly with silanol groups, so that, adsorption of sample molecules become highly restricted and they are rapidly eluted as a result. Exactly opposite applies in reversed phase system; water cannot wet the non-polar (hydrophobic) alkyl groups such as C_{18} of ODS phase and therefore does not interact with the bonded moiety. Hence water is the weakest solvent of all and gives slowest elution rate. The elution time (retention time) in reversed phase chromatography increases with increasing amount of water in the mobile phase.

Indo-American Journal of Pharma and Bio Sciences

Vol. 22, Issue 2, 2024

Fig-1: Model of HPLC-Waters

Adsorption Chromatography or Normal Phase Chromatography(3,4,5)

In normal phase chromatography, the stationary phase is a polar adsorbent and the mobile phase is generally a mixture of non-aqueous solvents.

The silica structure is saturated with silanol groups at the end. These OH groups are statistically disturbed over the whole of the surface. The silanol groups represent the active sites (very polar) in the stationary phase. This forms a weak type of bond with any molecule in the vicinity when any of the following interactions are present.

Dipole-induced dipole bonding

- Dipole-dipole bonding
- Hydrogen bonding
- π-Complex bonding

Indo-American Journal of Pharma and Bio Sciences

Vol. 22, Issue 2, 2024

These situations arise when the molecule has one or several atoms with lone pair electron or a double bond. The absorption strengths and hence k' values (elution series) increase in the following order- Saturated hydrocarbons < olefins < aromatics < organichalogen compounds < sulphides < ethers< esters < aldehydes and ketones < amines < sulphones < amides < carboxylic acids. The strength of interactions depends not only on the functional groups in the sample molecule but also on sterics factors. If a molecule has several functional groups, then the most polar one determines the reaction properties.

Chemically modified silica, such as the aminopropyl, cyanopropyl and diol phases are useful alternatives to silica gel as stationary phase in normal phase chromatography.

The aminopropyl and cyanopropyl phases provide opportunities for specific interactions between the analyte and the stationary phases and thus offer additional options for the optimizations of separations. Other advantages of bonded phases lie in their increased homogeneity of the phase surface.

Resolution with water in weak mobile phase may be most conveniently achieved by drying the solvents and then adding a constant concentration of water or some very polar modifier such as acetic acid or triethylamine (TEA) to the mobile phase. The addition of such polar modifiers serves to deactivate the more polar shape as well as the reproducibility of the retention times.

Indo-American Journal of Pharma and Bio Sciences

Vol. 22, Issue 2, 2024

Fig-2: Model of HPLC-Spectral

Chromatographic methods can be classified most practically according to the stationary and mobile phases, as shown in the table:

Table-1 : Classification of Chromatographic methods

Stationary phase	**Mobile phase**	**Method**
Solid	Liquid	Adsorption column, thin-layer, ion exchange, High performance liquid chromatography.
Liquid	Liquid Gas	Partition, column, thin-layer, HPLC, paper chromatography. Gas – Liquid Chromatography.

Indo-American Journal of Pharma and Bio Sciences

Vol. 22, Issue 2, 2024

The importance of Chromatography is increasing rapidly in pharmaceutical analysis. The exact differentiation, selective identification and quantitative determination of structurally closely related compounds are possible with chromatography. Another important field of application of chromatographic methods is the purity testing of final products and intermediates (detection of decomposition products and by-products). As a consequence of the above points, chromatographic methods are occupying an ever-expanding position in the latest editions of the pharmacopoeias and other testing standards.

The modern form of column chromatography has been called high performance, high pressure, high-resolution and high-speed liquid chromatography.

High-Performance Liquid Chromatography (HPLC) is a special branch of column chromatography in which the mobile phase is forced through the column at high speed. As a result the analysis time is reduced by 1-2 orders of magnitude relative to classical column chromatography and the use of much smaller particles of the adsorbent or support becomes possible increasing the column efficiency substantially.

