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(57) Abstract :
ABSTRACT This invention provides a dry powder formulation of Paclitaxel for intravenous administration, aimed at enhancing drug solubility, stability, and patient safety in cancer treatment. The formulation includes Paclitaxel as the active anticancer agent, Cyclodextrin (HP-ß-CD) as a solubility enhancer, Mannitol and Sucrose as stabilizers, Phosphate buffer to maintain pH, and L-Leucine as a flow enhancer. The specific concentration ranges of each component optimize the formulation's bioavailability and usability, while the elimination of toxic solvents such as Cremophor EL minimizes hypersensitivity risks. The preparation process involves forming a Paclitaxel-Cyclodextrin inclusion complex, adding stabilizers and modifiers under continuous stirring, and using spray drying to create a fine, free-flowing powder. The final product is packaged in sterile, airtight vials under a nitrogen atmosphere, ensuring stability against moisture and oxidation. Reconstitution with a sterile solvent enables safe, effective intravenous administration with flexible dosing. Reference Fig 1

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