

VENABIO® BAG 2D

It is especially recommended for media and buffer formulation, storage, mixing, and transportation in the biopharmaceutical industry.

VENABIO® BAG 2D is a single use bioprocessing container suitable for media and buffer formulation, storage, mixing and transportation. They help increase plant productivity by avoiding cleaning validation. The ethylene vinyl alcohol 0,01mm layer provides high oxygen and moisture impermeability equivalent to 1m thick of PE.

PROPERTIES

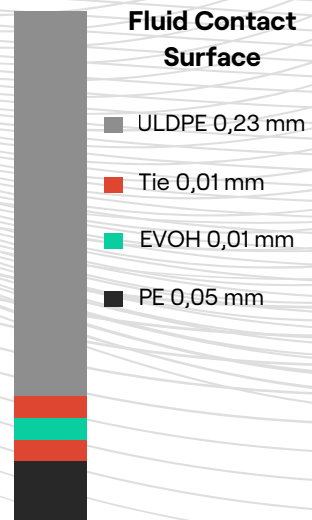
Versatile containers excel in a wide range of bioprocessing applications, providing a robust platform for your SUS solutions. From sterile storage and transportation of drug substances to cell culture media preparation, aseptic filling and dispensing, our containers offer unparalleled flexibility and adaptability to suit your specific needs.

- Manufactured in Barcelona (Spain) in an ISO 14644-1 Class 7 certified cleanroom
- Temperature ranging from -45°C to 60°C; Wider temperature ranges can be evaluated based on specific technical applications and end-user requirements
- 100% leak testing based on ASTM F2095-7
- Transport validation based on ASTM D 4169-22
- Successful 7-day hang test and integrity testing report
- Low extractable profile in both film and port
- The recommended sterilization method is gamma irradiation (25 kGy).
- Optionally sterilized (Sterility Assurance Level (SAL) of 10⁻⁶) according to ISO 11137-1
- Excellent resistance to many chemicals and polar solvents
- Low water sorption
- Compatible with pH ranging from 2.5 to 11
- Fully biocompatible, TSE/BSE and animal derived components free

CONSTRUCTION MATERIALS

At the heart of our single-use bioprocess containers lies a commitment to using only the highest-quality materials. Pharmaceutical-grade plastics ensure biocompatibility and inertness, eliminating the risk of contamination and protecting the integrity of your biotherapeutics. Reinforced construction provides superior strength and resistance to harsh environments, ensuring long-lasting performance even under demanding conditions. EVOH is used as oxygen barrier material, further safeguarding the purity of your products.

Physical Property	Method	Typical value post-sterilization
Film Thickness	-	0.325 mm
Haze	ASTM D-1003	7%
Clarity	ASTM D-1003	97%
Tensile Strength at break	ASTM D-882	13 MPa
Elongation at break	ASTM D-882	350%
Density	ASTM D-792	0.9 g/cm ³
Water vapor transmission rate	ASTM F-1249	0.32 gms./m ² /day (23° C, 100% RH)
O ₂ permeability	ASTM D-3985	<0.05 cm ³ /m ² /day/bar (23°C, 0%RH)
CO ₂ permeability	ASTM F-2476	<0.2 cm ³ /m ² /day/bar (23°C, 0%RH)



STERILIZATION

- Gamma (25kGy)*

*Sterilization available prior shipment.

BIOCOMPATIBILITY

- ADCF
- USP <85>
- USP <87>
- USP <88>
- USP <661.1>
- ISO 10993-4
- ISO 10993-5
- ISO 10993-6
- ISO 10993-10
- ISO 10993-11
- EP <3.1.5>

For complete validation package, please contact your sales representative.



EXTRACTABLES

- European Pharmacopeia 3.1.5
- USP <661.1>
- BPOG Extractables protocol (only performed on the film)

OTHER DOCUMENTATION

- Full validation guide and original extractable data available
- Certificate of Conformance
- Certificate of analysis per lot
- Batch release with USP <85> Bacterial Endotoxins and USP <788> Particulate matter in injections available per batch
- Transport validation, hang test and 100 % integrity tested with a validated pressure-decay methodology following the guidelines described in ASTM F2095

CONFIGURATIONS

DESCRIPTION	LONG (mm)	WIDE (mm)	Port 1	Port2	Port3	REFERENCE
VENABIO SAMPLING BAG 50mL 2x1/8	150	100	1/8	-	1/8	900300000050
VENABIO SAMPLING BAG 150mL 2x1/8	200	105	1/8	-	1/8	900300000150
VENABIO SAMPLING BAG 250mL 2x1/8	220	125	1/8	-	1/8	900300000250
VENABIO SAMPLING BAG 500mL 2x1/8	255	150	1/8	-	1/8	900300000500
VENABIO PROCESS BAG 1L 1/8 2x1/4	315	180	1/4	1/4	1/8	900300001000
VENABIO PROCESS BAG 2L 1/8 2x1/4	370	220	1/4	1/4	1/8	900300002000
VENABIO PROCESS BAG 5L 1/8 2x1/4	465	290	1/4	1/4	1/8	900300005000
VENABIO PROCESS BAG 10L 1/8 2x3/8	555	360	3/8	3/8	1/8	900300010000
VENABIO PROCESS BAG 20L 1/8 2x3/8	670	440	3/8	3/8	1/8	900300020000
VENABIO PROCESS BAG 50L 1/8 2x3/8	795	650	3/8	3/8	1/8	900300050000



CONTACT

