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# Technical Information

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# Kolliphor<sup>®</sup> P 188 Bio

# Kolliphor<sup>®</sup> P 188 Cell Culture

Poloxamer for Pharmaceutical & Biopharmaceutical Use

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® = Registered trademark of BASF in many countries.

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## 1. Introduction

BASF's Kolliphor P grade poloxamers are white, coarse - grained powders with a waxy consistency. They contain an appropriate quantity of the antioxidant BHT.

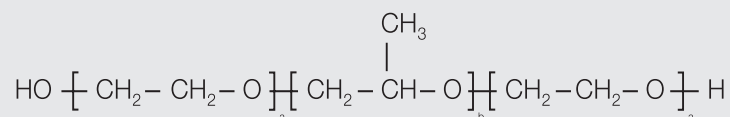
Poloxamers are ABA-type co-polymers of poly (ethylene oxide) (PEO=A) and poly (propylene oxide) (PPO=B). The approximate relative amount of PEO and the average molecular weight of the PPO are indicated in the name of the poloxamer. For example, P 188 succeeding the word Kolliphor® indicates a poloxamer with ca. 80% m/m PEO (P 188; 8x10= 80%) and approximately average molecular weight of PPO of 1800 (P 188; 18x100= 1800).

Kolliphor® P 188 Bio & Kolliphor® P 188 Cell Culture are designed for protection against shear stress in biologic drug manufacturing processes. It is also suitable as an excipient for parenteral formulations. Improvements in the manufacturing process and a validated RP-HPLC assay ensures the highest quality product for consistent performance and less variability versus other poloxamer 188 grades.

## 2. Technical properties

### Structural formula

The Kolliphor® P 188 Bio & Kolliphor® P 188 Cell Culture is a block copolymer that is a synthetic copolymer of ethylene oxide and propylene oxide represented by the following chemical structure:



Where in a and b blocks have the following values:

Poloxamer	a	b
188	75-85	25-30

### Appearance

Kolliphor® P 188 Bio & Kolliphor® P 188 Cell Culture is produced as a white to almost white prill/powder.



Figure 1: Appearance of Kolliphor® P188 Bio

### CAS Number

9003-11-6

### Solubility in water

Solubility in water at 25 °C measured gravimetrically is between 35-45 wt.%.

### Surface Tension

The static surface tension measured by the pendant drop method at 37 °C stabilizes after ca. 2 g/L.

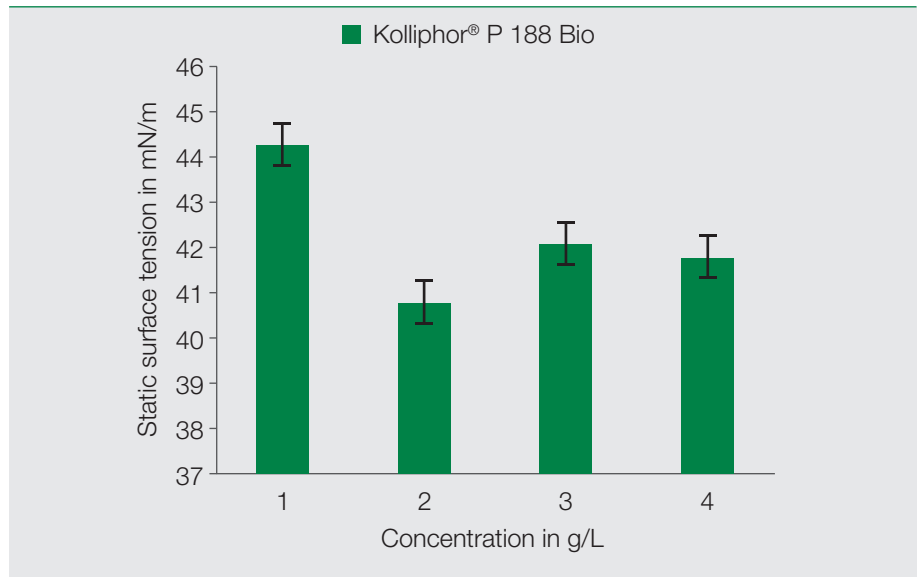


Figure 2: Surface tension as a function of concentration

### Molecular Weight

The average molecular weights for Kolliphor® P 188 Bio and Kolliphor® P 188 Cell Culture are targeted for different ranges within the current monograph specification. Kolliphor® P188 Cell Culture has a lower molecular weight target whereas Kolliphor® P 188 Bio is positioned higher. An example of the molecular distribution and positioning of the products is shown below in Figure 3.

