Drug Formulation and Packaging Compatibility

In order to ensure the safety of drug product quality, the packaging system that comes into direct contact with the drug product needs to meet compatibility requirements. Compatibility studies refer to the process of evaluating packaging components or systems that are in direct contact with the drug product without serious, or unacceptable, changes in effectiveness and stability of drug products, or safety risks. **CD Formulation** offers services that include extractability studies of packaging materials or components, leaching studies of the effects of contact between the drug product and the packaging system, and possible effects on the drug product and excipient active ingredient adsorption studies.

Our Services

Pharmaceutical packaging plays an important role in ensuring drug stability and will therefore directly affect the safety of drug use. It is required that before packaging materials for drugs, they must be tested to see if they are formally suitable for the intended use, and their effects on drug stability must be fully evaluated, and their effects on drug stability must be evaluated during long-term storage, under different environmental conditions (such as temperature, humidity, light, etc.), during transportation (such as contact reactions with drugs, adsorption of drugs, etc.), container (materials) for drug protection effects and their own physical, chemical and biological Inert, so when selecting and using pharmaceutical packaging materials must do compatibility studies.

The Main Contents of Drug and Package Compatibility Study:

Extraction studies: Extraction studies are extraction tests performed on packaging component materials using suitable solvents and under more vigorous conditions.

Migration test: It is used to monitor the substances that migrate from packaging material and enter into the formulation.

Safety studies: Calculation of daily exposures based on measured extractable and leachate levels compared to the PDE obtained in the toxicological assessment, to make conclusions about the compatibility of the packaging system with the drug.

CD Formulation has focused on packaging compatibility studies for many years, and is committed to providing solutions related to package compatibility studies for drugs, and can provide customers with packaging compatibility

study protocols, method development and validation, and related analytical testing services.

The Advantages of Our Services

With professional research in related fields, familiar with various regulations and technical guidelines for package material compatibility, we are able to develop comprehensive research programs based on the characteristics of each package material and formulation. We can provide customers with advice on the selection of package materials and manufacturers, provide communication support between customers and package manufacturers, and evaluate the results of package compatibility studies and provide solutions.

The platform is well-equipped with precision instruments such as HPLC, GC, LC-MS and GC-MS.

We have rich experience in on-site verification and are proficient in all the key points of on-site verification of pharmaceutical R&D.

Source:
https://www.formulationbio.com/drug-formulation-and-packaging-compatibility.html