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# Technical Information

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## Kolliphor® PS 80

Polysorbate 80 for pharmaceutical applications



## 1. Introduction

**BASF offers a broad portfolio of functional excipients including our pharmaceutical grade polysorbate 80, Kolliphor® PS 80.**

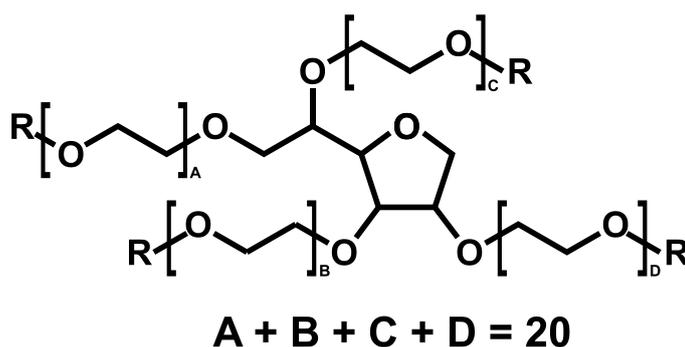
With consistent quality and reliable supply, Kolliphor® PS 80 is a versatile, multifunctional excipient that acts as a solubilizing agent for a variety of pharmaceutical formulations and as plasticizer for solid dispersions and oral dosage forms. In addition to these robust functionalities, Kolliphor® PS 80 is also a non-ionic surfactant and oil-in-water emulsifier that offers broad pH range applicability and good skin tolerance. Kolliphor® PS 80 is applicable for the development of oral and topical formulations.

## 2. Chemical information

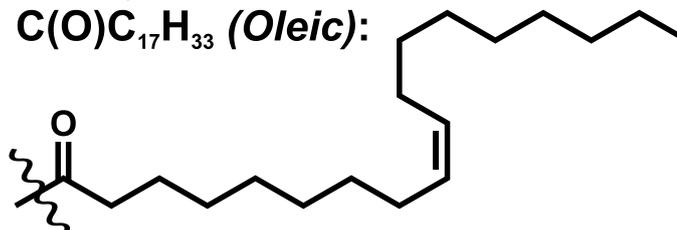
Chemical name	Polysorbate 80, Polyoxyethylene (20) sorbitan monooleate
CAS number	9005-65-6
Regulatory status	Kolliphor® PS 80 meets the current USP-NF, Ph. Eur., and JP monographs under its compendial name "Polysorbate 80". Furthermore, it meets the requirements of IPEC-PQG GMP for Excipients.
Sustainable sourcing	Roundtable on Sustainable Palm Oil (RSPO) certification available

Polysorbate 80 is a non-ionic surfactant and emulsifier for pharmaceutical applications, derived from polyethoxylation of sorbitan oleate esters (sorbitan monooleate).

### Chemical Structure:



R = H, or  
 C(O)C<sub>17</sub>H<sub>33</sub> (*Oleic*):



### 3. Selected chemical and physical parameters

Property	Kolliphor® PS 80 typical values
Appearance	Colorless or yellow, clear liquid with a faint characteristic odor
HLB*	15
CMC	35 mg/L
Specific gravity	1.06 to 1.09 g/cm <sup>3</sup>
Viscosity	300 to 500 cSt
Solubility in water	Dispersible in water

\* the polarity of non-ionic emulsifiers is temperature dependent; the polarity decreases with elevated temperatures, resulting in an increase in the lipophilicity of the emulsifier.

### 4. Applications

**Polysorbates are mainly used as solubilizers, emulsifiers, or suspension stabilizers for pharmaceutical applications.**

Depending on the HLB value and the miscibility in water of the product, polysorbates either act more as a solubilizer or emulsifier. Kolliphor® PS 80 is more suitable for use as a solubilizer of poorly water-soluble drug substances in either liquid or solid oral dosage forms.

This excipient also functions as a suspension stabilizer in addition to a skin penetration enhancer for topical applications.