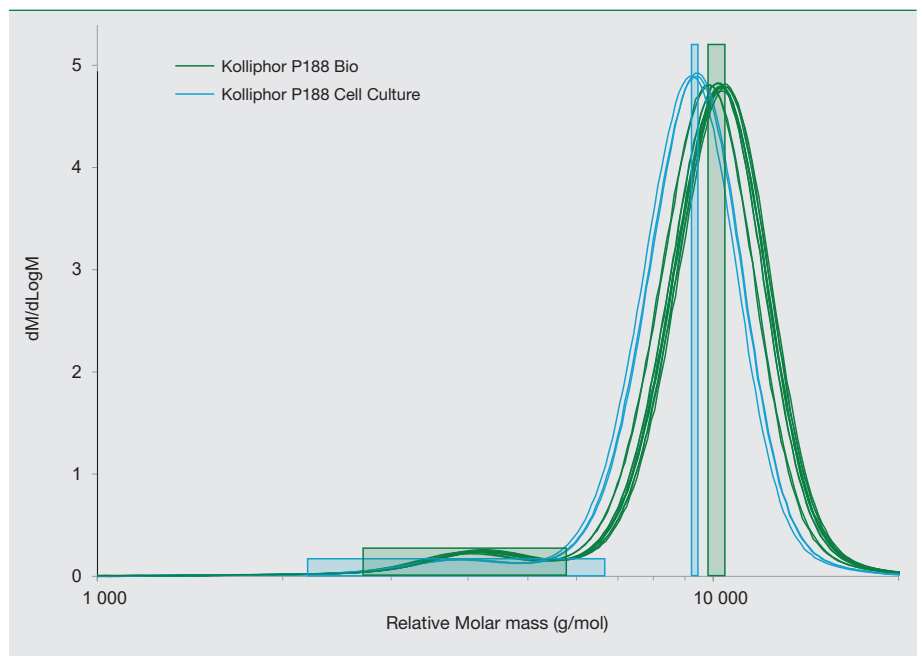


Figure 3: Size Exclusion Chromatogram of Kolliphor® P188 Bio & Kolliphor® P188 Cell Culture

The above graph was generated using size exclusion chromatography (SEC), note that the smaller peak to the left represents diblock polymers.

### Viscosity

Poloxamers exhibit a thermoreversible gelling behavior that occurs as a function of temperature. At low concentrations, aqueous concentrations exhibit Newtonian flow properties and negligible viscosity alterations to that of water, however, at higher temperatures, the solutions begin to exhibit non-Newtonian flow behavior. An example of the viscosity curve is evident in Figure 4 with the gel points clearly noted by the sharp increase in viscosity:

