



Poloxamers for Biopharma: Upstream Cell Culture Applications

For more than 50 years, BASF has been producing poloxamer 188 for use in a broad range of applications. Meanwhile, biomanufacturing processes have intensified, so BASF keeps pace with requirements for shear protection by developing the next generation poloxamer 188. Building on the worldwide adoption of Kolliphor® P188 Bio, we introduce our newest product, Kolliphor® P188 Cell Culture, which is designed to meet a tight molecular weight specification, delivering excellent performance in a broader range of cell culture bioprocesses. Both compendial, GMP products display consistent performance and are supported to an extremely high level by all BASF Pharma Solutions functions.

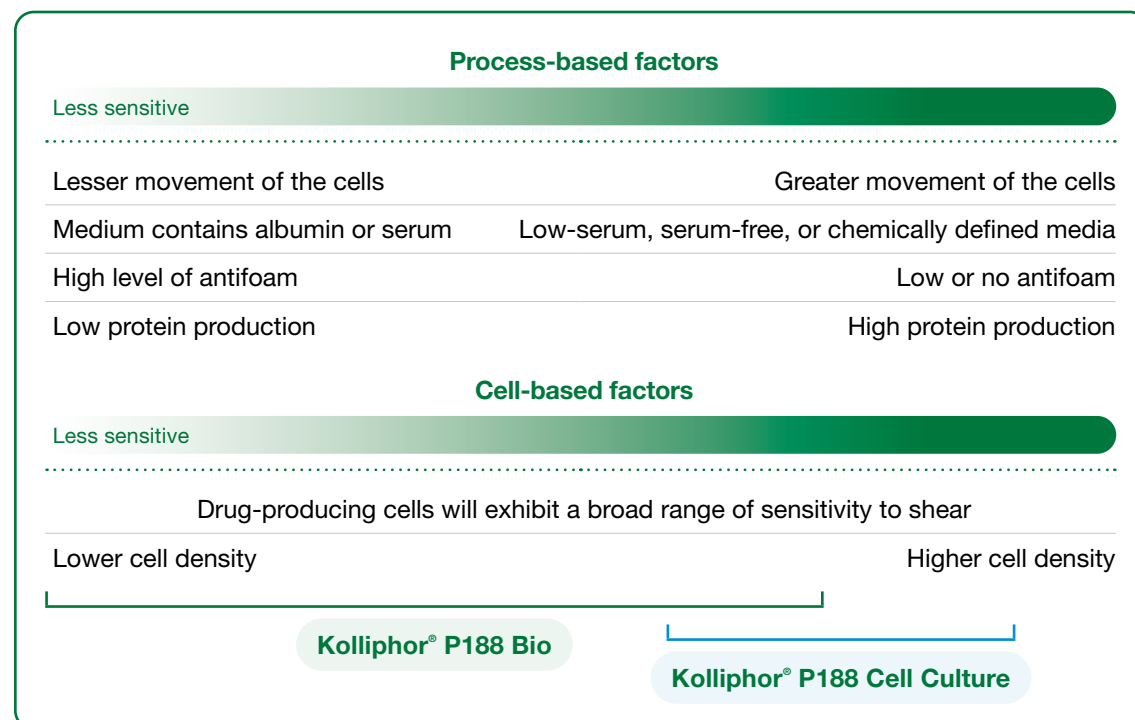
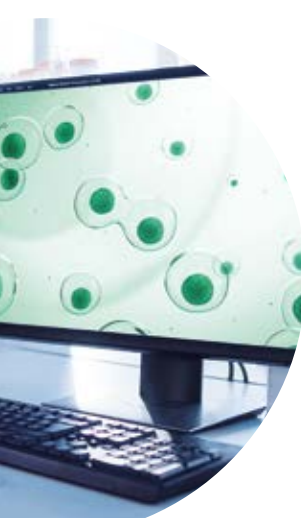


**Kolliphor®
P188 Bio**

**Kolliphor® P188
Cell Culture**

How Much Protection Do Your Cells Need?

Poloxamer 188 has a long publication history as well as documented use as shear protectant in the manufacturing of approved biologics. While many of the factors driving the need for shear protection are well described, critical parameters controlling performance continue to be investigated.



