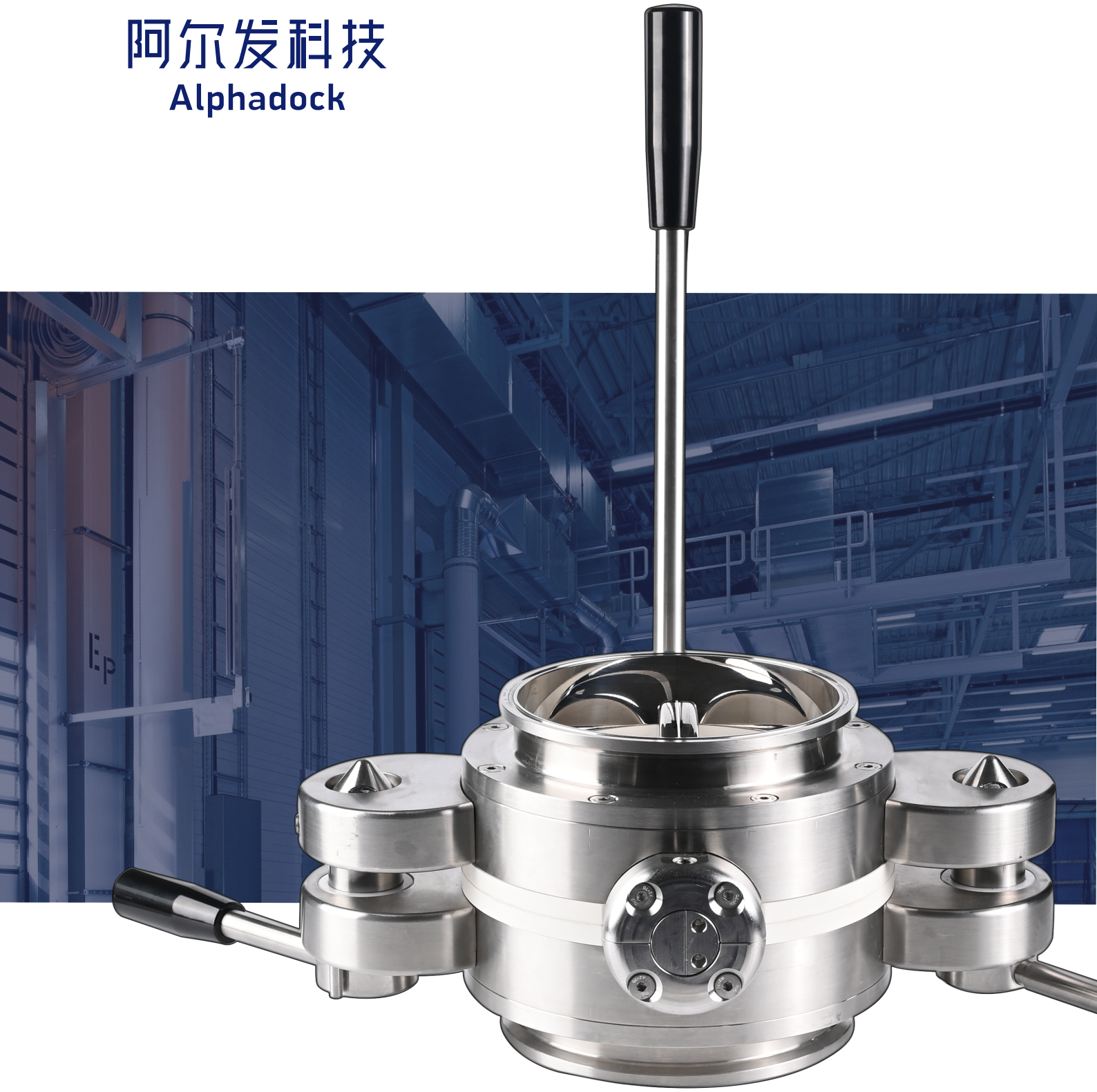
阿尔发科技
Alphadock



Alphadock Containment Valve System

OEB5 Assured: Superior Protection

Born to Engineer World-Class Split Butterfly Valves

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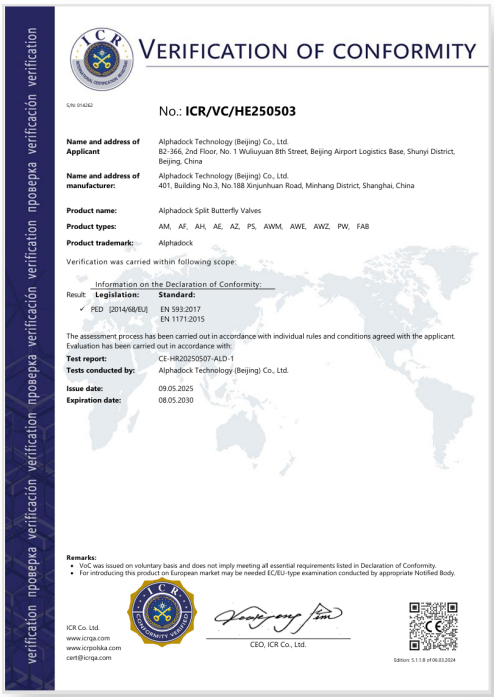
Company Profile

Alphadock has specialized in the development of OEB5 high-containment valve solutions for pharmaceutical solid dosage production for over a decade. Our split butterfly valves utilize a flexible docking system to effectively handle highly active/toxic solid materials, ensuring Occupational Exposure Limit (OEL) controlled at the nanogram level.

The product design balances process requirements with operational efficiency, supporting rapid integration, CIP/WIP, and significant reduction in maintenance costs. Through deep collaboration with leading pharmaceutical manufacturers, Alphadock continuously optimizes technical solutions, achieving dual enhancements in equipment performance and economic efficiency while ensuring personnel safety, product quality, and environmental compliance.

With mature industry expertise and innovative technologies, Alphadock has become a pioneer in high-risk material handling within China's pharmaceutical sector.



VERIFICATION OF CONFORMITY

No.: **ICR/VC/HE250503**

Name and address of Applicant	Alphadock Technology (Beijing) Co., Ltd. B2-366, 2nd Floor, No. 1 Wuliuyuan 8th Street, Beijing Airport Logistics Base, Shunyi District, Beijing, China
Name and address of manufacturer:	Alphadock Technology (Beijing) Co., Ltd. 401, Building No.3, No.188 Xinjunhuan Road, Minhang District, Shanghai, China
Product name:	Alphadock Split Butterfly Valves
