

Gain manufacturing efficiency and compliance with an integrated Weighing & Dispensing solution

The AX for Pharma Weighing & Dispensing module integrates with Microsoft Dynamics 365 to streamline your processes, with traceability and GxP compliance.

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

Weighing and dispensing materials are so important that in most cases are delivered with manual operations under severe supervision. **This means that the operators are required to fill in paper documents and then re-enter this information in the ERP solution.** The risks involved in these operations are very high.

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

The AX for Pharma Weighing & Dispensing 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.

In summary, **the dispensing module verifies the batch status, availability and expiry date, thus preventing the use of non-conformant or expired batches.**

READY FOR
**Microsoft
Dynamics 365**
FOR FINANCE AND
OPERATIONS

Highlights:

- Full integration with Microsoft Dynamics 365
- 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



KEY 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 365 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 Weighing & 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.

KEY FEATURES

Formula Management

- Define the list of components to be collected in the dispensing area.
- Manage the accepted tolerance for each component.

Production Control

- 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.

Dispensing order

- Manage dispensing orders for production, shipment and transfer.
- Release dispensing orders to the dispensing area and monitor the status.
- Record dispensing transactions with actual quantity and details about operations.

Cleaning management

- Manage dispensing room availability and status.
- Configure cleaning rules based on frequency and material type.
- Enforce cleaning operations.

Tools Management

- Manage information, accuracy and precision for scales, gauges and barcode readers.
- Manage scale calibration tests and their frequency.
- Manage recurrent verification tests for scales and gauges.
- Interface the module with barcode readers to speed up the process and reduce errors due to manual data entry, and with electronic scales (e.g. Mettler Toledo).

Weighing process

- Lead dispensing operators through the weighing process.
- Manage campaign to optimize the weighing process.
- Verify material types re approved for the dispensing room.
- 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 weighed quantity is within the tolerance range.
- Second person verification for critical steps.

Error Management & Prevention

- Real-time notification of occurred errors.
- Analyze error causes and manage error resolutions.

Report Management

- Dispensing labels.
- Dispensing orders and dispensing transactions reports.
- Production costs and variances reports.
- Calibration and verification report.
- Control report.

Inventory & Warehouse Management

- Automatic consumption of dispensed quantities.
- Control tolerance ranges during the dispensing process.
- Automatic inventory adjustments.

Compliance with 21 CFR Part 11

- Control critical actions with electronic signatures and audit trail Track the history of batch orders.
- Configurable security roles and permissions.
- Reason codes for traceability and control of actions.