

ANALYTICAL APPLICATIONS BY USING NEW DEVELOPED PORTABLE NEAR INFRARED (NIR) SYSTEM

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A compact and handheld near infrared (NIR) system using microspectrometer was developed. This system was suitable not only in the laboratory, but also in the field or in the process. This system was first applied for classification of geographical origin of herbal medicine such as ginseng and sesame. To identify the origin of ginseng on site, the portable NIR system is more suitable for real field application. For this study, using the compact NIR system, soft independent modeling of class analogies (SIMCA) with 1100-1750 nm NIR spectra was utilized for classification of geographical origin (Korea and China) of both ginseng and sesame. The accuracy of results is more than 90%. Quantitative analysis for petroleum such as toluene, benzene, tri-methyl benzene, and ethyl benzene was performed with partial least squares (PLS) regression with NIR 1100-1750 nm spectra. This study showed that the NIR method and gas chromatography (GC), which is a standard method, have good correlations. Furthermore, the sweetness of fruit was analyzed and the accuracy was confirmed by the developed compact NIR system.

[PD4-6] [04/19/2001 (Thr) 13:30 - 14:40 / Hall 4]

Studies on the Quality Evaluation of Pharmaceuticals (III) – Method Validation of Endotoxin Test in Amino acid injections

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Limulus Amebocyte Lysate(LAL) test (endotoxin test) is supposed to be a alternative to the rabbit pyrogen test in that the former is more convenient, specific and inexpensive. We applied the LAL test to the detection of bacterial endotoxins in 5 pharmaceutical amino acid injections using gel-clot method and kinetic turbidimetric method and validated the methods by investigating LAL reagent sensitivity, interferences, calibration curve, reproducibility and recovery. The determined LAL reagent sensitivity was 0.060 EU/mL and the calibration curve of endotoxin standard solutions by kinetic turbidimetric method was linear over the entire range from 0.0078125 to 50 EU/mL. The linear regression coefficient of determination was 0.998 and the limit of detection was 0.005 EU/mL. In all 5 injections, the amount of endotoxin estimated by the LAL test (gel-clot method and kinetic turbidimetric method) was well recovered and there are no significant interference (both enhancement and inhibition) factors. These results suggest that the LAL test was useful method for quantitative estimation of endotoxin, the probable major cause of pyrogenicity and expected for the substitutive method for pyrogen test in examined amino acid injections by applying criteria of not more than 0.2 EU/mg amino acid.

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Enantiomeric Resolution of β -agonists on several Chiral Stationary Phases

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