Product types:	AM, AF, AH, AE, AZ, PS, AWM, AWE, AWZ, PW, FAB
Product trademark:	Alphadock

Verification was carried within following scope:

Information on the Declaration of Conformity:

Result:	**Legislation:**	**Standard:**
✓	PED [2014/68/EU]	EN 593:2017 EN 1171:2015

The assessment process has been carried out in accordance with individual rules and conditions agreed with the applicant. Evaluation has been carried out in accordance with:

Test report: CE-HR20250507-ALD-1
Tests conducted by: Alphadock Technology (Beijing) Co., Ltd.
Issue date: 09.05.2025
Expiration date: 08.05.2030

Remarks:
- VoC was issued on voluntary basis and does not imply meeting all essential requirements listed in Declaration of Conformity.
- For introducing this product on European market may be needed EC/EU-type examination conducted by appropriate Notified Body.

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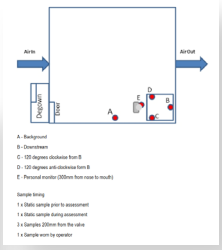
CEO, ICR Co., Ltd.

Edition: 5.1.1.8 of 06.03.2024

RESULTS

Airborne concentration of lactose (µg/m³)

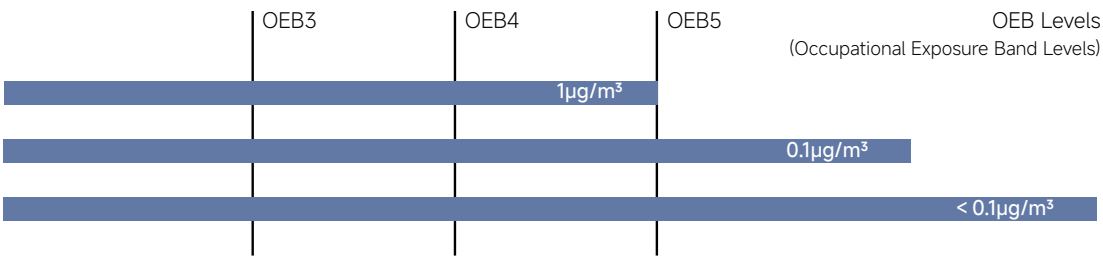
	Run 1	Run 2	Run 3
Location A - Background exposure	<0.00372	<0.00353	0.00101
Location B - Downstream	<0.00378	<0.00471	<0.00306
Location C - 120 degrees clockwise from B	<0.000439	0.0215	0.00875
Location D - 120 degrees anti-clockwise form B	<0.00194	0.00364	0.00337
Location E - Operator exposure	<0.00109	<0.00170	<0.00147



OEL Leakage Test Report
2024.6

Conducted by a third-party institute after Alphadock valves' 1-year usage

Schematic Diagram of OEB Classification



Using a suction port paired with a HEPA filter can further lower OEL (Occupational Exposure Limit) values.

