

DEVELOPMENT AND VALIDATION OF A RP-HPLC METHOD FOR SIMULTANEOUS DETERMINATION OF BENZYDAMINE HYDROCHLORIDE AND CETYLPIRIDINIUM CHLORIDE IN ORAL SPRAY SOLUTION

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INTRODUCTION

Benzydamine hydrochloride (Figure 1.a.) - non-steroidal anti-inflammatory drug with local anaesthetic and analgesic properties providing both rapid and extended pain relief as well as a significant anti-inflammatory treatment for the painful inflammatory conditions of the mouth and throat.

Cetylpyridinium chloride (Figure 1.b.) - quaternary pyridinium antiseptic with bactericidal activity against Gram-positive and, at higher concentration, some Gram-negative bacteria. It is used for the treatment of minor infections of the mouth and throat.

There are a number of methods available for determination of Benzydamine hydrochloride and Cetylpyridinium chloride, individually, but only a few methods for simultaneous determination of a combination of them in a final dosage form.

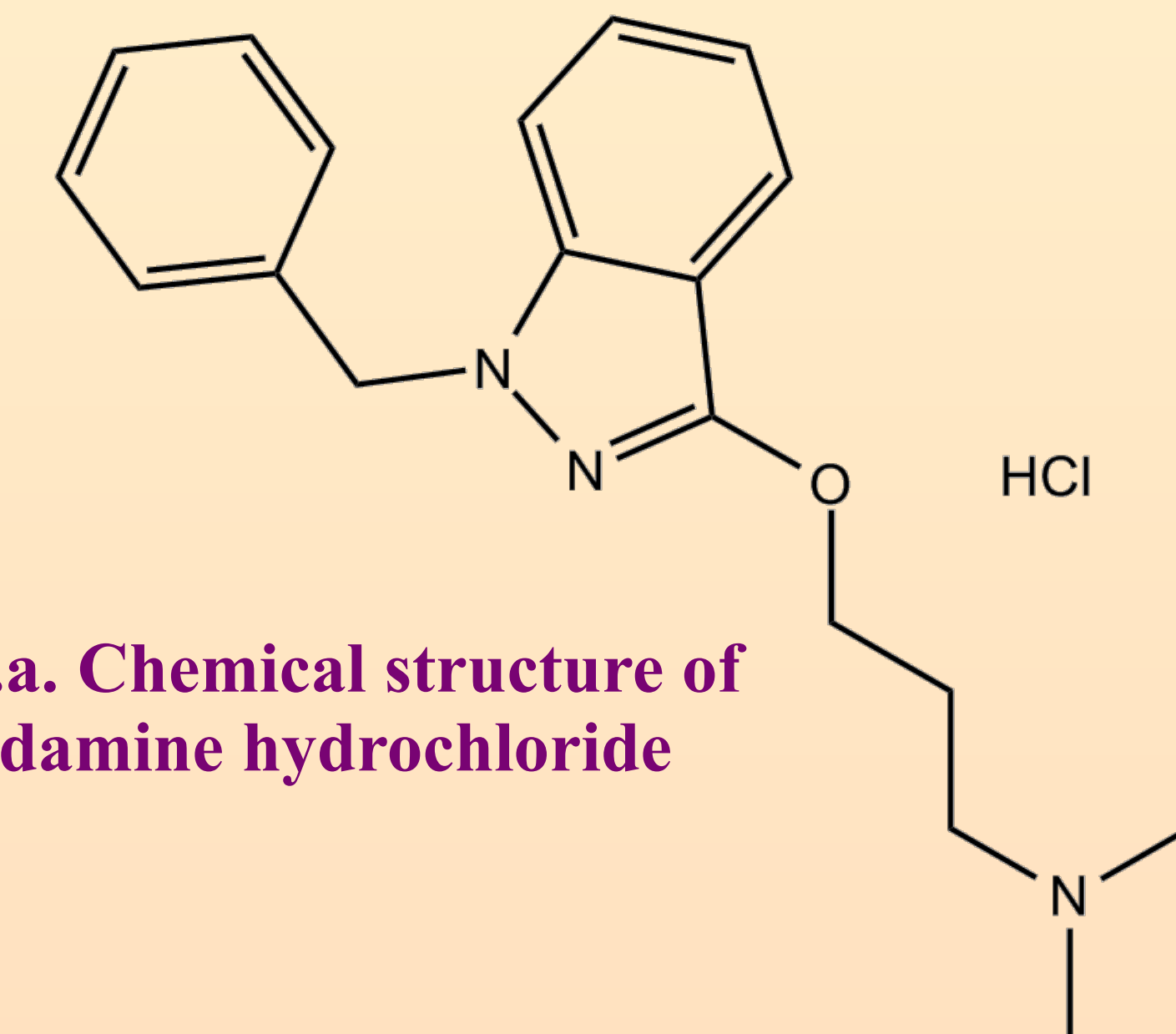


Figure 1.a. Chemical structure of benzydamine hydrochloride

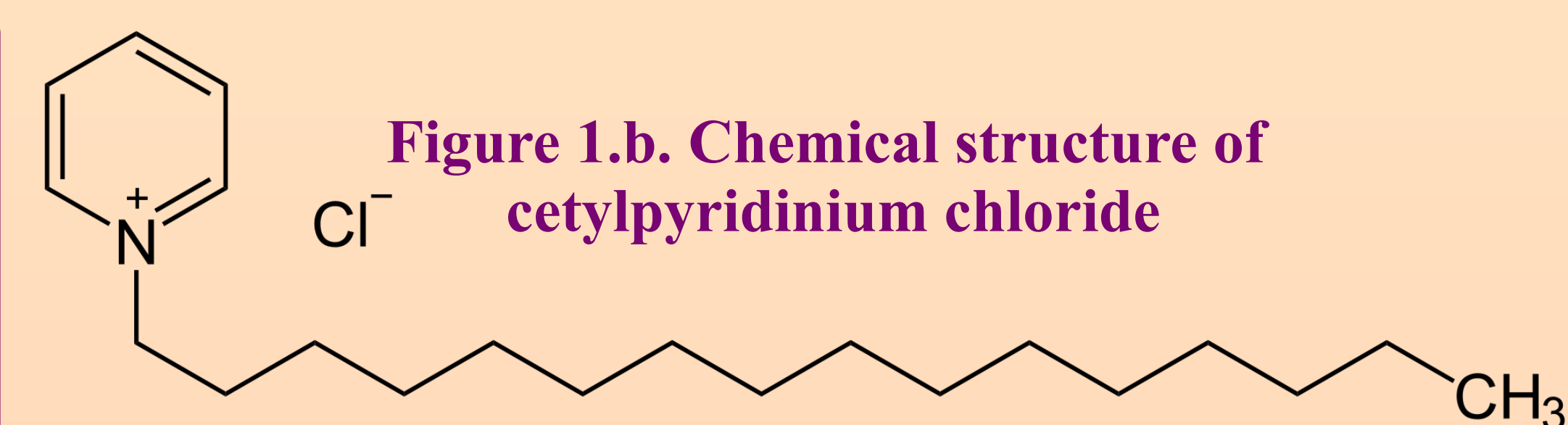


Figure 1.b. Chemical structure of cetylpyridinium chloride

AIM OF WORK

