

Integrated and traceable dispensing for full control and quality in formulation and weighing

The AX for Pharma Dispensing module integrates with Microsoft Dynamics AX to streamline your formulation and dispensing, with traceability and GxP compliance.

Solution Benefits

Effectiveness and efficiency

The Weighing and Dispensing module provides global and material-specific processing rules and guidance to: enforce standard operating procedures in the dispensing flow, manage potency adjustments, scale requirements and accuracy, weighing tolerances, operator training needs, material hazard warning messages, personal protective equipment requirements, container size and quantity and weigh-scale calibration requirements.

Simple and integrated Weighing and Dispensing module

The full integration of Dispensing module with Dynamics AX greatly reduces the chance of errors caused by inconsistent data, manual and paper-intensive systems. Support for electronic weigh-scale and extensive use of barcode labeling technology help to: ensure that the right material, in the correct quantity, with the right label, is delivered to production on time for manufacturing.

Traceability and control

The AX for Pharma Dispensing module manages the movement and control of all the dispensing batches and sub batches (e.g. containers, drums). Material to be dispensed is checked in real time to prevent the inadvertent usage and consumption of incorrect, expired, or rejected materials.

Regulatory compliance

The Dispensing module is fully compliant to 21 CFR Part 11 and EU Annex 11. The module allows users to secure critical actions with electronic signatures and keeps evidence of the actions history. It enables quick review and approval of materials with electronic signature verification.

The AX for Pharma Dispensing module provides manufacturers with a high level of control and visibility of work-in-progress materials in GxP environments.

Precisely weighing and dispensing materials is so important that it is delivered in most cases with manual operations under very severe supervision and controls. Consider the delicate task of manually entering paper documents in the dispensing list. You must enter materials, batches, containers, quantities, and then re-enter this information in the ERP solution. The risks involved in these operations and the relevant costs are very high.

The trend today is to rely more and more on powerful IT instruments to achieve lower costs, deeper control, and greater accuracy. One of the best options is to integrate the weigh and dispense operations in the ERP solution, as done by AX for Pharma. This provides important benefits: the ability to use a wealth of information instantaneously, ensure the best production outcome, reduce risks, and lower the total cost of validation.

The AX for Pharma Dispensing module enables you to connect scales to the ERP production and inventory modules, and it calculates the required quantities of active ingredients and fillers/compensating ingredients to be used. The full integration into ERP also allows the selection of materials according to the FEFO/FIFO method.

As soon as the dispensing operator scans the barcode label of the container being weighed, the dispensing module verifies the batch status, availability and expiry date, thus preventing the use of non-conformant or expired batches in production. The weight registered by the scale is immediately recorded in the production picking list for consumption, with inventory adjustments in case the actual weighed quantity differs from the theoretical one.



Highlights:

- Full integration with Microsoft Dynamics AX
- Standard integration with electronic scales and barcode devices
- Automated dispensing process to increase productivity and reduce risks
- Management of batch fractions and quantity adjustments
- Compliance with 21 CFR Part 11 and Annex 11
- Dispensing Validation Toolkit for IQ/OQ/PQ

WHAT'S NEW IN AX FOR PHARMA

- ✓ New release for **Microsoft Dynamics AX 2012 R3 CU9** since august 2015.
- ✓ Many **new features** including: Tamper evident seal management and Cleaning operations.
- ✓ Other **features** for room cleaning and **extended features** for scale calibration and verification.

Key Features

Formula Management	<ul style="list-style-type: none"> ✓ Define the list of components to be collected in the dispensing area ✓ Manage the accepted tolerance for each component
Production Control	<ul style="list-style-type: none"> ✓ Reserve multiple batches and sub-batches (e.g. containers) to be moved to the dispensing area ✓ Release batch orders to the dispensing area and view the dispensing status of production orders ✓ Manage additional quantities and picking lists
Tools Management	<ul style="list-style-type: none"> ✓ Manage scale information, accuracy and precision ✓ Verify the suitability of scales according to its precision and calibration status ✓ Manage scale calibration tests and their frequency ✓ Interface the Dispensing module with barcode readers to speed up the process and reduce errors due to manual data entry ✓ Integration with standard electronic scales (e.g. Mettler Toledo)
Weighing process	<ul style="list-style-type: none"> ✓ Lead dispensing operators through the weighing process with clear guidance and workflows ✓ Verify product, order, batch and container information prior to dispensing (item, batch and sub-batch number, quality status and expiry date) ✓ Receive tare weight, net weight, gross weight directly from the electronic scale ✓ Verify that the weighted quantity is within the tolerance range
Error Management & Prevention	<ul style="list-style-type: none"> ✓ Real-time notification of occurred errors ✓ Analyze error causes and manage error resolutions
Report Management	<ul style="list-style-type: none"> ✓ Dispensing labels (barcode labeling technology) ✓ Master Batch Record ✓ Reconciliation reports ✓ Production costs and variances reports
Inventory & Warehouse Management	<ul style="list-style-type: none"> ✓ Automatic consumption of dispensed quantities ✓ Control tolerance ranges during the dispensing process ✓ Automatic inventory adjustments
Compliance with 21 CFR Part 11	<ul style="list-style-type: none"> ✓ Control critical actions with electronic signatures and audit trail ✓ Track the history of batch orders ✓ Configurable security roles and permissions