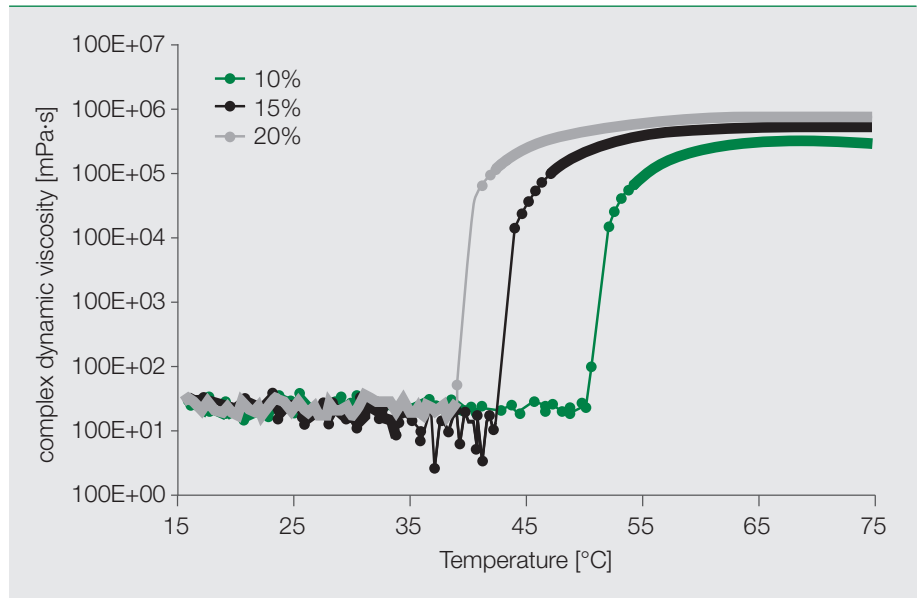


Figure 4: Viscosity changes of Kolliphor® P188 Bio solutions as function of temperature

### HLB

The HLB value of Kolliphor® P 188 Bio is approximately 16.

### Critical Micelle Concentration (CMC)

The critical micelle concentration for Kolliphor® P 188 Bio is ca.  $4.8 \cdot 10^{-4}$  mol/L @ 37 °C (4.1 g/L). Note that the CMC value decreases significantly as the temperature increases. Furthermore, due to the linear structure of the poloxamer, the value is difficult to ascertain as an inflection point using standard methods (such as Wilhelmy Plate Method). An example of the surface tension for Kolliphor® P 188 Bio as a function of concentration at 37 °C is shown in Figure 5.

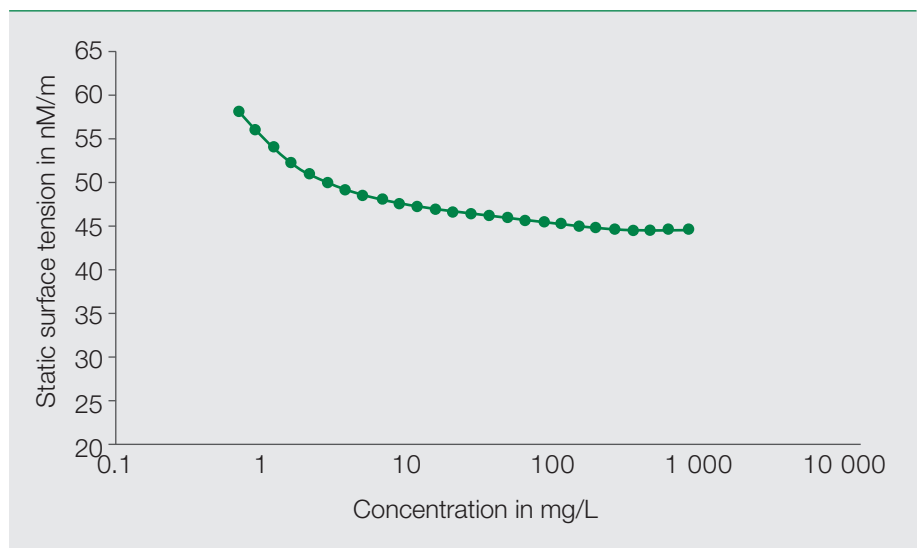


Figure 5: Surface tension as function of concentration

The micelle size is approximately 5 – 10 nm in diameter; this is shown in Figure 6 as determined via laser diffraction:

