International Journal of Scientific Research in Engineering and Management (IJSREM)
Volume: 08 Issue: 09 | Sept - 2024 SJIF Rating: 8.448 ISSN: 2582-3930

Analytical Method Development and Validation of Mefloquine Hydrochloride for the Determination in Tablet dosage form by using RP-HPLC Method

Miss. Kajal Tushar Bhawar- Pharmaceutical Chemistry-Pharate Collage Pharmacy
Dr. P. P. Jain
Dr. Santosh Waghmare

Abstract- A simple HPLC method for determination of mefloquine hydrochloride in tablets was developed and validated. The separation was carried out on an Xterra RP18 (250 x 4.6 mm id, 5 pm particle size) analytical column. The mobile phase was 0.05 M monobasic potassium phosphate buffer (pH 3.5)-methanol (40 + 60, v/v). The flow rate and wavelength were set to 1 mL/min and 283 nm, respectively. The method was specific for mefloquine hydrochloride in the presence of hydrolytic, oxidative, and photolytic degradation products. It was also linear, precise, accurate, and robust, being suitable for routine QC analyses and stability studies. The developed HPLC method was compared to a previously described spectrophotometric method.

***Key Words*:** HPLC Method, Mefloquine Hydrochloride, Analytical Method, Development, Validation.

1.INTRODUCTION-
PHARMACEUTICAL ANALYSIS

Pharmaceutical analysis is the branch of science which deals with identification of substances and determination of amount present in particular sample. Pharmaceutical analysis covers the bulk materials, dosage forms and more recently, biological samples in support of bio-pharmaceutical and pharmacokinetic studies. Analysis can be divided into areas called qualitative and quantitative analysis.Pharmaceutical products synthesized and identified using instrumental techniques. The Laboratory controls shall include the establishment of sound and appropriate specification standards and test procedure to assure that the final drug substances conform to the required standards of identity, strength, quality and purity. Modern physical methods of analysis are extremely sensitive, providing precise and accurate information about the standards of chemicals or drugs up to nanogram levels like HPLC.

2.DRUG PROFILE-

Drug: Mefloquine Hydrochloride

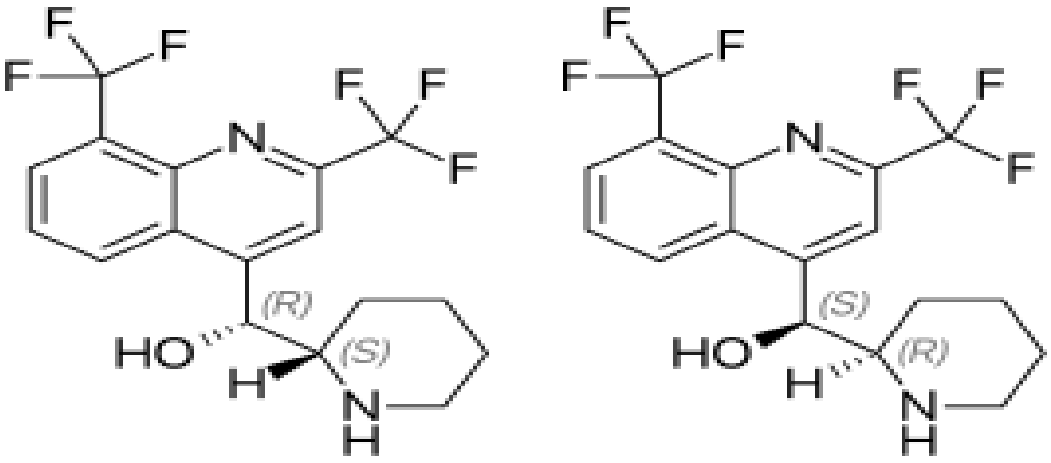
Malaria is a protozoan disease that places an enormous burden on human health in endemic areas around the world. The 2020 World Health Organization malaria report indicates a 60% decrease in the global malaria fatality rate between 2000 to 2019. Despite this, malaria remains a significant cause of morbidity and mortality; 90% of deaths from malaria

occur in Africa. Individuals at the highest risk for malaria are those in disease naïve populations, children under age, refugees in Central and Eastern Africa, nonimmune civilian and military travelers, pregnant women, and immigrants traveling to their place of origin.

