

A REVIEW ON CHROMATOGRAPHIC AND SPECTROPHOTOMETRIC METHOD FOR ESTIMATION OF OPIPRAMOL DIHYDROCHLORIDE IN PHARMACEUTICAL DOSAGE FORM

Purvangi S. Patel* and Dr. Dilip G. Maheshwari

L. J. Institute of Pharmacy, Nr. Sanand Cross Road, Sarkhej - Gandhinagar Highway,
Ahmedabad Gujarat-382210, India.

Article Received on
17 Jan. 2018,

Revised on 07 Jan. 2018,
Accepted on 28 Feb. 2018,

DOI: 10.20959/wjpr20185-11249

*Corresponding Author

Purvangi S. Patel

L. J. Institute of Pharmacy,
Nr. Sanand Cross Roads,
Sarkhej - Gandhinagar
Highway, Ahmedabad
Gujarat-382210, India.

ABSTRACT

Opipramol dihydrochloride is an **Antidepressant** and **Anxiolytic** drug. It is a member of the tricyclic antidepressants, opipramol's primary mechanism of action is much different in comparison. Most TCAs act as reuptake inhibitors, but opipramol dihydrochloride does not, and instead acts as a sigma receptor agonist. This is generally administered as tablet dosage form. Mostly the work is done on RP-HPLC with different methods and for its estimation the mobile phase used are usually the same that are in different ratio of Acetonitrile and Potassium Dihydrogen Orthophosphate. This review entails the different methods for estimation of Opipramol dihydrochloride like UV, HPTLC, HPLC, LC.

KEYWORDS: Opipramol dihydrochloride, Antidepressant, stability indicating method, UV-spectroscopy, HPLC (High Performance Liquid Chromatography), HPTLC (High Performance Thin Layer Chromatography), LC (Liquid Chromatography).

INTRODUCTION

Opipramol dihydrochloride has reported to be a rather potent sigma ligand with high affinity to sigma₁ and lower affinity to sigma₂ sites with pronounced D₂-, 5-HT₂- and H₁-blocking potential. So opipramol is an atypical anxiolytic and anti-depressive drug. It is a psychotropic drug commonly used for therapy of somatoform, general anxiety disorder, anxious depressive

states. The biphasic action initially makes prompt improvement of tension, anxiety and insomnia.

Chromatographic methods can be categorized in two ways. The first classification is based upon the physical means by which the stationary and mobile phases are brought into contact. In column chromatography, the stationary phase is held in a narrow tube through which the mobile phase is forced under pressure. In planar chromatography, the stationary phase is supported on a flat plate or in the interstices of a paper; here, the mobile phase moves through the stationary phase by capillary action or under the influence of gravity.

Spectrophotometry is a method to measure how much a chemical substance absorbs light by measuring the intensity of light as a beam of light passes through sample solution. The basic principle is that each compound absorbs or transmits light over a certain range of wavelength. This measurement can also be used to measure the amount of a known chemical substance. Spectrophotometry is one of the most useful methods of quantitative analysis in various fields.

- **UV-visible spectrophotometer:** uses light over the ultraviolet range (185 - 400 nm) and visible range (400 - 700 nm) of electromagnetic radiation spectrum.
- **IR spectrophotometer:** uses light over the infrared range (700 - 15000 nm) of electromagnetic radiation spectrum.

It was revealed that the UV and HPLC method are done for the estimation of opipramol dihydrochloride. And also the stability indicating HPTLC of opipramol HCl is done. But there is no method available for stability indicating RP-HPLC method for opipramol dihydrochloride hence there is need to study and develop stability indicating RP-HPLC method for opipramol dihydrochloride.

Reported methods are categorized depending on the following considerations

Opipramol dihydrochloride was analysed by different methods like UV-spectroscopy, HPLC, HPTLC, LC.

Methods for estimation of Opipramol dihydrochloride

SR. NO.	DOSAGE FORM	METHOD	DESCRIPTION
1.	Opipramol in bulk and tablet dosage form.	UV Zero order derivative spectrophotometric.	Detection wavelength: 254 nm Concentration range: 2-10µg/ml R²: 0.996 LOD : 0.2181 µg/ml LOQ : 0.7272 µg/ml
		UV First order derivative spectrophotometric.	Detection wavelength: 266 nm Concentration range: 2-10 µg/ml R²: 0.998 LOD : 0.1363 µg/ml LOQ : 0.4545 µg/ml
2.	Opipramol in plasma and urine.	HPLC	Column : guard column Mobile phase : Acetonitrile : Dipotassium hydrogen Orthophosphate(20:80) Flow rate : 1.2ml/min Temperature : 30°C
		TLC	Stationary phase : silica rapid F 254 , ICN Mobile phase : Ethylacetate : Methanol : Ammonium hydroxide 25% (50:450:1) Spot detection : 254nm
		GC-MS	GC column : Hewlett-Packard model 5890 B with an SE-54 fused-quartz silica capillary column. Column temperature : 70-300°C at 20°C/min. Carrier gas : Helium Flow rate : 1.5 ml/min MS model : TSQ 700 MS
3.	Opipramol in plasma	Quantitative determination by HPLC + UV	Column: Zorbax Eclipse XDB-C18 Column and ACE 5 CN guard column. Concentration range : 2-70 ng/ml Detection wavelength : 256 nm R² : 0.998. Retention time : 8.36 min.
4.	Opipramol in pharmaceutical dosage form.	RP-HPLC	Column : C18 column Mobile phase : Dipotassium hydrogen Orthophosphate : Acetonitrile Detection wavelength : 257nm Concentration range : 5-60 µg/ml Flow rate : 1ml/min Retention time: 4.43 min. Regression equation: Y=273255.34x+101066311 LOD : 0.05 LOQ : 0.15 % Assay : 98.96%
5.	Opipramol in tablet dosage form.	RP-UFLC	Column : Phenomenex Luna c ₈ column. Mobile phase : Potassium Dihydrogen Phosphate : Acetonitrile (60:40 v/v)

