Technical Information

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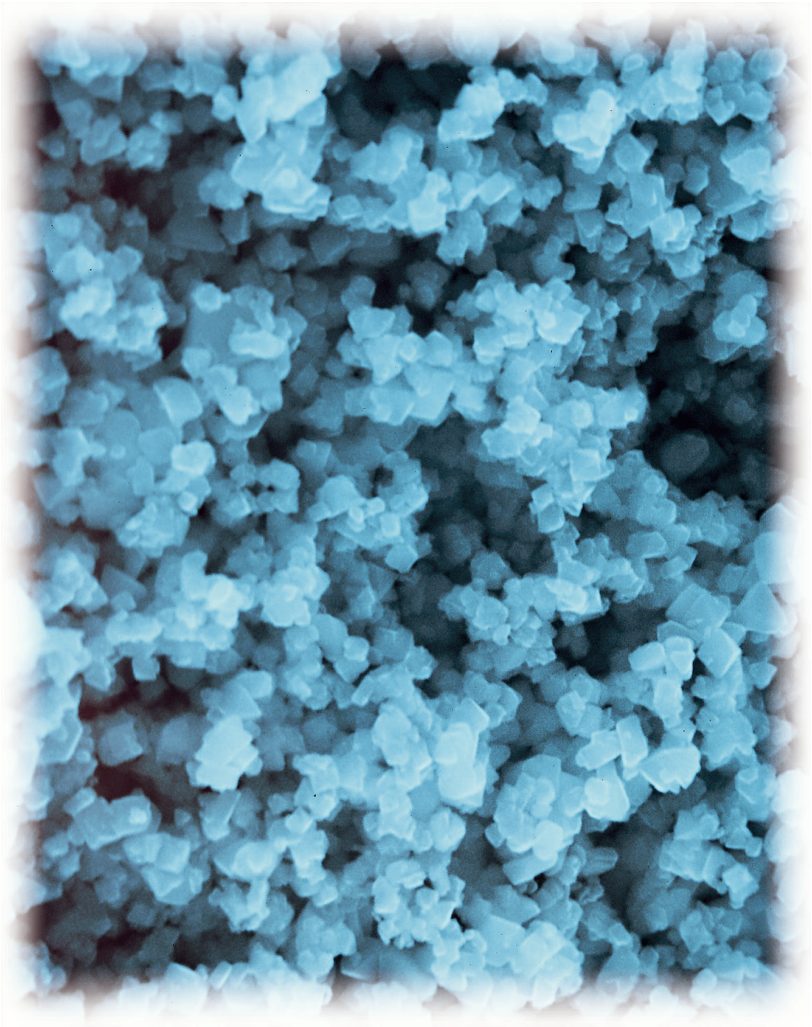
# Kolliphor® P 188 *micro*

**Microprilled Poloxamer 188**
**Solubilizer for the pharmaceutical Industry**

# Kolliphor® P 407 *micro*

**Microprilled Poloxamer 407**
**Solubilizer for the pharmaceutical Industry**



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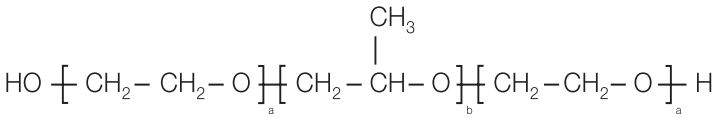
## 1. Introduction

### 1.1 General

The Kolliphor® P micro grades are microprilled poloxamers working as solubilizing agents. These products were developed to achieve superior properties.

### 1.2 Structural formula



for Kolliphor® P 188 micro: a = approx. 79 and b = approx. 28
The proportion of polyoxyethylene by weight is approx. 70%

for Kolliphor® P 407 micro: a = approx. 101 and b = approx. 56
The proportion of polyoxyethylene by weight is approx. 80%

### 1.3 Physical form

Kolliphor® P micro grades are white microprilled powders with a weak odour.

### 1.4 INCI name

| | |
|---|---|
| Kolliphor® P 188 micro | Poloxamer 188 |
| Kolliphor® P 407 micro | Poloxamer 407 |

### 1.5 CAS-No.

9003-11-6

## 2. Specification and properties

### 2.1 Chemical nature

The polymers are block copolymers of polyoxyethylene-polyoxypropylene. Both products have an average particle size of approx. 50 µm.

The products also contain approx. 100 ppm BHT.

### 2.2 Physicochemical properties

**Specifications**

See separate document: “Standard Specification (not for regulatory purposes)“ available via BASF’s WorldAccount: https://worldaccount.basf.com (registered access).

**The methods of determination are described in the current monograph "Poloxamers" of the USP-NF and the European Pharmacopoeia.**

**Particle size**

max. 10% residue on USP sieve ≤ 140 (106 µm)
max. 50% residue on USP sieve ≤ 270 ( 53 µm)

**Solubility**

Both products are readily soluble in water and ethanol (95%) and other mainly polar solvents. They are insoluble in ether, paraffin and fatty oils.

**Rheological properties**

Dilute aqueous solutions of both products show Newtonian flow properties that change to plastic flow properties. For Kolliphor® P 188 micro it changes at a concentration of approx. 60% and for Kolliphor® P 407 micro it changes at concentrations of above 15%. Both materials are thermoreversible. Kolliphor® P 188 micro shows a maximum viscosity at 60 to 75 °C whereas Kolliphor® P 407 micro shows the maximum between 30 to 60 °C.

