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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 immunoaffity clean-up step, 95% multi-DDT residues and two pesticides (a-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

(LCC) method. The monolayer of passage 2 and 3 exhibited tight barrier (TEER>1,000 ohmxcm^2) in 2~3 days after seeding. In the morphological studies by actin staining and SEM/TEM, the existence of tight junction was clearly observed. The transport of various anti-allergic drugs (albuterol, fexofenadine, dexamethasone, triamicinolone acetonide and budesonide) was investigated by using the HPLC. There was no significant difference in TEER value before and after transport studies for 60 min, which demonstrated the integrity of the monolayers. The amount of fexofenadine and dexamethasone across the monolayer linearly increased as the concentration of drug in the apical side increased. It was interesting to note a sigmoidal relationship between the drug lipophilicity and the permeability coefficient across the passage cultured human nasal epithelial monolayers, which is consistent with the permeability characteristics of β-blockers across primary conjunctiva and corneal culture in the literatures. Thus, the passage cultured human nasal epithelial monolayer in this study seemed to be a useful model for *in vitro* nasal drug transport studies.

[PE1-2] [04/18/2003 (Fri) 09:30 - 12:30 / Hall P]

Formulation and sustained release of acetaminophen hydroxypropylmethylcellulose (HPMC) matrix tablet

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Purpose. To develop a new heterodisperse 650mg acetaminophen HPMC matrix tablet with biphasic sustained release profiles.
Methods. Hydroxypropylmethylcellulose(HPMC) matrix tablets were prepared by wet-granulating drug with other excipients, followed by direct compression of the dried granule mixtures into tablet using a rotary tablet machine. Different kinds of disintegrants and solubilizers were also added to control the dissolution rate of acetaminophen matrix tablet. The dissolution was performed using USP dissolution method II in simulated gastric fluid(pH 1.2) and intestinal fluid (pH 6.8), respectively and then compared with commercial two-layered Tylenol ER tablet. The tablet hardness was measured using Erweka hardness tester.
Results. The disintegration time and dissolution rate of the HPMC matrix tablet were influenced by the type and amount of disintegrant, solubilizer and other excipients used. Most of all, HPMC type and content in the tablet formulation together with tablet hardness were very crucial for drug release. The HPMC matrix tablet initially released 50% dose within a few minutes like a commercial two-layered tablet. Both formulated and commercial Tylenol ER tablets released over 90% of the drug in 3 hours in all mediums.
Conclusions. Unlike the two-layered commercial tablet, the new HPMC matrix tablet could be easily prepared by using conventional tablet machine. By combining excipients in the HPMC-based matrix tablet formulation, the distinct biphasic release could be obtained. The current HPMC matrix tablet can be an alternative to commercial two-layered Tyrenol ER tablet.

[PE1-3] [04/18/2003 (Fri) 09:30 - 12:30 / Hall P]

Receptor-mediated gene delivery to hepatocyte with galatosylated polyethylenimine

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In the gene therapy, viral gene delivery systems are limited in use because of several drawbacks like host immune reactions. Hence, non-viral gene delivery systems such as cationic polymers or synthetic gene carriers are being widely investigated to overcome the problems in the use of viral