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Development and Validation of Analyticalmethod for Estimtion of Cariprazine Hydrochloride in Bulk and Tablet Dosage Form by Using Rp-Hplc Method

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ABSTRACT:-
Analytical methods which are measure of quality of the drug play a very comphrensive role in drug development and follow up activities. The overall drug development process require robust, accurate analytical methods to support to all stages of the process like preclinical studies to drug formulation, purity assessment, and clinical studies. Method development by RP-HPLC has been validated as per guideline given by ICH requirement to assure that the method consistently meets the predetermined specification and quality attributes.
Keywords:-Cariprazine, RP-HPLC, UV- Visible spectroscopy.

I. INTRODUCTION:-

Quality can be defined as the character, which defines the grade of excellence. A goodquality drug is something, which will meet the established product specifications, can besafely bought and confidently used for the purpose for which it is intended. To get a goodquality drug, the manufacturing for making a drug should have quality built into it.Analytical chemistry is the science that seeks ever improved means of measuring thechemical composition of natural and artificial materials. Analytical chemistry is a subdisciplineofchemistrythathasthebroadmissionof understandingthechemicalcompositionofallmattera nd developingthetoolsto elucidatesuchcompositions.[1]

II. MATERIALS AND METHODS

MATERIALSANDINSTRUMENTS

Materials:

TableNo 1.Listofthe Chemicalsused

Sr.No	Name ofchemicals	Name ofsupplier	Grade
1	CariprazineHydrochloride	ThermocilfineChemLtd.Pune	
2	Potassiumdihydrogen Phosphate	ThermocilfineChemLtd.Pune	AR
3	Ammoniumacetate	ThermocilfineChemLtd.Pune	AR
4	Sodiumhydroxide	ThermocilfineChemLtd.Pune	AR
5	Methanol	ThermocilfineChemLtd.Pune	HPLC
6	Acetonitrile	ThermocilfineChemLtd.Pune	HPLC
7	Water	ThermocilfineChemLtd.Pune	HPLC
8	Trimethylamine	ThermocilfineChemLtd.Pune	AR
9	AceticAcid	ThermocilfineChemLtd.Pune	AR

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10	Vraylar(Marketedformulation)	Purchasedfrom localmarket	

Equipment/Instrumentdetails

TableNo.2:List ofEquipment/Instrumentdetails

Sr.no	Instrumentname	Model
1	HPLCsystem	Thermo, P4000 Quaternary pump, UV6000PDADetectorwithCHROMQUEST software
2	UVSpectrophotometry	LabindiaUV3200
3	Digitalbalance	Shimadzu(1mgsensitivity)
4	Sonicator	Ultrasoniccleanerpowersonic420
5	Constanttemperaturewaterbath	ThermolabGMP
6	pHMeter	Thermoelectroncorporation Orion2star

Methoddevelopment

DeterminationofCariprazineHydrochlorideλ_{max}byUVspectroscopy:

A complete, precise and accurate method was developed for estimation of CariprazineHydrochloridebyUVspectrophotometer [ICHQ2B]

1) Solventselection:

In order to select suitable solvent for determination of Cariprazine Hydrochloride varioussolventswereselectedforthesolubilitystudies anditwasfoundthatCariprazineHydrochloride was soluble in the following solvents; Methanol, water and Acetonitrile.In the present investigation the mobile phase in the ratio of (60:40) Acetonitrile and 0.05MAmmonium acetatebuffer(pH4.8) wasselectedassolvent.

2) Selectionof wavelength(λ_{max})

UV Spectrophotometric method involves the determination of Cariprazine Hydrochloridebulk and pharmaceutical formulation andhas an absorption maximum at 218nm inmobile phase.The sensitivity of the RP-HPLC method that uses PDA detection dependsupon the proper selection of the wavelength. An ideal wavelength is one that gives goodresponse for thedrugsto bedetected**.**

3) Preparationofstandardstocksolution:

Standardstocksolutionwaspreparedbydissolvingaccuratelyweighed100mgofCariprazine Hydrochloride in mobile phase and the volume was made up to 100 ml withmobile phasein 100 ml volumetric flask (Stock solution-I,1000 mcg / ml). 10ml ofstock solution-I was diluted to 100 ml with mobile phase (Stock solution-II, 100 mcg /ml). 1 ml of stock solution-II was taken in 10 ml standard flask diluted to 10 ml withmobile phase to get the concentration 10 mcg / ml. The absorbance of resulting solutionwas measured against respective blank solution in the UV region of 200-400 nm, whichshowsmaximumabsorbanceofCariprazineHydrochlorideat 218nm.

4) Preparationofstandardcurve

Appropriate volume of aliquots from standard Cariprazine Hydrochloride stock solutionswas transferred to a series of 10 ml capacity of volumetric flasks. The volume wasadjustedtothemarkwithmobilephasetoobtainconcentrationsof5-25µg/ml.Absorbance spectra of each solution against mobile phase as a blank were measured atλ_{max} of 218 nm. Theobtained absorbancevaluesareplottedagainsttheconcentration togetthe calibration graph. The regression equation and correlation coefficient wasdetermined.

Validationparameters were carriedout forCariprazineHydrochlorideby calculatingrange, linearity, accuracy, precision, ruggedness, robustness, LOD and LOQ as per ICHguidelines.

