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Development and Validation of RP-HPLC Method For Estimation of Trimipramine in Tablet Dosage Form

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ABSTRACT:

A simple, precise, rapid, accurate and economic reverse phase high performance liquid chromatographic method have been developed for the estimation of Trimipramine maleate in tablet dosage form. The chromatographic analysis should be carried out on the cosmosil C18 column. On the basis of reversed phase HPLC mode and number of carbon present in molecule (analyte) stationary phase with C18 bonded phase i.e Inertsil ODS-3V (150 mm X 4.6 mm), 3 µm should be preference for selection. The selection of mobile phase was done after assessing the solubility of drug in different solvent as well on the basis of literature survey. A simple, precise and economic UV and RP-HPLC method should be developed and validation for estimation of Trimipramine maleate in pharmaceutical dosage form. The method validation carried out as per ICH guidelines by using various validation parameters such as Linearity, accuracy, precision, specificity and robustness.

Keywords: Trimipramine maleate, RP-HPLC, Validation,

Introduction:

HPLC is an analytical process utilizing special instruments designed to separate, quantify and analyze components of chemical mixture. Samples of interest are introduced to a solvent flow path; carried through a column packed with specialized materials for component separation; and component data is obtained through the combination of a detection mechanism coupled with a data recording system. A typical HPLC separation is based on the selective distribution of analytes between a liquid mobile phase and an immiscible stationary phase. The sample is first introduced by means of an injection port into the mobile phase stream that is delivered by a high-pressure pump. Next, the components of this sample mixture are separated on the column, a process monitored with a flow-through detector as the isolated components emerge from the column.

DRUG PROFILE:

Trimipramine maleate:
Structure:

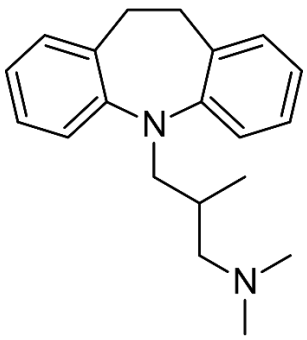

Fig. 6.1 Trimipramine maleate.

General profile of Trimipramine maleate

Category	Anti-depressant agent.
Chemical Name	3-(5,6-dihydrobenzo[b][1]benzazepin-11-yl)-*N*,*N*,2- trimethylpropan-1-amine
Molecular Formula	$C_{20}H_{26}N_2$
Molecular Weight	294.434 g/mol
Odour	Odourless
Description	White crystalline powder.
Solubility	soluble in organic solvents such as ethanol, DMSO, and dimethyl formamide (DMF), it is sparingly soluble in aqueous buffers.
Melting point	45°C
Odour	Odourless
PKa	9.24 (Strongest Acidic)
LOG P-	4.2

Reported Analytical Method:

Sr. No.	**Name of Drug**	**Mobile Phase composition**	**Discussion**	**Ref**
1	Trimipramine maleate	Methanol: acetonitrile (20:80, v/v)	The retention time of Trimipramine maleate was 10.4 min in plasma and 10.9 min in urine.	1
2	Trimipramine maleate	ammonium formate: Methanol (25:75V/V)	Retention time of Trimipramine maleate was 1.67Min for R configuration & 1.48 Min for S Configuration.	2
3	Trimipramine maleate	Methanol: water (60:40 % v/v)	The retention time of Trimipramine maleate was 9.1 min	3
4	Trimipramine maleate	sodium hydrogen phosphate solution - acetonitrile (60:40, v/v)	The retention times of Trimipramine maleate were 4.3 and 5.2 min. respectively	4
5	Trimipramine maleate	hexane/isoamyl alcohol 98:2 (v/v)	The retention time of Trimipramine maleate was 9.1 min.	5

Conclusion:

HPLC has gained the valuable position in the field of analysis due to ease of performance, specificity, sensitivity and the analysis of sample of complex nature. This technique was employed in the present investigation for estimation of Trimipramine maleate tablet formulation. HPLC Water2469 with GL-Science, YMC Pack C18, 5µ, 4.6 x 150mm column and UV/PDA detector with empower pro Software will be used for the study. The standard and sample solution of Trimipramine maleate tablet prepared in diluent. Different pure solvents of varying polarity in different proportions were tried as mobile phase for development of the chromatogram.

The above study gives the analytical methods for analysis of Trimipramine maleate in their bulk and combined dosage form by using RP-HPLC methods and UV spectroscopic methods. The validation parameters such as precision, accuracy, linearity, analysis time are performed. Literature survey reveals that various methods are reported for the development and validation of various drugs. These methods are reported and published for various parameters as ICH guidelines. These methods give ideas for development and validation of new analytical methods.

REFERENCES:

1. Mendham j., denny r. C., thomas m.; vogel's text book of quantitative chemical analysis; pearson education limited; 6th edition, 2008, 29-39.
2. Chatwal g. R., anand s. K.; instrumental methods of chemical analysis; himalaya publishing house, mumbai; 11th edition, 2005, 1.1-1.2, 2.108-2.109,
3. Kasture a. V., wadodkar s. G., mahadikk.r., more h.n.; pharmaceutical analysis instrumental methods; nirali prakashan; 12th edition, 2005; 148-156.
4. Skoog d., leqary j.; principle of instrumental analysis; thomsonasia pvt ltd. Singapore; 54th edition, 2004; 3-8.
5. Skoog d., holler f., timothy a., nieman n.; principles of instrumental analysis; saunders college publications, london; 4th edition, 1992; 1-2, 338-340.
6. Settle f.; handbook of instrumental techniques of analytical chemistry. 1st edition, 2004, 19-21, 609-617.
7. Corners k. A., textbook of pharmaceutical analysis, a wiley interscience publication, 1st edition, 1967, 475-478
8. Kasture a. V., wadodkar s. G., mahadikk.r., more h.n; textbook of pharmaceutical analysis-ii, nirali prakashan, 13th edition, 2005,1, 47-56
9. British pharmacopoeia, 1993, volume ii, 180-190.
10. Kakde r.b., kasturea.v., wadodkar s. G.; indian journal of pharmaceutical sciences, 2002, 64(1), 24-27.
11. Dyade g.k., sharmaa.k.; indian drugs, 2001, 38(2): 75-78.
12. Sethi p.d.; qualitativie analysis of drugs in pharmaceutical formulations, 3rd edition, 1997, 182-184.
13. Swarbrick james., boylanjames.c.; encyclopedia of pharmaceutical technology, volume i, marcel dekkerinc., new york, 1998, 217 - 224.
14. Lindsay sandy.; hplc by open learning; john wiley and sons, london, 1991, 30- 45.
15. Lough w.j., waineri.w.w.; hplc fundamental principles and practices, blackie academic and professional, 1991, 52-67.
16. G. D christian; in: analytical chemistry, 4th edition, john wiley and sons, United Kingdom, 1986, 1-6.