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Paper Authors

Santosh Karajgi, Mahajan Swati, R. B. Kotnal

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Hydrotropic Aqueous solubility for Quantitative Determination of Vortioxetine Hydrochloride in its Pharmaceutical Dosage Forms

Santosh Karajgi, Mahajan Swati, R. B. Kotnal

Department of Pharmaceutical Quality Assurance, BLDEA'S SSM College of pharmacy and Research center, Vijaypur 586103

Email: santosh.karajgi@gmail.com Mobile: 9739619395

Abstract—

OBJECTIVE: The main objective of study was to solubilise poorly water soluble drug Vortioxetine Hydrochloride, develop an analytical method for the quantitative estimation and validate the analytical method developed. Validation parameters studied like Range, Linearity, and Assay.

METHODS: Vortioxetine Hydrochloride is freely soluble in Distilled water when 1.0M Nicotinamide was used as solubilising agent. Vortioxetine Hydrochloride shows an Absorption maximum at 290.8nm in First order mode of measurement using Shimdzu UV Spectrophotometer 1800 spectronic model.

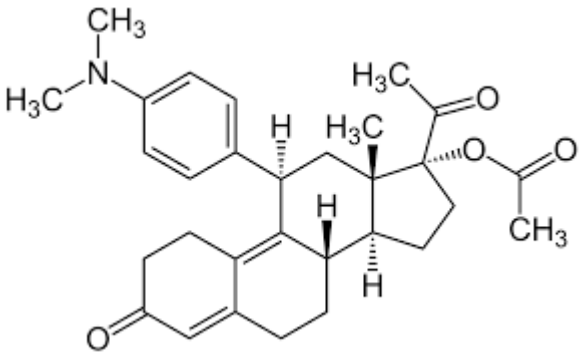
RESULT: At the absorption maximum 290.8nm, Vortioxetine Hydrochloride shows a linear response in the range between 15µg/ml to 30µg/ml concentration.

CONCLUSION: The current study is useful for the aqueous solubilisation and Quantitative determination of Vortioxetine Hydrochloride in pharmaceutical formulation thus avoiding toxic solvents.

KEYWORDS: Vortioxetine Hydrochloride, hydrotropic solubilisation, Solubility profile, linearity profile, Quantitative determination.

INTRODUCTION

Vortioxetine Hydrochloride is poorly water soluble drug and selective progesterone receptor used as Emergency contraception and for the treatment of uterine fibroids. Vortioxetine is a medication used to treat majordepressive disorder.(Anti-Depressive) validness is viewed as same to that of other antidepressants [1,2]. Therapeutic efficacy and bioavailability of drug is mainly depended upon the solubility of the drug. As there are several methods have been developed for the enhancement of solubility of poorly water soluble drugs. Among them one of the significant techniques is Hydrotropic solubilisation technique. Which involves addition of large amount of second solute increases aqueous solubility of other solute. Hydrotropy enhances the solubility of the drugs by the use of hydrotropes like Nicotinamide, Sodium benzoate, sodium salicylate, Urea [3, 4]. In this current study, an effort is made to improve the aqueous solubility of the selected drug Vortioxetine Hydrochloride by using Niacinamide as a solubilising agent, as there are no reported method is available so far to enhance water solubility and establish linearity of selected drug molecule by Hydrotropic solubilisation technique.



MATERIALS AND METHODS

MATERIALS

The study was carried out by using Shimadzu UV spectrophotometer Spectronic model 1800 with 1 cm matched quartz sample cells. The reagents used were Distilled water, Sodium benzoate, Sodium salicylate, Urea, Nicotinamide(Niacinamide). The study was carried out on Vortioxetine Hydrochloride Marketed formulation.

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METHODOLOGY

The procedure for solubility test is based on effort to dissolve chemical in water as a solvent with gradually more through mechanical methods. The solubilizing agents to be employed, in the preferential order, are Sodium benzoate, Sodium salicylate, Urea, Nicotinamide (Niacinamide). Solubility shall be resolute in a step by step route that involves effort to dissolve a chemical under test in selected solvents (in the order of preference) at reasonably high concentration using the series of mechanical procedures as cited in the table No 1. In the condition where the test chemicals fails to dissolve, try to increase the volume of solubilising agent so as to decrease the drug concentration by a factor of 10, and then the array of mechanical trials are repeatedly made in an effort to increase the solubility of the chemical at still lower concentration. To determine if the chemical has been dissolved depends entirely on visual examination. The chemical is said to be dissolved if the solution is absolutely clear and there is no sign of precipitation observed [5,7].

