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To increase detection sensitivity for multi-DDT residues (o,p-/p,p-DDT, o,p-/p,p-DDE, o,o-/o,p-DDD) analysis, a highly selective sample clean-up method was introduced prior to GC/MS analysis using immunoaffinity column. The immunoaffinity matrix was prepared by coupling IgG fraction of DDT antiserum to cyanogens bromide activated Sepharose 4B. Three DDT antisera (DDA-1, DDHP-2, DDCP-3) were test for affinity column ligand that obtained by immunizing respective DDT immunogen to rabbits, and IgG was purified using protein A affinity purification. A suitable eluent (30% methanol, 15% DMSO, 15% acetone in PBS) and DDCP-3 antibody were selected to elute multi-DDT residues from immunoaffinity column. When a sample that contained ten organic pesticides and multi-DDT residues was applied for the immunoaffinity clean-up step, 95% multi-DDT residues and two pesticides (α -BHC, cis-chlordane) were recovered in eluent leaving off most of pesticides in washing step (20% methanol in PBS). Therefore, the immunoaffinity method as a sample clean-up step using DDCP-3 antibody is highly efficient for selective analysis of multi-DDT residues by GC/MS.

[PD4-39] [04/18/2003 (Fri) 13:30 - 16:30 / Hall P]

Guidance for the Evaluation Method of Drugs of Abused *in vitro* Diagnostic Devices

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The purpose of this study is to provide KFDA's guidance for premarket notification submission and labeling for prescription use drugs of abuse in vitro diagnostic devices. To evaluate in vitro diagnostic devices the following performance characteristics should be described in detail within the submission; analytical sensitivity or minimum detection limit, cutoff concentration, specificity and cross reactivity, interference, precision, method comparison and stability. In this study, each of the evaluation settings for the device's characteristic performances is described in terms of its definition, content, study design and the experiments data are included for the sake of the manufacturers' guideline.

Poster Presentations - Field E1. Pharmaceutics

[PE1-1] [04/18/2003 (Fri) 09:30 - 12:30 / Hall P]

Transport of anti-allergic drugs across the passage cultured human nasal epithelial cell monolayer

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The purpose of this study was to investigate the transport characteristics of passage cultured human nasal epithelial cell monolayers grown on Transwell® inserts using liquid-covered culture