Development of simple, fast and efficient high performance liquid chromatography (RP-HPLC) method for simultaneous determination of Benzydamine hydrochloride and Cetylpyridinium chloride in final dosage form preparations.

MATERIALS AND METHODS

* Used reagents and reference substances:

- potassium dihydrogen phosphate (KH₂PO₄);
- 85 % o-phosphoric acid (H₃PO₄);
- triethylamine (C₂H₅)₃N;
- methanol (CH₃OH);
- acetonitrile (ACN);
- demineralised water ("in house" prepared with conductivity of 0.05 μS/cm)
- Benzydamine hydrochloride: purchased from MHRA, London, UK;
- Cetylpyridinium chloride: purchased as the US Pharmacopeia standard

** HPLC system and conditions:

- analytical column: InertSustain C8 4.6 mm x 100 mm, 5 μm;
- mobile phase: 35 % [25 mM KH₂PO₄ containing 0.1 % (v/v%) 85 % o-H₃PO₄] with pH 3.0 (adjusted with Triethylamine) : 5 % CH₃OH : 60 % ACN;
- isocratic conditions;
- flow rate: 1.1 ml/min;
- detection wavelength: 257 nm;
- column temperature: 35 °C;
- injection volume: 5 μl

RESULTS AND DISCUSSION

* Isocratic elution of the analytes achieved in 7 minutes (Figure 2)

- retention time of Benzydamine hydrochloride: 1.2 minutes
- retention time of Cetylpyridinium chloride: 5.1 minutes

** Tested for selectivity, linearity, precision, accuracy and robustness, giving results which show that the method is suitable for its purpose.

