

## **Assessing The Quality of Voren®, Remafen® and Remethan® Medicinal Tablets Sold in Malaysian Market**

Ainin Najiha Husna Abdul Rahman<sup>a</sup>, Syafawati Nadiyah Mohamed<sup>a</sup>, Rossuriati Dol Hamid<sup>a\*</sup>

### **Structured Abstract**

**Background:** Voren®, Remafen® and Remethan® medicinal tablets are the common brands sold in the local pharmacies that consist of diclofenac sodium as the active ingredient. These products are used to reduce pain from joint and muscles problem usually associates with arthritis. Assessing the quality of these products are very crucial due to the life threatening to overdose patients with cardiovascular diseases and Asian countries reported to have the most counterfeit drugs. There are various ways to assess the quality of drugs but in this study the quality of the drug is assessed based on diclofenac sodium content per tablet and its percent assay. The peak area of diclofenac sodium is measured using high performance liquid chromatography (HPLC). The quantification was based on external standard calibration curve, where there is linear relationship between the peak area of the analyte with its corresponding prepared concentration.

**Methods:** In this study, Voren®, Remafen® and Remethan® were bought from local pharmacies in Shah Alam. For each brand, about 20 tablets were removed from its blister pack and weighed to obtain the average weight that equivalent for 50 mg of the analyte. The analyte was then dissolved in methanol, sonicate for 30 min, centrifugation at 3000 rpm for 5 min and the supernatant was filtered prior introduce to HPLC. All standard and sample solutions were measured in triplicates using HPLC. The chromatographic separation was carried out in a C18 column (4.6 x 150 mm, 5 $\mu$ m particle size) using mobile phase composed of a mixture of acetonitrile and orthophosphoric acid in the ratio (65:35), respectively at a flow rate of 2.0 mL/min. The detection wavelength was set at 210 nm. The reliability of the HPLC method used in this study was also validated by its precision and percent recovery.

**Results:** The result showed the signal response based on the chromatogram standard where the peak diclofenac sodium was observed at a retention time of  $\approx$ 2.1 min. The HPLC method used in this study adequately precise (% RSD of <0.3%) and accurate with acceptable range of % recovery (84.67-101%). Based on the external calibration curve, the diclofenac sodium content in samples was determined using regression equation of  $y = 46.873x - 69.27$  with very strong correlation,  $R^2$  of 0.9968. The diclofenac sodium content (mg per tablet) in these three brands were between 49.1 and 50.6, which were very close the value claims by the manufacturer (i.e., 50 mg per tablet). The % assay in all these brands fall between 95.7 and 99.3 %, which within the US pharmacopeia safe limit.

**Conclusion:** All the three brands of medicinal tablet measured in this study pass the quality required in terms of its content per tablet. The diclofenac sodium content per tablet in all brands close to the content claims by the manufacturer and within the safe limit by the US pharmacopeia.

**Keywords:** Diclofenac Sodium, Voren®, Remafen® and Remethan®

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\*Correspondence: rossuriati2996@uitm.edu.my

<sup>a</sup>School of Chemistry and Environmental, Faculty of Applied Sciences, Universiti Teknologi MARA, 40450 Shah Alam, Selangor, Malaysia.