Millipore®
Preparation, Separation,
Filtration & Monitoring Products

Your Goal is ZERO POSITIVES. So is Ours.

Granulated and Ready-to-Use Culture Media for Secure Aseptic Process Simulation (APS)

When performing APS, you shouldn't have to worry about culture media compromising your validated process and you won't have to with our irradiated media. Every batch is carefully tested for sterility and growth performance.

Our granulated media also offer excellent cold filtration properties to avoid clogged filters and our media comes triple-wrapped making it cleanroom ready. for the ultimate security of your aseptic process.

Superior quality and reliability

- Choice of compositions: standard Tryptic Soy Broth or non-animal peptone broth
- Halal and Kosher certified granulated medium version available
- Flexible formats: granulated culture media in 500 g or up to 10 kg triple-wrapped drums; ready-to-use liquid in 10 L bags
- Validated irradiation process
- BSE/TSE and viable mycoplasma free
- Triple-wrapped for safe transfer to cleanrooms
- Proven growth performance exceeding EP and USP standards

The Life Science business of Merck operates as MilliporeSigma in the U.S. and Canada.

MERCK

Aim for Accuracy with Reliable Culture Media

True safety

Accurate and convenient media fill trials

False results due to low-quality culture media are a major concern in APS. With the robust validated process of our high-quality broths, you can eliminate media-related positives from your aseptic process simulation. Our stringent sterilization process inactivates all viable bacteria, yeast, mold, spores, and mycoplasma.

Our granulated and liquid media are both available as either Tryptic Soy Broth (TSB) or non-animal Vegetable Peptone Broth (VPB). Simply choose the format that suits your needs:

- **Dehydrated culture media:** Gamma-irradiated; highly soluble and filterable in low-dust granulated form; triple-wrapped for secure cleanroom use
- **Ready-to-use liquid broth:** Supplied triple-wrapped in gas-impermeable bags for aseptic connections; direct link to production vessels and delivery systems

Top standards

Internationally compliant quality — BSE/TSE free

Whether vegetable- or animal-based, every batch of our culture media is produced and tested in compliance with stringent international standards. We source all concerned bovine ingredients exclusively from countries classified by the OIE as negligible risk countries.

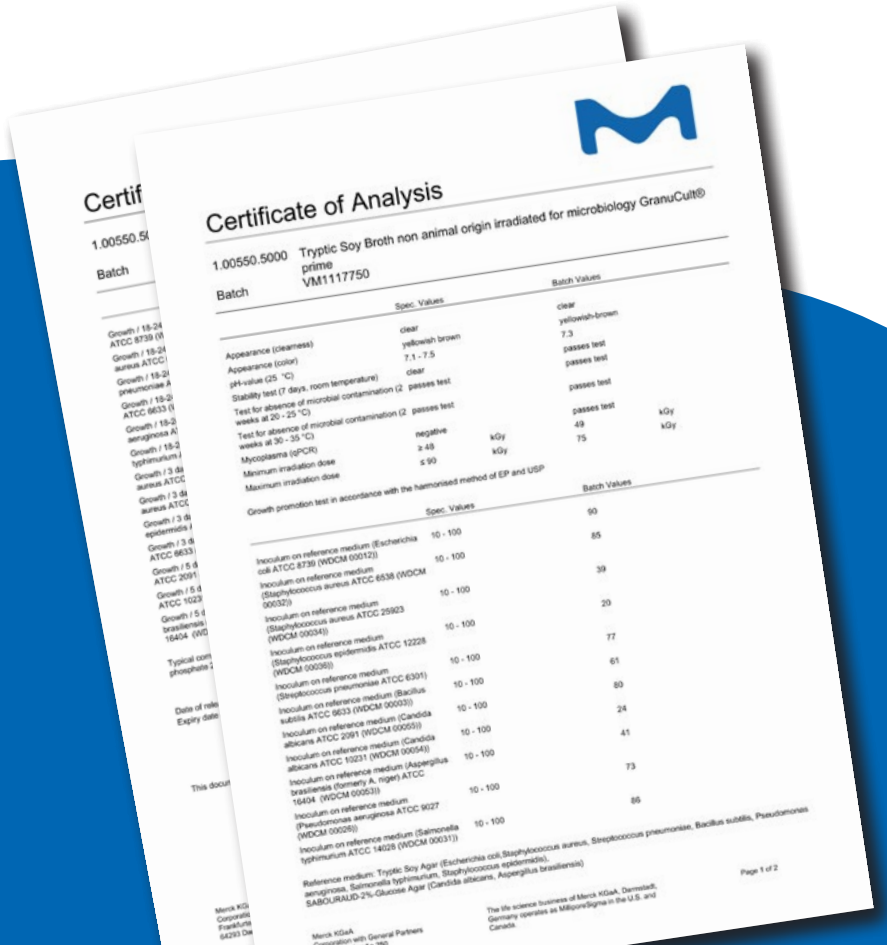
- EU Note for Guidance (EMA/410/01 Rev. 03) aimed at minimizing the risk of infection from animal spongiform encephalopathy via pharmaceutical products
- USDA standards for validation of aseptic preparations
- All culture media with bovine peptones already comply with the future EU Directive on minimizing the risk of BSE from products of animal origin