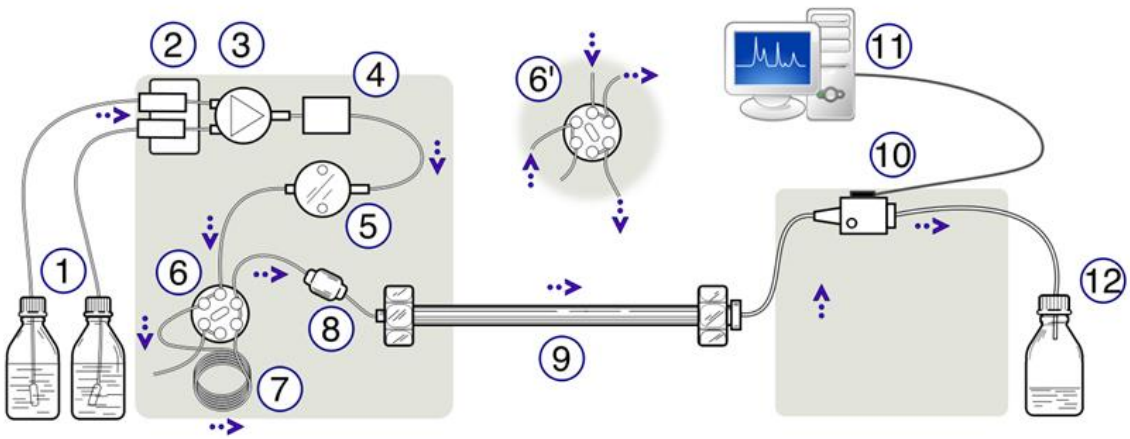


Figure 3. Schematic Diagram of a High Performance Liquid Chromatography. (1) Solvent reservoirs, (2) Solvent degasser, (3) Gradient valve, (4) Mixing vessel for delivery of the mobile phase, (5) High-pressure pump, (6) Switching valve in "inject position", (6') Switching valve in "load position", (7) Sample injection

Indo-American Journal of Pharma and Bio Sciences

Vol. 22, Issue 2, 2024

loop, (8) Pre-column or guard column, (9) Analytical column, (10) Detector (i.e. IR, UV), (11) Data acquisition, (12) Waste or fraction collector. Created by Yassne Mrabet.

The essential equipment consists of an eluent, reservoir, a high-pressure pump, and an injector for introducing the sample, a column containing the stationary phase, a detector and recorder. The development of highly efficient micro particulate bonded phases has increased the versatility of the technique and has greatly improved the analysis of multi component mixtures.

The systems used are often described as belonging to one of four mechanistic types, adsorption, partition, ion exchange and size-exclusion. Adsorption chromatography arises from interaction between solutes on the surface of the solid stationary phase. Partition chromatography involves a liquid stationary phase, which is immiscible with the eluent and coated on an inert support. Adsorption and partition systems can be normal phase (stationary phase more polar than eluent) or reversed phase (stationary phase less polar than eluent). Ion-exchange chromatography involves a solid stationary phase with anionic or cationic groups on the surface to which solute molecules of opposite charge are attracted. Size-exclusion chromatography involves a solid stationary phase with controlled pore size. Solutes are separated according to their molecular size, the large molecules enable to enter the pores eluting first

The various components of a HPLC system are herewith described.

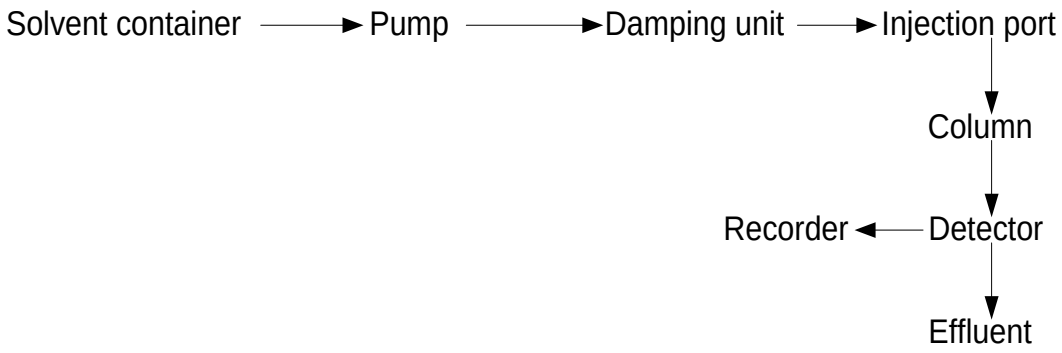


Fig-4: Various Components of HPLC

Indo-American Journal of Pharma and Bio Sciences

Vol. 22, Issue 2, 2024

System Components:

Solvent delivery system:

The mobile phase is pumped under pressure from one or several reservoirs and flows through the column at a constant rate. With micro particulate packing, there is a high-pressure drop across a chromatography column. Eluting power of the mobile phase is determined by its overall polarity, the polarity of the stationary phase and the nature of the sample components. For normal phase separations eluting power increases with increasing polarity of the solvent but for reversed phase separations, eluting power decreases with increasing solvent polarity. Optimum separating conditions can be achieved by making use of mixture of two solvents. Some other properties of the solvents, which need to be considered for a successful separation, are boiling point, viscosity, detector compatibility, flammability and toxicity.

The most important component of HPLC in solvent delivery system is the pump, because its performance directly effects the retention time, reproducibility and detector sensitivity. Among the several solvent delivery systems (direct gas pressure, pneumatic intensifier, reciprocating etc.) reciprocating pump with twin or triple pistons is widely used, as this system gives less baseline noise, good flow rate, reproducibility etc.

Solvent degassing system:

The constituents of the mobile phase should be degassed and filtered before use. Several methods are employed to remove the dissolved gases in the mobile phase. They include heating and stirring, vacuum degassing with an aspirator, filtration through 0.45 filter, vacuum degassing with an air-soluble membrane, helium purging ultra sonication or purging or combination of these methods. HPLC systems are also provided with an online degassing system, which continuously removes the dissolved gases from the mobile phase.

Indo-American Journal of Pharma and Bio Sciences

Vol. 22, Issue 2, 2024

Gradient elution devices:

HPLC columns may be run isocratically, i.e., with constant eluent or they may be run in the gradient elution mode in which the mobile phase composition varies during run. Gradient elution is a means of overcoming the problem of dealing with a complex mixture of solutes.

Sample introduction systems:

Two means for analyte introduction on the column are injection in to a flowing stream and a stop flow injection. These techniques can be used with a syringe or an injection valve. Automatic injector is a microprocessor-controlled version of the manual universal injector. Usually, up to 100 samples can be loaded in to the auto injector tray. The system parameters such as flow rates, gradient, run time, volume to be injected, etc. are chosen, stored in memory and sequentially executed on consecutive injections.

Liquid chromatographic detectors**:**

The function of the detector in HPLC is to monitor the mobile phase as it emerges from the column. Generally, there are two types of HPLC detectors, bulk property detectors and solute property detectors.s

*Bulk property detectors**:***

These detectors are based on differential measurement of a property, which is common to both the sample and the mobile phase. Examples of such detectors are refractive index, conductivity and dielectric constant detectors.

*Solute property detectors**:***

Indo-American Journal of Pharma and Bio Sciences

Vol. 22, Issue 2, 2024

Solute property detectors respond to a physical property of the solute, which is not exhibited by the pure mobile phase. These detectors measure a property, which is specific to the sample, either with or without the removal of the mobile phase prior to the detection. Solute property detectors which do not require the removal of the mobile phase before detection include spectrophotometric (UV or UV-Vis) detector, fluorescence detectors, polarographic, electro-chemical and radio activity detectors, whilst the moving wire flame ionization detector and electron capture detector both require removal of the mobile phase before detection.

UV-VIS and fluorescent detectors are suitable for gradient elution, because many solvents used in HPLC do not absorb to any significant extent.

Column-packing materials:

The heart of the system is the column. In order to achieve high efficiency of separation, the column material (micro-particles, 5-10 μm size) packed in such a way that highest numbers of theoretical plates are possible.