PROCEDURE

a) Trial 1 starts with solubility testing of the drug in 1M solution of the solubilizing agent in Distilled water as per order of preference. If complete solubility is accomplished, then further solubility trials are not required.

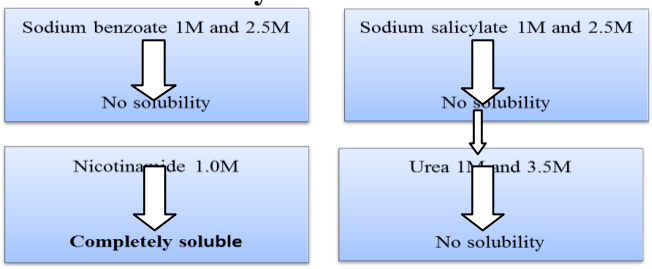
b) If the chemical under test is insoluble in either Medium of dilution or Medium of Treatment, then move on to Trial 2 by adding up a sufficient amount of medium, just about 1.5M to attempt for dissolving the drug. If the chemical under test get dissolved in medium at 1.5M concentration, further steps are not required. If the drug not dissolves in one medium or the other (if both agents are checked in this trial), stop the attempts to dissolve the chemical. If the drug is soluble in any of these solvents, no extra solubility measures are required.

c) If the drug is still insoluble in either of the media applied in Trial 2, then go on with Tier 2, 2.5, by increasing the concentration. If the drug is soluble, no further solubility trials are needed. The details are given in table 1. If the chemical under test is not dissolving, drop the solubilizing agent and try another solubilizing agent in the preferential order as referred in the flow chart.

Table No: 1 Identification of ideal solubilising agent

Concentration	Trial 1	Trail 2	Trail 3	Trial 4
Drug	10mg	10mg	10mg	10mg
Solubilizing agent	1M, 1.5M	1M, 1.5M	1M, 1.5M	1M, 1.5M

Solubility Flow chart



The results found were satisfactory and Vortioxetine Hydrochloride is completely soluble in 1.0M Nicotinamide

VALIDATION

To ascertain the experimental conditions, the method was subjected to validation parameters like range, linearity and assay using marketed formulation at 290.8nm (at N=4) UV first derivative absorption maximum. However, the present method should be revalidated according to ICH or USFDA guidelines. [8, 9]. The details are given in table 2 and figures 1 to 11.

Table No: 2 Linearity data table and Range

Concentration	Absorbance	Derivative
15µg/ ml	1.981 A	2.400A
20µg/ ml	1.493 A	1.800A
25µg/ ml	1.095 A	1.400A
30µg/ ml	0.837 A	1.000A

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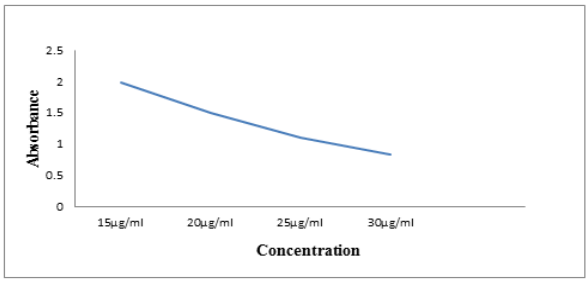

Figure 1: Linearity graph of experimental data for Vortioxetine Hydrochloride at N=5