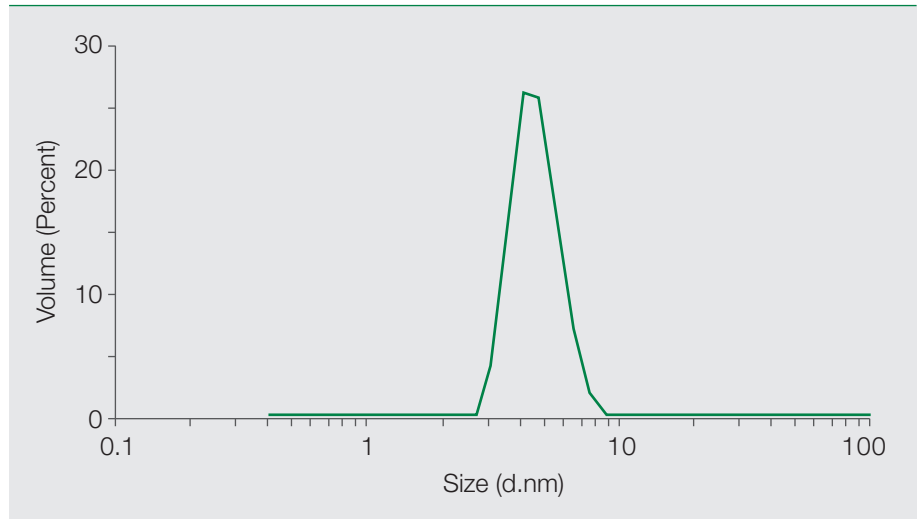
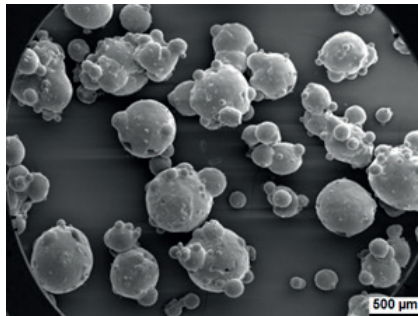


Figure 6: Micelle size as measured by laser diffraction

#### Particle Size

Kolliphor® P 188 Bio & Kolliphor® P 188 Cell Culture exhibit spherical prill particles of a mean diameter of approximately 500  $\mu\text{m}$  in size. An example of the size and morphology of these particles is shown in the scanning electron microscope image (SEM).



A closer image of the particles is shown below at a higher magnification:

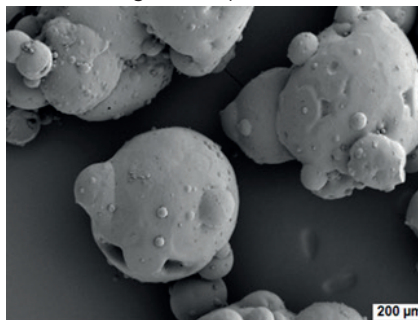


Figure 7: SEM images of Kolliphor® P188 Bio

#### Cloud point

The cloud point for Kolliphor® P 188 Bio is  $>100^{\circ}\text{C}$  for a 1% and a 10% aqueous solution.

#### Density

The bulk density of Kolliphor® P 188 Bio & Kolliphor® P 188 Cell Culture is approximately  $0.56 \text{ g/cm}^3$ .

### Moisture sorption

The uptake of moisture for Kolliphor® P 188 Bio & Kolliphor® P 188 Cell Culture is dependent on the relative humidity of the environment, at moisture levels above 80% (RH) significant moisture uptake is possible and shown in Figure 8.

