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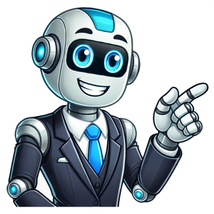

pharmaceutical excipients have important functions such as serving as carriers improve drug stability solubilization and slowing down the drug release they are importent ingredients that may affect the quality safety and effectiveness of the preparation classified by function and purpose pharmaceutical excipients can be used in different drug forms including injection where pharmaceutical excipients are antioxidants cosolvents and isotonic regulators etc oral solid preparations where pharmaceutical excipients are lubricants fillers and adhesives and diluents etc oral liquid preparations where pharmaceutical excipients are dispersants stabilizers and suspending agents etc besides pharmaceutical excipients can also serve as anti-adhesives correctives and propellants for external use however the various properties of excipients and various extermal factors may affect the compatibility between apis and excipients therefore researchers often start to investigate api-excipient compatibility in the early stage of formulation development the laws and regulatory agencies have made rigrid regulations on the compatibility of apis and excipients of various dosage forms scientists are required to follow these scientific principles and carry out rational experimental designs lets see what regulary rules are there to guide the api-excipient compatibility studies formulationbio.com/api-excipient-compatibility.htmlpharmaceutical ingredients improve bioavailability and manufacturability without compromising the stability of the APIs. The API-excipient compatibility analysis provided by CD Formulation can help drug developers select and determine suitable formulation excipients and technology. # OBJECTIVE The objective is to assess potential interactions between excipients and APIs, reducing risk early in formulation development. # SCOPE This guideline applies to initial studies on screening excipients for formulation development at research and development departments. # RESPONSIBILITY Authorized users are responsible for conducting the procedure. The Asst. Manager/Sr. Asst. Manager/Deputy Manager, R&D, must provide training and implementation guidance. # ACCOUNTABILITY The Head of Research & Development Department or their nominee is accountable for ensuring compliance with this guideline. # PROCEDURE To conduct Drug-Excipient Compatibility Studies: 1. Choose excipients based on functionality, manufacturing process, delivery characteristics, widespread use, and commercial availability. 2. Consider physicochemical properties, potential degradation mechanisms, and reference product composition (if applicable). 3. Select excipients through stability testing of target formulations. 4. Prepare binary powder mixes by mixing drug with individual excipients using suitable means or justified. 5. Compact or prepare slurries as required. 6. Label samples appropriately. 7. Expose compatibility study samples to accelerated temperature and humidity conditions (40 ± 2°C and 75 ± 5% RH) or room conditions (25 ± 2°C and 60 ± 5% RH). 8. Analyze duplicate samples at initial stages (Stage 0), followed by 4-week intervals as required. The stability of a drug substance or product is evaluated under various conditions to assess its consistency and effectiveness over time. ========== The stability of a drug substance or product should be determined through Assay and Impurities (as applicable) testing. The test results are then examined in different room conditions, with temperatures ranging from 25±2°C/60±5% RH, and storage durations of 0 and 4 weeks.