#### Solubilization

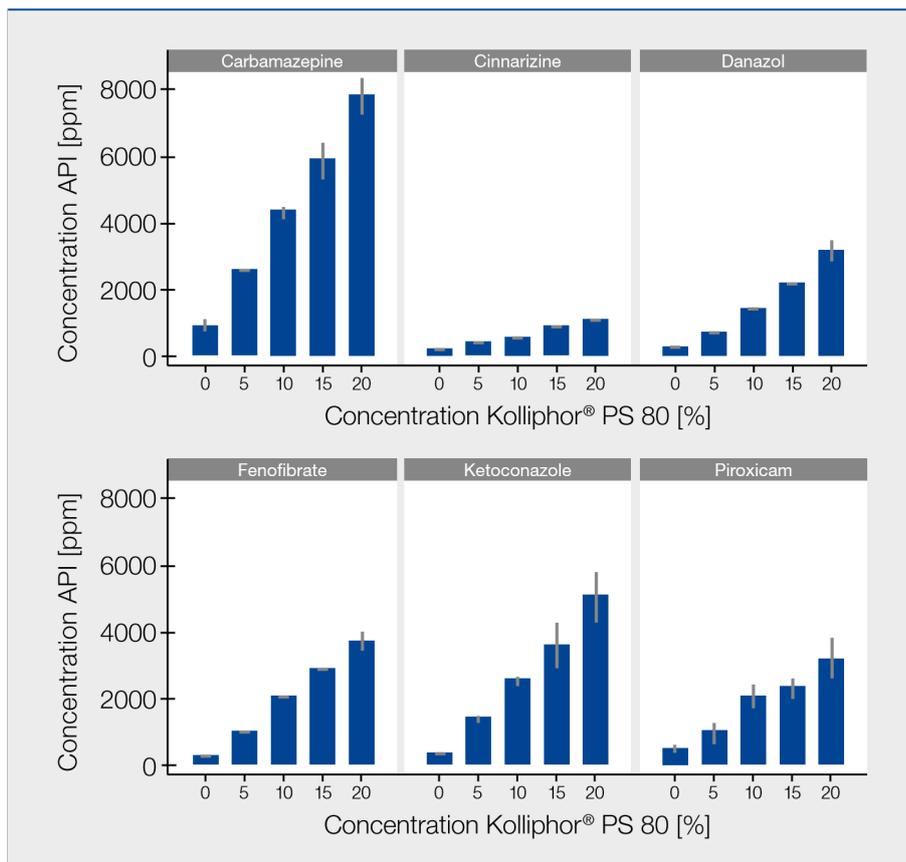
##### Solubilization performance based on model APIs

The formulation of poorly water soluble active pharmaceutical ingredients (APIs) poses a distinct challenge to pharmaceutical formulators. With newly discovered APIs trending towards an increase in lipophilicity and complexity, drug solubilizers such as Kolliphor® PS 80 have become essential for the development of stable and efficacious formulations.

A high-throughput screening robot was used to study the solubilizing performance of Kolliphor® PS 80 based on model APIs with different physicochemical profiles. Kolliphor® PS 80 was tested as a drug solubilizer at concentrations of 0, 5, 10, 15, and 20%. The upper-limit concentration of 20% which exceeds typical usage levels in standard pharmaceutical liquid or solid formulations was established to allow for an assessment of a potential saturation effect.

The selected model APIs differed in molecular weight, estimated logP values, estimated water solubility, and melting point. The table below shows an overview of these attributes for all selected model compounds.

API	Molecular weight (g/mol)	logP	Water solubility (ppm)	T <sub>m</sub> (°C)
Carbamazepine	236.27	2.1	154	201 – 206
Cinnarizine	368.51	5.19	1.72	117 – 120
Danazol	337.46	3.62	0.71	224 – 227
Fenofibrate	360.83	4.86	17.6	81
Ketoconazole	531.43	4.3	9.31	146
Piroxicam	331.35	2.2	143	198 – 200



*Solubility enhancement of model APIs by using Kolliphor® PS 80 (polysorbate 80).*

Kolliphor® PS 80 demonstrated a significant improvement in the solubility. Regardless of the physicochemical attributes of the model API, the solubilization of all APIs was concentration dependent. The solubilization capacity of Kolliphor® PS 80 can be attributed to its long C18:1 chain length allowing for interaction with hydrophobic APIs and thus enhanced solubilization performance.