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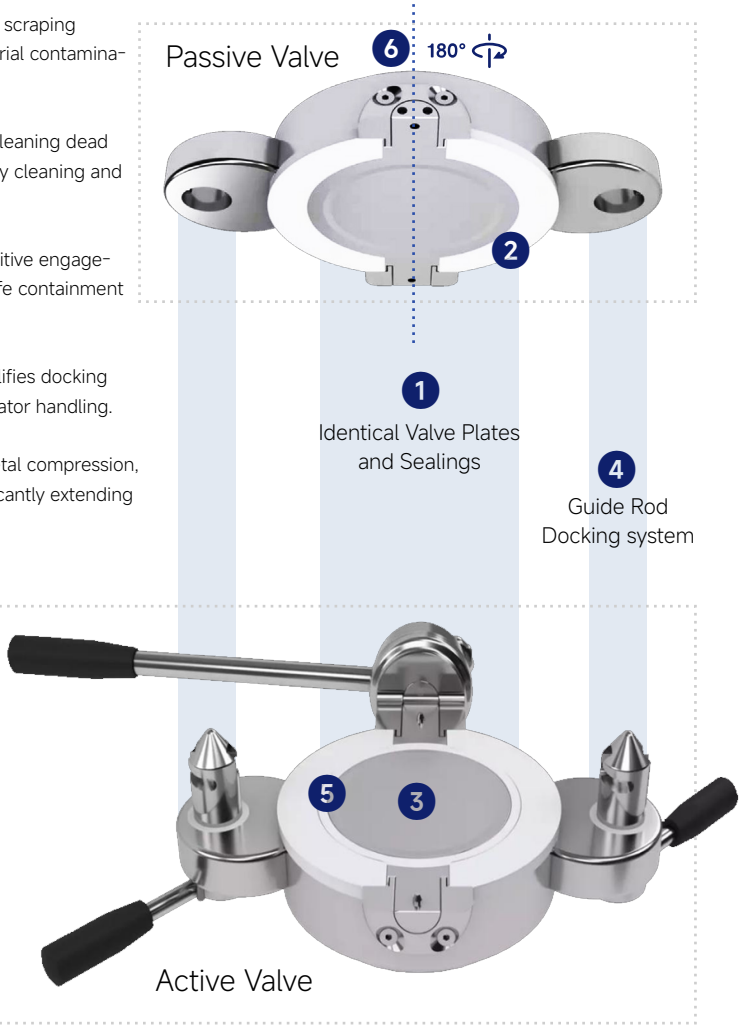
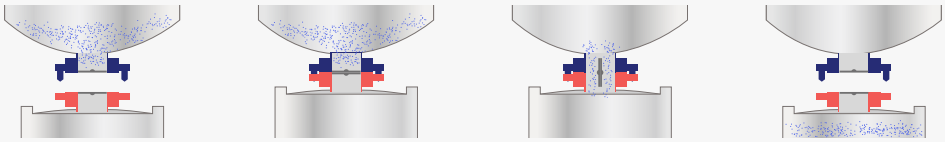
Highlights

1. Symmetrical valve body design eliminates scraping during docking/opening, minimizing material contamination.
2. Flush surface contact after locking: zero cleaning dead zones with smooth surfaces, ensuring easy cleaning and drying.
3. The interlocking valve plate maintains positive engagement even when rotated 90°, ensuring safe containment requirements.
4. Maximum ±14mm aligning tolerance simplifies docking operations, enables effortless single-operator handling.
5. Elastomeric sealing prevents metal-to-metal compression, eliminates valve plate deformation, significantly extending the service life.
6. The passive valve can be rotated 180° to dock, enhancing docking efficiency.
7. Modular component design enables quick installation, easy replacement and convenient maintenance.
8. CIP/WIP system available.
9. Customized design solution can meet high-end requirements.

Product Docking Diagram



Operation Sequence



1 Before Docking

Both active and passive valves have a fixed butterfly plate with a sealing ring. They remain closed and cannot be opened when not docked.

