Filtration Products

Filtration of active pharmaceutical ingredients (APIs)

Chemical synthesis

EATON

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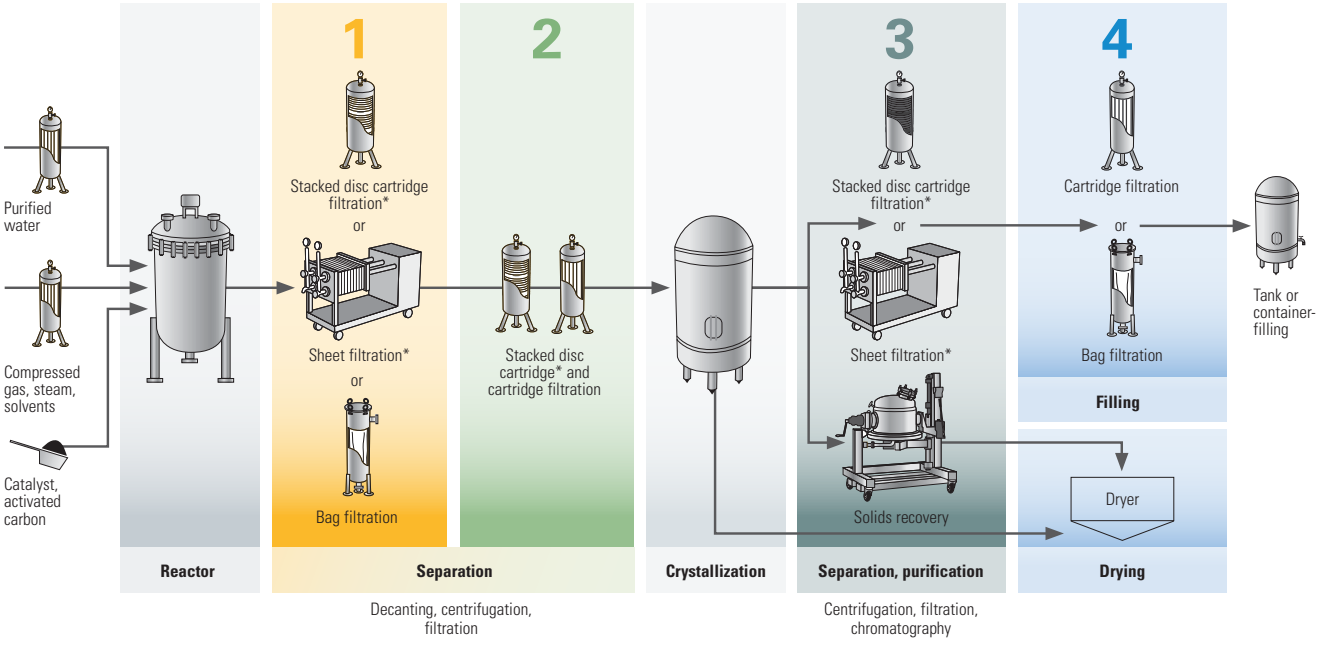
Active Pharmaceutical Ingredients

APIs (Active Pharmaceutical Ingredients) are combined or formulated with excipients to produce pharmaceutical or medical products. The production of APIs involves either biotechnological or chemical processes. In both cases, filtration plays a key role throughout the entire manufacturing process in ensuring the production of high-quality ingredients and pharmaceuticals. In the chemical manufacturing process, various filtration methods, including sheet, stacked disc cartridge, bag, or cartridge filtration are employed for diverse purposes. These include the separation of undesired particles and microorganisms, the extraction of crystallization products and the protection of system components.

As active ingredients, APIs are responsible for the pharmacological effect, imposing stringent requirements, standards and specifications for production. These guidelines, known as cGMP (Current Good Manufacturing Practice), for the pharmaceutical manufacturing process are established and regularly updated by the responsible organizations, such as the European Commission or the FDA (Food and Drug Administration). When selecting filtration systems, manufacturers of active ingredients must adhere to solutions that are compliant to cGMP standards.

Chemical API production process (simplified)



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

Eaton offers filtration systems with the ideal combination of depth filter media and filtration device at every stage of the active pharmaceutical ingredient production:

1

The chemical reactor is followed by the first separation phase. Solids, such as the catalyst bound to activated carbon, or other reaction by-products are filtered out first. In addition to bag filtration, sheet or stacked disc cartridge filtration is particularly suitable. In many cases, the combination of BECO® standard or BECOPAD® depth filter sheets made of cellulose, in an enclosed frame filter, such as the BECO INTEGRA PLATE™ is the optimal solution for solids separation. If the requirements for chemical compatibility with regard to raw materials or sealing materials are higher, stacked disc cartridge filtration is recommended. A system consisting of BECODISC® stacked disc cartridges and the enclosed BECO INTEGRA® DISC stacked disc cartridge housing is a clean solution in this case. Optionally, the system can also be equipped with stacked disc cartridges with increased cell spacing.

2

Following the solids separation, clarifying filtration takes place for the separation of fine particles. Depending on the desired purity of the filtrate, this step is carried out in several stages using a combination of stacked disc cartridge and cartridge filtration to protect downstream components.

3

Active pharmaceutical ingredients are processed in the drug either in powder or in liquid form. There are therefore two alternative process routes.

In liquid form, the active pharmaceutical ingredients undergo various filtration steps after crystallization. BECOPAD depth filter sheets are ideal for the separation of fine particles and colloids, for the reduction and separation of microorganisms and for the protection of a final membrane filtration. The use of BECODISC BC activated carbon stacked disc cartridges with BECO CARBON™ depth filter sheets is recommended for the separation of undesirable organic by-products or decolorization.

Single-sheet filters such as the BECO INTEGRA SOLO™ are used in solids extraction after crystallization.

4

A further, final filtration stage is carried out to protect the tank or container filling. Depending on the requirements, the liquid active ingredients are filtered using filter bags or filter cartridges.

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QUALITY SYSTEM CERTIFICATION DNV ISO 9001