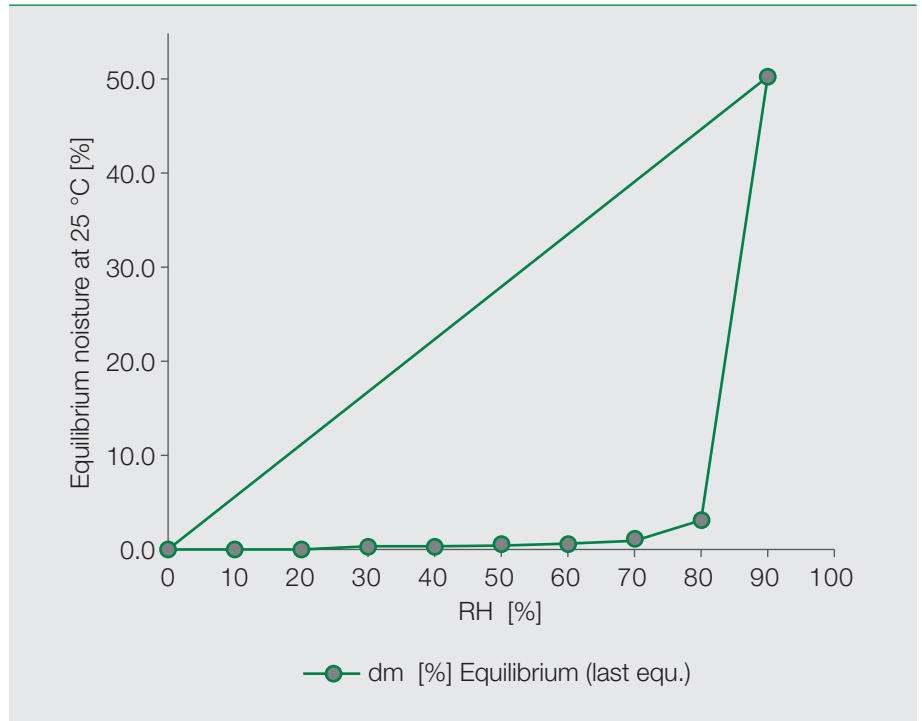


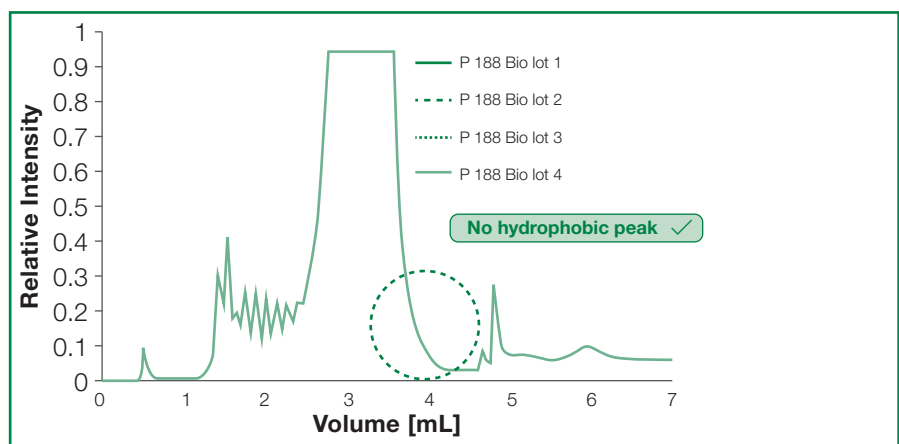
Figure 8: Moisture uptake as a function of relative humidity

### BHT

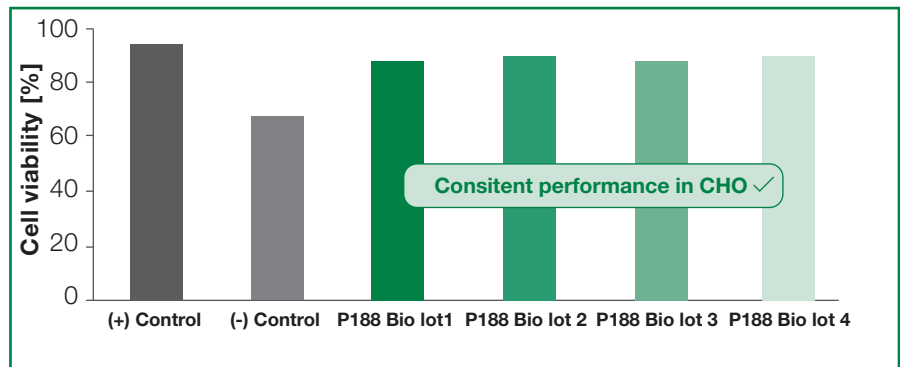
Kolliphor® P 188 Bio & Kolliphor® P 188 Cell Culture utilize 50 – 125 ppm BHT as an antioxidant – this protects the quality and performance of the P 188 in the litany of pharmaceutical applications. The primary degradation mechanism is oxidation, and is typically monitored via the pH, hydroxyl value and molecular weight of the poloxamer.