Analytical method development for the

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estimationCariprazineHydrochlorideby RP- HPLC

1) ProcedureforPreparationofselectedmobile phase:

A mixture ofAcetonitrile and 0.05 Mammonium phosphate buffer (pH 4.8) in the ratioof 60:40 v/v was taken. Then the solution was filtered through 0.45µ nylon membranefilter,degassed and used asthemobile phase.

Preparationofbuffer

0.798gm of ammonium acetate was weighed accurately and transferred in 200ml beaker.200ml of water was added, sonicated and the pH was adjusted to 4.8 with glacial aceticacidandfinallyfiltered through 0.45µm nylon membranefilter.

Selectionofmobile phase

During the selection of the mobile phase a series of trials were carried out with differenttypes and ratios of solvents and buffers of different pH of the mobile phase. The retentionbehavior of Cariprazine Hydrochloride was studied with the mobile phase. The selectionof the best and suitable mobile phase that provides satisfactory separation of peaks forCariprazine Hydrochloride led to the solvent system of 60:40 % Acetonitrile: 0.05 Mammonium acetate buffer as mobile phase. All solvents filtered through 0.45µm nylonmembrane filterandfor degassed sonicatedfor 25 min.

2) SelectionofChromatographicColumn,RetentionTime determination

Selectionofchromatographiccondition

Proper selection of the method depends up on the nature of the sample (ionic/ ionizable /neutral molecule), its molecular weight and solubility. The reverse phase HPLC wasselected for the initial separation because of its simplicity, suitability, ruggedness and itswiderusage.

Table No.3:-Trial1

Column:	CHEMSILODS-C18(250mm X4.6 mm),5µmcolumn
FlowRate:	1ml/min
InjectionVolume:	20µL
ColumnTemperature:	Ambient
Wavelength	218 nm
Run time	10min
Mobilephase	Acetonitrile :Phosphate buffer ofpH4(50:50%v/v)

Table No.4 Trial2

Column:	CHEMSILODS-C18(250mm X4.6 mm),5µmcolumn
FlowRate:	1.0ml/min
InjectionVolume:	20µL
ColumnTemperature:	Ambient
Wavelength	218 nm
Run time	10min

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Mobilephase	Acetonitrile:Phosphate buffer ofpH4.8(70:30%v/v)

Table No.5 Trial 3

Column:	CHEMSILODS-C18(250mm X4.6 mm),5µmcolumn
FlowRate:	1ml/min
InjectionVolume:	20µL
ColumnTemperature:	Ambient
Wavelength	240 nm
Run time	10min
Mobilephase	Acetonitrile:ammonium acetate buffer of pH 4 :Methanol(60:30:10%v/v/v)

OptimizedMethod

Optimizedmethodforthe estimationofCariprazineHydrochloridebyRP-HPLCwasfinallyachieved byusingthefollowingchromatographicconditions.

Procedure

Preparation of mobile phase: A mixture of Acetonitrile and 0.05 M Ammonium acetatebuffer (pH 4.8) in the ratio of 60:40 v/v was taken. Then the solution was filtered through0.45µnylon membranefilter, degassed

DiluentsPreparation: MobilephasewasusedasDiluents.

Table No.6 Chromatographicconditions

Column:	CHEMSILODS-C18(250mmX 4.6mm), 5µm column
FlowRate:	1ml/min
InjectionVolume:	20µL
ColumnTemperature:	Ambient
Wavelength	218 nm
Run time	10min
Mobilephase	Acetonitrile :Ammoniumacetate bufferofpH4.8(60:40%v/v)

Preparationofstandardsolution:

10 mg of Cariprazine Hydrochloride and transferred into a 100ml clean dry volumetricflask add about 70ml of diluents was added and sonicated to dissolve it completely andthe volume wasmade upto the markwiththe same solvent.

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(Stocksolution)

Preparationofsamplesolution

10 Tablets of Cariprazine Hydrochloridewere weighed and powdered in glass mortar.The powder equivalent to the amount of active ingredient present in 10tablets wastransferred into a 500 ml clean dry volumetric flask, 350 ml of diluents was added to itand was shaken by mechanical stirrer and sonicated for about 30 minutes by shaking atintervals of five minutes each and was diluted up to the mark with diluent and allowed tostand until the residue settles before taking an aliquot for further dilution (stock solution).0.1ml of upper clear solution was transferred to a 10 ml volumetric flask and diluted withdiluent up to the mark and the solution was filtered through 0.45 mcg / ml filter beforeinjectinginto HPLC system.

METHODVALIDATION

The objective of validation of an analytical procedure is to demonstrate that it is suitableforitsintendedpurpose.AccordingtoICHQ2B guidelines,typicalanalyticalperformance characteristics that should be considered in the validation.

1. SPECIFICITY

A) CariprazineHydrochlorideidentification

Solutionsofstandardandsamplewerepreparedasperte stprocedureandinjectedintothe HPLCsystem.Thechromatogramswere recordedwhichshowninresults.

B) Placebointerference

A study to establish the interference of placebo was conducted. A sample of placebo wasinjected into the HPLC system as per the test procedure. The chromatogram of placebowasshown in results.