2 Docking and Locking

After docking and locking, the two valve plates form an integrated sealed valve plate that can be opened simultaneously.

3 Opening

Operate the actuator to open the valve plate, and the material can be transported in containment through the valve.

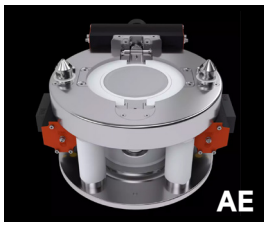
4 Unlocking and Undocking

After the material transfer is completed, the actuator is operated to close the valve plate, and the active valve and passive valve can be unlocked and separated, respectively forming a contained environment with equipment and IBC.

Product Lines

1 Active Valve

Integrated on equipment, supporting both manual and automatic operation, and able to integrate additional functions such as suction port, compensation damper, lifting system and etc.

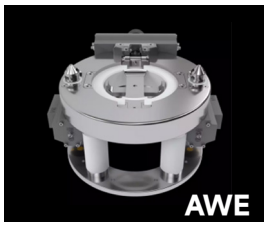


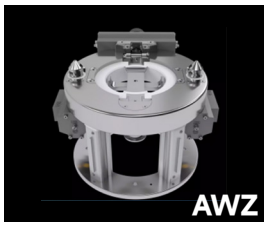
2 Passive Valve

Can be independently installed at the inlet/outlet of IBC containers.

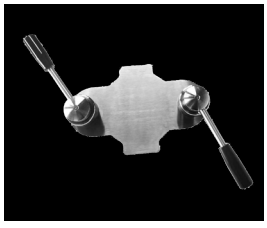
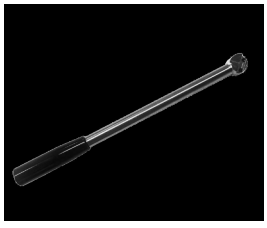
3 Wash-in-Place (WIP)

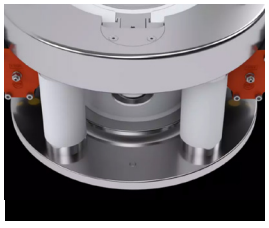
WIP can be achieved by wash valves; Automatic active wash valves can be integrated into IBC cleaning station to realize full-process automated control.





4 Accessories



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Manufacturing of API and Intermediate Products

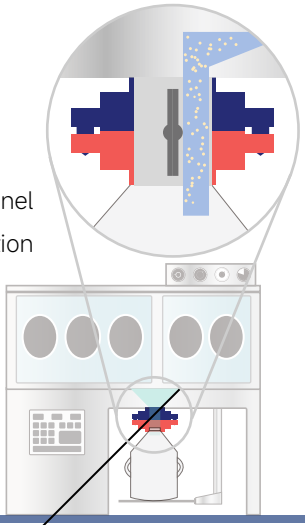
Passive Valve

Active Valve

Safe Container Feeding

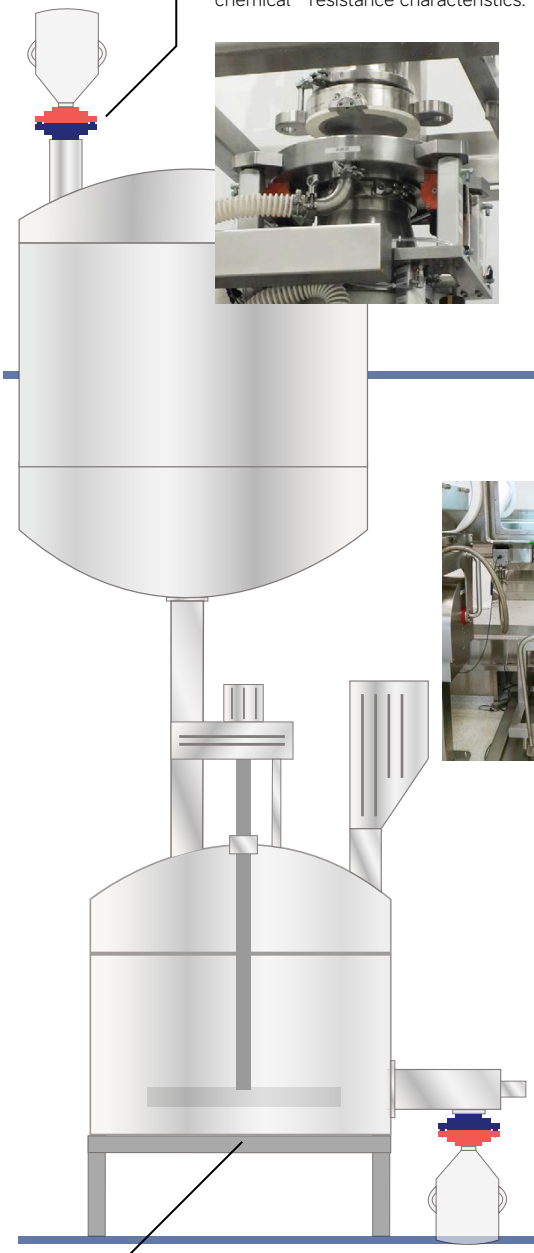
• Ensure the containment of IBC containers, assist in material transfer and improve production.
• Possess high - temperature and chemical - resistance characteristics.