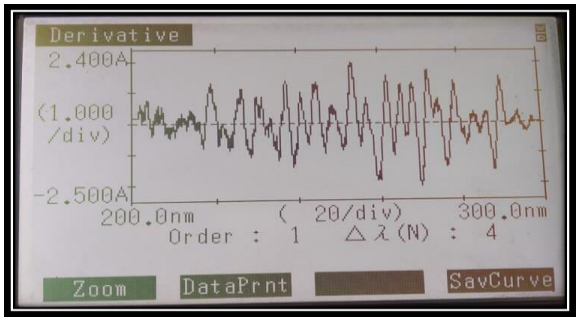

Figure 2: Instrumental response First order Derivative spectrum 15µg/ml

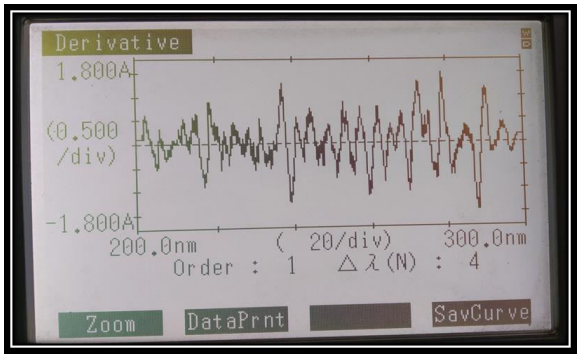

Figure 3: Instrumental response First order Derivative spectrum 20µg/ml

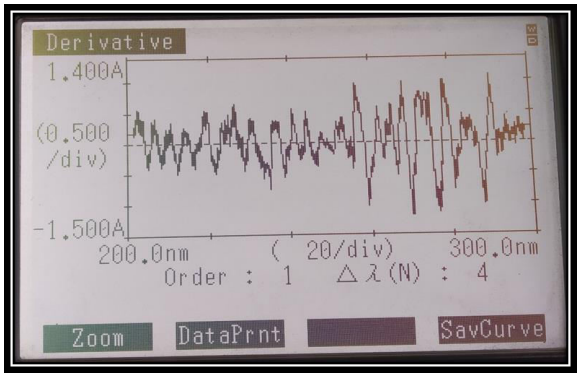

Figure 4: Instrumental response First order Derivative spectrum 25µg/ml

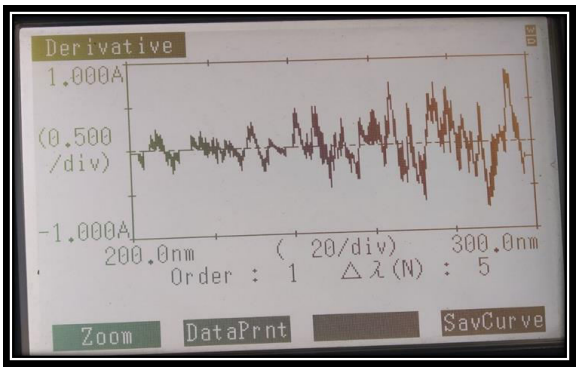

Figure 5: Instrumental response First order Derivative spectrum 30µg/ml

ASSAY

Table 3.0 Table for experimental data of validation parameter Assay

Concentration	Max	Absorbance	Derivative
30 µg/ml	290.8	0.752A	0A

Table No: 4 Optimum conditions for Linear graph

Parameters	Conditions
Solubilizing agent	Nicotinamide
Concentration	1.0M
Solubility of Vortioxetine Hydrochloride	1.0 mg/ml
Range	15 to 30µg/ml
Regression Equation	y=0.04X+1.97
LOD	0.00934 µg/ml
LOQ	0.05439 µg/ml
Assay	99% (n=5)
Assay	SD 0.9901
Assay	CoV 0.9995

RESULTS AND DISCUSSION

After following above procedures, Vortioxetine Hydrochloride was found to be freely soluble in 1.0M Niacinamide (1.0 mg/ml) and not in other solubilizing agents. To check the reproducibility of the procedure, the serial dilutions of 15, 20, 25, 30 µg/ml solutions were prepared and subjected to linearity study. A graph of derivative values versus concentration was plotted and the results were found to be precise. The assay values were found to be accurate with low standard deviation values and low values of co efficient of variation. The details are given in the table 4.

CONCLUSION

The current newly developed method offers an accurate, reproducible, linear, economical, time saving method with a suitable concentration range for the determination of Vortioxetine Hydrochloride using an environment friendly method which avoids the use of harmful and toxic solvents which are health hazardous. The report is also useful for the routine analysis of Vortioxetine Hydrochloride in pharmaceutical formulations. These studies are further applicable for dissolution, disintegration, pharmacological evaluations, pharmacokinetic and pharmacodynamic studies of Vortioxetine Hydrochloride. Future scope of this report involves the complete validation profile according to internationally accepted guidelines like ICH and USFDA etc.

AUTHORS CONTRIBUTIONS

All the authors have contributed equally.

CONFLICT OF INTERESTS

Declared none

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