C) Blankinterference

A study to establish the interference of blank was conducted. Diluent was injected intoHPLC system as per the test procedure. The chromatogram of blank is shown in resultschapter.

2. LINEARITY

Appropriate volume from the stock solution was diluted to get the finalconcentration of5,10,15,20,25µg/mLforCariprazineHydrochloride .Thenthechromatogramwasrecorded.Foreachconcentration,plotthegraphconcentrationversusnumberofth eoreticalplates.

Procedure

Each level solution was injected into the chromatographic system and the peak area wasmeasured. A graph of peak area versus concentration (on X-axis concentration and on Y-axisPeak area)wasplottedandthe correlation coefficientwascalculated.

3. ACCURACY

AssaywasperformedintriplicateforvariousconcentrationsofCariprazineHydrochloride equivalent to 50, 100, and 150 % of the standard amount was injected intothe HPLC system per thetestprocedure.

PreparationofStandardstocksolution:

Weigh accurately about 10 mg of Cariprazine Hydrochloride and transferred into a 100mlclean dry volumetric flask about 70ml of diluents was added and sonicated to dissolve itcompletelyandvolumewasmadeuptothemarkwitht hesamesolvent(Stocksolution).Further 1 ml of Cariprazine Hydrochloride from above stock solutions werepipetteintoa10mlvolumetricflaskanddilutedupt othemarkwithdiluents.Chromatogramisshownin results.

4. PRECISION

a) Repeatability

Preparationofstocksolution(solutionA)

Weigh accurately about 10 mg of Cariprazine Hydrochloride,and transferred into a100ml clean dry volumetric flask about 70ml of diluent was added and sonicated todissolve it completely and volume was made up to the mark with the same solvent.Further 1.0 ml of Cariprazine Hydrochloride of the solution A was pipette into a 10mlvolumetric flask and dilutedupto themark withdiluents.

Procedure

The standard solution was injected for five times and the area was measured for all fiveinjections in HPLC. The %RSD for the area of five replicate injections was found to bewithin the specified limits. The chromatograms are shown inresults. The results aretabulated.

b) IntermediatePrecision(analysttoanalyst variability)

To evaluate the intermediate precision (also known as the ruggedness) of the methodprecisionwasperformedondifferentdaysbyus ingdifferentcolumnsofsamedimensions.Chromatogr amsare shown inresults. Resultsaretabulatedin Table.

5. LimitofDetection(LOD)andLimitofQua ntification(LOQ)

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The LOD and LOQ of the developed method were determined by analysing progressivelylowconcentrationofthestandardsolutio nusingthedevelopedmethods.TheLODistheconcentr ationoftheanalytethatgivesameasurableresponse(sig naltonoiseratio3.3).

6. ROBUSTNESS

The robustness of the proposed method was determined by analysis of aliquots fromhomogenouslotsbydifferingphysicalparameters likeflowrateandmobilephasecomposition,
temperature variations which may differ but the responses were still withinthe specified limitsof theassay.

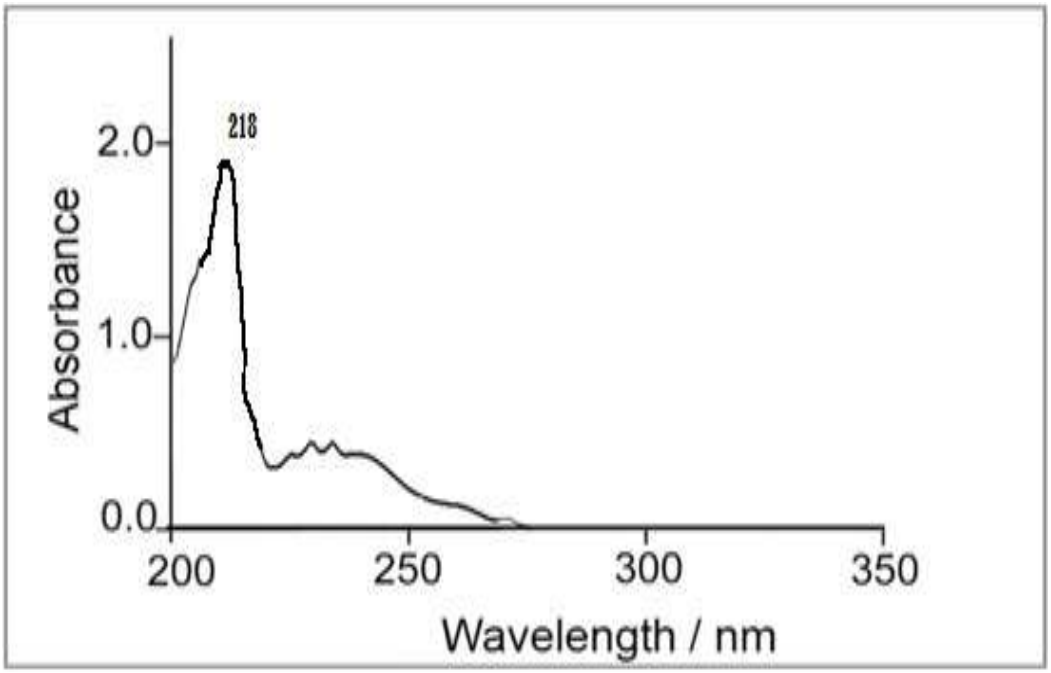
7. SystemSuitability

SamplesolutionofCariprazineHydrochloridewasinje ctedthreetimesintoHPLCsystemaspertestprocedure. Thesystemsuitabilityparameterswereevaluatedfrom standardchromatogramsobtained,bycalculatingthe% RSDofretentiontimes,tailingfactor,theoreticalplates andpeak areasfrom three replicateinjections.