Total confidence

Comprehensive documentation

Detailed documentation is available for every culture medium we supply. Not only does this support critical attributes of your aseptic process simulation, it also simplifies your audits.

- **BSE/TSE certificates** provide full traceability of all animal-derived material and facilitate compliance with requirements -specified products are annually certified acc. to JAKIM MS and MUIHAS halal standards and also by KF Kosher and Fidelity Kosher.
- **Quality agreements with suppliers** ensure the consistent quality of our products
- **Certificates of Analysis** include detailed information about each product, such as actual results obtained from quality control testing



Granulated Culture Media

Minimal dust, maximum security and performance

Our granulated culture media has been carefully formulated to ensure pharmaceutical manufacturers can perform efficient media fill trials with minimal risks.

- Reduced dust spread during preparation lowers health risks and prevents environmental contamination. Less dust on equipment also eases handling and cleaning.
- Excellent solubility significantly reduces preparation time and effort.
- Optimized cold filtration properties, from raw materials to final product, help prolong filter life and reduce replacements, saving time and costs.
- Irradiated at a high dose to reduce microbial cross-contamination and risk of false positives due to resistant organisms.
- Growth promotion and sterility performance in compliance with harmonized pharmacopeia and ISO® EN 11133 guidelines regarding production and performance testing.

Optimized cold-filtration avoids clogs and costs

Most aseptic filling processes involve a sterile filtration step, which is typically part of the process simulation with culture media. The large amounts of liquid running through the filters make this step both time-consuming and expensive. This is of particular concern when problems, such as clogs, occur.

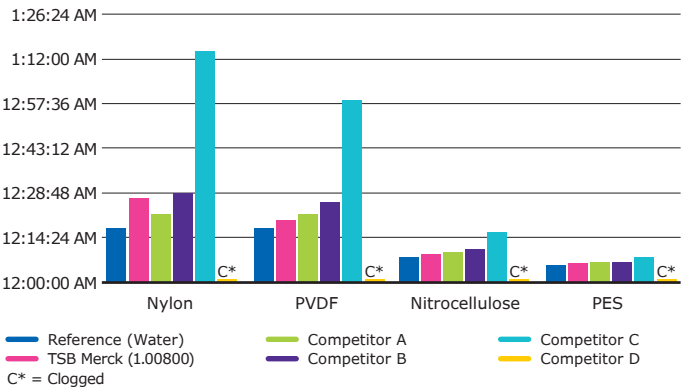
To avoid such challenges, we take every measure to ensure the reliable cold-filtration properties of its granulated culture media. Filtration tests are performed at every stage and for every batch:

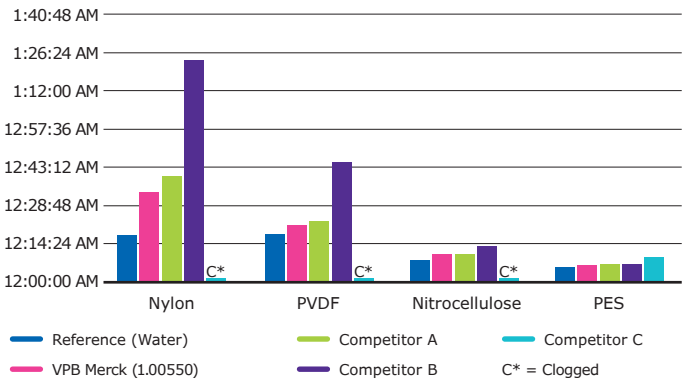
- Qualification of raw materials
- Control of incoming peptones
- Pre-batch samples and in-process testing
- End product testing

Filterability study

A study was conducted to compare the filtration performance of our conventional and non-animal TSB with other commercially available culture media. Tests were performed on four commonly used filters. Comparison was based on three runs for each combination of media batch and filter.

Figures 1 and 2 illustrate the average time needed to filter two liters of media through a 47 mm diameter filter. The results demonstrated the excellent filtration properties of our TSB and VPB — even with more challenging nylon and PVDF filters. Our Tryptic Soy Broth and Vegetable Peptone Broth demonstrated superior filtration performance when compared to culture media from other producers.