		Kolliphor® P188 Bio	Kolliphor® P188 Cell Culture
CAS Number	90003-11-6	●	●
Compendia	Ph. Eur., USP-NF JPE ¹ CP ²	● ● ●	● ●
Production	Manufactured in accordance with IPEC-PQG GMP Guide for Pharmaceutical Excipients 21 CFR Parts 210/211 at a multi-purpose site in Geismar, LA Special cleaning and other controls	● ●	● ●
Packaging	102kg plastic drum with double plastic liners Additional sizes: 25kg, 12.5kg, 5kg	● ●	●
Biological Testing	Specific germs, TYMC, TAMC, endotoxin, cell culture	●	●
Analytical Testing	RP-HPLC (for hydrophobic impurities) SEC (for average molecular weight) Trace metals ³	● ● ●	● ● ●

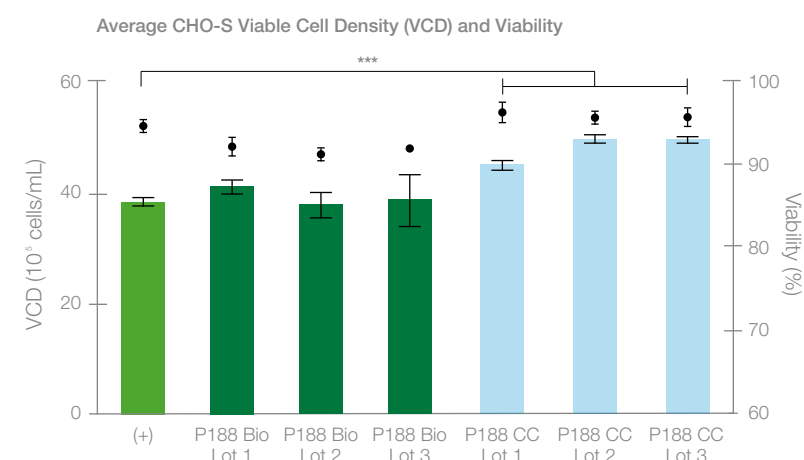
1 The product meets the test requirements of the current monograph of "Polyoxyethylene (160) Polyoxypropylene (30) Glycol" JPE, containing BHT.
2 The product meets the acceptance criteria stipulated in the "Poloxamer 188" monograph of ChP 2020, applying the methods named in the product specifications.
3 Data available upon request. Not a release parameter.

Kolliphor® Poloxamer Family

Enabling Biopharma Manufacturing with Options in Shear Protection

Kolliphor® P188 Bio is one of the highest quality, most controlled, poloxamers commercially available. We aim to deliver the same level of quality in our Kolliphor® P188 Cell Culture, which has additional molecular weight control for bioprocessing applications where a lower average molecular weight is beneficial.

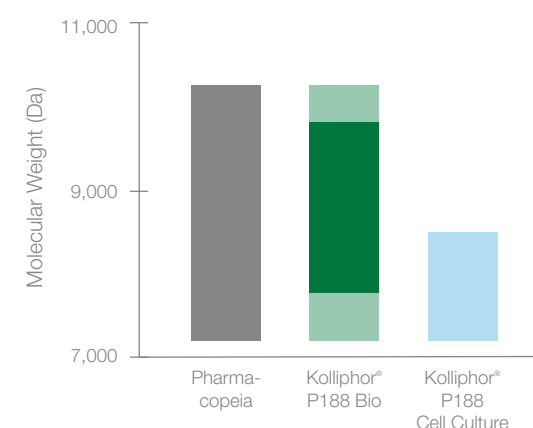
Two Products with Excellent Cell Culture Performance



Kolliphor® P188 Bio (green) and Kolliphor® P188 Cell Culture (blue) both perform well in high shear conditions (i.e. baffled flasks; 300 rpm) using GMP-banked CHO-S cells over 4 days in triplicate.

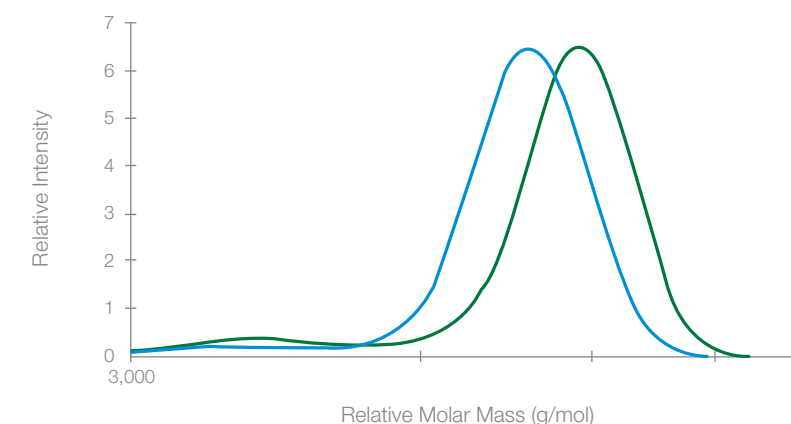
While the average cell viability was similar among the lots of poloxamer 188 tested, by day 4 there was a **statistically significant difference in viable cell numbers** in cells grown using Kolliphor® P188 Cell Culture when compared to the positive control.