## Orals

### Drug solubilization via hot melt extrusion (HME)

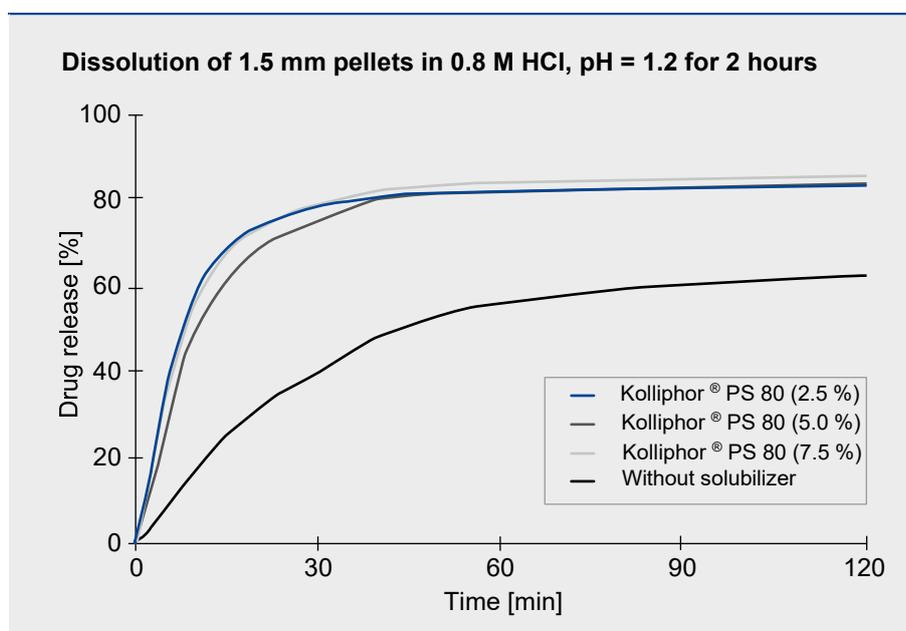
The solubilization performance of Kolliphor® PS 80 for the API Ritonavir was investigated in formulation obtained by hot melt extrusion (HME) employing Kollidon® VA 64 (copovidone) as a matrix.

Formulation	
API	Ritonavir
Polymer	Kollidon® VA 64
Solubilizer	Kolliphor® PS 80

API	Polymer	Solubilizer
30.0%	70.0%	-
30.0%	67.5%	2.5%
30.0%	65.0%	5.0%
30.0%	62.5%	7.5%

Process	
16 mm Twin Screw Extruder PTW Thermo Fischer	
Throughput	1 kg/h
Screw speed	200 rpm
Extrusion temperature	135 °C
Pelletization	1.5 mm



The dissolution curves show the effectiveness of Kolliphor® PS 80 on dissolution of Ritonavir from a Kollidon® VA 64-based matrix. Even at the low concentration of 2.5%, Kolliphor® PS 80 had a significant impact on increasing drug availability, demonstrating approximately 80% drug release within the first 30 minutes. The release was independent of the tested concentrations (i.e., 2.5, 5.0, and 7.5%) of the solubilizer.

### Enteric coating

An enteric coating that is emulsified by Kolliphor® PS 80 to form a sprayable suspension.

Step	Ingredient	Chemical Name	Amount (g)
1	Water	Water	200
	Kolliphor® PS 80	Polysorbate 80	3.0
2	Kolliwax® GMS II	Mono- and di-glycerides	8.0
	Triethyl citrate	Triethyl citrate	25.0
3	Water	Water	208
4	Kollicoat® MAE 30 DP	Methacrylic acid copolymer dispersion	556

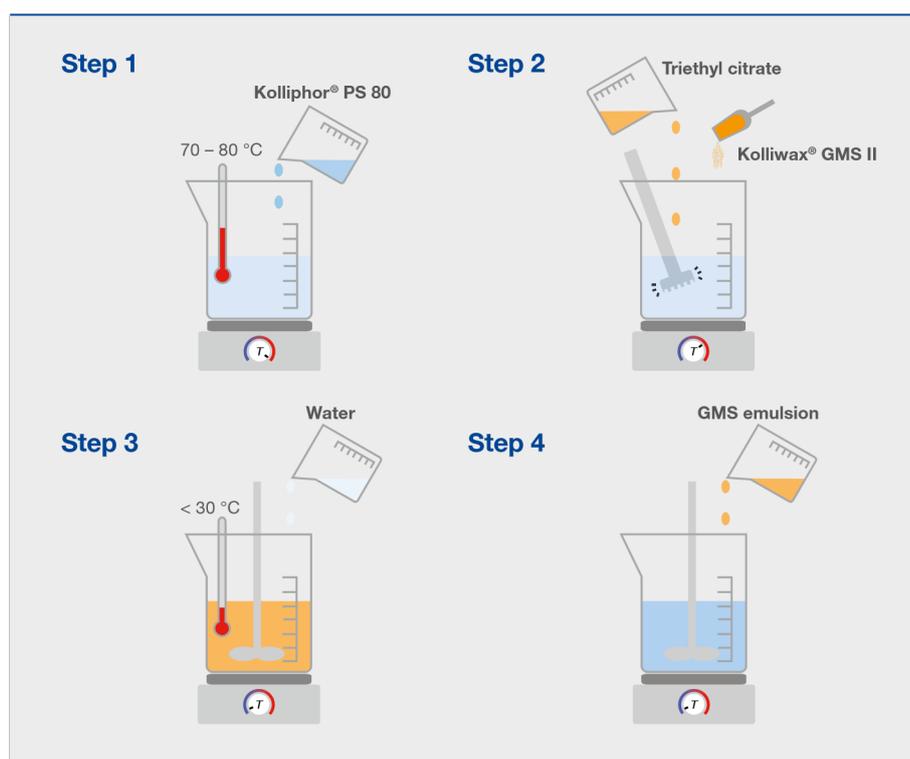
### Procedure

**Step 1: Surfactant Solution** Dissolve Kolliphor® PS 80 in approx. half of the total water amount. Heat the solution to a temperature of 70 – 80 °C.

