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Simultaneous Determination of NSAID and Antimicrobial Preservatives Using Validated RP-HPLC Method: An Application in Pharmaceutical and Clinical Laboratories

Najmul Hasan^{1*}, Mithun Chaham², Shabana Naz Shah³, Hira Khalid⁴ and Abdul Jabbar⁵

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

²Division of Biotechnology, Faculty of Science, Maejo University, Chiang Mai 50200, Thailand

³Department of Pharmaceutical Chemistry, Research Institute of Pharmaceutical Sciences, Faculty of Pharmacy, University of Karachi, Karachi-75270, Pakistan

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

⁵Provincial TB Control Laboratory, National TB Control Programme, Peshawar, Pakistan

Abstract

A stability indicating, accurate, specific, precise and simple high performance liquid chromatographic method has been developed and validated for the simultaneous determination of Dexibuprofen along with its preservatives i.e. Sodium Benzoate, Methylparaben, and Propylparaben in pharmaceutical dosage forms of oral solution and in serum. Acetonitrile: Acetic Acid (0.1 M) (50:50:0.3 v/v/v) (pH 5.5) was the mobile phase at flow rate 1.0 mL min⁻¹ using a Hibar[®] plBondapak[®] C₁₈ column monitored at wavelength of 230 nm. The calibration curve was linear with a correlation coefficient of more than 0.9995 for the drugs. The averages of the absolute and relative recoveries were found to be 100.07%, 99.92%, 99.91% and 99.97% for Dexibuprofen, Sodium Benzoate, Methylparaben and Propylparaben respectively with 5 to 25 ng mL⁻¹ limit of quantification and 1.5 to 7 ng mL⁻¹ limit of detection. The drugs were subjected to stress conditions of hydrolysis (acid, base, oxidation, and thermal degradation). Maximum degradation was observed in base and 35% H₂O₂, while found almost stable in the other stress conditions. The studies of forced degradation, prove the stability indicating power of the method. The developed method was validated in accordance to ICH guidelines.

The proposed High-performance liquid chromatographic method was successfully applied to quantify the amount of Dexibuprofen and three most common microbial preservatives in bulk, dosage form and physiological fluid.

Keywords: Dexibuprofen; Oral solution; Parabens; Benzoate; RP-HPLC; Serum

Abbreviations: MP: Methylparaben; PP: Propylparaben; SBZ: Sodium benzoate; DBPN: Dexibuprofen; HPLC: High Performance Liquid Chromatography; ICH: International Conference on Harmonization; NSAID: Non-Steroidal Anti-Inflammatory Drug

Introduction

Dexibuprofen (DBPN, Figure 1) is the pharmacologically effective (S⁺ Enantiomer of Ibuprofen) and chemically is 2-[4-(2-methylpropyl)phenyl] propanoic acid [1]. In contrast to Ibuprofen the administration of dexibuprofen may offer the advantage of delivering the well-known antipyretic, analgesic and anti-inflammatory properties of Ibuprofen in a more efficient way, with a better safety profile than the racemic Ibuprofen formulations [2]. It is a widely used as nonsteroidal anti-inflammatory and analgesic agent for many years [3,4] and for the symptomatic treatment of osteoarthritis, primary dysmenorrhea,

muscular skeletal pain or dental pain and reduces gastric damage and improves analgesic and anti-inflammatory effect than racemic Ibuprofen [5]. Dexibuprofen is rapidly absorbed, and peak serum concentrations is achieved within 1.5-2 hours of oral administration [6]. It has been established there is a significant correlation between serum Dexibuprofen levels and the resultant degree of pain relief, particularly 1 hour after administration [7].

Methylparaben (C₈H₈O₃) (MP, Figure 1) Propylparaben (C₉H₁₀O₃) (PP, Figure 1) and Sodium benzoate NaC₆H₅CO₂ are the well-known preservatives that are used primarily for their bactericidal and fungicidal properties. Parabens that include MP and PP, are a group of the alkyl esters of p-hydroxybenzoic acid, have a low toxicity profile and a long history of use. It readily absorbed from the gastrointestinal tract or through the skin [8]. Usage of MP is toxic at higher concentrations, has an estrogenic effect [9]. The estrogenic activity of parabens increases with the length of the alkyl group and is believed that PP is estrogenic to a certain degree as well [10]. Sodium

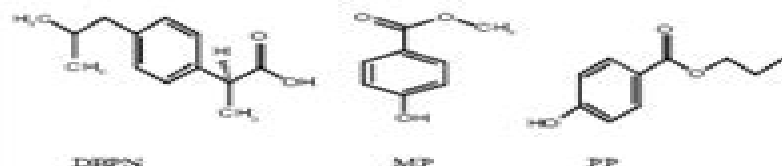


Figure 1: Chemical structures of Dexibuprofen (DBPN) Methylparaben (MP) and Propylparaben (PP).

*Corresponding author: Najmul Hasan, Department of Microbiology, Faculty of Science, University of Karachi, Karachi-75270, Pakistan, Tel: 0092-333-368-9333; E-mail: najmul.hasan@gmail.com

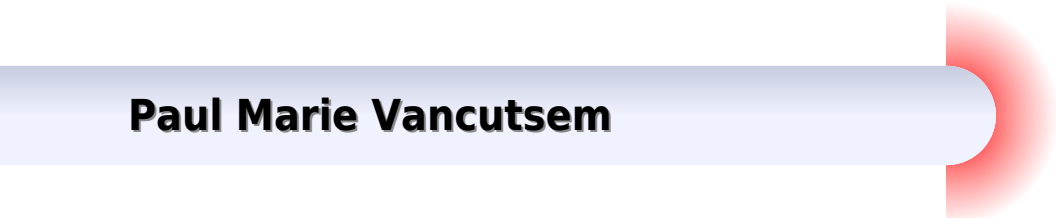
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Simultaneous Determination Of Nsaid And Antimicrobial

Paul Marie Vancutsem



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