			Flow rate :1ml/min Detection wavelength :253nm Concentration range :200-1000ng/ml Retention time :2.72 min LOD :11.95ng/ml LOQ :36.21ng/ml
6.	Opipramol in bulk and tablet dosage form.	RP-HPLC-PDA	Column :Inertsil column Mobile phase : Acetonitrile : Ammonium acetate (65:35% v/v) Flow rate :1.2 ml/min Detection wavelength : 254nm Concentration range :10-35 µg/ml Retention time :5.572 min R² : 0.998 Accuracy :100.23% - 101.81% LOD :0.00842 µg/ml LOQ : 0.0255 µg/ml
7.	Opipramol Hcl in bulk and tablet dosage form.	HPTLC	Detection wavelength : 256nm. Mobile phase : Toluene: Methanol (7:3 % v/v). Concentration range : 100-600 ng band ⁻¹ . Retention factor : 0.45 ± 0.006. % Assay : 99.56 ± 1.48.
8.	Opipramol in pharmaceutical preparations and biological fluids.	Electroanalytical determination.	Electrode : glassy carbon electrode PH : 3.7 Acetate buffer. PH Range : 0.33-12 Voltage : +0.86 V Quantification Range : 2*10 ⁻⁶ to 6*10 ⁻⁵ M
9.	Opipramol in pharmaceutical dosage form.	LC	Mobile phase : Acetonitrile : Water (35: 45% v/v) Temperature : 25°C Column : Nucleosil C18 Column.

CONCLUSION

This review portray the reported Spectroscopic and Chromatographic methods developed and validated for estimation of Opipramol dihydrochloride. According to this review it was concluded that for Opipramol dihydrochloride different Spectroscopic and Chromatographic methods are available for single. All methods are found to be simple, accurate, economic, precise, and reproducible in nature. As per review most of works have used the reversed-phase HPLC and UV absorbance detection because this provided with best available reliability, repeatability, analysis time and sensitivity.

ACKNOWLEDGEMENT

The authors are thankful to Dr. K. Pundarikakshudu, Director of L. J. Institute of Pharmacy, Ahmedabad, India for providing valuable guidance, all the facilities and encouragement to carry out the work.

REFERENCES

1. Satyakam M, NM Rath., Anurag A, Jitendra V, "Opipramol : A Novel Drug", *Delhi Psychiatry Journal.*, 2013; 16(2): 409-411.
2. ICH, Q2A(R1)., Stability Studies and Test Procedures: Text and Methodology International Conference on Harmonization, IFPMA, Geneva, Switzerland, 2005.
3. Fazil Khan, BM Gurupadayya, AM Nasefa, Sai Prudhvi, "Development and Validation of Zero and First Order Spectrophotometric Method for Determination of Opipramol in Bulk and Pharmaceutical Dosage Form" *International Journal of Pharmacy and Pharmaceutical Sciences*, 2015; 7(3): 0975-1491.
4. Marianne L.P, Joachim T, "Identification and Determination of Opipramol Metabolites in Plasma and Urine" *Journal of Analytical Toxicology*, 1998; 22.
5. Irak O.G, Ozilhan S, Toptan S, Alkan E, Eren S, "Application of the Quantitative Determination of Opipramol in Human Plasma by High Performance Liquid Chromatography with UV Detection" NovagenixBioanalytical R and D Center, Ankara, 06970.
6. Nemala Appala R, Mr. J. Raghu R., V. Kiran Kumar., VVSS Appala R, "New High Performance Liquid Chromatography Method for Determination of Opipramol in Pharmaceutical Dosage Form" *Indo American Journal of Pharmaceutical Research*, 2016; 2231-6876.
7. Rohith SB., Gurupadayya BM., Chandan RS., "Development and Validation of a RP-UFLC Analytical Method for the Determination of Opipramol in Tablet Dosage Form" *Research Gate*, 2015.
8. Prasanthi PG., Vijaya Lakshmi M, Mahesh K. and Nalluri B, "Development and Validation of RP-HPLC-PDA Method for the Estimation of Opipramol hydrochloride in Bulk and Tablet Dosage Form" *Indian Drugs.*, 2017; 54(7): 46-50.
9. Santosh RB., Padmanabh BD., "Development and Validation of Stability Indicating HPTLC Method for Determination of Opipramol Hydrochloride as Bulk and in Tablet Dosage Form" *World Journal of Pharmaceutical Research*, 2015; 4(9): 1952-1962.
10. Erdal T and Bengi U, "Electroanalytical Determination of Opipramol in Pharmaceutical Preparations and Biological Fluids", *Taylor and Francis.*, Analytical letters., 2013; 41: 2013-2032.
11. Ebru CD., Dilara Basat., Hale SC., Guleren A, Bengi U, "Determination of pKa values of Opipramol in Acetonitrile-Water Binary Mixtures by using Chromatographic and Spectrophotometric methods", High Quality Scholarly Publishing.