IJBPAS, December, Special Issue, 2021, 10(12): 74-80

ISSN: 2277–4998

International Journal of Biology, Pharmacy and Allied Sciences (IJBPAS)

'A Bridge Between Laboratory and Reader'

www.ijbpas.com

IN VITRO EXAMINE OF RISPERIDONE IN DRUG TABLET DOSE STRUCTURE USING REVERSE PHASE FLUID CHROMATOGRAPHIC (RP-HPLC) STRATEGY

D. ANITHA[1], M. MANORANJINI[2*] AND K. PARAMESWARARAO[3]

1, 2: Department of Chemistry, P. B. Siddartha College of Arts & Sciences, Vijayawada, A.P, India

3: Department of Chemistry, Andhra Loyala College, Vijayawada, A.P, India

***Corresponding Author: E Mail: Dr. M. Manoranjini: dr.manoranjanimedikonda@gmail.com**

Received 19th Aug. 2021; Revised 20th Sept. 2021; Accepted 29th Oct. 2021; Available online 1st Dec. 2021

https://doi.org/10.31032/IJBPAS/2021/10.12.2008

ABSTRACT

The present investigation was to create and approve another reverse phase fluid chromatographic (RP-HPLC) strategy to measure in vitro examine of risperidone in drug tablet dose structure. The separation was performed on Inertsil ODS C-18 (150 x 4.6 mm, 5µ) molecule size section, and infusion volume was 10µL utilizing a UV 2301 Spectrophotometer to screen the identification at 260 nm. The mobile phase comprised of methanol: 0.1% formic acid in the proportion 40:60%v/v, and the stream rate was kept up at 1.0 ml/min. the technique was approved as far as reasonableness, linearity, exactness, accuracy, solidness, and affectability. Linearity was seen over the scope of focus 4.0-12.0µg/ml, and the correlation coefficient was found phenomenal >0.9999. The technique was exact and had relative standard deviations (%RSD) under 2.0%. Exactness was found in the scope of 99.90 to 101.7%.The developed procedure was vigorous in various variable conditions and reproducible. This proposed technique can be utilized as quality control device for the assessment of risperidone in routine disintegration test investigation.

Keywords: Risperidone, RP-HPLC, Validation

INTRODUCTION:

Risperidone **(The Merck Index, 2001; British Pharmacopoeia, 2007; Tripathi KD, 2019) (Figure 1)**. 3-[2-[4-(6-fluoro-1,2-benz-oxazol-3-yl) piperidin-1-yl]ethyl]-2-methyl-6,7,8,9-tetra-hydro-pyrido [1,2-a]pyrimidin-4-one compound used for treatment certain mental/mood disorders (such as schizophrenia, bipolar disorder, irritability associated with

autistic disorder). It is available in the local pharmacy under various brands i.e, Respidon (2.0mg, Torrent Pharmaceuticals), used in the treatment of schizophrenia.

Writing audit uncovered that there are not many logical strategies revealed for the examination of risperidone either independently or in mix with other dose forms **(Bhavana A. Kokane, 2014; Suthar, AP.,2009; Ashour Safwan, *et al*., 2013; Alivelu Samala, *et al*., 2013;Sanka Krishna, *et al*., 2014; Cheng-tung chen, *et al*., 2015)**. Basing on this understanding there is a requirement for the improvement of another investigative strategy for the estimation of risperidone in pharmaceutical definition. The goal of the present research is to develop and validate a HPLC method for risperidone to be employed in routine analysis.

MATERIAL AND METHODS:

i. **Instrumentation:** HPLC framework PEAK LC 7000 furnished with isocratic HPLC PEAK 7000 conveyance framework, manual Rheodyne injector with a 10µl circle switch (77251), logical column; Inertsil ODS C-18 (150 X 4.6 mm, 5µ) with PEAK LC programming variant was utilized. UV 2301 Spectrophotometer was utilized to decide the frequency of most extreme absorbance and Electronic equilibrium DENVER (SI234) was utilized for gauging purpose.

ii. **Chemicals and Solvents:** The functioning standard medication of risperidone unadulterated was mercifully given as a talented sample by Doxis laboratories, India. Every one of the synthetic substances utilized like methanol, acetonitrile, water were of HPLC grade and were bought from Merck synthetic compounds private restricted, Mumbai, India. The promoted detailing brand Respidon (2.0mg of risperidone, Torrent Pharmaceuticals) was bought in nearby pharmacy.

iii. **Preparation of working standard test arrangements:** 100mg of unadulterated medication was gauged and moved (working standard) into a 100ml volumetric jar. The diluent methanol was added and sonicated to break up it totally and made sufficient with a similar solvent. Further 1.0ml of the above stock arrangement was pipetted into a 10ml volumetric flask and weakened sufficient with diluent. The substance were blended well and separated through Nylon channel paper. Working standard arrangements of risperidone in the obsession extent of 4.0-12µg/ml was prepared from the above and injected to the chromatographic column.