Silica (SiO_2 X H_2O) is the most widely used substance for the manufacture of packing materials. It consists of a network of siloxane linkages (Si-O-Si) in a rigid three dimensional structure containing inter connecting pores. Thus a wide range of commercial products is available with surface areas ranging from 100 to 800 m^2/g. and particle sizes from 3 to 50 μm.

The silanol groups on the surface of silica give it a polar character, which is exploited in adsorption chromatography using non-polar organic eluents. Silica can be drastically altered by reaction with organochloro silanes or organo alkoxy silanes giving Si-O-Si-R linkages with the surface. The attachment of hydrocarbon change silica produces a non-polar surface suitable for reversed phase chromatography where mixtures of water and organic solvents are used as eluent. The most popular material is octadecyl-silica (ODS-Silica), which contains C_{18} chains, but materials with C_2, C_6, C_8 and C_{22} chains are also available. During manufacture, such materials may be reacted with a small mono functional silane (e.g. trimethyl chloro silane) to reduce further the number of silanol groups remaining on the surface (end-

Indo-American Journal of Pharma and Bio Sciences

Vol. 22, Issue 2, 2024

capping). There is a vast range of materials which have intermediate surface polarities arising from the bonding to silica of other organic compounds which contain groups such as phenyl, nitro, amino and hydroxyl. Strong ion exchangers are also available in which sulphonic acid groups or quaternary ammonium groups are bonded to silica. The useful pH range for columns is 2 to 8, since siloxane linkages are cleaved below pH-2 while at pH values above eight, silica may dissolve.

In HPLC, generally two types of columns are used, normal phase columns and reversed phase columns. Using normal phase chromatography, particularly of non-polar and moderately polar drugs can make excellent separation. It was originally believed that separation of compounds in mixture takes place slowly by differential adsorption on a stationary silica phase. However, it now seems that partition plays an important role, with the compounds interacting with the polar silanol groups on the silica or with bound water molecules.

While normal phase seems the passage of a relatively non-polar mobile phase over a polar stationary phase, reversed phase chromatography is carried out using a polar mobile phase such as methanol, acetonitrile, water, buffers etc., over a non-polar stationary phase. Ranges of stationary phases (C_{18}, C_8, -NH_2, -CN, -phenyl etc.) are available and very selective separations can be achieved.

2.2. METHOD DEVELOPMENT:(6,7,8,9)

Analytical method is a detailed description of different steps necessary to perform analytical tests which may include preparation of samples, reagents, use of apparatus, generation of calibration curve and use of formulae for calculations.

Analytical method development is required to analyze Herbal Products, New process & reactions, New molecules, Active ingredients(Macro analysis), Residues(Micro analysis), Impurity profiling etc., .

USP has published specific guidelines for method validation for compound evaluation. USP defines eight steps for validation

Indo-American Journal of Pharma and Bio Sciences

Vol. 22, Issue 2, 2024

- Accuracy
- Precision
- Specificity
- Limit of detection
- Limit of quantitation
- Linearity and range

Analytical Methodology provides the following to an analyst;

- The required data for a given analytical problem
- Required sensitivity
- Required Accuracy
- Required Range or analysis
- Required Precision

These are the minimum requirements of the specifications of the method for the intended purpose. The steps of method development consist of the following steps which are common to most types of projects:

- Method development plan definition
- Background information gathering
- Laboratory method development
- Generation of test procedure

A method should be developed with the goal to rapidly test preclinical samples, formulation prototypes and commercial\

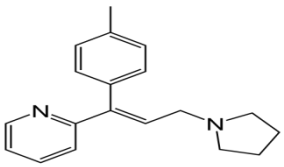
Indo-American Journal of Pharma and Bio Sciences

Vol. 22, Issue 2, 2024

DRUG PROFILE

TRIPROLIDINE

CAS NO : 486-12-4



IUPAC name : 2-[(1E)-1-(4-methylphenyl)-3-(pyrrolidin-1-yl)prop-1-en-1-yl]pyridine

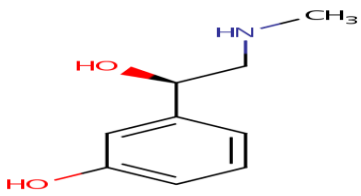
Molecular formula : $C_{19}H_{22}N_2$

Molecular weight : 278.3914 g/mol.

