



Manufacture of drug loaded particles applying hot melt technology

About Glatt Pharmaceutical Services GmbH & Co. KG (GPS)

GPS is a CDMO focused on the development and manufacturing of difficult to make solid dosage forms with a deep expertise in formulation and process of multiparticulates, controlled release and functional coatings. The two sites in Binzen, Germany and Ramsey, New Jersey have over 20 years of experience in this field. GPS Binzen lately also integrated the clinical supplies management to offer fully integrated services. The site currently has 130 employees and is installed for small scale to industrial scale to enable smooth scaling up of processes and formulation. Certified EU-GMP and FDA inspected.

About the project

In a first approach (highly) drug loaded multiparticulates will be developed, applying hot melt coating technologies. Alternatively, a development of tablets could be possible.

APIs with different physico-chemical properties, various drug loads, excipients and quantitative compositions shall be evaluated.

For this, Glatt's Wurster or selected other fluid bed technologies will be used. The influence of API and excipients properties on the process behavior as well as on the API release shall be evaluated.

Standard in-process-controls like particle size analysis by sieving, laser diffraction other optical methods, as well as analytical tests like assay or dissolution testing will be performed to evaluate the quality of the respective formulations.

Manufacture of drug loaded pellets or tablets

Hot melt coating

Lipid 1

Lipid 2

Lipid 3

API 1

API 2

API 3

Conc. 1

Conc. 2

Conc. 3