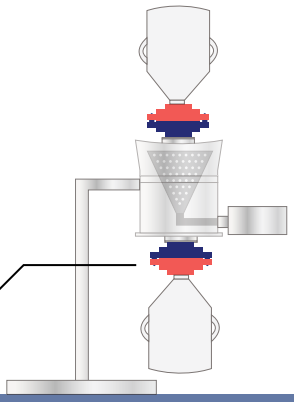
Dispensing Funnel Cross-Section



Powder Dosing

• Integrated Modular Dosing Station: provides weight verification during the dosing process.
• Isolator-Integrated Dispensing Funnel: enhances valve sealing performance and minimizes product loss during material transfer.





Dryer Discharging

• Filter/Dryer to IBC & Other Containers: enables safe material discharging into IBCs and other containers.

Closed Grinding/Screening

• Sealed Feeding/Discharging: ensures contamination-free material handling in closed-loop operations.

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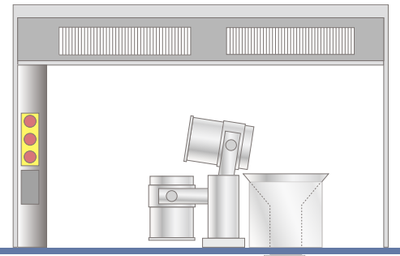
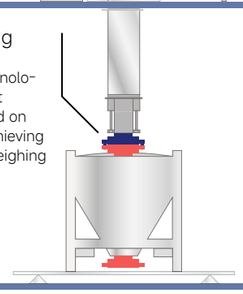
High Containment Downstream Pharmaceutical Production

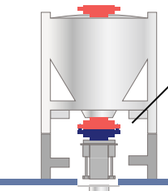
Full-Process Integrated Interface: enables seamless transition in multi-stage production



Material Dispensing

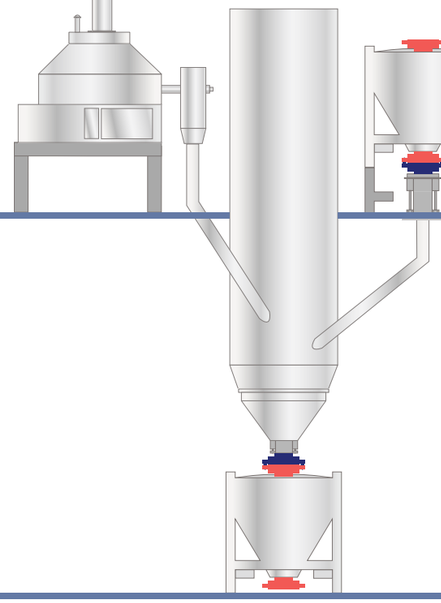
• Weight Isolation Technology-Driven: an intelligent weighing solution based on automated docking, achieving high-precision batch weighing and dispensing control.

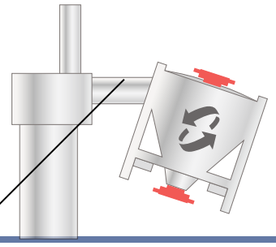




Manual and Automated Modes

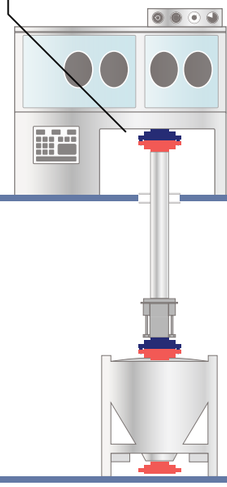
• Flexible Operation Configuration: In addition to automated operation, the valve can be optionally equipped with hand levers for manual operation to meet diverse application needs, thereby reducing costs and operational complexity.





