

# ADC Isolator

NANOGRAM-LEVEL  
FLEXIBLE CONTAINMENT



ONFAB

Process Containment

## Reliable Single-Use Protection for the Most Potent Formulations

Antibody-drug conjugates (ADCs) are rapidly emerging as powerful therapies in the fight against cancer. But getting them to a patient-ready state is a challenge due to the high potency of their ingredients and ever-present safety concerns for manufacturers.

ADC manufacturing involves a number of components - including antibodies, payloads, and linkers - making the process inherently complex and specialized. These components are also frequently manufactured across multiple sites, necessitating meticulous coordination and even more care when handling the toxic compounds. These factors often result in an even higher failure rate in clinical trials compared to many other drug classes.

In turn, we are witnessing even wider adoption of single-use systems throughout production facilities around the world. Trust **ONFAB's ADC Isolator** with your most complex and sensitive pharmaceutical manufacturing compounding needs. Deploying multiple components and features that facilitate a broad spectrum of applications, it installs quickly, is easy to use, and delivers nanogram-level performance while reducing costs and risk associated with cleaning protocols when compared to rigid isolator technology.



*ONFAB's fan set controls the air flow in your isolator to improve containment performance*

### QUALITY STATEMENT

ONFAB was founded in 2004 and has grown to become a global leader in the bespoke design, manufacture and installation of flexible containment systems for the pharmaceutical and life sciences industries. Our team of engineers are committed to the highest standards of excellence, meeting the requirements of ISO 9001 ISOQAR. From our facilities in the USA, UK, and Europe, we advise on protection for your workforce and how to streamline and validate the manufacturing process.



Cert No. 12431



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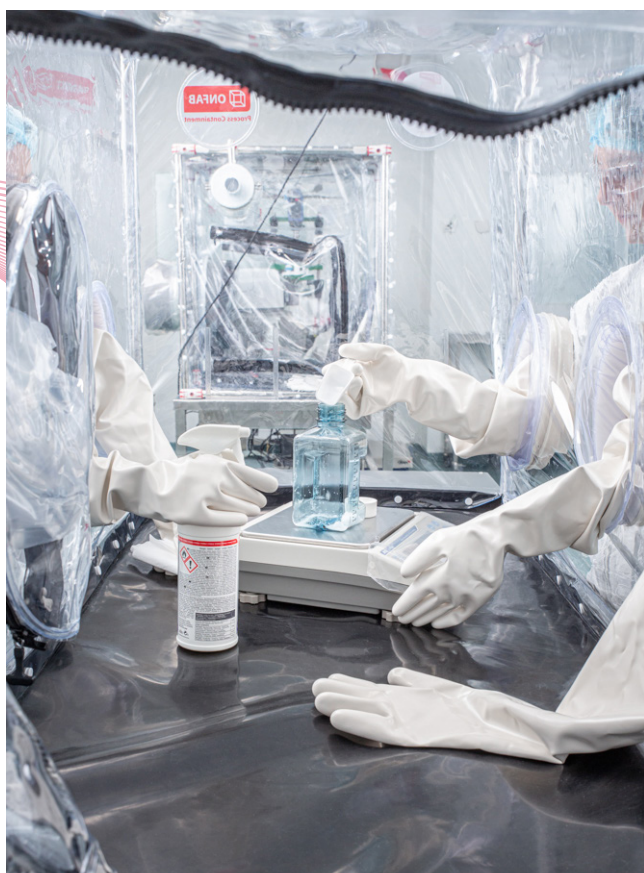


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## Key Applications

Key applications of the ONFAB ADC Isolator include the following:

- **Weighing & dispensing** - The ONFAB ADC Isolator offers the convenience of a dedicated space to remove raw materials from bulk containers, weigh them, and then transfer contents into clean containers and to processing areas.
- **Toxin linker compounding** - The product's nanogram-level containment and negative pressure provide peace of mind when combining highly potent ADC ingredients.
- **ADC containment & transfer** - Airtight protection and the ability to control environmental conditioning simplifies drug containment, keeping your team and your ADC safe all the way through final transfer.



ONFAB's ADC Isolator is designed to fulfill multiple applications from a single location

## KEY DESIGN FEATURES

- **Fully disposable assembly** for quick and easy cleanup
- **Non-cleaning validation** for faster setup times and filter disposal without contamination
- **Negative pressure** for increased airflow and reduced spread of airborne pathogens
- **Pre-start pressure decay test** to ensure isolator integrity
- **HEPA filtration** to help eliminate particulate matter
- **Easily adjustable table** to raise and lower height
- **PTFE solvent drip tray** to help control spills and drips
- **Equipment shelf** for easy organization
- **Nanogram performance levels** for improved precision



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## Technical Features

- Containment performance below 10ng/m<sup>3</sup>
- Automatic pre-start pressure test system
- Glove sleeves and base resistant to solvents
- Heavy duty anti-static film construction
- ONFAB automated pressure control system
- Gas tight zipper access
- No API contamination of stainless steel parts
- H14 air inlet and transfer filters
- 2x stage H14 single-use exhaust filters
- Adjustable height table
- Tailored sizing options available
- Fully integrated BIBO continuous liner system



**Technical drawings are available - please contact us for access.**



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## Typical Containment Test Data

The following results reflect the airborne concentration of naproxen sodium over task (ng/m<sup>3</sup>).

	Powder Handling Runs			Dismantling Run
Test Location	Run 1 (43 mins.)	Run 2 (43 mins.)	Run 3 (40 mins.)	Run 1
Pre-Trial Background*	< 0.83	< 0.83	< 0.83	N/A
Personal 1	< 0.58	< 0.58	< 0.63	< 0.82
Personal 2	N/A	N/A	N/A	< 0.83
Position 1	< 0.58	< 0.58	< 0.63	< 0.83
Position 2	< 0.58	< 0.58	< 0.63	< 0.83
Position 3	< 0.58	< 0.58	< 0.63	< 0.83
Position 4	< 0.58	< 0.58	< 0.63	< 0.83
Position 5	< 0.58	< 0.58	0.69	N/A
Position 6	< 0.58	< 0.58	< 0.63	N/A
Position 7	< 0.58	< 0.58	< 0.63	N/A

\*Pre-Trial Background run time was 30 minutes.



[Click here to schedule an ADC Isolator demonstration!](#)

*\*DISCLAIMER: The data presented in this brochure represents sample results from a specific study on the airborne concentration of naproxen sodium. While we are confident that similar results can be achieved under comparable conditions, individual results may vary depending on specific processes and operational environments. We recommend you conduct your tests using ONFAB's ADC Isolator to verify performance in your unique context. The information provided is for reference only.*



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