



Jm



SEPARATIONS

filters

■ **bags**

installations

centrifuges

jm separations

bag technology

JM Separations is a reliable name amongst all of the consultants and total suppliers for the biopharmaceutical process industry. After all, those of you that sift through all of those suppliers automatically end up at JM Separations. By introducing know-how and expertise in separation technology and biopharmaceutical fluid handling into the market for more than 30 years, JM Separations has now developed into a dynamic total supplier in the field of separation and sterile fluid handling systems in Europe.



production facility

quality and in-place procedures

Due to the new developments into the biopharmaceutical industry, JM Separations BV has started their own production facility for production of sterile fluid handling bags, manifolds and tankliners. The production facility is FDA and EMEA compliant, and all procedures and protocols are according to cGMP guidelines. The production takes place in a 4500 m² cleanroom, class 10.000 (ISO 141611-1, class 4) divided over three (3) locations.



During the production, the following tests are performed on the JM Bag Technology Products:

- IPC leak tests
- IPC seal strength tests
- IPC seal strength test of the ports and mounted components
- 100% visual control of finished products
- Process parameters release (temperature, pressure and time)

validation

jm bag film

The film used for the JM Bag Technology is a state-of-the-art film based on the current demands which are present for these products within the (bio)pharmaceutical industry. It is manufactured within a class 10.000 (ISO 14644-1, class 4) cleanroom according to cGMP procedures.

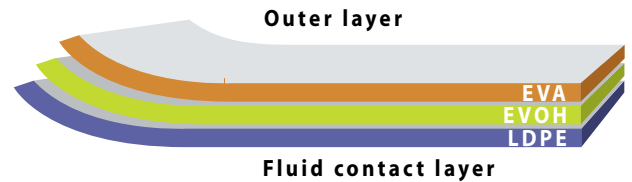
The materials which are used comply to the FDA regulations 21CFR175.105 and 21 CFR177.1520.

The film has excellent barrier characteristics, is very strong but still flexible and easy to handle and complies to all USP and EP regulations.

As well the film as the completed bags have also passed a very extensive validation study. At this moment, the JM Bag Technology is the product which has the most extensive regulatory file available for our customers. This film is used through out the complete product line of the JM Bag Technology products, so there is only one(1) film to validate.



The film is a multi-layer laminate and is built up as follow:



Physical Tests:

- O₂ transmission (ASTM D-3985)
- CO₂ transmission (ASTM D-1434)
- H₂O vapour transmission (ASTM E-96-80)
- Elongation tests, tensile strength tests and 100% modulus (ASTM D-638)
- Tear resistance tests (ASTM D-1004)

USP Biologicals / ISO 10993:

- Implantation tests (ISO 10993-6)
- Cytotoxicity tests (ISO 10993-5)
- Sensitization tests (ISO 10993-10)
- Irritation Tests (ISO 10993-10)
- Acute System Toxicity Test (ISO 10993-11)
- Kinetic LAL (USP 26, NF21, 2003 <85>)

USP Chemicals:

- Material Characterization Study
- USP 26, Physicochemical Testing (<661> "containers – physicochemical tests – plastic")

EP conformity testing

- EP 3rd. edition, chapter 3.1.5

Sterilization validation

- AAMI/TIR 27 VD max

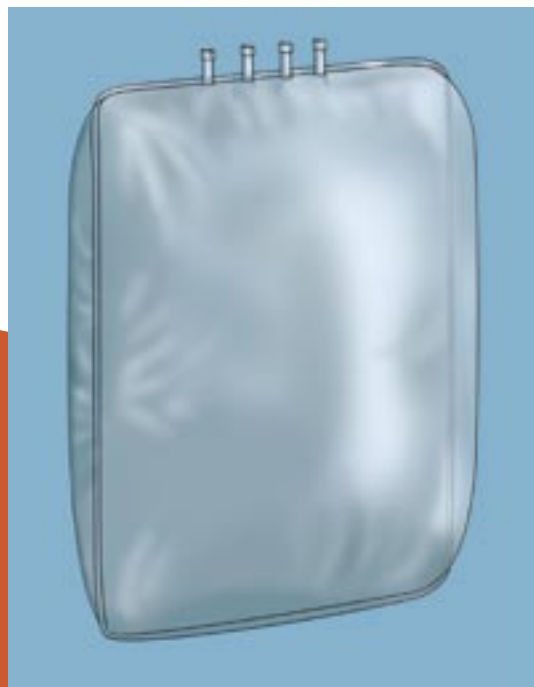
Comprehensive extractible studies available

A complete validation guide is available.

jm bags

standard pillow bags

- SIZES** From 50 ml up to 50 litre
Bags larger than one litre have a handle bar incorporated for easy transportation.
- PORTS** Up to 4 connections possible with diameters from 1/4" up to 3/4". Sample / injection ports are also possible.
- TUBING** All sizes and materials are available.
- CONNECTIONS** All commercially available connectors.
- ACCESSORIES** Filter capsules, sample bags, tubing manifolds, etc.