PHENYLEPHRINE

Iupac name : 3-[(1R)-1-hydroxy-2-(methylamino)ethyl]phenol

CAS NO : 59-42-7



Molecular formula : $C_9H_{13}NO_2$

Molecular weight : 167.205 g/mol.

Indo-American Journal of Pharma and Bio Sciences

Vol. 22, Issue 2, 2024

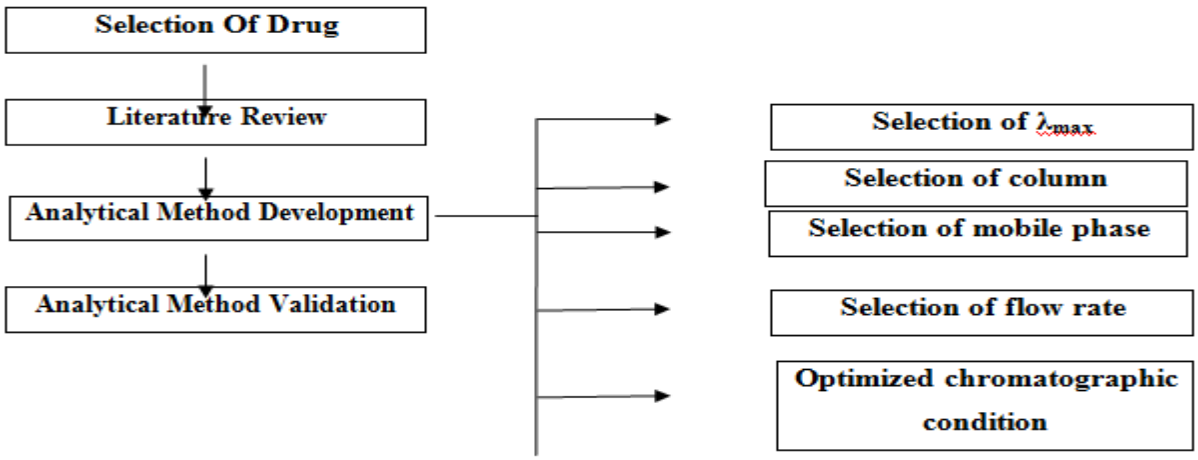
3. LITERATURE REVIEW

1) A.B.N. Nageswara Rao et al.; Developed an exact, particularly interesting, cautious and reproducible isocratic RP-HPLC strategy was made and following embraced for the organized evaluation and tablet segment structures. The 1.0 ml/min and UV disclosure at 225nm. The hour of Triprolidine and Phenylephrine were viewed as 3.34 min and 4.75 min autonomously. Support limits like precision, and region methodology showed the assessment of mass and dynamic medicine present in tablet segment.

4.AIM AND OBJECTIVE

The creating audit reveals that few HPLC systems for the examination Triprolidine and Phenylephrine alone and in mix in with different solutions. Generally couple of frameworks are similarly uncovered for assessment from plan .we mean to support a Strength showing RP-HPLC procedure by concurrent affirmation with major, quick, more prominent responsiveness and speedier elution.

5. PLAN OF WORK



Indo-American Journal of Pharma and Bio Sciences

Vol. 22, Issue 2, 2024

SL.No	Instrument	Model
1	HPLC	Shimadzu, model No. SPD-20MA LC+20AD, Software- LC-20 Solution
2	UV/VIS spectrophotometer	LABINDIA UV 3000+
3	pH meter	Adwa – AD 1020
4	Weighing machine	Afcoset ER-200A
5	Pipettes and Burettes	Borosil
6	Beakers	Borosil

