Early Formulation Assessment Services

Streamline Your Drug Development with Galvita's Innovative Formulation Platform

Introduction

Selecting the right formulation for a given active pharmaceutical ingredient (API) is vital. The right formulation not only ensures clinical development success and product stability but also enhances performance and patient acceptability.

At Galvita AG, our team of formulation specialists is dedicated to designing and developing cutting-edge, patient-friendly drug delivery systems using our proprietary TIP technology. Understanding the critical importance of both time and quality in pharmaceutical development, we offer a comprehensive five-step feasibility study. Our feasibility study is completed within six weeks, ensuring rapid progress through the clinical evaluation process.

To expedite your molecule’s journey to clinical trials, we also provide full support for the GMP manufacturing of clinical trial material. Partner with Galvita AG to accelerate your drug development with precision and innovation.

Project Overview

Step 1: Project Assessment

- Assessment of PDE/OEL Values, need for specialized equipment, DP release specifications

Step 2: Solvent screening

- Screening of solvents to ensure the API's successful loading into TIP microcapsules

Step 3: Drug loading of TIP microcapsules Screening of different loading degrees between 10% and 45% to load the API into the TIP microcapsules

- Analysis of the results using Scanning Electron Microscope (SEM) images of loaded particles to demonstrate loading into the porous structures of TIP particles
- Visual analysis of the most promising samples using cross-sectional SEM microphotographs to assess loading quality

Step 4: Solid-state characterization of loaded TIP microcapsules

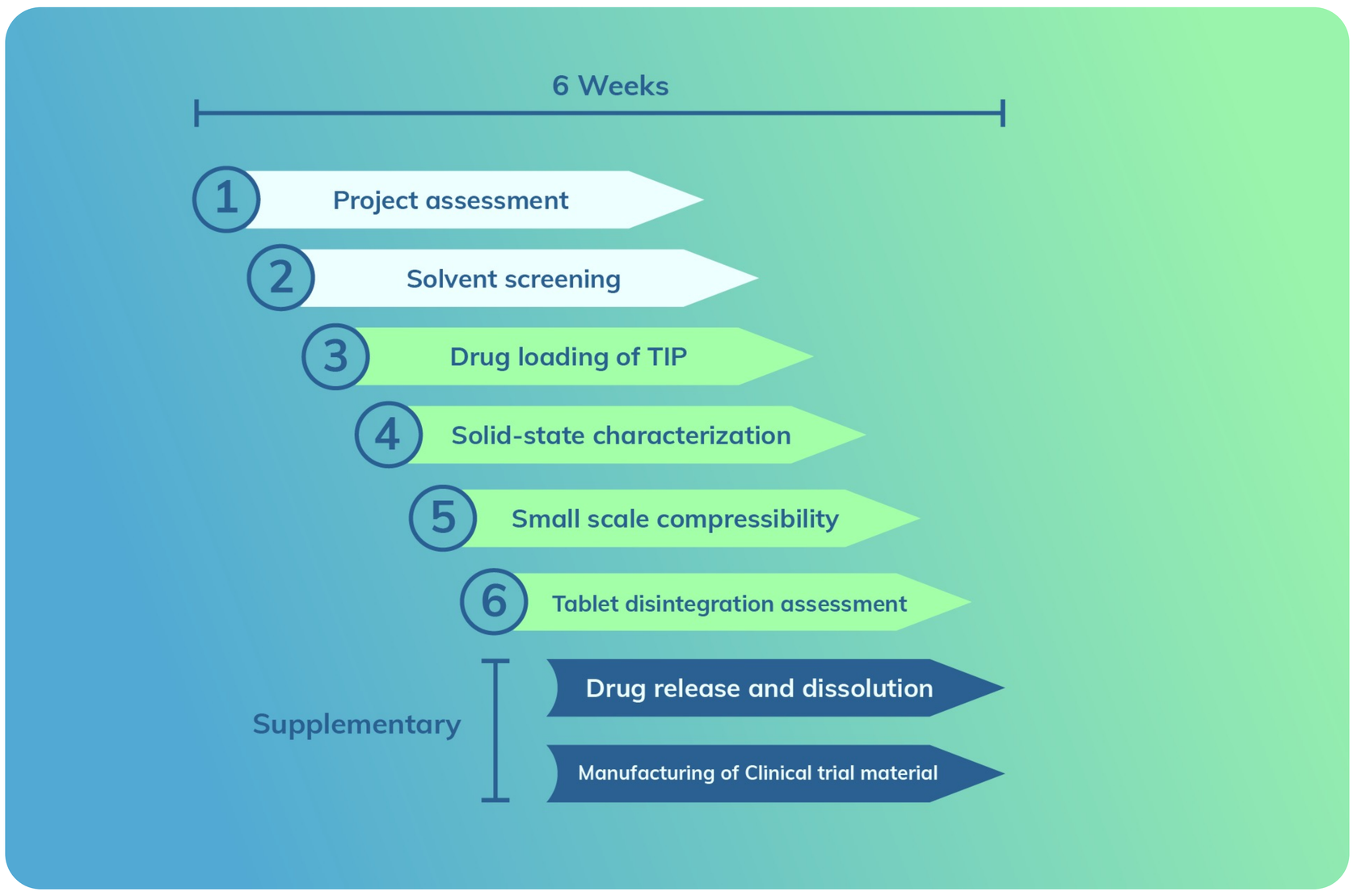
- TIP microcapsules maintain APIs in either stable amorphous or crystalline forms. The evaluation includes comparing X-Ray Powder Diffraction and Differential Scanning Calorimetry tests on the loaded and pure API samples. Based on the product's technical specifications, either amorphization or crystallization strategies are proposed
- Measurement of residual solvent amounts using Gas Chromatography methods

Step 5: Small-scale compressibility and compactibility assessments

- Powder compaction is performed, and the hardness and tensile strength are determined

Step 6: Tablet Disintegration Assessment

- Testing of the performance of orally disintegrating tablets (ODTs) and assessing the endurance of loaded API-TIP microcapsules under compression
- Measurement of disintegration time in water and artificial saliva. SEM analysis is performed on the disintegrated microcapsules to assess their integrity and mechanical endurance



We will be happy to advise you and align your strategy with the level of anticipated business risks that you are willing to take.

We're excited to partner with you, offering expert advice and a customized strategy that aligns perfectly with the level of business risk you're ready to embrace. Together, we'll transform potential challenges into remarkable opportunities for growth.

Email us at
info@galvita.com

Visit us at
galvita.com