## 3. Functionality

The absence of performance critical hydrophobic impurity ensures reproducible performance of Kolliphor® P 188 Bio & Kolliphor® P 188 Cell Culture

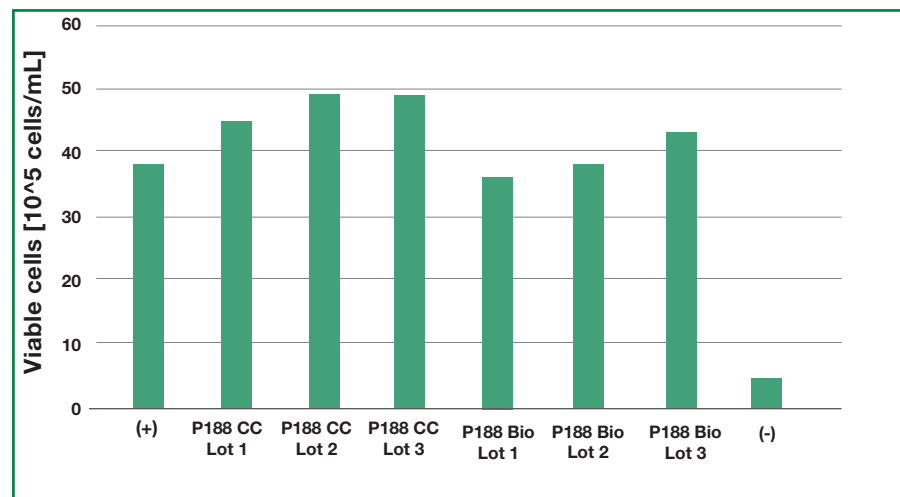


Four independent lots of Kolliphor® P188 Bio were tested.  
RP-HPLC assay shows **no hydrophobic peak** at retention time of 4mL.



The cell culture assay shows **high cell viability** as expected for lots with good performance.

Example Kolliphor® P 188 Bio & Kolliphor® P 188 Cell Culture used as cell culture shear protectant



CHO-S cells were grown in baffled flasks at high shear conditions (~350 rpm) in media with 0.25g/L of poloxamer 188 for 4 days. Graph shows viable cells at Day 4

## 4. Handling/Processing instructions

### P 188 Solution in Water

Poloxamer 188 is soluble in water. To make a poloxamer 188 solution, add room temperature water to a beaker with a magnetic stirrer on a stirrer plate. Establish a water vortex with a visible funnel at a medium speed. Slowly pour poloxamer 188 powder in the middle of the funnel. Reduce mixing speed to avoid foaming. Continue mixing until all solute disappears and filter sterilize using a 0.22µm filter.

## 5. Stability and Safety

The product is typically stable for 48 months after date of production provided storage under recommended conditions. The actual retest period and storage conditions can be found in the document “Quality & Regulatory Product Summary” in RegXcellence.

While the poloxamer monograph does not require storage conditions, BASF recommends storing the poloxamer at temperatures < 30°C.

Studies indicate the product is stable in the original packaging up to 40°C, 75% RH

The actual version of the safety data sheet is accessible via MyProductWorld and sent with every consignment.

## 6. Available Articles and Packaging

Product name	PRD-No.*	Article numbers	Packaging
Kolliphor® P 188 Bio	30631540	50424596	0.5 kg Plastic sample bottle
		50519573	102 kg Plastic drums with double polyethylene liners
		50519572	25 kg Plastic drums with double polyethylene liners
		50519927	12.5 kg Plastic pail with double polyethylene liners
		50519924	5 kg Plastic pail with double polyethylene liners
Kolliphor® P 188 Cell Culture	30843515	50835064	0.5 kg Plastic sample bottle
		50835047	102 kg Plastic drums with double polyethylene liners

\* BASF's commercial product number.

## 7. Documents, Quality & Regulatory Information



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[RegXcellence](#): specification, compliance documents, regulatory product summary

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