### 2.3 Regulatory status

Products meet current USP-NF and Poloxamer Ph. Eur. monographs.

Poloxamer chemistries are also listed as monographs in "Japanese Pharmaceutical Excipients (JPE)".

## 3. Application and processing

### 3.1 Applications

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.

This allows a very cost and time saving production.

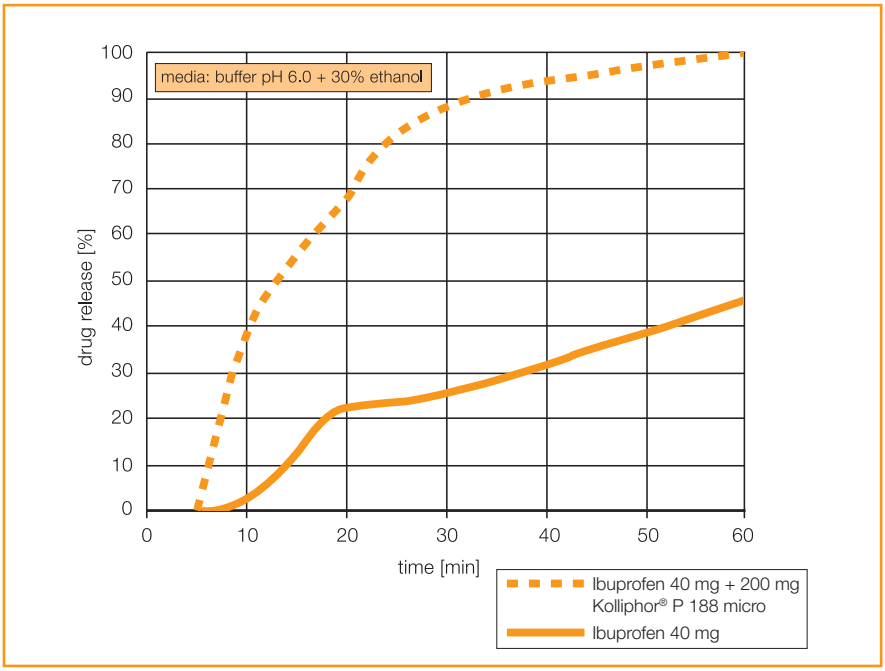
It is advised not to use the Kolliphor® P micro grades outside the scope of recommended use. BASF especially advises customers to test Kolliphor® P micro grade batches for applicatability in biotechnological processes. Any application outside the recommended use is at customer's own risk and responsibility.

### 3.2 Formulation examples

To show the good properties of Kolliphor® P micro grades a number of poorly soluble actives were tested.

In this case a very easy manufacturing method was chosen to show only the influence of the solubilizer. At first both materials, active and Lμtrol micro grades were blended for 10 min.

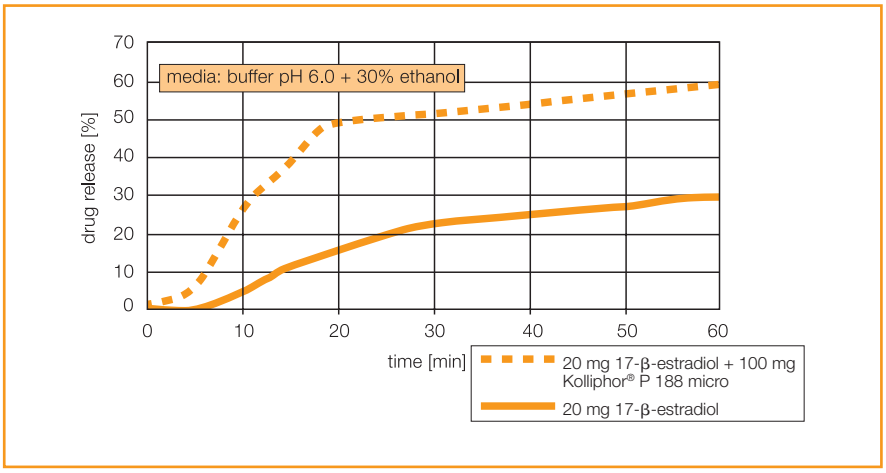
After mixing, the material was filled into capsules and the dissolution profile was determined in an aqueous dissolution media. To give detectable values of the reference material (without solubilizer) the dissolution media was mixed with certain amounts of a solvent (ethanol).




**Ibuprofen dissolution with and without Kolliphor® P micro**

Clearly can be shown that the poloxamer particles influence the dissolution profile of the poorly soluble active. A very high release rate can be achieved only by blending both materials.

The same behaviour can be shown with the very poorly soluble active 17-β-estradiol.




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

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

These results show the good solubilizing properties of Lutrol micro.

**4. Storage conditions**

Ambient/room temperature

**5. Stability**

The material can be stored for 2 years at max. 30 °C in unopened containers.

**6. Toxicological data**

A toxicological summary is available on request under Secrecy Agreement.

**7. PRD-Nos.**

| | |
|---|---|
| Kolliphor® P 188 micro | 30554049 |
| Kolliphor® P 407 micro | 30555081 |

**8. Packaging**

| | |
|---|---|
| Kolliphor® P 188 micro | 25 kg fibre-drum<br>0.5 kg sample |
| Kolliphor® P 407 micro | 25 kg fibre-drum<br>0.5 kg sample |

**Note**



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