	Nylon	PVDF	Nitrocellulose	PES
Reference (Water)	00:17:38	00:17:40	00:08:07	00:05:29
Merck	00:27:06	00:20:14	00:09:23	00:06:09
Competitor A	00:21:49	00:21:54	00:09:58	00:06:30
Competitor B	00:28:44	00:25:52	00:10:51	00:06:26
Competitor C	01:14:14	00:58:33	00:16:27	00:08:00
Competitor D	clogged	clogged	clogged	clogged

Figure 1: Filterability Comparison Tryptic Soy Broth (TSB)

	Nylon	PVDF	Nitrocellulose	PES
Reference (Water)	00:17:38	00:17:40	00:08:07	00:05:29
Merck	00:33:54	00:21:17	00:10:13	00:06:09
Competitor A	00:39:56	00:22:52	00:10:26	00:06:32
Competitor B	01:23:32	00:44:51	00:13:27	00:06:40
Competitor C	clogged	clogged	clogged	00:09:16

Figure 2: Filterability Comparison Vegetable Peptone Broth (VPB)

More data about the study is available in a comprehensive application note. To obtain a copy, please contact your sales representative, or visit: **SigmaAldrich.com/aps**

Filters used in study

Manufacturer	Material	Pore Size	Ordering No.
Merck	Nylon Membrane	0.20 µm	**GNWP04700**
Merck	Durapore® Polyvinylidene Fluoride (PVDF)	0.22 µm	**GVWP04700**
Merck	Nitrocellulose Membrane	0.22 µm	**GSWP04700**
Merck	Millipore Express® Plus Polyethersulfone (PES)	0.22 µm	**GPWP04700**

Ready-to-Use Liquid Media

Pre-filtered and ready to go

Our ready-to-use culture media include Tryptic Soy Broth (TSB) prepared according to European and US pharmacopeias. Alternatively, you can choose our Vegetable Peptone Broth (VPB). These liquid broths are first sterilized by autoclave, and then undergo a two-step pre-filtration process consisting of a particulate filter to avoid clogging, and a 0.2 µm filter for sterilization. The media is supplied in 10 liter bags that are triple-layered and gamma-irradiated at 9–20 kGy for enhanced safety.

Gas-impermeable bags for greater safety and convenience

The self-collapsing bags include an 80 cm long tube with an MPC connector (male insert 3/8”) or a Lynx® connector, which enables direct connection to the filling line. An injection port with a septum allows the supplementation of the broth medium, for example with neutralizers, antibiotics inactivators, or growth supplements.

MPC connector

Lynx® connector

Connections of bag: injection port, outlet tubing, inlet tubing (from left to right)

Handle at top of bag for convenient use

Tripple-bagged 10 L bag containing TSB in transport box

Ordering Information

Description	Granulated	Ready-to-use	Package Size	Ordering No.
GranuCult® Prime Tryptic Soy Broth (irradiated)	•		5 kg	**1008005000**
GranuCult® Prime Tryptic Soy Broth (irradiated)	•		500 g	**1008000500**
GranuCult® Prime Tryptic Soy Broth – non-animal origin (irradiated)	•		5 kg	**1005505000**
GranuCult® Prime Tryptic Soy Broth - non-animal origin (irradiated)	•		500 g	**1005500500**
GranuCult® Prime Vegetable Peptone Broth - Halal & Kosher (irradiated)	•		5 kg	**1027545000**
GranuCult® Prime Vegetable Peptone Broth - Halal & Kosher (irradiated)	•		500 g	**1027540500**
GranuCult® Plus Thioglycolate Broth - non-animal origin (irradiated)	•		5 kg	**1087205000**
Tryptic Soy Broth (self-collapsing bag, irradiated, MPC connector)		•	10 L	**1463160001**
Vegetable Peptone Broth (self-collapsing bag, irradiated, MPC connector)		•	10 L	**1463320001**
Vegetable Peptone Broth 10l Lynx® (self-collapsing bag, irradiated, Lynx® S2S connector)		•	10 L	**1467490001**

Please contact your local sales representative for customized solutions.

See the benefits in action

Watch our video to learn more about our culture media.

SigmaAldrich.com/aps

To place an order or receive technical assistance:
SigmaAldrich.com/support

For local contact information:
SigmaAldrich.com/offices

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We have built a unique collection of life science brands with unrivalled experience in supporting your scientific advancements.

Millipore® Sigma-Aldrich® Supelco® Milli-Q® SAFC® BioReliance®

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