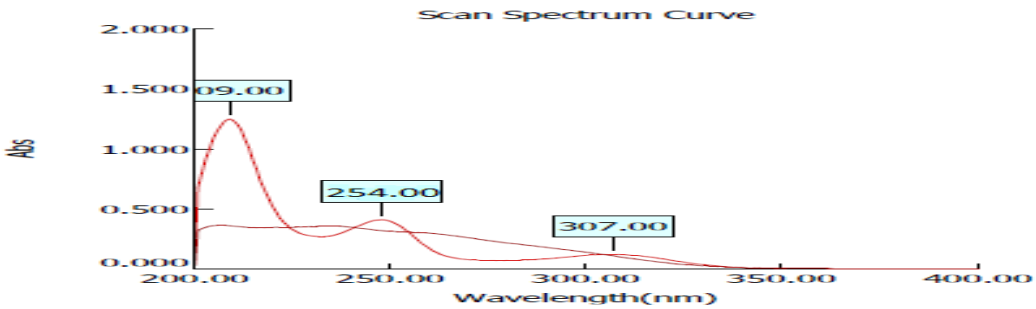
5.2: CHEMICALS USED

Table 5.2: Chemicals used

SL.No	Chemical	Brand
1	DECITABINE	Mavyret
2	CEDAZURIDINE	Mavyret
3	KH_2PO_4	FINER chemical LTD
4	Water and Methanol for HPLC	LICHROSOLV (MERCK)
5	Acetonitrile for HPLC	MOLYCHEM
6	Ortho phosphoric Acid	MERCK

7.RESULTS AND DISCUSSION

7.1WAVELENGTH DETECTION:



Chromatogram for Triprolidine and Phenylephrine

Indo-American Journal of Pharma and Bio Sciences

Vol. 22, Issue 2, 2024

Column	Inertsil C18 (4.6 x 250mm, 5µm)
Buffer pH	3.0.
Mobile phase	30% buffer 70% Methanol
Flow rate	1.0ml per min
Wavelength	254 nm
Temperature	Ambient.
Run time	10min.

Results of system suitability parameters Triprolidine and Phenylephrine

S.No	Name	Retention time(min)	Area (µV sec)	Height (µV)	USP resolution	USP tailing	USP plate count
1	Triprolidine	2.669	124505	223532	**1.2**	1.2	4523.3
2	Triprolidine	2.5264	123442	134544	1.2	1.2	5020.2
3	Triprolidine	2.5265	123431	124386	1.2	1.2	4061.2
4	Triprolidine	2.5266	125432	134568	1.2	1.2	5032.4
5	Triprolidine	2.5267	122434	146852	1.2	1.2	5076.4
6	Triprolidine	2.5268	124438	145782	1.2	1.2	6024.8
7	Phenylephrine	3.855	1308495	154566	1.3	1.3	6090.3
8	Phenylephrine	3.902	1309496	156428	1.3	1.3	5023.2
9	Phenylephrine	3.903	1306498	152634	1.3	1.3	8060.7
10	Phenylephrine	3.904	1342499	158426	1.3	1.3	7080.1

VALIDATION PARAMETERS:

PRECISION:

Injection	Peak Name	Rt	Area	Height
1	Triprolidine	3.699	1302729	341432.2
2	Triprolidine	3.790	1302947	523341.4
3	Triprolidine	3.663	1303236	374642.4
4	Triprolidine	3.658	1303977	327514.3
5	Triprolidine	3.647	1309759	374028.1
6.	Triprolidine	3.645	1309789	346280.2
mean			1304529.8	
Std.dev			2961.1	
%RSD			0.2	

Indo-American Journal of Pharma and Bio Sciences

Vol. 22, Issue 2, 2024

Injection	Peak Name	Rt	Area	Height
1	Phenylephrine	3.616	123149	248742.3
2	Phenylephrine	3.634	123766	281441.2
3	Phenylephrine	3.460	124271	271721.2
4	Phenylephrine	3.446	124691	284393.8
5	Phenylephrine	3.437	124956	256318.0
6	Phenylephrine	3.438	125845	226813.0
mean			124162.7	
Std.dev			725.6	
%RSD			0.6	

INTERMEDIATE PRECESSION (RUGGEDNESS):