III. RESULTS AND DISCUSSION

Methoddevelopmentby RP-HPLC

Determination by Cariprazine hydrochloride λ_{max} UV spectrophotometer: Acomplete,preciseandaccurate methodwas developedforestimationofCariprazineHydrochlorid ebyUVspectrophotometer[ICHQ2B].SpectrumofCa riprazineHydrochlorideinmobilephaseAcetonitrilea nd0.05MAmmoniumacetatebuffer(pH4.8)(60:40v/v)wasrecordedonUVspectrophotometer.RecordedU Vspectrumisshown in figureno.1



FigureNo.1:UVSpectrumofCariprazineHydrochloride

Cariprazine Hydrochloride showed maximum absorbance at wavelength 218 nmwhenanalyzedbyUVspectroscopy.

VALIDATIONOF THERP-HPLCMETHOD

Specificity

The chromatograms of standard and sample are identical with nearly same retentiontime. No interference due to placebo at the retention time of analyte which shows thatthemethodwasspecific.Thechromatogramsforsp ecificitystudies(standard,placeboandblank) arein Fig.No.2

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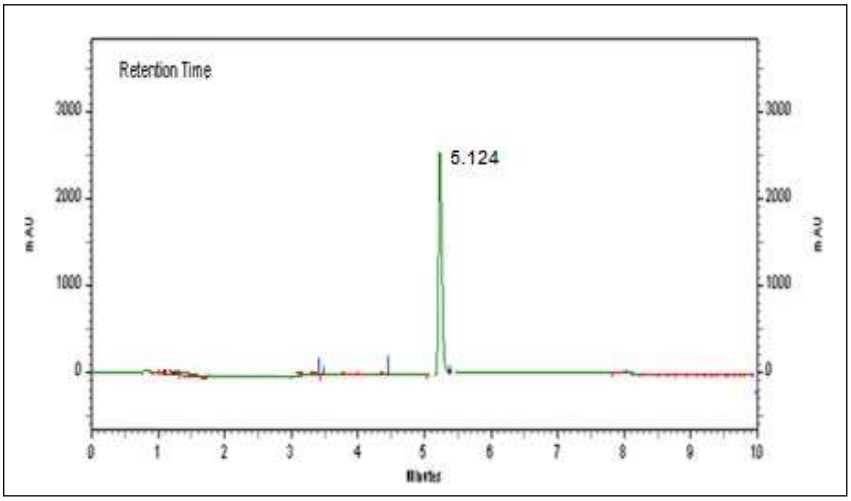
Fig.No.2StandardchromatogramforCariprazineHydrochloride



Nameofdrug	Retention Time(min)	Theoretical plates(N)	USP Resolution	USP Tailing
Cariprazine Hydrochloride	5.124	2956	5.1	1.4

Linearity

Linearity study for Cariprazine Hydrochloride was performed in range 5-25 µg/ml.Chromatograms

Table no. 7ResultsforCariprazineHydrochloride LinearitybyRP-HPLC

Sr.no.	Concentration(µg/ml)	Theoretical plates(N)
1	05	2869
2	10	2899
3	15	2925
4	20	2952
5	25	2982
Correlationcoefficient		0.9993

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Linearity graph of Cariprazine Hydrochloride showed equation of line y = 5.58x +2841withR^2=0.999.Hence the methodislinearconcentrationrange 5-25µg/ml.

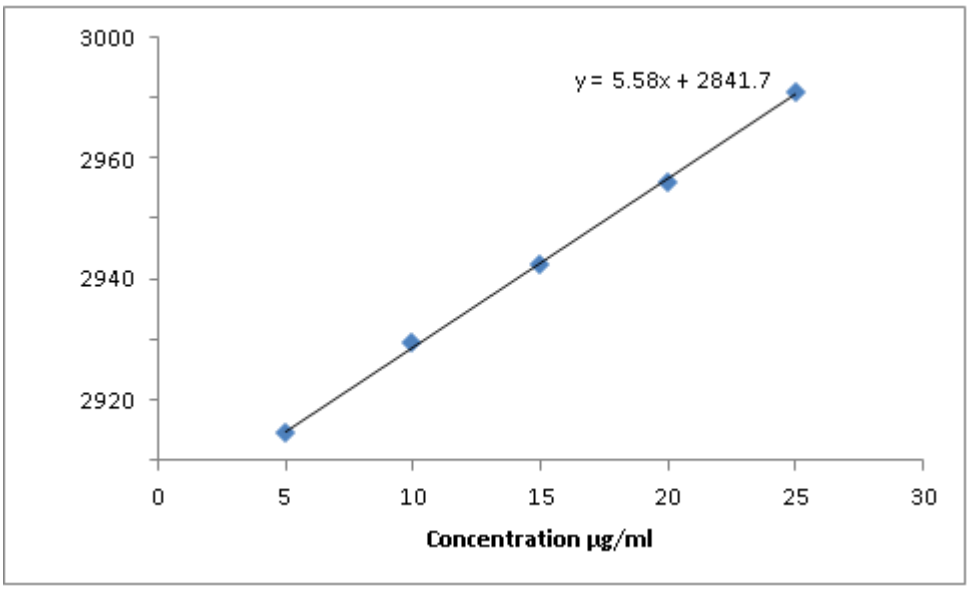

Fig no.3 LinearitygraphforCariprazineHydrochloride

Accuracy(%Recovery)