Average Molecular Weight by Pharmacopeia Methods



Molecular Weight specification according to pharmacopoeia methods for Kolliphor® P188 Cell Culture (blue) and Kolliphor® P188 Bio (green). The dark green band shows the typical range of commercially available lots.

Average Molecular Weight Distribution by SEC



Kolliphor® P188 Bio & Kolliphor® P188 Cell Culture: Transparency of Key Information

BASF is committed to providing you the technical, quality, and regulatory support you need to effectively manage this critical raw material. BASF makes available a broad range of quality and regulatory documents to our customers via our Virtual Pharma Assistant (VPA) tools. Because of the unique needs of the biopharma industry, there is also the possibility to support ad-hoc and customized requests for information not covered by our standard documentation. Furthermore, our commitment to closely partner with the biopharma industry enables us to be transparent about key information, which can equip the Quality and Regulatory stakeholders at our customers with a clear and confident view of how **Kolliphor® P188 Bio & Kolliphor® P188 Cell Culture** can mitigate risk for the biopharma manufacturer.

Exceptional Quality & Regulatory Support



The Pharma Solutions Regulatory Team has a global and regional presence with a decades-long track record of enabling our Pharma customers to register finished drug products worldwide. We do this by efficiently offering high-quality expert solutions through proactive and transparent communication.

Our global Quality Team supports our customers worldwide with regards to any quality-related questions.

A regional footprint secures quick and regional-specific solutions in alignment with global standards for topics like audits, statements and complaints.

In close exchange with authorities and international associations, we are constantly improving our quality systems to provide the best service to our customers in more and more demanding markets. For this purpose we cooperate closely with the production sites and ensure GMP-compliant production and testing in accordance with the latest requirements of the pharmaceutical authorities.

This document, or any information provided herein does not constitute a legally binding obligation of BASF and has been prepared in good faith and is believed to be accurate as of the date of issuance. Unless expressly agreed otherwise in writing in a supply contract or other written agreement between you and BASF:

- (a) To the fullest extent not prohibited by the applicable laws, BASF EXPRESSLY DISCLAIMS ALL OTHER REPRESENTATIONS, WARRANTIES, CONDITIONS OR GUARANTEES OF ANY KIND, WHETHER EXPRESS OR IMPLIED, WRITTEN OR ORAL, BY FACT OR LAW, INCLUDING ANY IMPLIED WARRANTIES, REPRESENTATIONS OR CONDITIONS OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, SATISFACTORY QUALITY, NON-INFRINGEMENT, AND ANY REPRESENTATIONS, WARRANTIES, CONDITIONS OR GUARANTEES, ARISING FROM STATUTE, COURSE OF DEALING OR USAGE OF TRADE and BASF HEREBY EXPRESSLY EXCLUDES AND DISCLAIMS ANY LIABILITY RESULTING FROM OR IN CONNECTION WITH THIS DOCUMENT OR ANY INFORMATION PROVIDED HEREIN, including, without limitation, any liability for any direct, consequential, special, or punitive damages relating to or arising therefrom, except in cases of (i) death or personal injury to the extent caused by BASF's sole negligence, (ii) BASF's willful misconduct, fraud or fraudulent misrepresentation or (iii) any matter in respect of which it would be unlawful for BASF to exclude or restrict liability under the applicable laws;
- (b) Any information provided herein can be changed at BASF's sole discretion anytime and neither this document nor the information provided herein may be relied upon to satisfy from any and all obligations you may have to undertake your own inspections and evaluations;
- (c) BASF rejects any obligation to, and will not, automatically update this document and any information provided herein, unless required by applicable law; and
- (d) The user is responsible for confirming that the user has retrieved the most current version of this document from BASF as appropriate

© 2024 BASF MarComm-2024-XXXXX

Access to standard quality and regulatory documentation is now more efficient than ever. Retrieve your documents 24/7 from your World Account or sign-up for new RegXcellence®, your free online Quality & Regulatory Assistant that provides a unified platform for compliance documents, filing assistance and audit information.



Sign-up today at:
virtualpharmaassistants.basf.com

Request a sample:
pharma.basf.com/request-a-sample

 BASF Pharma Solutions


We create chemistry

Marcom_2024_00195