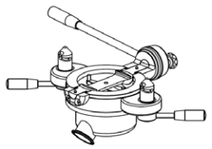
Efficient API transfer

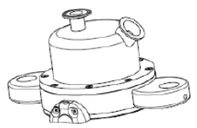
• Seamless Integration with Multiple Equipments: IBCs mounted with passive valves can be seamlessly transferred within different process units, thus eliminating leakage risks due to passive valve replacement.

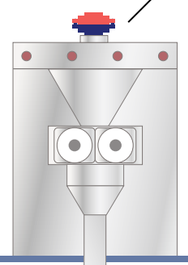


Wash-in-Place System (WIP)

• Enable closed in-situ cleaning via active washing valves, with drain port devices required for inverted installations.
• Certain designs can adopt rated pressure to adapt to working condition cycles such as recirculation, irrigation, or high-pressure cleaning.

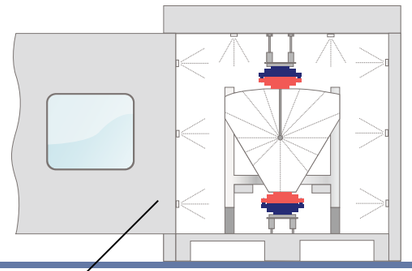






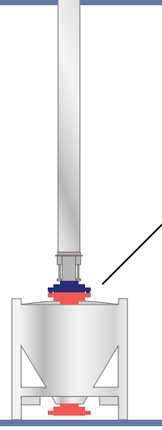
Safety-Optimized IBC Mixing System

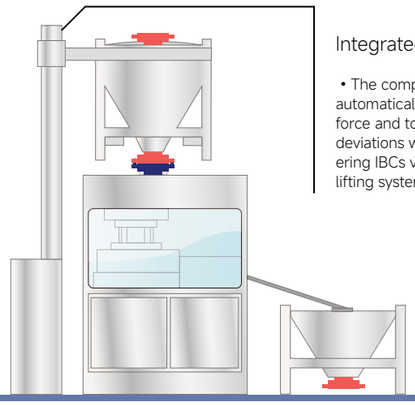
• Integrated auxiliary active covers to enhance IBC safety (passive covers are also available for active valves integrated on equipment).



Accuracy of Repeated Docking

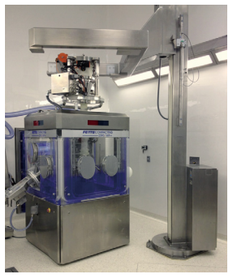
• A ±14mm docking tolerance significantly improves the effectiveness of automatic docking system, ensuring convenient and safe repeated operations.





Integrated Lifter for Convenient Docking

• The compensator automatically adjusts docking force and tolerates allowable deviations when lifting/lowering IBCs via the mechanical lifting system.



Effective IBC-cleaning

• Fully automated washing valves can be integrated into IBC cleaning stations for the whole process of automation control.
• Specifically engineered for efficient decontamination and reliable high-temperature performance.

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Specification Parameters

Product	AM	AF	AH	AE	AZ
Size	DN 050 - DN 300	DN 100 - DN 300	DN 100 - DN 300	DN 100 - DN 300	DN 100 - DN 300
Containment Performance	<1.0 μg/m^3	<1.0 μg/m^3	<1.0 μg/m^3	<1.0 μg/m^3	<1.0 μg/m^3
Operation	Manual	Manual	Manual	Automatic	Automatic
Process Interface	Tri-Clamp/ Flange	Tri-Clamp/ Flange	Tri-Clamp/ Flange	Tri-Clamp/ Flange	Tri-Clamp/ Flange
Flow Direction	Both Directions	Both Directions	Both Directions	Both Directions	Both Directions
Product-Contact Parts (standard/customised: Alloy59、HC276, etc.)	1.4404/316L	1.4404/316L	1.4404/316L	1.4404/316L	1.4404/316L
Non-Product-Contact Parts (standard)	1.4301/304	1.4301/304	1.4301/304	1.4301/304	1.4301/304
Elastomers	EPDM/FPM/FFKM (white or black)	EPDM/FPM/FFKM (white or black)	EPDM/FPM/FFKM (white or black)	EPDM/FPM/FFKM (white or black)	EPDM/FPM/FFKM (white or black)
Cleaning	WIP/CIP	WIP/CIP	WIP/CIP	WIP/CIP	WIP/CIP

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