The recovery experiment was performed by the standard addition method. Accuracystudies were performed at concentration 50%, 100% and 150% .i.e. (5, 10 and 15µg/ml).Obtained chromatogramand recoveryresultsareshownbelow

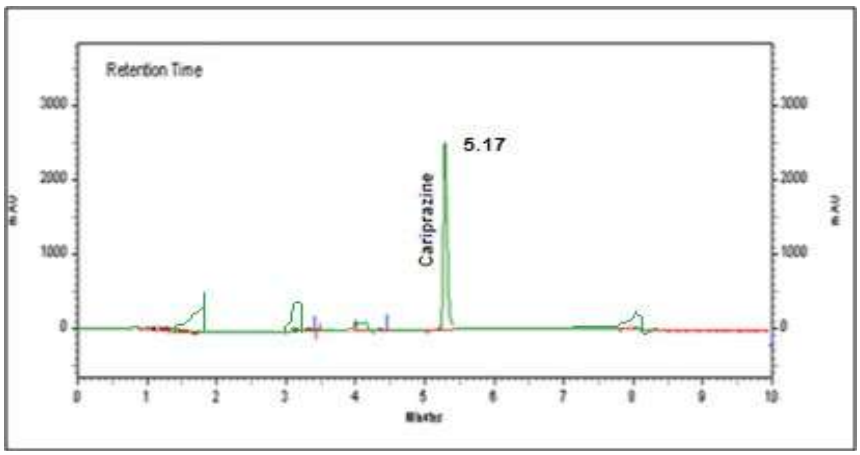

Figure.No.4: Standard chromatogram of Cariprazine Hydrochloride foraccuracy

Nameofdrug	**Retention time(min)**	**Theoretical plates(N)**	**USP Resolution**	**USPTailing**
Cariprazine Hydrochloride	5.17	2959	5.0	1.4

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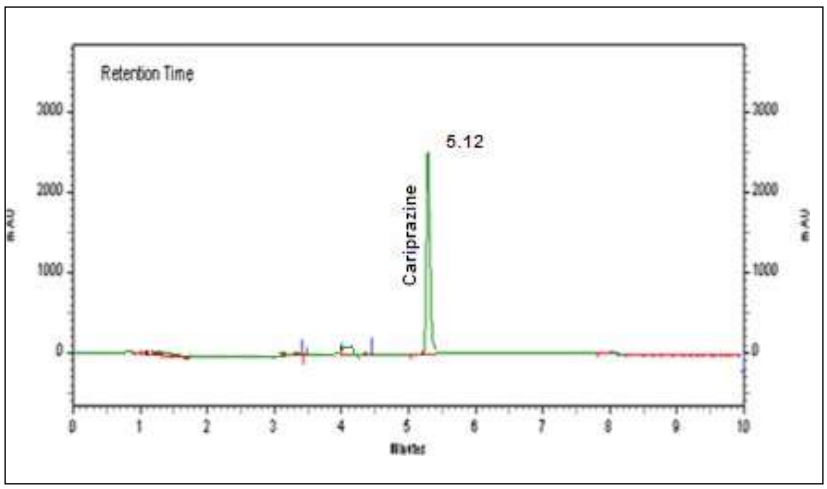

Figure.No.5:Chromatogramofaccuracyfor50%Conc.(5µg/ml)

Nameofdrug	Retention time(min)	Theoretical plates(N)	USP Resolution	USPTailing
Cariprazine Hydrochloride	5.12	2817	5.1	1.4

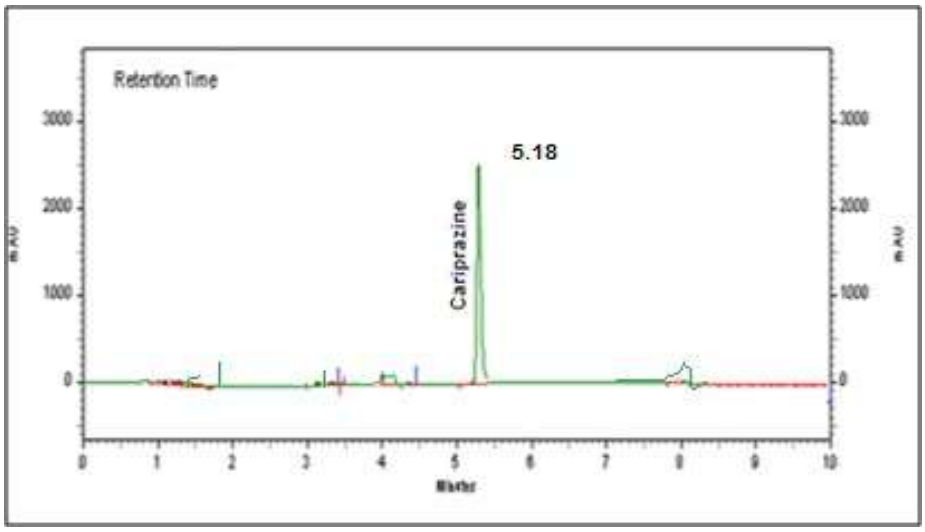

Figure.No.6:Chromatogramofaccuracyfor100%Conc.(10µg/ml)