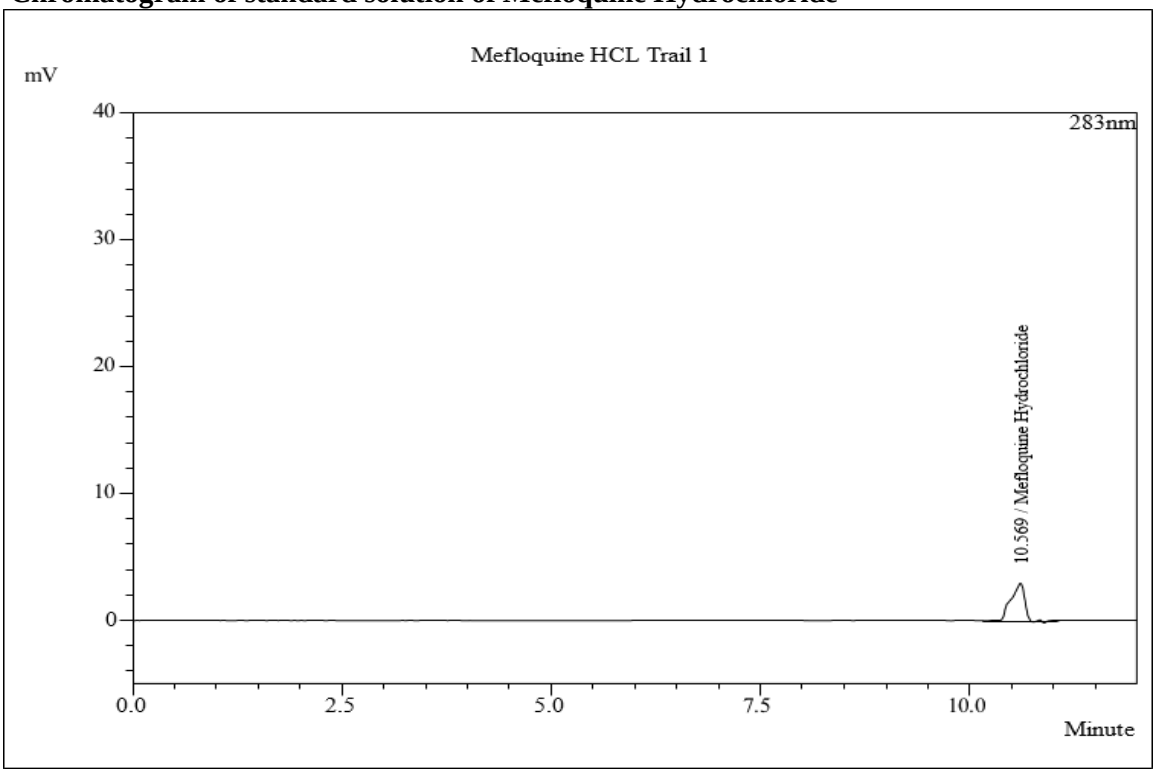
Description-

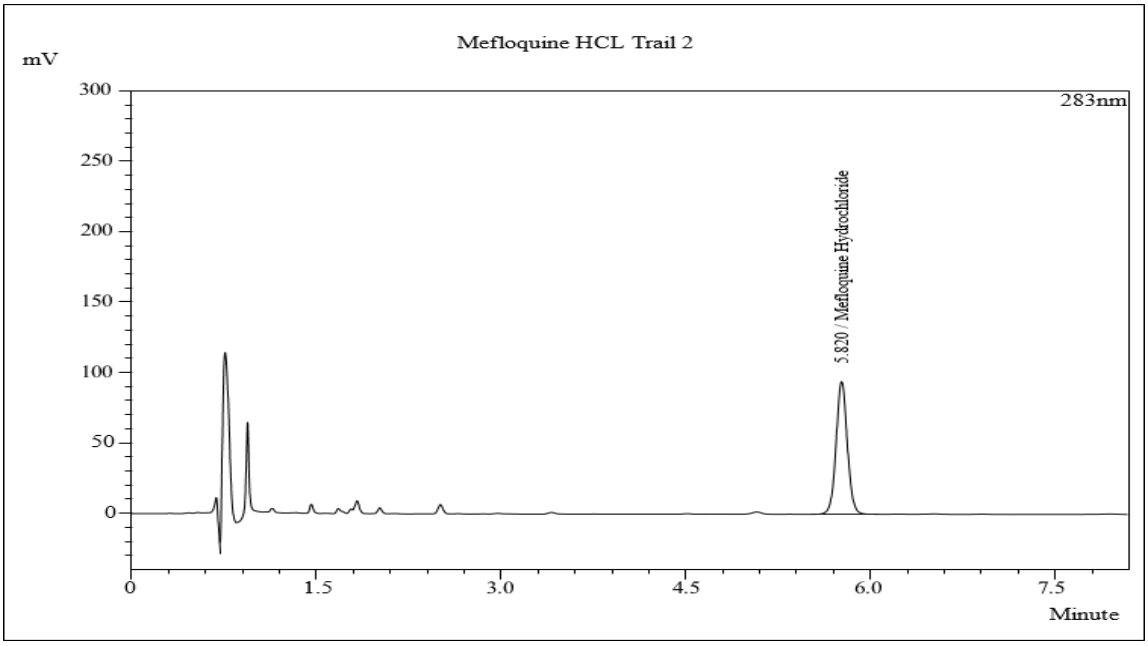
Mefloquine, commonly known as Lariam, is an antimalarial drug used for the prevention and treatment of malaria caused by infection with Plasmodium vivax and Plasmodium falciparum. The drug was initially discovered by the Walter Reed Army Institute of Research (WRAIR) during a malaria drug discovery program between 1963 until 1976. It was approved by the FDA in 1989, and was first marketed by Hoffman Laroche.5 This drug has been the subject of widespread controversy due to concerns regarding neurotoxic effects; product information warns of potential serious neuropsychiatric effects.