**Step 2: Emulsification** Add Kolliwax® GMS II and triethyl citrate while homogenizing with a high-shear mixer. Keep homogenizing the mixture for 10 min.

**Step 3: GMS Emulsion** Let the mixture cool under stirring while slowly adding the remaining half of the water amount.

**Step 4: Spray Suspension** Slowly add the cold GMS emulsion to the coating dispersion. Continue stirring to obtain a homogeneous mixture.



**Note:** Pigments can be dispersed into the remaining water amount and added accordingly in step 3. Before spraying, the suspension should be passed through a 0.5 mm sieve.

## Topicals

### Light cream

A light-weight, airy cream that is emulsified by Kolliphor® PS 80.

Phase	Ingredient	Chemical name	Wt%
A	Kollicream® IPM	Isopropyl myristate	20
	Kolliwax® GMS II	Mono- and di-glycerides	1.45
	Kolliphor® PS 80	Polysorbate 80	3.55
B	Deionized water	Water	73.1
	Carbopol® ETD 2020 polymer	Acrylates/C10-30 alkyl acrylate crosspolymer	0.2
C	Triethanolamine	Triethanolamine	1
D	Phenoxyethanol	Phenoxyethanol	0.7

### Procedure

1. Weigh out phase A into an appropriately sized beaker. Place the mixture under an overhead mixer and set to 50 rpm. Heat the mixture to 80 °C.
2. In a separate beaker, weigh out the water for phase B and heat to 80 °C. Sprinkle Carbopol® while stirring.
3. Add phase A to phase B under shear and then neutralize with triethanolamine (phase C).
4. Homogenize mixture at 5000 rpm for 2 minutes.
5. Place the mixture under an overhead mixer and allow to cool under mild shear.
6. When the formulation has cooled to 45 °C, add in phenoxyethanol (phase D).

### Rich cream

A rich, luxurious cream that is stabilized with Kolliphor® PS 80.

Phase	Ingredient	Chemical name	Wt%
A	Kollicream® 3C	Cocoyl caprylocaprate	20
	Kolliwax® GMS II	Mono- and di-glycerides	2.5
	Kolliphor® PS 80	Polysorbate 80	2.5
B	Deionized water	Water	73.1
	Carbopol® ETD 2020 polymer	Acrylates/C10-30 alkyl acrylate crosspolymer	0.2
C	Triethanolamine	Triethanolamine	1
D	Phenoxyethanol	Phenoxyethanol	0.7

### Procedure

1. Weigh out phase A into an appropriately sized beaker. Place the mixture under an overhead mixer and set to 50 rpm. Heat the mixture to 80 °C.
2. In a separate beaker, weigh out the water for phase B and heat to 80 °C. Sprinkle Carbopol® while stirring.
3. Add phase A to phase B under shear and then neutralize with triethanolamine (phase C).
4. Homogenize mixture at 5000 rpm for 2 minutes.
5. Place the mixture under an overhead mixer and allow to cool under mild shear.
6. When the formulation has cooled to 45 °C, add in phenoxyethanol (phase D).

## 5. Product details

Product details	
PRD number	30776819
Packaging and article numbers	190 kg lacquered steel drum (ART 50729133) 25 kg lacquered steel drum (ART 50740519)
Sample and article number	0.5 kg amber glass bottle (ART 50729134)
Regulatory and Quality	Refer to the individual document quality and regulatory product information (QRPI), available on <a href="#">RegXcellence®</a> and from your local BASF sales representative. The QRPI document covers all relevant information including retest periods and storage conditions.
Certification	EXCiPACT GMP, Kosher, Halal, RSPO
Handling and Safety	Refer to the safety data sheet (SDS) for instructions on safe and proper handling and disposal. SDS are available on request and are sent with every consignment.
Product Specification	The current version of the product specification is available on <a href="#">RegXcellence®</a> and <a href="#">MyProductWorld</a> or from your local BASF sales representative.
Regulatory and Quality	Refer to the individual document quality and regulatory product information (QRPI), available on <a href="#">RegXcellence®</a> and from your local BASF sales representative. The QRPI document covers all relevant information including retest periods and storage conditions.

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