Nameofdrug	Retention time(min)	Theoretical plates(N)	USP resolution	USPtailing

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Cariprazine Hydrochloride	5.180	2954	5.1	1.4

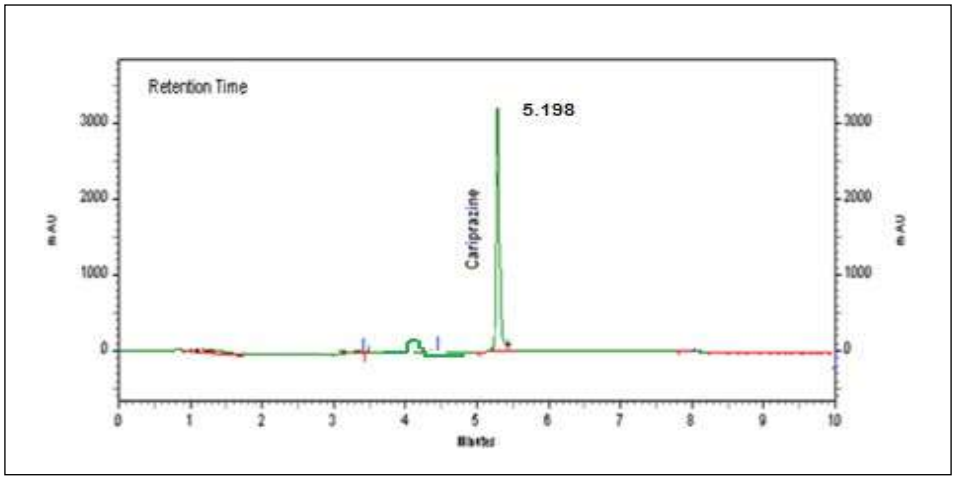

Figure.No7:Chromatogramforaccuracyfor150%Conc.(15µg/ml)

Nameofdrug	**Retention time(min)**	**Theoretical plates(N)**	**USP resolution**	**USPtailing**
Cariprazine Hydrochloride	5.198	2996	5.1	1.4

TableNo.8:ResultsforCariprazineHydrochlorideAccuracy

Spike Level	**Concentration(µg/ml)**	**Replicate number**	**Theoretical plates(N)**	**% Recovery**	**Mean% Recovery**
50%	5	1	1508.4	99.8%	100.2%
		2	1495.5	99.4%	
		3	1503.5	99.0%	
100%	10	1	2950.7	99.3%	99.3%
		2	2950.8	99.6%	
		3	2953.8	99.1%	
150%	15	1	4443.5	99.0%	99.2%
		2	4435.4	99.2%	

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		3	4431.9	99.5%	
SD					0.4496
%RSD					0.004515

Themeanrecoverieswerefoundtobefrom99.2-100.2%.Therecoveryresultindicatesthat theproposed methodisaccurate.

MethodPrecision

a) Intermediate Precision: (Repeatability) The standard solution was injectedforfivetimesandtheareawasmeasuredforallfiveinjectionsinHPLC.

TableNo.9:ResultsofCariprazineHydrochloride forintermediateprecision(Repeatability)

Injectionnumber	**Retention time(min)**	**Theoretical plates(N)**	**Cariprazine Hydrochloride**
1	5.170	2954	0.0428
2	5.168	2956	0.0431
3	5.165	2953	0.0432
4	5.148	2949	0.0433
5	5.153	2951	0.0435
Mean			0.0431
S.D.			0.0002
%RSD			0.54

The RSD values of Cariprazine Hydrochloride found to be 0.54 %. (Table No. 7.2).The%RSDfortheareaoffivereplicateinjectionsw asfoundtobewithinthespecifiedlimitsLowvaluesindi catingthatmethod isrepeatable.

b) Intermediate precision:-

The standard solution was injected for five times and the areas for all five injectionsweremeasuredinHPLC.The%RSDforthear eaoffivereplicateinjectionswasfound to be within the specified limits. Two analysts as per test method conducted thestudy.

