Filtration in API manufacturing

Chemical synthesis

When manufacturing medicinal products, APIs are combined or formulated with other excipients to produce a pharmaceutical product and then presented in a final dosage form, for example a tablet, ointment or liquid

APIs (Active Pharmaceutical Ingredients) are the active ingredients in medicinal products.

APIs or bulk pharmaceutical substances are manufactured using chemical and biotechnological processes, the latter being further differentiated into fermentation and extraction processes. Fermentation uses biological processes to produce active ingredients on an industrial scale with the help of microorganisms or cells. During the extraction process, the active ingredient is isolated or obtained from natural resources.

After either chemical synthesis or biotechnological manufacturing or extraction, the active ingredient then undergoes various separation and purification steps until it can be presented in its final dosage form as a medicinal product.

For chemical synthesis, Eaton offers a broad range of products for various filtration tasks in the individual process steps.

The core component of chemical synthesis is the chemical reactor, which is followed by other additional steps, such as separation, purification, crystallization, drying and filling.

Filtration is used to perform important separation and purification tasks during the manufacturing of APIs, such as:

- Removal of catalysts and reaction by-products (e.g. particulates, molecular impurities) immediately after synthesis
- Removal of unwanted discolorations or impurities during purification
- Extraction of products and active ingredients after crystallization
- Protection of plant components
- Media filtration

High standards and cGMP (current Good Manufacturing Practice) requirements must be observed to ensure quality and purity. For this reason, medicinal products and their active ingredients undergo a strictly regulated development process. From laboratory research to clinical development, scale-up/pilot manufacturing and process validation, these steps ensure reproducible results.

EATON

Powering Business Worldwide

Maximum efficiency and purity in the manufacturing of APIs

Compliance with the high standards and requirements of the pharmaceutical industry is the main challenge customers face.

As a key component in the manufacturing process of APIs, filtration systems are used to improve the quality of the end product or protect plant components. Given that they come into direct contact with the product, the filtration systems must meet the highest demands in terms of efficiency, purity and cleanability.

Chemical API production is carried out using a variety of solvents and under a range of application conditions, including pH levels, pressure and temperature. As a result, filter components must be resistant to these conditions and obtain reliable results.

Robust, reusable and easy-to-clean filtering devices with replaceable depth filter media are used to prevent cross-contamination.

Depth filtration ensures reliable processes through efficient and effective separation.

Eaton offers filtration systems with the ideal combination of the filtration device and depth filter media for every phase of manufacturing APIs.

BECO® or BECOPAD® depth filter sheets and BECODISC® stacked disc cartridges are ideal for separating high particle loads, fine particulates and colloids, reducing and separating microorganisms to protect membrane filters, and adsorptively separating by-products.

The depth filter sheets in BECO INTEGRA® SOLO single-sheet filters or the stacked disc cartridges with increased cell spacing in BECO INTEGRA DISC stacked disc cartridge housings can be used to separate and extract precipitates and products resulting from crystallization.

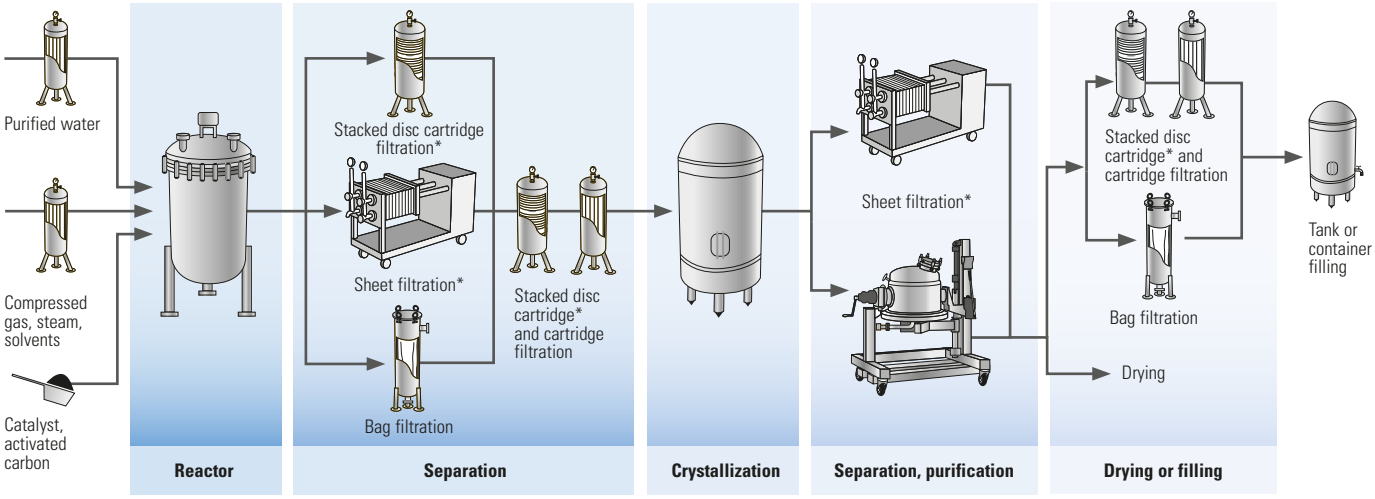
For special pharmaceutical product types, Eaton can ensure the highest level of safety and product quality via the batch-based testing of endotoxin content. This meets the requirements of the USP biocompatibility tests (USP Class VI). These and other tests are documented in the Validation Guide.

The BECODISC BC and BECO CARBON™ depth filter media provide a clean solution for adsorption and discoloration. The activated carbon is bonded in the filters, which saves users the need to dose and separate loose activated carbon or clean production areas and components, such as pipelines. Since the activated carbon content is precisely defined in the filter material, a high, reproducible product quality and filtration performance is also ensured.

The BECODISC BC activated carbon cartridge is available in polypropylene (PP) or polyamide (PA) versions for a wide range of applications. Expanded polytetrafluoroethylene (ePTFE) seals provide a particularly high chemical resistance to critical solvents.

The product portfolio ranges from laboratory and pilot tests to series production, and can be used in the development and production transfer stages as well as for the qualification of filtration products. Processes can therefore be easily replicated under laboratory or pilot conditions, and laboratory developments can be transferred to the pilot or production stage.

Simplified process flow diagram for chemical synthesis



* Eaton depth filter sheets meet national and international quality standards, such as European Directive (EU) 1935/2004 and FDA guidelines (Food and Drug Administration) from the USA. The plastic components of the stacked disc cartridges (polypropylene) meet European Directive (EU) 10/2011.

North America
44 Apple Street
Tinton Falls, NJ 07724
Toll Free: 800 656-3344
(North America only)
Tel: +1 732 212-4700

Europe/Africa/Middle East
Auf der Heide 2
53947 Nettersheim, Germany
Tel: +49 2486 809-0

Friedensstraße 41
68804 Altlußheim, Germany
Tel: +49 6205 2094-0

An den Nahewiesen 24
55450 Langenlonsheim, Germany
Tel: +49 6704 204-0

Greater China
No. 7, Lane 280,
Linhong Road
Changning District, 200335
Shanghai, P.R. China
Tel: +86 21 2899-3687

Asia-Pacific
100G Pasir Panjang Road
#07-08 Interlocal Centre
Singapore 118523
Tel: +65 6825-1620

For more information, please email us at *filtration@eaton.com* **or visit** *www.eaton.com/filtration*

EN
07-2023

Powering Business Worldwide