

Getinge cGMP GEW Washer/Dryer Air Exhaust Unit for APIs

Containment of APIs Released Through Component Washing

Active Pharmaceutical Ingredients (APIs) are a normal byproduct of pharmaceutical production, research and development that can be released into the loading and service area via the component cleaning/washing process.

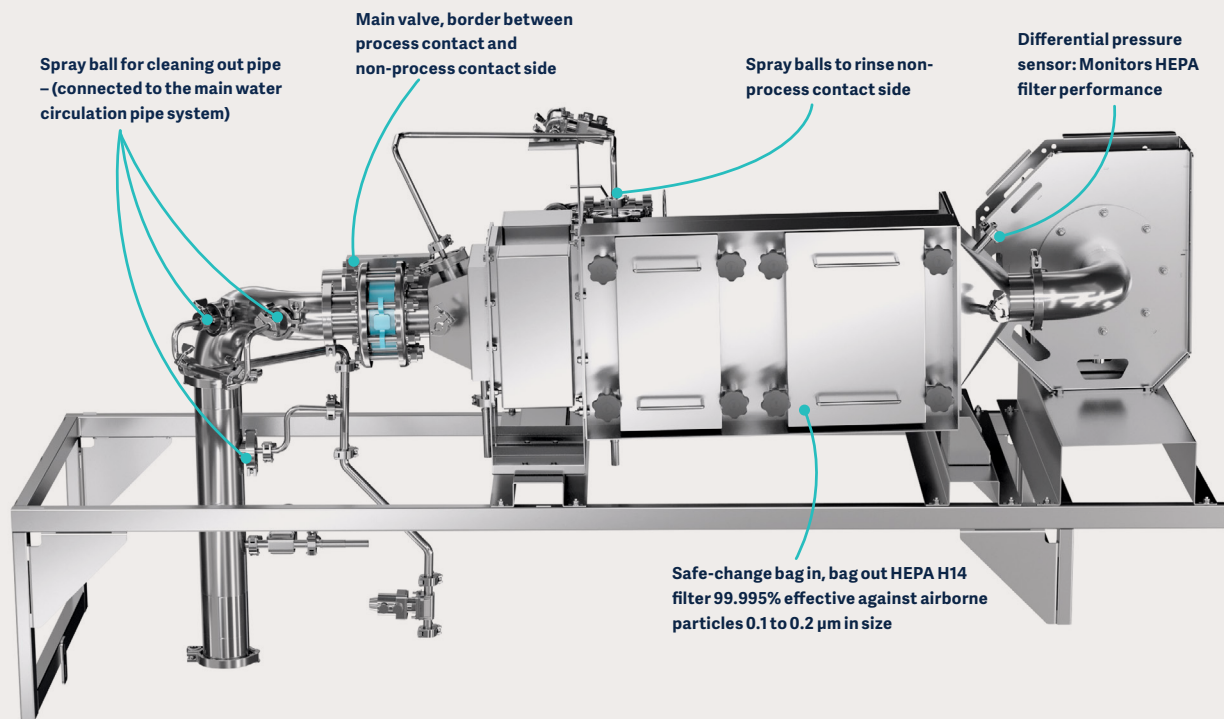
Over time, APIs of level 4 and above can pose hazards to workers when agents accumulate in the body. Pharmaceutical companies that manufacture drugs with hazardous or potentially hazardous APIs therefore need a solution that works with cGMP washers to ensure the safety of personnel and the environment during the cleaning of drug manufacturing equipment and component parts.

Key Benefits

- Assured personal safety – personnel are protected from API particulate release in production, service and loading areas.
- Environmental protection – APIs are captured in bag-in, bag-out HEPA filtration that prevents release into the environment.
- cGMP compliance – process contact side includes a slope of 2%, dead legs of $\leq 2D$ and a surface roughness of $Ra \leq 0.5 \mu m$ to ensure all parts on the process contact side of the Air Exhaust Unit meet cGMP polishing requirements. The non-process contact side, is engineered with a sanitary design in mind to meet best practices in the pharmaceutical industry.
- Easy shipping – can be removed before shipment to reduce packing size and total machine height and improve the delivery of the machine to the installation site.



Solving the Customer Challenge of API Exposure



Containing Hazardous Active Pharmaceutical Ingredients (APIs)

The Getinge Air Exhaust Unit is an optional, standalone solution that captures potent and highly potent APIs and prevents their release into the service area. The system uses a highly effective HEPA filtration system to capture the residual HPAPIs and APIs removed during the equipment cleaning process. The Air Exhaust Unit relies on multiple system parameters that are consistently monitored to ensure reliable system performance, protecting you, your employees and your environment from the potential dangers of API exposure. In addition, the Air Exhaust Unit provides level 5 OEB containment for the highest level of personal safety from API particulates.

Insoluble APIs and HPAPIs, in particular, endanger personnel and the environment when necessary containment equipment is not used during the component washing process. The Getinge Air Exhaust Unit provides a solution that works with cGMP washers to clean components and production equipment for drug manufacturing that includes APIs. The Air Exhaust Unit is available on Getinge cGMP GEW models 101210 and 131313 washers.

Pharmaceutical Production Solutions

Getinge is an industry leader in product solutions for pharmaceutical production sterility testing, API handling and aseptic filling. Our isolation technology and isolator manipulation devices are trusted worldwide to provide a safe and controlled environment for your most critical steps. Learn more: <https://www.getinge.com/int/solutions/life-science/pharmaceutical-production/>.

OEB Level