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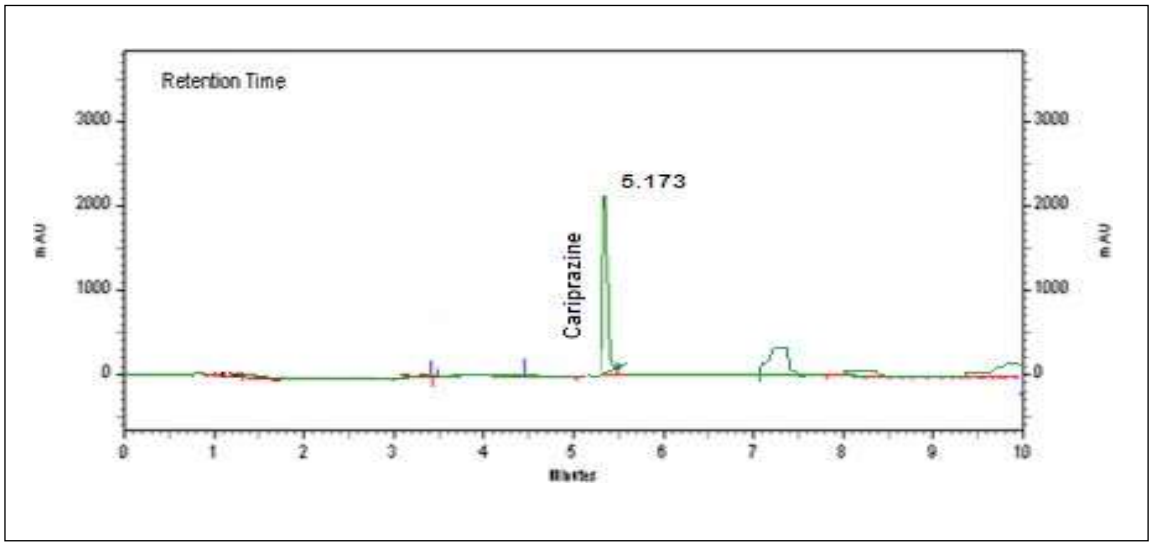

Fig no.8 ChromatogramforIntermediateprecision

Nameofdrug	Retention time	Theoretical plates(N)	USP resolution	USPtailing
Cariprazine Hydrochloride	5.173	2948	5.1	1.4

TableNo.10:ResultsofCariprazineHydrochlorideforintermediateprecision(reproducibility)

Parameter	%Assay
Mean*	99.10
SD	0.376
%RSD*	0.38

The RSD values of Cariprazine Hydrochlorideare not more than 2.0 and % assayvalue wasfound within98 %-102%.,which revealthatthe method isprecise.

LimitofDetectionandLimit ofQuantification
TheLODandLOQofthedevelopedmethodweredeter minedbyanalyzingprogressivelylowconcentrationof thestandardsolutionusingthedevelopedmethods.

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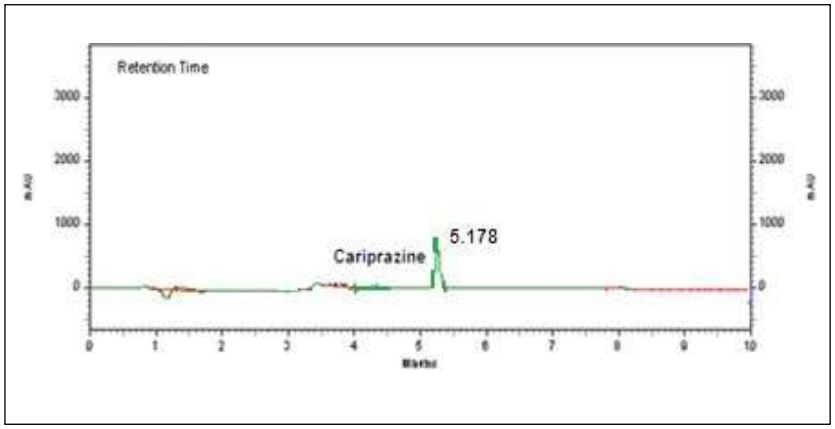

Fig no.9 LODforCariprazineHydrochloride

Nameofdrug	Retention time(min)	Theoretical plates(N)	USP Resolution	USP Tailing
Cariprazine Hydrochloride	5.178	2109	5.1	1.4

LimitofQuantification

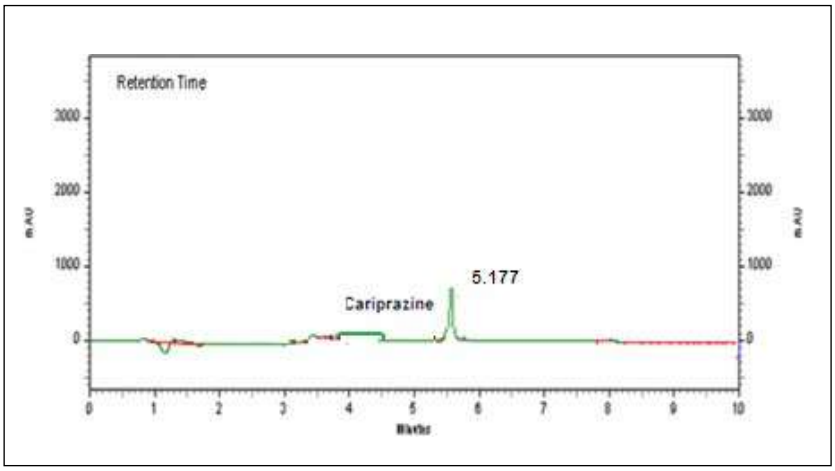

Fig no.10 LOQforCariprazineHydrochloride

Nameofdrug	Retention Time(min)	Theoretical Plates(N)	USP Resolution	USP Tailing
Cariprazine Hydrochloride	5.177	2156	5.1	1.4

The limit of detection (signal-to-noise ratio ≥ 3) for Cariprazine Hydrochloride wascalculated to be 4

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ng/ml.The value of the lower limit of quantification was found tobe 12.5 ng/ml

Robustness

a) Effectofvariationinflowrate

A study was conducted to determine the effect of variation in flow rate. The flow ratewas varied at 0.8ml/min to 1.2 ml/min.

