

Oral Solid Dose Starter Kit

- Minimize project risks by implementing MES best practices
- Reduce implementation costs with faster project delivery
- Standardize processes using out-of-the-box functionality



Introduction

The Syncade Oral Solid Dose starter kit allows you to transform your manufacturing process into automated workflows with minimum risk using standardized MES objects. The starter kit draws on proven best practices, enabling you to minimize risk to project scope and schedule. Out-of-the-box components accelerate project delivery using proven manufacturing processes and support you in achieving 21 CFR Part 11 and Annex 11 compliance.

Based on Emerson's expertise in pharmaceutical manufacturing processes, starter kits allow you to quickly and effectively automate your oral solid dose process. The package includes five recipes, covering granulation (wet and dry), solution preparation, compression, and coating.

Easily Automate Your Process

The Oral Solid Dose starter kit includes business process flow diagrams that graphically represent the layout of the manufacturing process. The kit includes equipment and material master configurations, providing a fully configured solution. Recipes are fully documented, including operator instructions, making it easier to automate the process. The five pre-defined recipes are delivered through an easy-to-use installer.

Starter kits are designed to meet 80% of your project needs. Using the standards, guidelines, and configurable recipe objects provided, you can easily adopt and implement the out-of-the-box functionality to suit your manufacturing process. Localization or process modifications can easily be applied through parameterized components to ensure the implementation fits your process.

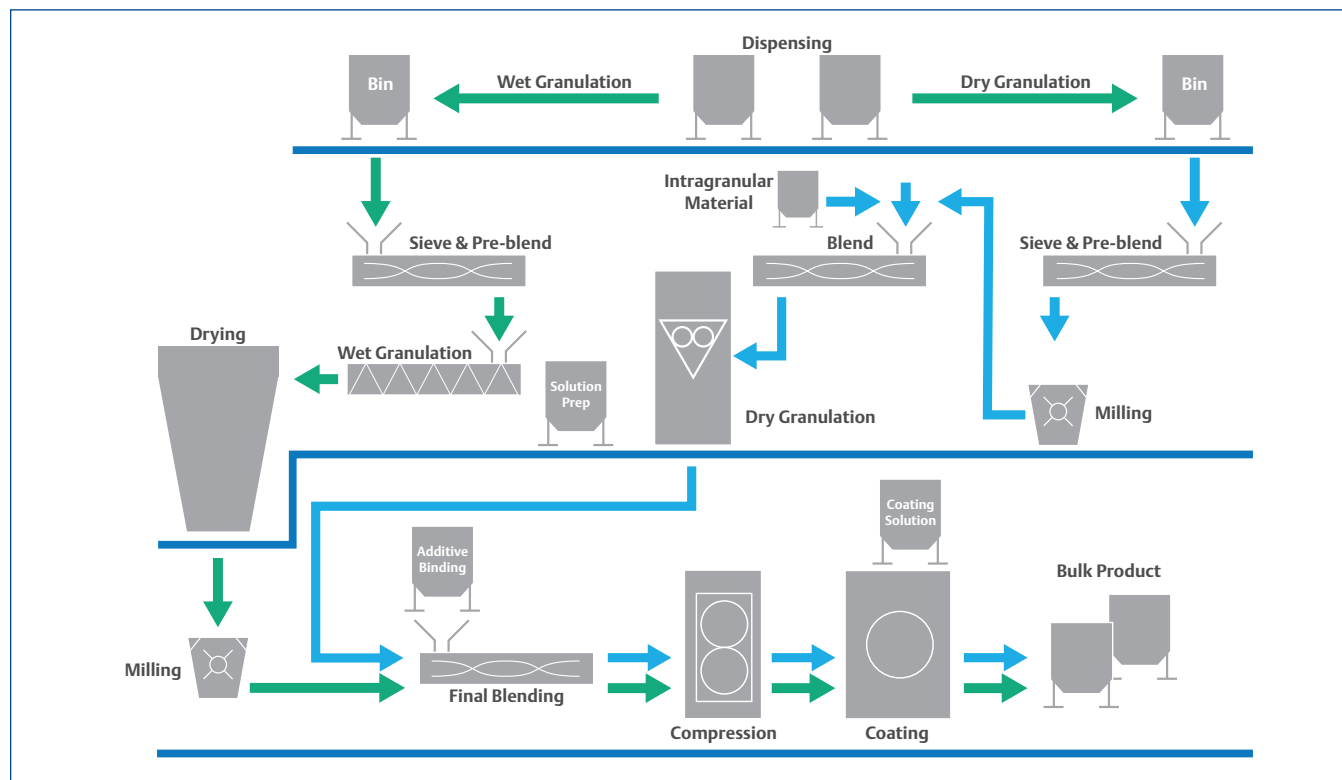
The Oral Solid Dose starter kit is designed to support communication with process control systems (PCS) using easily identifiable points of integration. Parameters such as mix rates, temperatures, and other setpoints are managed on a product/equipment basis.

Minimize Project Risks

All recipes included in the Oral Solid Dose starter kit use parameterized components as recipe objects. This unique approach provides your project team with a simplified way to modify recipes. Using reusable recipes, parameterized components enable support for multiple products and equipment trains. This flexible design ensures the starter kit meet the needs of your process while minimizing project risks and reducing the time for development, test, and validation.

In addition to business process flow diagrams, functional specifications are included. These specifications provide complete documentation of the recipes as well as details on operations, unit procedures, equipment classes, and material

definitions. The delivery of functional specifications provides greater clarity from the onset of the project, leading to lower implementation costs and faster project delivery.



Automate your oral solid dose business process.

Standardize Processes Across Sites

The Oral Solid Dose starter kit provides a solid foundation to drive standardization across multiple sites. The business process flows supplied can be used to encourage a culture of reusability. Where possible, aligning site(s) processes with the starter kit process flows reduces the need for customization and ensures a standard approach when implementing MES in your oral solid dose process. The drive to maintain standardization across multiple sites greatly reduces the risk and implementation costs associated with deploying MES across an enterprise.

Emerson Expertise

Emerson has a proven track record of delivering MES projects in the Life Sciences industry. An iterative approach to project delivery helps ensure that projects reflect your requirements.

With years of experience in design, implementation, startup, and optimization, you can trust Emerson to solve your cGMP manufacturing challenges.

Requirements

- Syncade Manufacturing Execution System using Workflow 4.9 SP1-314 or greater.
- Windows Server 2012 or Windows 2016.
- Microsoft SQL Server 2012 or 2016.
- Client browsers supported for recipe execution include Safari, Chrome, and IE 10 or higher.

Emerson

North America, Latin America:

☎ +1 800 833 8314 or

☎ +1 512 832 3774

Asia Pacific:

☎ +65 6777 8211

Europe, Middle East:

☎ +41 41 768 6111

🌐 www.emerson.com/syncade

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