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DEVELOPMENT AND VALIDATION OF RP-HPLC METHOD FOR ESTIMATION OF TRIMIPRAMINE MALEATE IN PHARMACEUTICAL 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 various pharmaceutical dosage form like tablet, capsule, gel, etc.

The selection of mobile phase as well as stationary phase is finalized after assessing the solubility of Trimipramine maleate in different organic solvent as well on the basis of literature survey. The Trimipramine maleate having anti-depressant activity, it is odourless, white crystalline powder. Also soluble in different organic solvent and sparingly soluble in aquatic buffer.

KEYWORDS: *Trimipramine maleate, RP-HPLC, Validation,*

INTRODUCTION

HPLC is an analytical process utilizing special instruments designed to separate, quantify and analyse components of chemical mixture. RP-HPLC is the choice for the majority of samples. It consists of a non-polar stationary phase and an aqueous, moderately polar mobile phase. One common stationary phase is silica which has been treated with alkyl dimethyl silylchloride (RMe2SiCl), where R is a straight chain alkyl group such as octadecyl ($C_{18}H_{37}$) or octyl (C_8H_{17}). The retention time is therefore longer for molecules which are more non-polar in nature, allowing polar molecules to elute more readily.

By using the reverse phase HPLC method for the estimation of Trimipramine maleate in different pharmaceutical dosage form like Tablet, Capsule, etc. the new precise, economical, simple, rapid & accurate method are developed and validate. For the estimation chromatographic analysis method used. As per the study of different literature survey selection of column, Selection of stationary as well as mobile phase is good for accurate result. In the estimation of Trimipramine maleate the analysis of single dose formulation of Trimipramine maleate tablet can also be successfully performed by the RP-HPLC method. No interference of additives, matrix etc. is encountered in these methods.



Figure 1.1: Typical HPLC Waters System

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DRUG PROFILE

Trimipramine Maleate

Structure

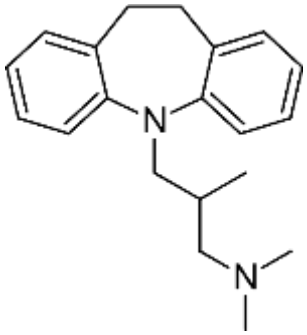


Fig. 6.1 Trimipramine Maleate.

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

After the study of different literature survey on drug Trimipramine maleate following analytical methods are found to be reported and research gap are also found.

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
6	Trimipramine maleate and Opipramol	ammonium formate with 0.1% formic acid:methanol 25:75(v/v)	The retention time of Trimipramine and Opipramol were found to be 1.67 min and 1.48 min respectively.	6

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CONCLUSION

- The develop new, simple, sensitive, accurate, and economical analytical method for the determination of assay of Trimipramine maleate in capsule dosage form by RP-HPLC.
- Validate the proposed method in accordance with USP and ICH guidelines for the intended analytical application i.e., to apply the proposed method for analysis of the drug in its dosage form.
- The method shows good reproducibility; moreover, the RP-HPLC method is accurate, precise, specific, reproducible and sensitive.
- The analysis of single dose formulation of Trimipramine maleate tablet can also be successfully performed by the RP-HPLC method. No interference of additives, matrix etc. is encountered in these methods.
- Further studies on other pharmaceutical formulations would throw more light on these studies. Suitability of these methods on biological samples needy also studies.

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