TableNo.11:Results for Cariprazine Hydrochloride Robustness by RP-HPLC (Variationinflowrate)

Sr.No	Flow rate (ml/min)	Theoretical plates(N)	Robustnessresults
			USPTailing
1	0.8	2948	1.53
2	1.0	2954	1.48
3	1.2	2978	1.48
SD			0.0057
%RSD			0.38

Theeffectofvariationofflowratewasevaluated.Asthe %RSDofretentiontimeand asymmetry were within limits for variation in flow. Hence the allowable flow rateshouldbewithin 0.8 ml to 1.2 ml.

b) Effectofvariationofmobilephasecompositio n

A study was conducted to determine the effect of variation in mobile phase ratio bychanging the ratio of mobile phase. The organic composition in the Mobile phase wasvariedfrom±2%v/v.

TableNo.12:Robustness results for Cariprazine Hydrochloride by RP-HPLC(variationinmobilephasecomposition)

Sr.No	Mobilephase composition(v/v)	Theoretical plates(N)	Robustnessresults
			USPTailing
1	Mobile phase +2%	2978	1.3
2	Mobilephase-2%	2948	1.4
%RSD			0.42

The effect of variation of mobile phase composition was evaluated. As the % RSD ofretentiontimeandasymmetrywerewithinlimitsforv ariationinmobilephasecomposition.

SystemSuitability

Sample solution of Cariprazine Hydrochloride was injected three times into HPLCsystem as per test procedure

TableNo.13:System suitability results for Cariprazine Hydrochloride by RP-HPLC

Injectionnumber	Concentration(µg/ml)	Theoreticalplates(N)	Robustness results

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			USPTailing
1	10	2952	1.3
2	10	2956	1.4
3	10	2950	1.4
SD			0.0057
%RSD			0.42

From the system suitability studies it was observed that all the parameters were withinlimit. Assayforthe drugcanbe performedwiththeselectedsystemconditions.

IV. CONCLUSION

A RP-HPLCmethodwasdeveloped andvalidated successfully forestimation ofCariprazine Hydrochloride in bulk and tablet dosage form. The present study wasvalidated as per the ICH guidelines and the method was found to be accurate, precise,linear, specific and reproducible for the determination ofCariprazine Hydrochlorideinusedinstruments.

REFERENCE

[1]. DouglasA,SkoogDM,WestF.AnalyticalChemistry,8thed.Philadelphia:SaundersCollegePub;1990:2-7.
[2]. ChristianGD.AnalyticalChemistry,6thed.USA:JohnWileyandSons;2003:126-133.
[3]. DavidCL.Pharmaceuticalanalysis.6thed.London:Blackwellpublishing;1994.
[4]. :2-4.
[5]. Chatten LG. Pharmaceutical chemistry, Vol. II, New York: Marcel Dekker Inc;1996:23-25.
[6]. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Vol. II. New Delhi:CBSpublisher and distributors;1986:13-17.
[7]. Chauhan A, Mittu B, Chauhan P. Analytical method development and validation:Aconcisereview. JAnal Bioanal Tech 2015; 233-238.
[8]. Puthuri R, Muthukumaran M, Krishnamoorthy B. A review on analytical methoddevelopment and validation of pharmaceutical technology.Pharmatutor. ART-1671.
[9]. Siddiqui MR, Alothman ZA, Rahamn N. Analytical techniques in pharmaceuticalanalysis: Areview.ArabianJChem2013;1-12.
[10]. VermaRM.AnalyticalChemistry.3rded.Delhi:CBSpublishers;1994:5-7.
[11]. SharmaBK.Instrumentalmethodsofchemicalanalysis.7thed.Meerut:GoelPublishingHouse; 2000.
[12]. KaurH.InstrumentalMethodsofChemicalAnalysis.3rded.Meerut:PragatiPrakashan; 2006:789-812.
[13]. WillardHH,MerrittLL,DeanJA,SettleFA.InstrumentalMethodsofAnalysis.7thed. NewDelhi:CBSPublishers;1986:1-9.
[14]. KailaHO.AnalyticalStudy ofPharmaceuticalSubstances:MethodDevelopmentandValidationStudy:FewCaseStudies,thesisPhD,SaurashtraUniversity;2011.
[15]. PatilPN.HplcMethodDevelopment:AReview JournalofPharmaceuticalResearch &Education.2017;1(2):243-260.
[16]. Mukherjee A, Bera A. A Detailed Study of Validation Parameters and SystemSuitability Test in HPLC Research Journal of Pharmaceutical, Biological andChemicalSciences2012;3(4):426-447.
[17]. Rohith T, Ananda S, Sajan PG, Gowda NM. Development and Validation ofUPLCMethodfortheDeterminationofDuloxetineHydrochlorideandItsImpuritiesinActive PharmaceuticalIngredient.J AnalBioanalTech2015,6:1.