iv. **Preparation of sample arrangement:** 10 detailing tablets of risperidone (Respidon (2.0mg, Torrent Pharmaceuticals) were squashed to a finely powdered material. Powder identical to 10mg of medication was taken in a 10ml volumetric cup containing 5.0mL of mobile phase and

was shaken to break down the medication and then separated through Nylon film channel paper. 1.0 ml volume of the filtrate was acclimated to the imprint with a similar solvent to acquire grouping of 100µg/ml. The same procedure as described in working standard was used for the assay of sample respectively.

RESULTS & DISCUSSIONS:

i. **Method development:** In order to make suitable procedure conditions for beneficial assessment of the current medicine different boundaries like mobile phase organization, stream rate, and pH were varied and improved condition was enlightened for assessment.

OPTIMIZED METHOD

Mobile Phase: Methanol: 0.1%formic acid in the proportion 40:60 %v/v

Column: Inertsil (ODS 3v 150*4.6, 5mm)

Flow Rate: 1.0ml/min

Temperature: Ambient

Volume: 10µl

Detector: 260nm

Diluent: Water: Methanol (50:50%v/v))

Procedure: Inject 10µL of standard, sample into chromatographic system and measure the areas for the risperidone peak **(Figure 2)** and calculate the % assay by using the formula.

During starting preliminaries, top shape, goals and maintenance time were not in the line of agreeableness. At that point, further trails were finished by changing the mobile phase proportion, flow rate, pH and chromatographic section. A sharp peak with great symmetry of risperidone was acquired **(Figure 2)** during the trail when the mobile phase structure was methanol: 0.1%formic acid in the proportion 40:60 %v/v at a flow rate of 1.0ml/min with UV detection at 260nm individually.

ii. **Method Validation:** The proposed method was endorsed by (ICH2005) fitting for linearity, precision, precision, explicitness, a breaking point of discovery, farthest point of evaluation, force, toughness and system reasonableness.

System Suitability: System appropriateness test was finished by injecting on newly masterminded standard stock plans of risperidone and the system reasonableness parameters like objectives, following variable, theoretical plates and support time was considered and recorded.

Specificity: The distinction of the strategy was overseen by taking a gander at the measure and maintenance times when standard, clear and test arrangements were blended into the HPLC framework utilizing the improved conditions. A run season of 5.0min was searched for a standard course of action and equivalent support times were looked for the tests also. Along these lines the made procedure was unequivocal for risperidone **(Table 2)**.

Linearity: Working standard arrangements of risperidone in the obsession extent of 4.0-12µg/ml were imbued into the

chromatographic framework. Alignment twist of risperidone was obtained by plotting the peak area extent versus the associated groupings of medicine and the relationship coefficient was resolved. From the adjustment twist **(Figure 3**) it has been shown that the technique is immediate in the scope of 4.0-12µg/ml. The relapse condition of the line is seen to be y = 21185x-88969 and relationship coefficient is obtained as 0.9999.The particulars of the linearity results were given in **Table 3**.

Limit of discovery and Quantification: The LOD and LOQ estimations of risperidone was evaluated utilizing sign to commotion proportion and observed to be 0.0009µg/ml and 0.003µg/ml separately, which were assessed**.**

Precision: Repeatability of the method was checked by duplicate implantations of 8.0µg/ml of for risperidone was done on various events on a similar day as intraday accuracy and on succeeding days as the intraday exactness assessments. The %RSD regards apparently was 0.33 for intraday accuracy and the acknowledgments are given in Table 4 that exhibited the precision of the proposed methodology

Accuracy: Exactness was surveyed at three particular obsessions proportionate to 50, 100 and150% of the unique fixing, by including a known proportion of risperidone standard to an illustration of known concentration and calculating the recovery of risperidon with RSD (%) and % recovery for each obsession. The recoveries of the strategy given in **Table 5** were seen to be in the extent of 99.0 to 101.7% which shows that the technique is significantly precise and suitable for the assessment of risperidone.

Robustness: The generosity study was performed by slight adjustment in stream pace of the mobile phase. Risperidone at 40µg/ml center was inspected under these changed preliminary conditions. It was seen that there were no checked changes in chromatograms, which exhibited that the made technique was amazing in nature **(Table 6)**.

Ruggedness: Roughness of the proposed framework was performed by utilizing six copy imbuements of standard and test approaches of risperidone which were planned and assessed by various expert on three different days and the attributes were bestowed also as rate relative standard deviation % RSD appeared apparently was 0.67, showing the procedure to be extreme.

