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Original Article

A MODEST UV SPECTROPHOTOMETRIC ASSISTED BY CHEMOMETRIC APPROACH FOR VERIFICATION OF ACETAMINOPHEN LEVEL IN VARIOUS MANUFACTURED TABLETS AND SYRUPS IN INDONESIAN PHARMACIES

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ABSTRACT

Objective: This study aimed to verify the paracetamol level in some fabricated tablets and syrups in Indonesian pharmacies.

Methods: The fabricated tablets and syrups were analyzed using a spectrophotometer UV that was assisted by the chemometric approach. Partial least squares (PLS) and principal component regression (PCR) were the chemometric methods employed to verify the paracetamol level in pharmaceutical products. There were 25 different samples (tablets and syrups) applied in this study. The validation study was employed in this study to verify the approach according to the ICH guidelines. The double-distilled water was applied as a solvent before the samples were analyzed using a spectrophotometer.

Results: This technique was efficient and require double-distilled water only as a solvent. The results of this study reveal that there was a deviation in absorbance of the samples with RSD ranging from (0.15-0.45). The technique was linear, ranging from 1.0–6.0 µg·ml$^{-1,}$ with an R^2 (0.9991) obtained at 242 nm. The percentage recovery was applied to study the accuracy of the technique and was acquired at 99.18%. The results have shown that the approach was the potential to be applied in estimating the level of paracetamol in tablets and syrups.

Conclusion: The detection of paracetamol levels in tablets and syrups using UV spectrophotometric showed satisfactory outcomes. The application of the chemometric approach by using PLC and PCR as the statistical assessment indicated that there was no significant distinction among the validated methods. Furthermore, the method can be used by industries particularly small industries to secure medicines that comply with Indonesian rules.

Keywords: Acetaminophen, Pharmacies, Spectrophotometer, Syrups, Tablets

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INTRODUCTION

Indonesia is one of the developed countries and the pharmaceutical sector is a potential sector that contributes to the economy of Indonesia. Thus, the quality of the drugs spreading all over the country becomes great attention for many stakeholders such as the government, the manufacturers, and consumers [1]. Developing pharmaceutical products must be related to product quality. Furthermore, finding a suitable method for verifying the quality of pharmaceutical products becomes an imperative task [2].

Paracetamol (PAR) or known as acetaminophen, is generally applied as an antipyretic, anti-inflammatory, and analgesic. These effects occur owing to the production of cyclooxygenase (COX) 1 and 2 by prostaglandin is impeded by PAR [3]. The chemical structure of PAR that is illustrated in (fig. 1) shows that PAR activity is different compared to the other non-steroidal anti-inflammatory drugs (NSAIDs) owing to in peripheral tissues, the PAR has a mild impact on COX. Hereafter, the PAR influences blood platelet function and increases blood clotting time [4]. However, the application of PAR can be used for several issues such as fever, muscle ache, toothache, and arthritis [5].

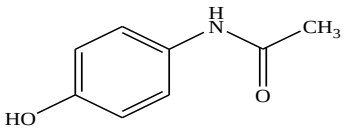

Fig. 1: The chemical structure of N-(4-Hydroxyphenyl) acetamide

Nowadays, the Covid-19 becomes a specter that haunted us and it can lead to several symptoms, whether heavy or mild such as fever, cold, and flu. However, some people who have good immunity want to continue their activity without worrying about those symptoms. Thus, fast healing is demanded to do the treatment, particularly for people with busy rosters, and demand to be vigilant and focused as soon as possible. Furthermore, it has been achieved successfully by pharmaceutical industries by merging two and more substances in their drug productions to medicate those symptoms in order to enhance PAR activity. Various components have been applied for PAR production, as illustrated in (fig. 2) [5]. However, verification of a specific substance in multicomponent formulations is a huge challenge for many researchers in order to improve the health care system. This is also imperative to access the drugs before spreading the medicines to the pharmacies [6]. Thus, the development of analytical techniques is imperative. Consideration of a suitable method is required, such as fast, modest, inexpensive, and at the same time, the method does not influence the reliability, precision, and accuracy of the results. The studies have unveiled numerous techniques for the detection of drugs, whether in single or multi-components [7-9]. Furthermore, only HPLC and UV approaches can be applied for the determination of paracetamol [10-14].

According to their studies, chromatographic methods are time-consuming and require too many solvents, which is not suitable for quality control laboratories. Furthermore, analytical experts are required to operate the instruments. Meanwhile, spectrophotometric techniques are considered inexpensive and fast. This instrument is not only can be purchased and easily found in most labs but also can be operated by anyone who is not an expert in

analytical instruments. The spectrophotometers offer substitute resolutions for complex mixtures of analytes with the requirement of prior separation or extraction [15-17].

Finding a selective and sensitive method to analyze paracetamol in tablets and syrups using a modest technique has encouraged us to develop a spectrophotometric approach that can be applied to the determination of the various combination. This technique applied a handy procedure with slight modification and does not apply sophisticated tools. Furthermore, the solvent used should be an eco-friendly product, such as the use of double-distilled water. The purpose of this study is to apply a spectrophotometric method supported by a chemometrics technique to increase the selectivity of this study. Partial Least Squares (PLS) and Principal Component Regression (PCR) are the chemometrics technique applied to verify the quantity of PAR in the products chosen. Chemometrics can be described as the interaction between the statistical and mathematical approaches in chemical analysis to stipulate the information by arranging the data. In this study, this method was applied to collect data from the spectrum and supply fast analysis with acceptable precision and accuracy without the requirement of sample preparation, which takes time [18-21].

