

ABSTRACT**Method Validation of Gas Chromatography – Mass Spectrometry for Determination of Vitamin D₃ in Multivitamin Tablet Preparation****Evi Nur'ain Murandani**

Vitamin D₃ is a fat-soluble vitamin that is available with other vitamins in multivitamin tablet. As a health supplement, the amount of vitamin D₃ in multivitamin tablet is 400 IU or equivalent to 10µg in each tablet. Due to the low level of vitamin D₃ contained in this complex sample matrix, a specific and sensitive method is needed to ensure the product quality, safety and efficacy. Therefore, Gas Chromatography – Mass Spectrometry is used in this study, because of its high sensitivity, high resolution, and specifically detection of the analytes at low concentration in samples. The objective of the present study was to validate the GC-MS methods in terms of specificity, linearity, range, accuracy and precision. The proposed method was carried out without derivatization. The optimum condition was reached by oven temperature program with initial temperature of 150°C for 2 minutes, then increased by 25°C/minute to the final temperature of 280°C for 10 minutes. The time needed for running is about 17.20 minutes. From the result of the method validation, the retention time of vitamin D₃ was 8 minutes with resolution of 2.86. The method showed a linear response ($r=0.997$) with V_{xo} of 3.54%. The average of percent recovery of the sample was 98.71% with relative standard deviation of 2.57%. Detection and quantitation limits were found to be 0.61 ppm and 1.85 ppm, respectively.

Keywords : Validation, GC-MS, Vitamin D₃, Multivitamin