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R E S E A R C H A R T I C L E

Development and Validation of Tramadol Hydrochloride Capsules by RP-HPLC Method

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A B S T R A C T

A simple, fast and precise reverse phase high performance liquid chromatography method was developed for the determination of Tramadol Hydrochloride in capsules by using HiQ W C_{18}(250mm×4.6mm, i.d., 5µ) column with mobile phase of acetonitrile: methanol : 25Mm sodium dihydrogen ortho phosphate (30:30:40) adjusted to pH3 with 1Mm SLS was used. The flow rate was 1mL/minute and UV detection at 215nm.The retention time for Tramadol Hydrochloride was 4.7minutes.The linearity range was found to be 5.13 – 15.39µg/mL. The proposed method was validated as per ICH guidelines.

Keywords: Tramadol Hydrochloride, RP-HPLC, capsule

A R T I C L E I N F O

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C O N T E N T S

1. Introduction

Tramadol hydrochloride is chemically cyclohexanol, 2 ((dimethyamino) methyl) 1-(m-methoxyphenyl)-hydrochloride [1]. It is a centrally acting opioid analgesic used to treat severe pain. It possesses weak agonist and opioid receptor, release the serotoin and inhibit the reuptake of norepinephrine [2]. Tramadol is a synthetic analogue of the phenanthrene alkaloid codeine and, as such, is an opioid and also a prodrug (codeine is metabolised to morphin, tramadol is converted to ortho-desmethyltramadol [3].

2. Materials and Methods

Reagents and chemicals

HPLC grade acetonitrile, methanol (Molychem, Mumbai), SLS (Loba chemie, Mumbai), Sodium dihydrogen ortho phosphate (Nice chemicals, Mumbai) ortho phosphoric acid. The standard sample of tramadol hydrochloride was provided by our guide and capsule were purchased from local pharmacy [4,5].

Chromatography condition

The separation was achieved on HiQ W C18 (250×4.6)mm 5µ. Column using a mixture of acetonitrile: methanol: 25mm sodium dihydrogen ortho phosphate (30:30:40) adjusted to pH 3 with 1Mm SLS as mobile phase.The elution was carried out at the flow rate of 1mL/minutes.The detection was made at 215nm at ambient temperature the data was analysed [6].

Preparation of standard solution

Accurately weighed 29.2mg of tramadol hydrochloride in 50ml volumetric flask, 5ml methanol was added and dissolved by sonication and made up to the final volume with methanol (55µg/ml) [7]. From the above solution (500µg/ml) 5ml was pipetted out into a 100ml volumetric flask, the final volume was made up with mobile phase(25µg/ml). From the above solution (25µg/ml) 4ml was pipetted out into a 10ml volumetric flask, final volume was made up with mobile phase (10µg/ml).

Preparation of sample solution:

20 capsules were taken, average weight of capsules is found to be containing 50mg of tramadol hydrochloride, from this a quantity of capsule powder having an equivalent to 50mg of tramadol hydrochloride (173.04 mg) was transferred to 100ml volumetric flask. It was dissolved by adding methanol and sonicated for 5mint then make up the final volume with methanol (500µg/ml). From the above solution (500µg/ml), 1ml was pipetted out into a 5o ml volumetric flask and final the volume was made up with mobile phase (10µg/ml)[9].

Validation Parameter

System suitability:

For system suitability, six replicates lf standard solutions were injected and parameters studied were number of theoretical plates, peak area, resolution, retention time and tailing factor [10,11].

Accuracy:

The accuracy of the experiment was established using recovery technique. The result of recovery was well within the acceptable limit.

Precision:

The validation of the proposed method was verified by system precision and method precision. The system precision was evaluated by measuring the peal area responses of tramadol hydrochloride for 5 replicate injections of the standard solutions. The method precision was determined by quantifying the sample solutions as per the proposed method, which yielded quite concurrent results, indicating reliability of the method[12].

Linearity and range:

During linearity study, it was observed that the absorbance value of tramadol hydrochloride in the marketed formulation were linear in the concentration range of5.13-15.39µg/Ml of the test concentration with R2 close to one for this method of analysis.

Robustness and Ruggedness:

Robustness of the method is determined by analysing the sample in duplicate with varying the method conditions i.e., very small changes in flow rate, showed there were no marked changes in chromatographic behaviour and content of the drug, as evident from the low value of RSD indicating the method is robust. The method was also confirmed by ruggedness study, analysing the product day to day, analyst to analyst and instrument to instrument [13,14,15].

3. Results and Discussion

Estimation of tramadol hydrochloride in capsule dosage form by RP-HPLC method was carried ort using optimized chromatographic conditions. The typical chromatogram of tramadol hydrochloride shown in figure-1. The retention time of tramadol hydrochloride were found to be around were 4.7 mints. The resolution value of more than 2 indicates satisfactory result in quantitative work and the high resolution value obtained indicate the complete separation of the drugs. The linearity was studied in the concentration range from 5.13-15.39 µg/ml for tramadol hydrochloride.

The regression co-efficient (R2) value for tramadol hydrochloride was found to be 0.999, respectively. The mean recovery for tramadol hydrochloride was 50-150% which is largely within the 98.0-102.0% range that is considered acceptable and it reveals that the method is accurate. The validation of the proposed method was verified by system precision and method precision. The %RSD was found to be NMT 2.0 for tramadol hydrochloride drug indicate the proposed method is precise. The results of analysis show that the amounts of drugs were in good agreement with the label claim of the formulation.

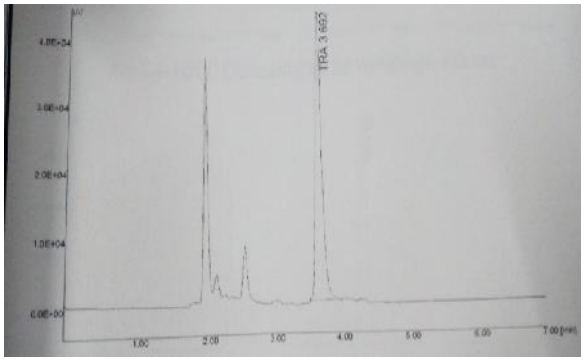

Fig 1: Typical standard chromatogram for Tramadol Hydrochloride

4. Conclusion

The proposed method is simple, accurate, cost effective, less time consuming and the statistical analysis proved that the method is reproducible and efficient for the particular drug of tramadol hydrochloride. The developed method could be conveniently adopted for routine analysis in quality control laboratories.

Table 1: Assay of tramadol hydrochloride in capsule

Drug name	Label claim mg/tab	Mean peak area		Amount found ±SD mg/tab	% Label claim ± SD
		Standard	sample		
Tramadol hydrochloride	50	350571.4	350613.7	50.02±0.31	100.04±0.31

Table 2: System suitability parameters

S.No	Parameters	Obtained Values
1	Theoretical plates (N)	5342
2	Tailing factors (T)	0.09
3	Retention time (min)	4.7
4	% RSD of peak retention time	0.3%

Table 3: Summary of validation parameters

Parameters	Data
Linear range	5.13 – 15.39µg/ml
Correlation coefficient	0.999
% Recovery	98 – 102%
System precision	0.57%
Method precision	0.22%
Robustness(%RSD)	100.4%
Ruggedness(%RSD)	98 – 102%

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