Assessment of risperidone in pharmaceutical subtleties: Analysis of advanced tablets (**Respidon - 2.0mg**) was finished using the above said improved mobile phase and HPLC conditions. The % medicine substance of tablets gotten by the proposed strategy for risperidone was seen to be 99.98% separately making the assessment of risperidone in estimations structures was precise inside the affirmation level of 95% to 100%. The outcomes are given in **Table 7**.

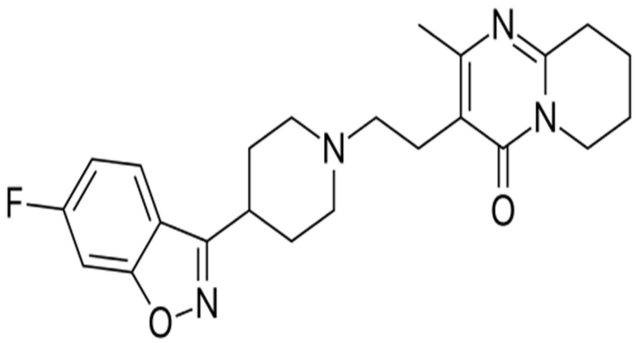

Figure 1: Structure of Risperidone

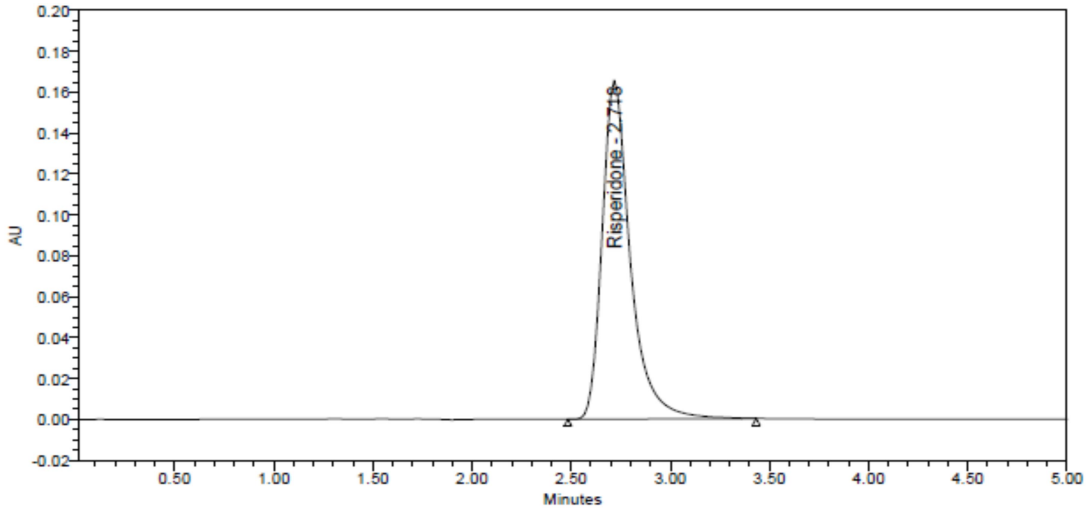

Figure 2: Chromatogram for optimized method

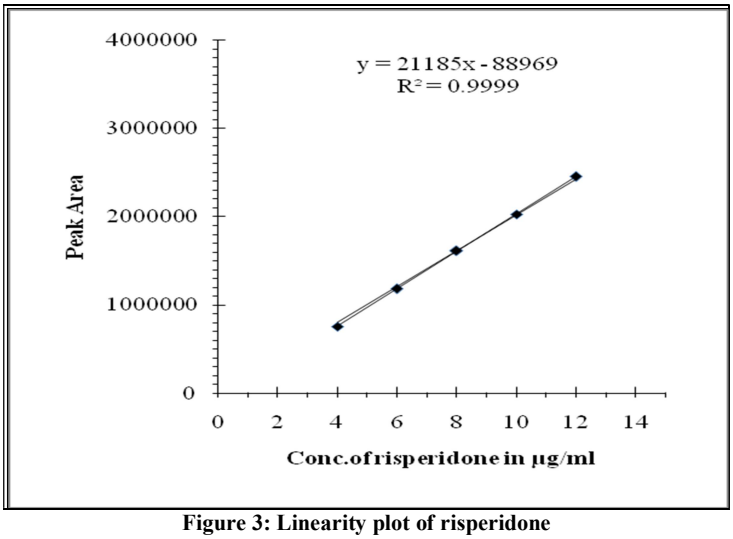

Figure 3: Linearity plot of risperidone

Table 1: System suitability data of Risperidone

Parameter	Risperidone
Retention time	2.720
Theoretical plates	1944
Tailing factor	1.40
% RSD	0.31

