Anatomy of a world-class high containment micronization plant

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Dec Group has produced a broadcast-quality video featuring its high containment micronizing technology and materials handling systems as seen in a world-class production facility.

The video features a two-floor large scale high containment micronization plant that is equipped with a full suite of containment technology solutions ensuring OEL levels are kept well under the target while allowing fully streamlined processes.

Containment Performance Target

Despite its size and high throughput, the plant succeeds in surpassing Containment Performance Target (CPT) levels of <25ng. All processes are managed using a fully integrated control system for completely automated micronization including drum charging, separation, pack-off and inline sampling.

The triple chamber drum charging isolator is supplied with a drum docking chamber with integrated drum lift and tipper systems where the drum is docked onto the rear of the charging chamber. The video shows the drum internal transfer door for transferring contents to the main charging chamber.

The waste transfer chamber is equipped with both an internal continuous liner system CLS port and an external rapid transfer port (RTP) with CLS designed to reduce the particle concentration of materials exiting the chamber.

New generation MC DecJet® spiral jet mill micronization

Input API is charged from the charging isolator and fed via gravity into a dedicated micronising isolator and into a gravimetric feeder, which introduces the API at the correct mass flow rate into an interchangeable MC DecJet® 200 and MC DecJet®300 systems mounted on slide rails. The

chamber provides double-sided access to the jet mill and the gravimetric feeder mounted on rails for operation ease.

Gas product separation is performed in a high containment cyclone filter unit chamber incorporating full differential pressure control with an automated filter sleeve shaking. Final exhaust gas exiting the cyclone is filtered through double push-push exhaust HEPA filter and an integrated continuous liner system waste port maintains high containment when removing the filter. From an ergonomic perspective, this cyclone chamber also allows for a double-sided access.

Analytical Sampling

A dedicated sampling isolator equipped with a Dec MPTS Sampling System enables in process samples to be taken directly below the discharge rotary valve from the cyclone filter without interrupting production. Analytical samples are weighed inside the isolator prior to transfer to the QC lab.

Triple Chamber Pack-off Isolator

This unit includes a drum transfer airlock chamber interconnected to the lower drum docking chamber to which the product is transferred from the upper filling chamber through Dec's rotary valve and continuous liner system CLS with closure device.

The plant is equipped with an integrated Clean-In-Place (CIP) skid with inline detergent metering which allows for automated cleaning recipes to be developed and stored.

Watch the video

https://vimeo.com/537131456

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