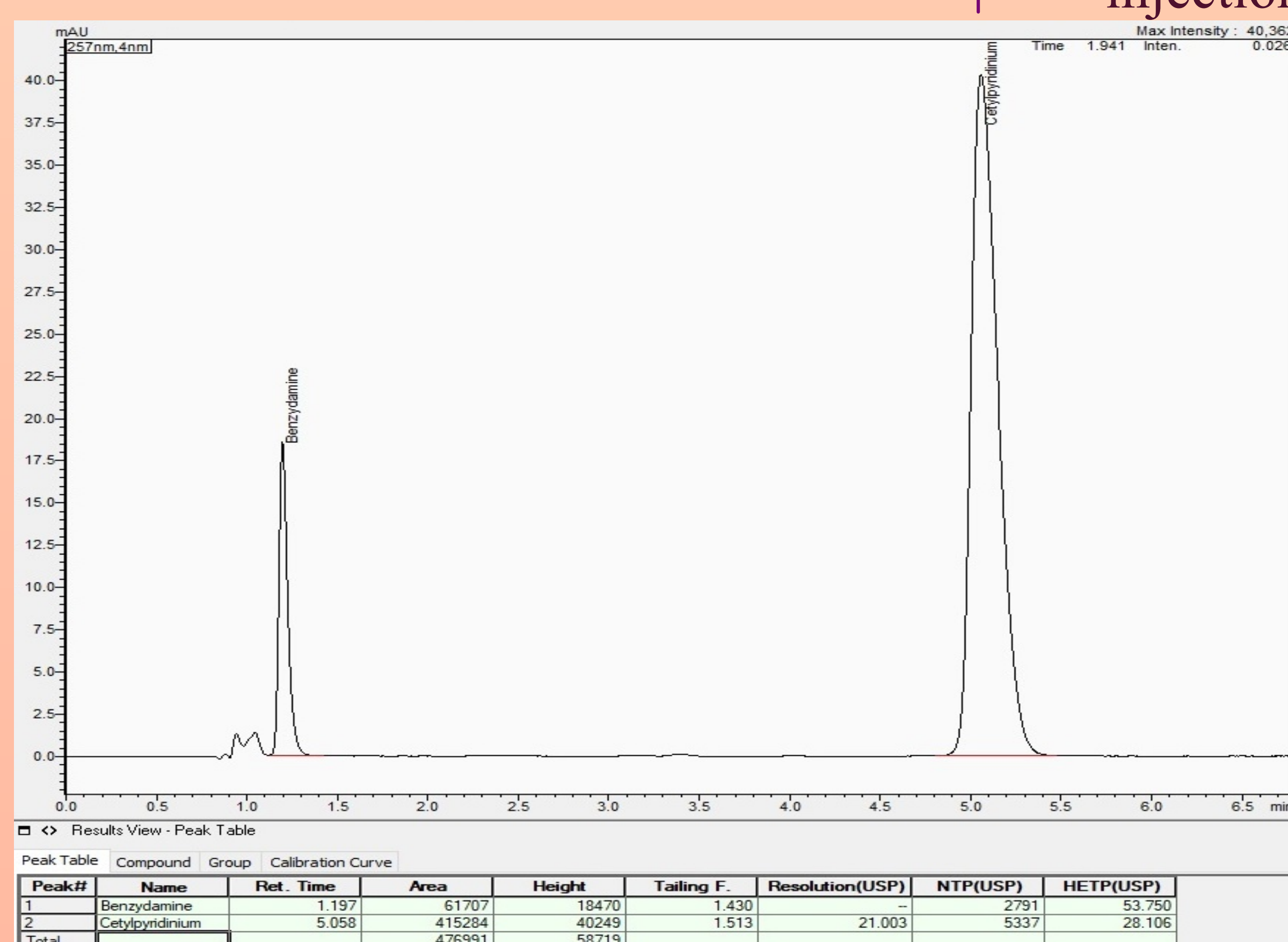


Figure 2. Chromatogram with peaks from Benzydamine hydrochloride and Cetylpyridinium chloride with their spectral characteristics respectively (Figure 2.a. and Figure 2.b).