INJECTION	Peak name	Rt	Area	Height
1	Triprolidine	2.554	1300148	438467.1
2	Triprolidine	2.557	1304520	436873.3
3	Triprolidine	2.563	1305937	438572.1
4	Triprolidine	2.562	1306476	435587.5
5	Triprolidine	2.561	130871	432826.4
6	Triprolidine	2.561	130872	432838.3
mean			1305070.2	
Std.dev			3061.8	
%RSD			0.2	

INJECTION	Peak name	Rt	Area	Height
1	Phenylephrine	3.790	122487	241421.6
2	Phenylephrine	3.657	122626	233417.3
3	Phenylephrine	3.663	122632	281751.1
4	Phenylephrine	3.646	122702	241843.6
5	Phenylephrine	3.662	122962	281564.1
6	Phenylephrine	3.663	122972	284917.2
mean			122681.8	
Std.dev			174.8	
%RSD			0.1	

ACCURACY:

Table 7.14 Details of Accuracy 50 %

INJECTION	Peak Name	RT	Area	Height
1	Triprolidine	2.572	132457	86026
2	Triprolidine	2.573	132458	85549
3	Triprolidine	2.576	134242	84196
4	Phenylephrine	3.881	122487	21744
5	Phenylephrine	3.882	122489	21909
6	Phenylephrine	3.792	122392	21382
Mean			371513.5	
Std.Dev			253899.3	
% RSD			0.532	

Indo-American Journal of Pharma and Bio Sciences

Vol. 22, Issue 2, 2024

Details of Accuracy 100 %

INJECTION	Peak Name	RT	Area	Height
1	Triprolidine	2.306	132405	86096
2	Triprolidine	2.243	132452	86549
3	Triprolidine	2.223	133232	84176
4	Phenylephrine	3.546	124465	21784
5	Phenylephrine	3.542	122428	25909
6	Phenylephrine	3.546	124345	21372
Mean			372523.5	
Std.Dev			2508918.3	
% RSD			0.535	

Details of Accuracy 150 %

INJECTION	Peak Name	RT	Area	Height
1	Triprolidine	2.592	142526	76083
2	Triprolidine	2.573	142527	76348
3	Triprolidine	2.223	143532	74275
4	Phenylephrine	3.841	135545	21682
5	Phenylephrine	3.882	132558	25508
6	Phenylephrine	3.842	134345	21476
Mean			338742.3	
Std.Dev			840776.2	
% RSD			0.575	

%Concentration (at specification Level)	Area	Amount Added (mg)	Amount Found (mg)	% Recovery	Mean Recovery
50%	656659.5	5.0	5.036	100.7%	99.84%
100%	1304258	10.0	10.003	100.0%	
150%	1854608	14.4	14.224	98.780%	

%Concentration (at specification Level)	Area	Amount Added (mg)	Amount Found (mg)	% Recovery	Mean Recovery
50%	65800	5.3	5.34	100.8%	100.51%
100%	124353	10	10.10	100.01%	
150%	177940	14.2	14.45	99.68%	

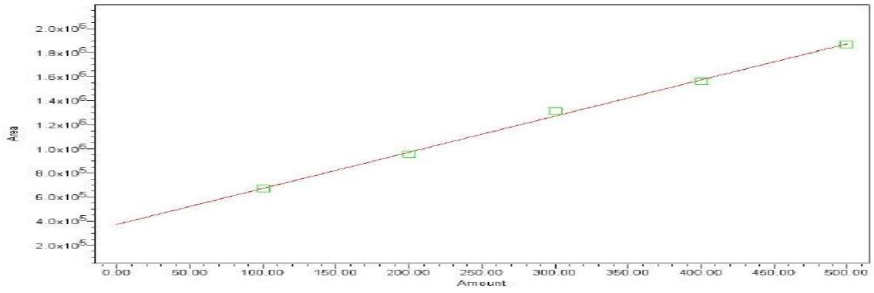
3.4 LINEARITY:

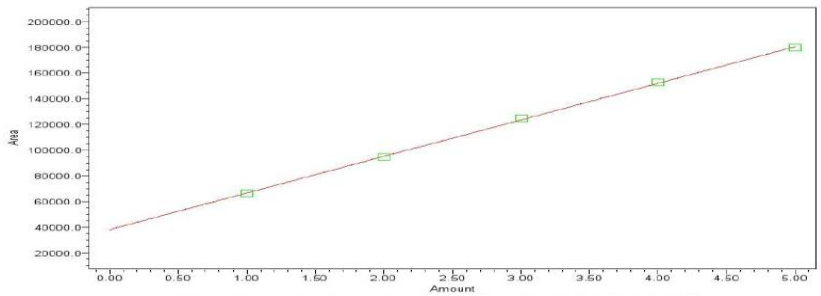
Table-8 Area of different concentration of Triprolidine

S.No.	Linearity Level	Concentration	Area
1	I	100ppm	668934
2	II	200ppm	956781
3	III	300ppm	1313873
4	IV	400ppm	1563458
5	V	500ppm	1867084
Correlation Coefficient			0.999

Table-9 Area of different concentration of Phenylephrine

S.No	Linearity Level	Concentration	Area
1	I	1ppm	66510
2	II	2ppm	94701
3	III	3ppm	124802
4	IV	4ppm	152731
5	V	5ppm	179732
Correlation Coefficient			0.999





Indo-American Journal of Pharma and Bio Sciences

Vol. 22, Issue 2, 2024

Parameters	Triprolidine	Phenylephrine
Slope (m)	66574	12529
Intercept (c)	53592	50245
Correlation coefficient (R^2)	0.999	0.999

6.3.5: TRIPROLIDINE AND PHENYLEPHRINE

Drug name	Baseline noise(µV)	Signal obtained (µV)	S/N ratio
Triprolidine	52	152	2.9
Phenylephrine	52	156	3

Drug name	Baseline noise(µV)	Signal obtained (µV)	S/N ratio
Triprolidine	52	522	10.03
Phenylephrine	52	524	10.1

6.3.7: ROBUSTNESS:

S. No	Flow Rate (ml/min)	System Suitability Results	
		USP Plate Count	USP Tailing
1	0.6	5339.9	1.4
2	0.8	4673.4	1.3
3	1.0	5216.0	1.4

S. No	Flow Rate (ml/min)	System Suitability Results	
		USP Plate Count	USP Tailing
1	0.8	7063.3	1.3
2	1.0	6090.3	1.2
3	1.2	6998.0	1.3

Indo-American Journal of Pharma and Bio Sciences

Vol. 22, Issue 2, 2024

S.No	Change in Organic Composition in the Mobile Phase	System Suitability Results	
		USP Plate Count	USP Tailing
1	10% less	4508.4	1.3
2	*Actual	4673.4	1.4
3	10% more	4318.1	1.3

S.No	Change in Organic Composition in the Mobile Phase	System Suitability Results	
		USP Plate Count	USP Tailing
1	10% less	6387.7	1.2
2	*Actual	6090.3	1.2
3	10% more	6232.5	1.2

SUMMARY AND CONCLUSION

The ICH and USP essentials .it accumulated the technique saw as straight. The system was seen as having level of precision and exactness.

BIBILIOGRAPHY

1.A.B.N. Nageswara et al, Triprolidine and Phenylephrine in Mass and Medication Portion Construction. 2011: 3 (5) 318-325.

Mahmoud M. Sebaiy 1 et,al RP-HPLC Method for Simultaneous Estimation of

Sparfloxacin, Gatifloxacin, Piperazine and Tinidazole.

2. Dhandapani B.Thirumoorthy validation of spectroscopic method for the estimation of

metronidazole and norfloxacin in syrup dosage form Revised on 29 March 2015,

3. Soumya Jyoti Ghosh, Chakraborty.Simultaneous determination and validation of

Mebendazole and Piperazine in combined dosage pharmaceutical formulation. 2010;

2(1): 367-374.

4. JelamVazir et,al,and Ikhuoria M.. 2008; 7(6): 670-680.