Technical Information

Kolliphor® P 188 *micro*Microprilled Poloxamer 188

Kolliphor® P 407 *micro*Microprilled Poloxamer 407

Poloxamer for Pharmaceutical Use in micronized solid form

September 2024 | Supersedes issue dated May 2013 | Last change DAWF-2024-0763

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® = Registered trademark of BASF in many countries.



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).

The Kolliphor® P 188 micro and Kolliphor® P 407 micro have the same chemistry as Kolliphor® P 188 and P 407 but possess a much small particle size which is obtained by an advanced solidification process called microprilling. Microprilled poloxamers were developed to achieve superior properties, including a Particle Size Distribution targeted for direct blending.

BASF offers different grades of poloxamers for different applications. Separate TIs are available for:

Kolliphor® P 188

Kolliphor® P 188 Bio and Kolliphor® P 188 Cell Culture

Kolliphor® P 338

Kolliphor® P 407

2. Chemical & Physical Properties

Structural Formula

The Kolliphor® P 188 & 407 is a block copolymer that is a synthetic copolymer of ethylene oxide and propylene oxide represented by the following chemical structure:

$$\begin{array}{c} {\rm CH_3} \\ {\rm I} \\ {\rm HO} \stackrel{+}{\leftarrow} {\rm CH_2-CH_2-O} \stackrel{+}{\rightarrow} {\rm CH_2-CH-O} \stackrel{+}{\rightarrow} {\rm CH_2-CH_2-O} \stackrel{+}{\rightarrow} {\rm H} \\ \end{array}$$

Where the **a** and **b** blocks have the following values:

Poloxamer	а	b
188	80	27
407	101	56

CAS number

9003-11-6

Particle Morphology

The term "prilling" refers to the process of obtaining the final solid form of the poloxamer through a special drying process directly from the melted product, rather than through subsequent milling. In the case of microprilling, this process allows for particles with smaller sizes compared to regular prilling. The process allows for a more consistent particle shape and improved flowability as evident in the below Scanning Electron Microscopy (SEM) images.

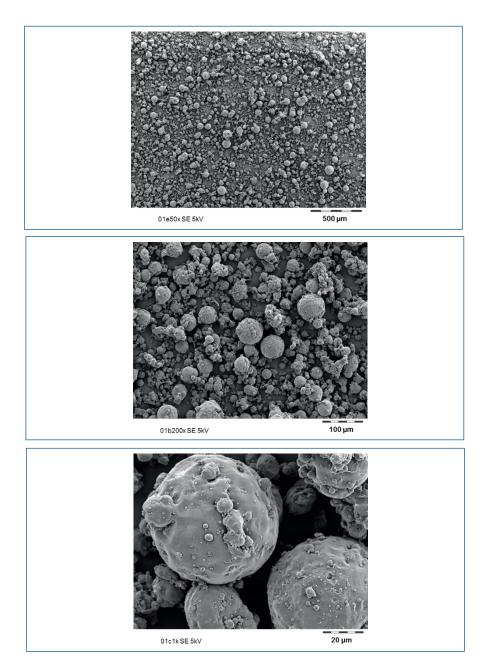
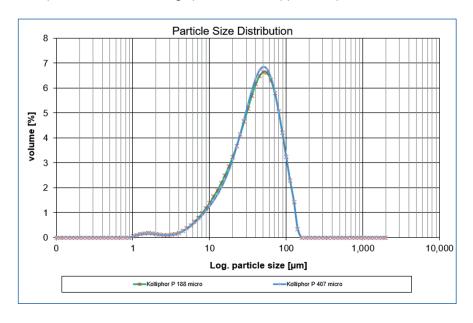


Fig. 1: Scanning Electron Microscopy (SEM) images of Kolliphor® P 188 micro.

Particle Size Distribution

Both products have an average particle size of approx. 50 µm



Example Particle Size Distribution for Kolliphor® P 407 micro and P 188 micro for Technical Information only. Developed by unvalidated in-house method.

The products also contain approx. 100 ppm BHT antioxidant.

3. Functionality

Kolliphor® P micro grades can be used in several pharmaceutical application fields:

- Dissolution enhancer for actives in tablets and capsules
- Lubricant for actives incompatible with Mg-stearate, e.g. Ibuprofen
- Polishing agent for film-coated tablets
- Dispersing/wetting agent
- Water soluble lubricant e.g. for effervescent tablets

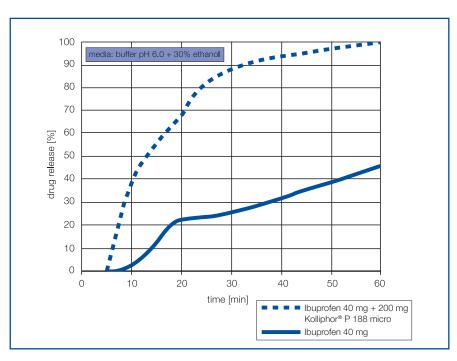
Due to the low average particle size that is in the same range as for active ingredients, a direct blending with the active is possible with a low tendency of demixing.

4. Example application

Solubilizing impact of Kolliphor® P micro grades on poorly soluble actives.

In this instance, a deliberately simple manufacturing method was selected to isolate the effect of the solubilizer. Initially, the active ingredient and Kolliphor® P micro grades were blended together for a duration of 10 minutes.

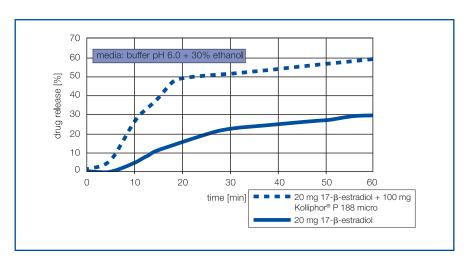
After the blending process, the resulting material was encapsulated, and its dissolution profile was assessed using an aqueous dissolution media. To achieve measurable values for the reference material (without the solubilizer), the dissolution media was supplemented with specific quantities of ethanol as a solvent.



Ibuprofen dissolution with and without Kolliphor® P micro

The impact of poloxamer particles on the dissolution profile of Ibuprofen is evidently demonstrated. A very high release rate can be achieved only by blending both materials.

The same behavior can be shown for the very poorly soluble active $17-\beta$ -estradiol.



17-β-estradiol dissolution with and without Kolliphor® P micro

The addition of Kolliphor® P micro 188 increased the drug release after 60 min from 30% up to appr. 60%.

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5. Stability & Safety

This product is typically stable for 36 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.

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

6. PRD and Article numbers

PRD-No.*	Product name**	Article number	Article	Packaging
30631537	Kolliphor® P 188 micro Geismar	50539400	0.5 kg technical sample	PE bottle
		50424308	25 kg commercial article	Fiber drum with PE liner
30631539	Kolliphor® P 407 <i>micro</i> Geismar	50424593	0.5 kg technical sample	PE bottle
		50424341	25 kg commercial article	Fiber drum with PE liner

^{*}BASF's commercial product number

7. Documents, Quality & Regulatory Information

Virtual Pharma Assistants



Meet your Virtual Pharma Assistants! MyProductWorld, RegXcellence $^{\tiny{\textcircled{\tiny 0}}}$ and ZoomLab $^{\tiny{\text{TM}}}$

www.virtualpharmaassistants.com

MyProductWorld: article numbers, sample order, safety data sheet, sustainability information

RegXcellence: specification, compliance documents, regulatory product summary

ZoomLab: formulation assistance to predict starting formulations and expedite drug formulations.

^{**}Geismar refers to the production site of the poloxamer polymer, which is BASF Geismar, Louisiana, USA

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September 2024