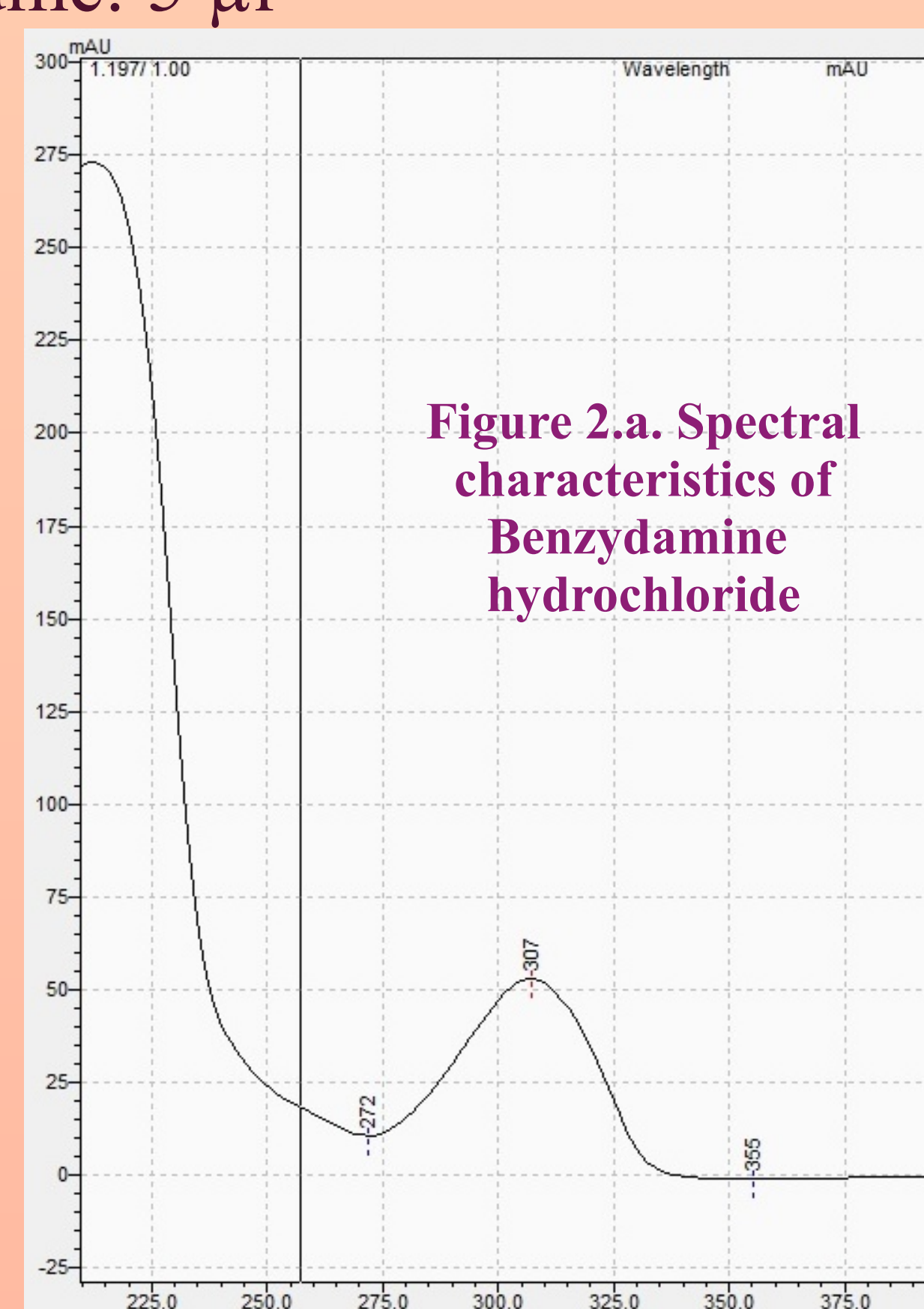


Figure 2.a. Spectral characteristics of Benzydamine hydrochloride

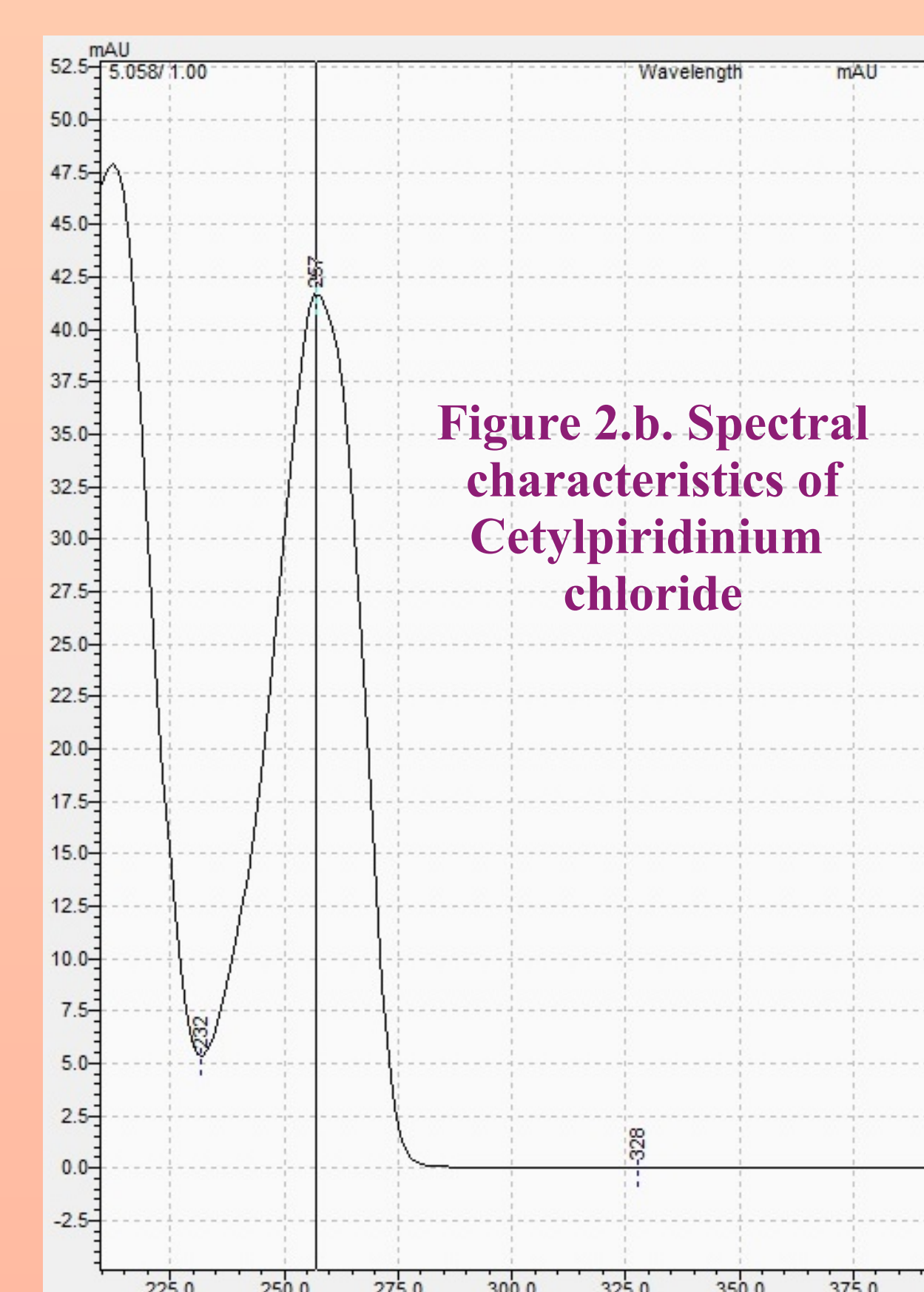


Figure 2.b. Spectral characteristics of Cetylpyridinium chloride

CONCLUSION

The developed analytical method for simultaneous determination of Benzydamine hydrochloride and Cetylpyridinium chloride in a final dosage form by HPLC was found to be rapid, simple, reliable and require low cost reagents. The method was validated and proved as suitable for its intended use. The proposed method, can be successfully used for routine analysis in quality control laboratories for simultaneous determination of Benzydamine hydrochloride and Cetylpyridinium chloride.

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