Table 2: Specificity data for Risperidone

S. No	Sample name	Rt
1	Standard	2.718
2	Sample	2.715
3	Blank	-
4	Placebo	-

Table 3: Linearity data for Risperidone

S. No	level	Area
1.	50(4.0µg/ml)	757541
2.	75(6.0µg/ml)	1181906
3.	100(8.0µg/ml)	1609171
4.	125(10.0µg/ml)	2027639
5.	150(12.0µg/ml)	2453266
Correlation coefficient		0.9999
LOD		0.0009µg/ml
LOQ		0.003µg/ml

Table 4: Precision data for Risperidone

S. No.	RT	Area	%Assay
Injection1	2.715	1597675	99.6
Injection 2	2.711	1594147	99.0
Injection 3	2.718	1593766	99.3
Injection 4	2.716	1592595	99.1
Injection 5	2.712	1588537	99.0
Injection 6	2.717	1597358	99.8
Mean			99.3
Std. Dev.			0.33
*%RSD			0.33

*Mean of six readings

Table 5: Accuracy data for risperidone

S. No.	Accuracy level	Injections	%recovery
1	50%	1	99.8
		2	99.1
		3	99.0
2	100%	1	99.6
		2	99.0
		3	99.3
3	150%	1	100.6
		2	101.7
		3	100.0

Table 6: Robustness data for risperidone

Parameter	RT	Theoretical plates	Asymmetry
Decreased Flow Rate (0.9ml/Min)	2.987	1829908	1.39
Increased Flow Rate (1.1ml/Min)	2.473	1829908	1.39

Table 7: Results of risperidone in formulations

Drug	Brand	Dosage	Amount Found	%Assay
Risperidone	Respidon	2.0mg	99.98 mg	99.98

CONCLUSIONS:

A supported, fundamental and precise, strength showing HPLC technique was made for the assessment of risperidoneeee in pharmaceutical plans. Parcel of risperidone was cultivated on the Inertsil ODS C-18 column at an UV identification frequency of 260nm. In these conditions, the drug was eluted at a maintenance season of 2.720min and the run was passed on up to 10min. A five-point alignment twist was inherent the center extent of 4.0-12µg/ml with the relapse

condition to be y = 21185x - 88969 with a connection coefficient of 0.9999 independently giving the wide importance of the proposed RP-HPLC technique.

A very high % recovery i.e., more than 100% was found in the recovery study that made the proposed strategy to be exact. Likewise, the proposed strategy was separated and was tracked down that the technique proposed can be related for the preliminary of the risperidone in a wide degree of center interests.

ACKNOWLEDGMENTS

The authors are gratified to the Department of Chemistry, P.B.Siddartha College of Arts & Sciences, Vijayawada, AP, India for providing encouraging environment and facilities for research work.

REFERENCES

[1] Ashour Safwan Kattan Nuha (2013) Sensitive Method for the quantitative determination of risperidone in tablet dosage form by HPLC using chlordiazepoxide as internal standard Int. J. biomed. Sci, Vol 9 No 3 Pages 91-97.

[2] Alivelu Samala Santhosh Pawar Sowmya Manala *et al* (2013) Development and validation of RP-HPLC method for estimation of risperidone in tablet dosage form Research J. Pharm. and Tech Vol 6 No 6 Pages .659-661.

[3] British Pharmacopoeia (2007) Medicines and HealthcareProducts Regulatory Agency (M.H.R.A).

[4] Bhavana A. Kokane., Dr.Jaiprakash V.Kokane. *et al* (2019) RP-HPLC method development and validation for estimation of risperidone in bulk & dosage forms Int. J. Pharm. Sci. Rev. Res Vol 54 No1 Page. 29-32.

[5] Cheng-tung chen, Cheng-wei cheng (2015) Development and validation of RP-UPLC method for determination of related substance in risperdal consta Chromatogr. Sep.Tech, Vol 6, Page 6.

[6] Sanka Krishna., Divan Prakash V (2014) Method development and validation for estimation of risperidone in novel liquid solid formulation by RP-HPLC Der Pharmacia letter Vol 6 No 1 Pages 166-174.

[7] Suthar AP and Dubey SA (2009) Determination of risperidone and forced degradation behavior by HPLC in tablet dosage form. Int.J.pharma Tech res. Vol 1 No 3 Pages 568-574.

[8] The Merck Index (2001) Merck Research Laboratories, Division of Merck and company, 13th ed, NJ, USA, Page 1627.

[9] Tripathi KD (2019) Essentials of Medical Pharmacology,5thed, Jaypee Brothers, Medical Publishers, New Delhi Pages 747, 150, 391, 394, 396, 397.

[10] International Conference on Harmonization ICH (2005) Validation of analytical procedures: methodology Q2 (R1).