Structure

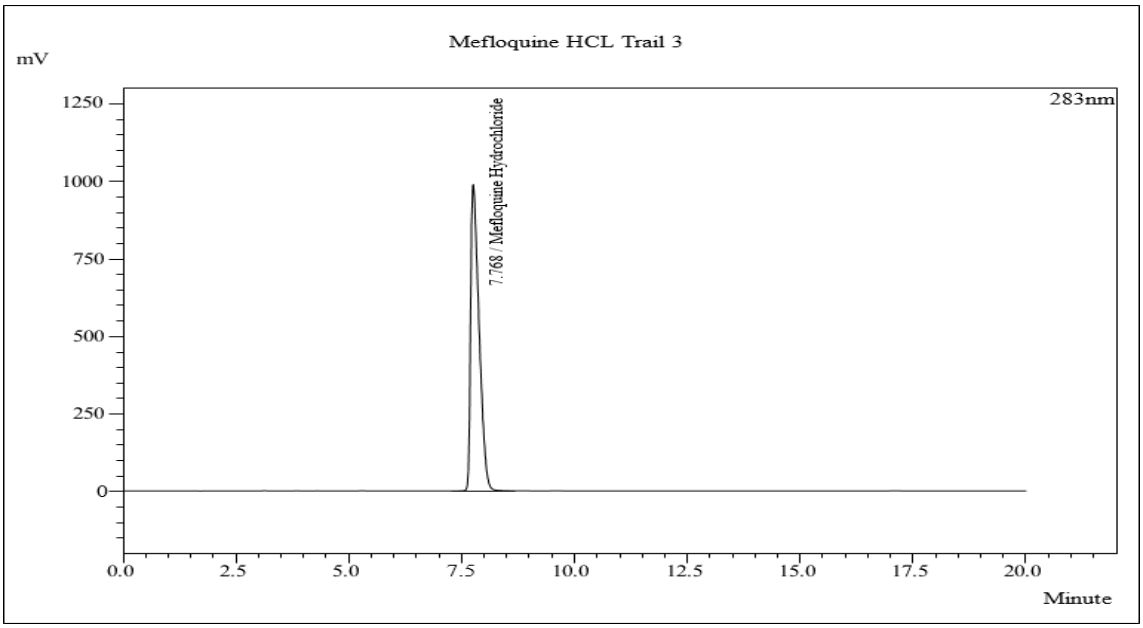


Chromatogram of standard solution of Mefloquine Hydrochloride





Chromatogram of standard solution of Mefloquine Hydrochloride



Chromatogram of standard solution of Mefloquine Hydrochloride

Conclusion- For routine analytical purpose, it is always necessary to establish methods capable of analyzing huge number of samples in a short time period with due accuracy and precision. Mefloquine Hydrochloride is official in Indian Pharmacopoeia.

A very few analytical methods appeared in the literature for the determination of Mefloquine Hydrochloride includes HPLC, HPTLC and UV- Visible spectrophotometric methods. In view of the above fact, some simple analytical methods were planned to develop with sensitivity, accuracy, precision and economical. In the present investigation HPLC method for the quantitative estimation of Mefloquine Hydrochloride in bulk drug and per ICH guidelines pharmaceutical formulations has been developed. HPLC methods were validated as and results of linearity, precision, accuracy, Specificity, System suitability and robustness pass the limit. The HPLC method is more sensitive, accurate and precise compared to the previously reported method. There was no any interference of excipients in the recovery study. The low value of %RSD, molar extinction coefficient (L mol-1 cm-1) suggested that the developed methods are sensitive. The proposed high- performance liquid chromatographic method has also been evaluated over the accuracy, precision and robustness and proved to be convenient and effective for the quality control of Mefloquine Hydrochloride. Developed method was found simple and cost effective for the quality control of Mefloquine Hydrochloride.

Moreover, the lower solvent consumption leads to a cost effective and environmentally friendly Spectroscopic procedure. Thus, the proposed methodology is rapid, selective, requires a simple sample preparation procedure, and represents a good procedure for Mefloquine Hydrochloride.

REFERENCES-

1. Kar A. (2005). Pharmaceutical Drug Analysis. 2nd ed. New age international limited publishers, pp. 452-474.

2. Sethi P.D. (1997). Quantitative Analysis of drugs in Pharmaceutical Formulations. 3rd ed. CBS publishers and distributors, New Delhi, pp. 17-19.

3. J. Bassett, R. C. Denney, G.H. Jeffery and J. Mendham. (1978). Vogel's Text Book of Quantitative Inorganic Analysis. 4th ed. Longman Group Ltd: England,
pp. 1-9.

4. Masoom, R. Zeid, A. AlOthman, a. Nafisur, R. (2013). Analytical techniques in pharmaceutical analysis: A review, *Arabian Journal of Chemistry*, pp. 1878- 5352.

5. Panchumarthy, R., Naga, N. Pravallika, D. Navya, S. (2015). A Review on Step- by-Step Analytical Method Validation, *IOSR Journal of Pharmacy*, 5(10). pp. 07- 19.

6. Skoog D., Holler, J., Crouch, S., (2007). Principles of Instrumental Analysis. 6th ed. Belmont, CA: Thomson Brooks/Cole, pp. 169–173.

7. Mendham, J., Denney, R.C., Barnes, J.D., Thomas, M.J. Vogel's Textbook of Quantitative Chemical Analysis. 6th ed. Publication of Pearson Education; pp. 172- 173, 301-308.