

A Brief HPLC Study on Dorzolamide Hydrochloride

Mahathi Jyothirmaye Kapa¹, Ceeri Sai Priya², Dr. Vinutha. K³

^{1,2}Dept of Pharmaceutical

³Assist.Professor, Dept of Pharmaceutical Quality Assurance

^{1, 2, 3}Sarojini Naidu Vanita Pharmacy Maha Vidyalaya Osmania University, Hyderabad, India, 500017

Abstract- The main idea is to develop and validate a fast, sensitive, and accurate reversed-phase high-performance liquid chromatography (RP-HPLC) method for the quantitative determination of dorzolamide hydrochloride (a carbonic anhydrase inhibitor used to treat glaucoma) in bulk and pharmaceutical dosage forms (e.g., ophthalmic solution). The methodology and parameters are selected according to the drug and desired outcome. Chromatographic separation was performed on an 18 column, stationary phase, using an adapted isocratic mobile phase composed of a mixture of buffer (for example, phosphate buffer) and organic solvent (for example, acetonitrile or methanol) at a controlled flow rate (for example, 1.0 mL/min). Detection was performed using a UV-Vis detector at the maximum absorption wavelength of dorzolamide (usually around 254nm). Percentage recovery studies yielded results close to 100%, confirming the high accuracy of the method. The developed RP-HPLC method is suitable for reliable and routine quality control analysis of dorzolamide in pharmaceutical preparations, ensuring its quality and therapeutic efficacy.

Dorzolamide, often referred to as dorzolamide hydrochloride (DOR), is a potent topical carbonic anhydrase inhibitor developed primarily to avoid the severe systemic side effects of oral CAIs such as acetazolamide. It is used in eye drops to reduce increased intraocular pressure associated with glaucoma and ocular hypertension. HPLC is a widely preferred technique for quantitative analysis due to its sensitivity, selectivity, and accuracy, especially in pharmaceutical formulations (e.g. eye drops) and biological fluids.

Keywords- PCB Defect Detection, YOLOv8, Deep Learning, Real-Time Inspection, Computer Vision, Flask Web Application, Automated Optical Inspection (AOI), Surface Defect Classification, Industrial Automation, Smart Manufacturing.

I. KEY APPLICATIONS AND CO-ANALYSIS

Pharmaceutical formulation (eye drops): The most common application is the determination of dorzolamide in its finished dosage form for routine quality control and material assay.

Simultaneous determination: Dorzolamide is often co-formulated with other anti-glaucoma drugs, especially timolol maleate, several HPLC methods have been developed for the simultaneous determination of these two compounds in binary mixtures, and sometimes also a ternary mixture including brimonidine or latanoprost.

Stability-indicator methods: Specific HPLC methods, often reverse-phase (RP-HPLC) or ultra-performance liquid chromatography (UPLC), have been developed and validated as “stability-indicators”. This means they can accurately quantify dorzolamide in the presence of its degradation products, excipients, and other co-formulated drugs, proving the robustness of the method under various stress conditions (acid, base, heat, UV light).

Typical chromatographic conditions (RP-HPLC):

Most of the reported methods are based on reversed-phase HPLC (RP-HPLC) due to its suitability for separating slightly polar to non-polar pharmaceutical compounds.

- **Stationary phase (columns):** C18 columns are largely the preferred columns (e.g., RP-YMC packed ODS, Hypersil C18, Inertsil ODS 3V). Column dimensions are typically 150 times or 250 times the particle size.
- **Mobile phase:** The mobile phase is usually a mixture of an aqueous buffer (often phosphate buffer at an acidic pH) and an organic solvent.
- **Common organic solvents:** Acetonitrile is the most common organic modifier. Methanol is also used, sometimes in combination with acetonitrile.
- **“Green” solvents:** Some modern methods explore the use of more environmentally friendly solvents such as isopropanol to replace acetonitrile for more sustainable analysis.

Test:

- **UV detection:** The most widely used detection technique is UV-visible spectrometry. The typical detection wavelength depends on whether

dorzolamide is analyzed alone or with co-formulated drugs, often using:

- 254nm or 250nm (often used for DOR and other components).
- **Diode-array detection (DAD):** Allows simultaneous monitoring of different components at their respective optimal wavelengths and confirms peak purity.
- **Flow rate:** Usually maintained between 1.0 mL/min and 1.2 mL/min.
- **Run time:** Many methods insist on short run times, often less than 10 minutes, making them suitable for high-throughput quality control laboratories.

products N. Sher1*, N. Shafi1 , H. Naseem2 , M. A. Khan3 - Pakistan Journal of Chemistry, 2020

Method validation:

All HPLC methods reported for dorzolamide have been validated in strict accordance with international guidelines (e.g., ICH guidelines) for the following parameters:

- Linearity and range: demonstrating a linear relationship between drug concentrations.
- Accuracy (recovery): Proving that the method can accurately recover the drug from the sample matrix.
- Precision (repeatability): showing consistency in the results of analyzes both intra-day (same day) and inter-day (different days/analysts).
- Specificity: Confirming that the drug peak is well separated from excipients, degradation products and co-formulated drugs.
- Sensitivity (LOD and LOQ): determining the limits of detection (LOD) and quantification (LOQ).

II. CONCLUSION

In summary, HPLC is the definitive and most robust analytical technique for the determination of dorzolamide in its various pharmaceutical forms, with most methods adapted for speed and simultaneous analysis with common co-formulated anti-glaucoma agents such as timolol and RP-HPLC procedures.

REFERENCES

- [1] Stability indicating rphplc method for analysis of dorzolamide hcl in the bulk drug and its pharmaceutical dosage form sharath h. m. *1, channabasavaraj k. p.1, jose g. babu1, jagadish s. modiyal- International Journal of Pharmacy and Pharmaceutical Sciences ISSN- 0975-1491 Vol 3, Issue 3, 2011
- [2] A Novel RP-HPLC method for simultaneous estimation of Dorzolamide and Timolol maleate in ophthalmic