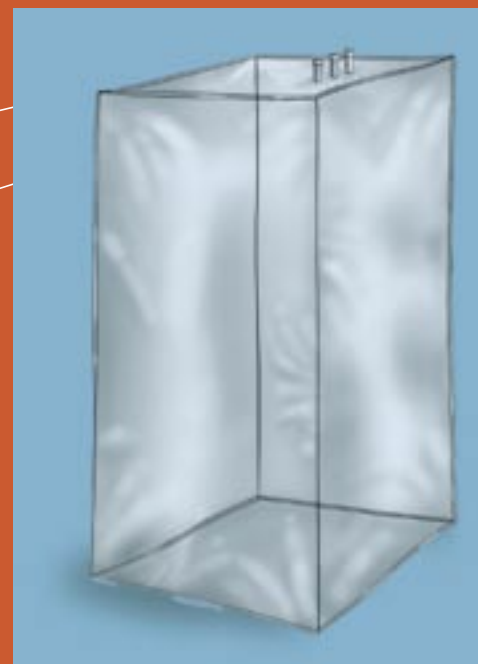


cylindrical tank bags

- SIZES** From 50 litre up to 500+ litre
Fits into commercial available cylindrical tanks and custom designed cylindrical tanks.
- PORTS** Up to 4 connections possible with diameters from 1/4" up to 3/4". Bottom outlet ports are also possible.
- TUBING** All sizes and materials are available.
- CONNECTIONS** All commercially available connectors.
- ACCESSORIES** Filter capsules, sample bags, tubing manifolds, etc.

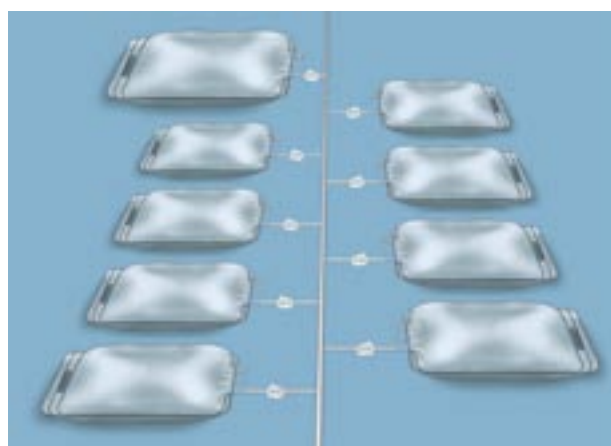
cubic tank bags

- SIZES** From 50 litre up to 1.000+ litre
Fits into commercial available cubic tanks and custom designed cubic tanks.
- PORTS** Up to 4 connections possible with diameters from 1/4" up to 3/4". Bottom outlet ports are also possible.
- TUBING** All sizes and materials are available.
- CONNECTIONS** All commercially available connectors.
- ACCESSORIES** Filter capsules, sample bags, tubing manifolds, etc.



rectangular bags

- SIZES** From 50 litre up to 1.000+ litre
Fits into commercial available rectangular tanks and custom designed rectangular tanks.
- PORTS** Up to 4 connections possible with diameters from 1/4" up to 3/4". Bottom outlet ports are also possible.
- TUBING** All sizes and materials are available.
- CONNECTIONS** All commercially available connectors.
- ACCESSORIES** Filter capsules, sample bags, tubing manifolds, etc.



bag manifolds

These can be made exclusively of small bags, manifolded together through different flowpaths, or starting from a larger bag with the addition of a complete sample and/or preparation flowpath.



- TUBING** All sizes and materials are available.
- CONNECTIONS** All commercially available connectors.
- ACCESSORIES** Filter capsules, sample bags, tubing manifolds, etc.

Tankliners

- SIZES** Up to 1.000+ litre.
LDPE fluid contact layer.
Fits into all commercially available containers.



accessories

accessories

In addition to the JM bags, there is also a complete line of bag related



Tubing

- C-Flex™
- Pt-Cured silicone tubing
- Reinforced (silicone) tubing
- Pharmed™ tubing
- Tygon 3350™ Silicone tubing



Connectors

- Complete line of CPC™ quick-disconnect connectors
- Steamable single-use CPC™ connector
- Sterile connectors
- All types of Y and straight connectors and reducers
- Plastic Tri-Clover hosebarb adapters
- Luer-lock™ connectors
- Other commercial available connectors.

Filters

We can implement and install all commercially available gamma irradiable capsule filters, independent of the supplier.

This gives the end-user the opportunity to use the (already) validated capsule filters.

Other Accessories

- Barb-Lock™ hose connection systems
- Custom tubing manifolds
- Mini sanitary to hose barb fitting
- Sanitary to hose barb fitting



hardware hardware

Stainless Steel Containers

JM Separations developed its own transport container system can accommodate the JM bags. This container is made out of stainless steel and is available for different volume bags. The container is set-up in such a way that the filled JM bag is optimally protected during the transportation.

There are separate storage chambers for the bottom drain tubing (assembly), the top tubing assembly and the bag itself which are all very easily accessible. Furthermore, depending on the volume of the bag, the height can be adapted to create an optimal fit during the transportation.

Additionally, the container can be transported by any forklift device and can be stacked (full or empty). Further, a special rack is mounted on the side to assure that the labeling or batch-record will remain with the product stored in the JM bag(container).





211 bis av. J.F. Kennedy - B.P. N° 1140
03103 Montluçon Cedex - France
☎(33) (0)4 70 03 88 55 (+)
Fax (33) (0)4 70 03 82 60
interbiotech@interchim.com

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