The application of chemometric techniques offers several advantages when applied for the verification of pharmaceutical products, such as being free from disturbances and the determination being more accurate. Furthermore, the PLS application can improve the selectivity owing to the capability of PLS such as the errors can be minimized and the processing of data is faster with several absorbances and concentrations of analytes [22,23], whereas the least significant principal substances can be deleted by the PCR technique. The PLS and PCR models are specified by several parameters such as (1) root mean square error of calibration (RMSEC), (2) predicted residual sum of squares (PRESS), (3) root mean standard error of prediction (RMSEP), (4) root mean square error of cross-validation (RMSECV) and (5) merit fig. that can be described into several parameters such as selectivity, sensitivity, detection limit, and quantification limit [24, 25].

MATERIALS AND METHODS

Instrumentation

UV visible spectrophotometer model Thermo Scientific Evolution 201 double beam was applied. The scan was performed at intervals of 0.1 nm ranging from 230 to 400 nm, integration time at 0.05 sec, and scan speed at 1200 nm·min^{-1}. UV Insight Software was employed. Balance Fujitsu (Japan), stirring hot plate (Australia), sonic bath (India), and shaking water bath (China) were used in this research. The Unscrambler software was applied to interpret the data obtained from the spectrophotometer analysis.

Reagents (Chemicals and materials)

PAR (99.72% purity) was supplied from Sigma Aldrich, Indonesia as a reference standard. Marketed tablets and syrups containing PAR with various compositions are purchased from Indonesian pharmacies and listed in table 1. Double distilled water (Merck) was used throughout the experiment.

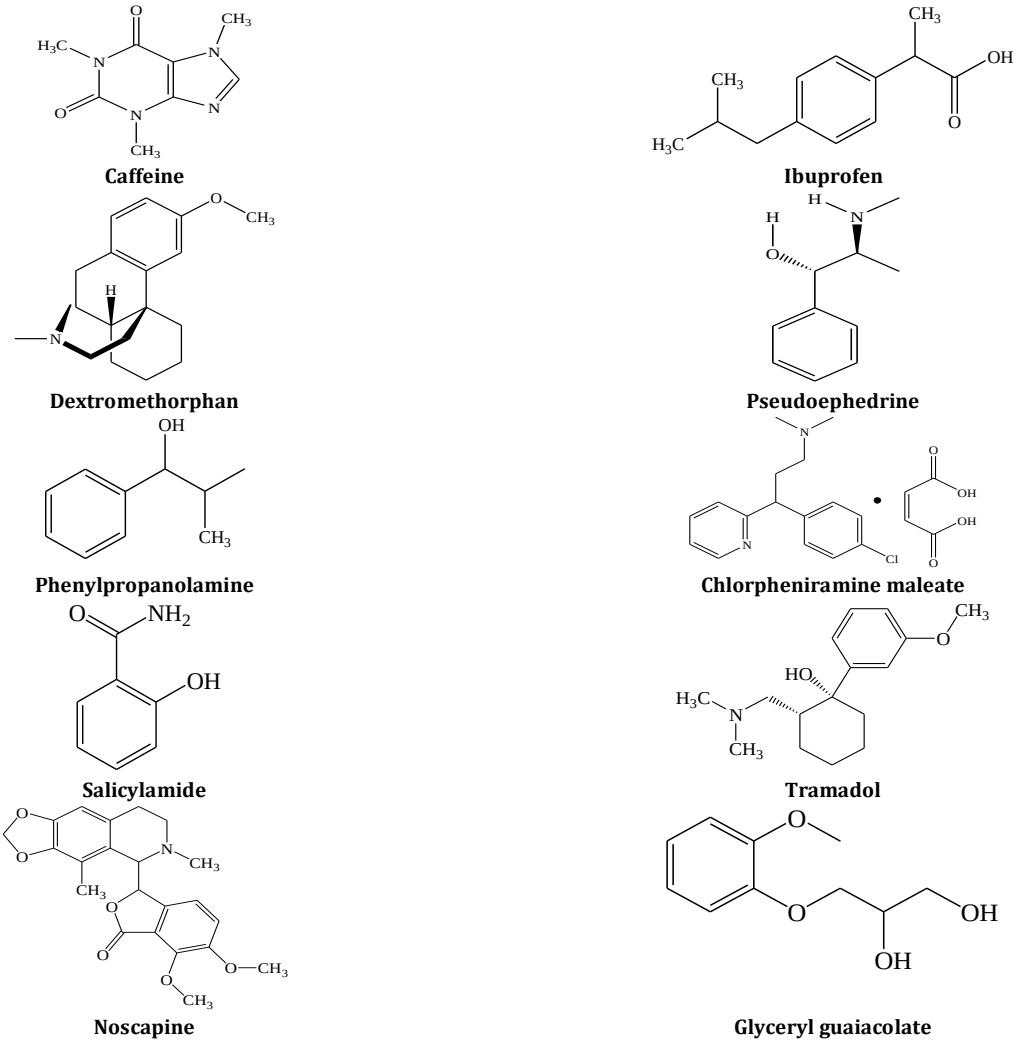

Fig. 2: Chemical structures of several compounds that are generally applied in several drugs fabricated in Indonesian pharmacies to support the activity of paracetamol