



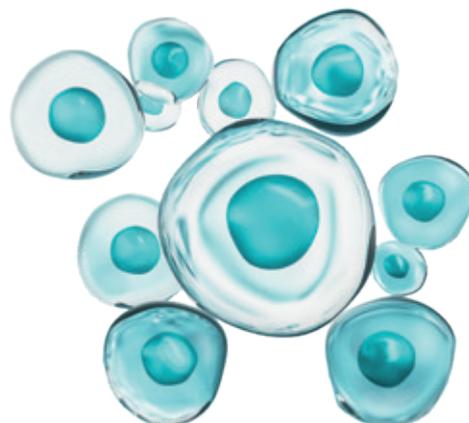
Kolliphor® P 188 Bio

High purity poloxamer designed for biologics manufacturing

Cell cultures used in biologics manufacturing have stringent requirements that must be met in order to ensure high cell viability and consistent biologic drug yield. For protection from shear stress, poloxamer 188 has a long publication history as well as documented use in the manufacturing of approved biologics.

With over 50 years experience in EO/PO chemistry, BASF is committed to providing Kolliphor® P 188 Bio, which is designed to meet your needs in quality, consistency, and performance in cell culture systems.

- ✓ Consistent performance lowers manufacturing risk
- ✓ Validated RP-HPLC assay to ensure highest purity
- ✓ Enhanced packaging
- ✓ Compendial grade with Drug Master File



 **BASF**
We create chemistry

Pharma Solutions. Focusing on your needs with platform solutions.

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Product Details

Brand/Trade name

Kolliphor® P 188 Bio

Intended use

Produced in accordance with IPEC-PQG GMP Guide for Pharmaceutical Excipients and 21 CFR Parts 210/211

cGMP quality

cGMP

Monograph quality

EP, USP, JPE

Documentation

COA, Drug Master File, Third-party Audit Report, additional regulatory documents

Packaging

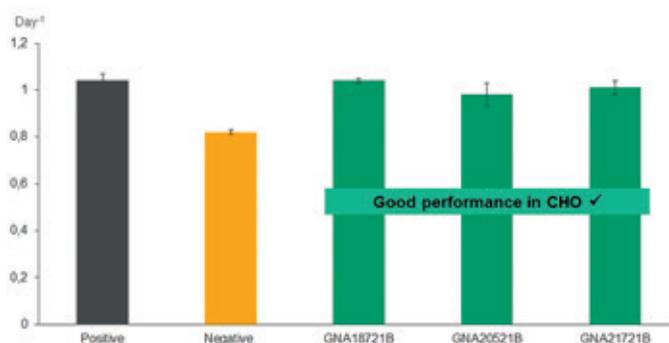
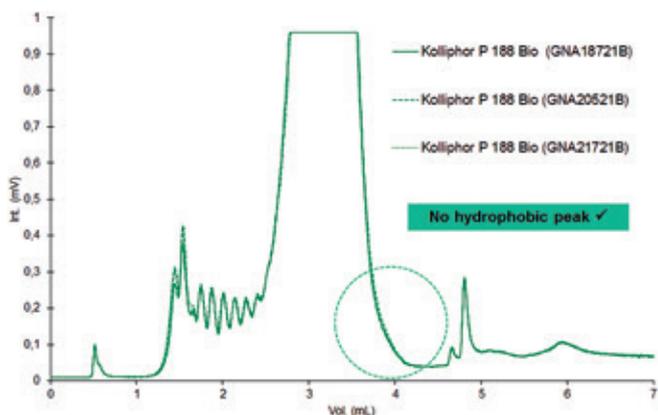
- 500 g samples
- 5 kg, 12.5 kg, 25 kg, 102 kg
- In HDPE drums
- Double PE liners
- Tamper-evident seals

Validated cleaning process

Stringent controls for highest purity

Quality tests for cell culture suitability

- Endotoxin
- Total yeast and mold count (TYMC)
- Total aerobic microbe count (TAMC)
- Cell culture growth and viability assay
- Analytical chemistry analysis



Three independent lots of Kolliphor® P 188 Bio were tested. RP-HPLC assay shows no hydrophobic peak at retention time of 4 mL (left). The cell culture assay shows cumulative CHO cell count on day four as expected for lots with good performance.

Quality & Regulatory Status

Kolliphor® P 188 Bio is manufactured in Geismar, Louisiana, USA under cGMP conditions and complies with the following compendia: Ph. Eur, USP/NF, JPE.

Did you know...

BASF is the leading manufacturer of poloxamer P 188 (Kolliphor® P 188) with over 50 years of experience in EO/PO chemistry. In bioprocessing, poloxamer 188 has been extensively researched and has been found to be the most effective mammalian cell culture ingredient to provide shear protection during manufacturing of biologic drugs.

Get your sample today!
pharma-solution@basf.com