

Research Article

Dual Wavelength RP-HPLC Method for Simultaneous Determination of Two Antispasmodic Drugs: An Application in Pharmaceutical and Human Serum

Najmul Hasan,¹ Mathuree Chaiharn,² Sauleha Khan,³ Hira Khalid,⁴ Nawab Sher,⁵ Farhan Ahmed Siddiqui,⁵ and Muhammad Zain Siddiqui⁶

¹ Department of Microbiology, Faculty of Science, University of Karachi, Karachi 75270, Pakistan

² Division of Biotechnology, Faculty of Science, Maejo University, Chiang Mai 56290, Thailand

³ Department of Chemistry, Faculty of Science, University of Karachi, Karachi 75270, Pakistan

⁴ Department of Chemistry, Government College University, Lahore 54000, Pakistan

⁵ Faculty of Pharmacy, Federal Urdu University of Science & Technology, Karachi 75300, Pakistan

⁶ Department of Chemistry, Faculty of Science, Federal Urdu University of Science & Technology, Karachi 75300, Pakistan

Correspondence should be addressed to Najmul Hasan; najmul.edu_pak@gmail.com

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A reverse-phase stability indicating HPLC method for simultaneous determination of two antispasmodic drugs in pharmaceutical parenteral dosage forms (injectable) and in serum has been developed and validated. Mobile phase ingredients consist of Acetonitrile:buffer:sulfuric acid 0.1 M (50:50:0.3 v/v/v), at flow rate 1.0 mL/min using a Hbar μ bondapak ODS C₁₈ column monitored at dual wavelength of 266 nm and 205 nm for phloroglucinol and trimethylphloroglucinol, respectively. The drugs were subjected to stress conditions of hydrolysis (oxidation, base, acid, and thermal degradation). Oxidation degraded the molecule drastically while there was not so much significant effect of other stress conditions. The calibration curve was linear with a correlation coefficient of 0.9999 and 0.9992 for PG and TMP, respectively. The drug recoveries fall in the range of 98.56% and 101.24% with 10 μ g/mL and 33 μ g/mL limit of detection and limit of quantification for both phloroglucinol and trimethylphloroglucinol. The method was validated in accordance with ICH guidelines and was applied successfully to quantify the amount of trimethylphloroglucinol and phloroglucinol in bulk, injectable form and physiological fluid. Forced degradation studies proved the stability indicating abilities of the method.

1. Introduction

Chemically, phloroglucinol (1,3,5-trihydroxybenzene, PG) and its methylated derivative tri-O-methylphloroglucinol (TMP), Figure 1, are established pharmaceutical agents inhibit the action of catechol-O-methyl transferase, inducing relaxation of smooth muscles, and decreasing glycerol-induced abdominal pain and are also characterized by a swift and strong spasmolytic activity, hence relieving pain. Therefore, PG is often used in combination with trimethylphloroglucinol as an antispasmodic drug and is regarded to be effective in decreasing smooth muscle spasms. PG/TMP combination is recommended against biliary calculi, severe

pain of urinary or gastrointestinal tract, pain of abdominal region, spastic conditions of the female genital system, and pain in gynecology [1–7].

Literature survey reveals that some of the analytical methods for phloroglucinol are available including extraction and high-performance liquid chromatography (HPLC) [8–10], HPLC-mass spectrometry [11, 12], gas chromatography-mass spectrometry [13], and spectrophotometry [14]. Other reported methods include titrimetry, spectrophotometry, paper chromatography, and flow injection analysis [15–20].

However, there is no simple and sensitive method to be followed on industrial basis especially in general quality control laboratories. Previously mentioned methods involve

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