European Pharmacopoeia (EP) and the Scientific and Standardization Committee of the International Society on Thrombosis and Haemostasis based on the reliability, convenience and simplicity of the chromogenic assay. A correlation study was carried out with a one-stage factor VIII:C clotting assay and the performance of the chromogenic assay was evaluated using two test kits that fulfilled the requirements of EP for factor VIII concentrates test. Although chromogenic assay has partly differences in measurement principle and standardization, this assay has a high correlation with clotting assay in various types of factor Ⅷ concentrates and factor Ⅷ standard. We conclude that the chromogenic assay for factor VIII:C concentrates correlates well with the clotting assay and shows good analytical performance.

[PD4-17] [10/19/2001 (Fri) 09:00 - 12:00 / Hall D]

Capillary Electrophoretic Analysis of PEGylated Interferon Alpha

Na Dong Hee°, Park Eun Ji, Lee Seung Seok, Lee Sang Deuk, Jo Young Woo, Lee Sung Hee, Kim Won Bae, Lee Kang Choon

Drug Targeting Laboratory, College of Pharmacy, SungKyunKwan University, Research Laboratories, Dong-A Pharm. Co, Ltd

Capillary electrophoretic method for characterization of PEGylated interferon alpha (IFN) was developed. IFN was modified by the reaction of amine residues with an active ester of monomethoxy polyethylene glycol at various molar ratios. As a CE method, capillary electrophoresis sodium dodecyl sulfate nongel sieving (CE-SDS-NGS) was performed using an uncoated capillary filled with a hydrophilic replaceable polymer network matrix. The results were compared to those obtained using SDS-PAGE with barium iodide staining and matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF MS). CE-SDS-NGS showed good resolution between each PEGylated IFN species as well as the native IFN. The total amount and distribution of PEGylated IFN species were directly measured and the relative standard deviation (RSD) was around 1-3%. The distribution profile of PEGylation determined by CE-SDS-NGS was found to be consistent with that obtained by SDS-PAGE. CE-SDS-NGS provides a novel approach for the analysis of PEGylated proteins and shows the advantages of speed, high resolution, automation, and quantitation over SDS-PAGE.

[PD4-18] [10/19/2001 (Fri) 09:00 - 12:00 / Hall D]

Diagnosis of Organic Acidurias by GC-MS combined with Solid-Phase Extraction and Methoxime-tert.-Butyldimethylsilylation

Paik ManJeong°, Lee YoonSuk, Kim KyoungRae, Lee HongJin

College of Pharmacy, Sungkyunkwan University. Hallym University Hospital

Organic acidurias are inherited metabolic disorders generally caused by the diminished activity or absence of specific enzymes involved in the metabolic pathway. Solid-phase extraction of urinary organic acids using Chromosorb P was performed after methoximation of keto acids in alkalinized urine samples, followed by conversion to stable tert.-butyldimethylsilyl (TBDMS) derivatives for the profiling analysis by gas chromatography-mass spectrometry. Each organic acid was identified through home-built TBDMS library matching. The diagnostic usefulness of the present organic acid profiling analysis was demonstrated by comparing urinary profile of normal subject to those of patients with methyl malonicaciduria, isovaleric aciduria and propionic aciduria.

[PD4-19] [10/19/2001 (Fri) 09:00 - 12:00 / Hall D]

Validation of Ethoxycarbonylation combined with tert.-Butyldimethylsilylation for the