

# Kolliphor® PS Polysorbates

Polysorbates for oral and topical  
pharmaceutical applications





**BASF PHARMA SOLUTIONS** OFFERS  
HIGH-QUALITY POLYSORBATES  
AND RELIABLE SUPPLY FOR OUR  
CUSTOMERS **WORLDWIDE.**  
OUR COMPREHENSIVE PORTFOLIO OF  
**SURFACTANTS AND EMULSIFIERS,**  
INCLUDING KOLLIPHOR® PS  
POLYSORBATES, ENABLES OPTIMAL  
FORMULATION DESIGN AND  
ENHANCED DRUG SOLUBILITY.



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# Introduction

BASF offers a range of high-quality pharmaceutical grade polysorbates for your solubilizing, emulsifying, and stabilizing needs in oral and topical formulations.

<b>Kolliphor® PS 20</b>	Polysorbate 20	Ph. Eur., USP/NF
<b>Kolliphor® PS 60</b>	Polysorbate 60	Ph. Eur., USP/NF, JPE
<b>Kolliphor® PS 80</b>	Polysorbate 80	Ph. Eur., USP/NF, JP

Applicable for both oral and topical formulations, Kolliphor® PS polysorbates are versatile non-ionic surfactants for a diverse range of applications. Kolliphor® PS polysorbates function as solubilizers and emulsifiers that can be used alone or in conjunction with other surfactants to tune final formulation properties.

With our Kolliphor® PS polysorbates, BASF offers pharmaceutical polysorbates with a commitment to consistent supply and reliable quality. Through process excellence and high-quality sourced raw materials, BASF achieves controlled production with lot-to-lot consistency, for ease and readiness of use.

BASF's Kolliphor® PS polysorbates are derived from responsibly sourced, RSPO-certified palm oil, and are Halal and Kosher certified. BASF's Kolliphor® PS polysorbates are reliably produced to meet cGMP standards, and are accompanied by full ICH stability data. Kolliphor® PS polysorbates are manufactured in Duesseldorf, Germany, where we produce pharmaceutical lipid-based excipients in IPEC-GMP conditions in a certified EXCiPACT® environment.





# Kolliphor® PS Polysorbate portfolio

Kolliphor® PS polysorbates are polyethoxylated sorbitan esters of lauric, stearic, and oleic fatty acids. Kolliphor® PS polysorbates are water-soluble, with relatively high HLB (hydrophilic-lipophilic balance) values. As high HLB surfactants and emulsifiers, they can be combined with low HLB surfactants (sorbitan monolaurate, sorbitan monostearate) to produce stable, tunable emulsions in water.



## Pharmaceutical uses

**Kolliphor® PS polysorbates** are a series of **amphiphilic, non-ionic surfactants** that are widely used in a variety of pharmaceutical applications including oral tablets, solutions, suspensions and topical formulations.<sup>1</sup> In routine formulations, polysorbates are included in amounts specific to their desired function and intended application (Table 1).

**Table 1.** Common pharmaceutical polysorbate functions and usage levels.<sup>1</sup>

Function	Concentration (wt%)
Emulsifiers in oil-in-water emulsions	1 – 15
Solubilizing agent in oral preparations	1 – 10
Plasticizer or co-plasticizer	1 – 10
Emollient in topical formulations	1 – 15
Non-ionic surfactant in lipophilic bases	1 – 5



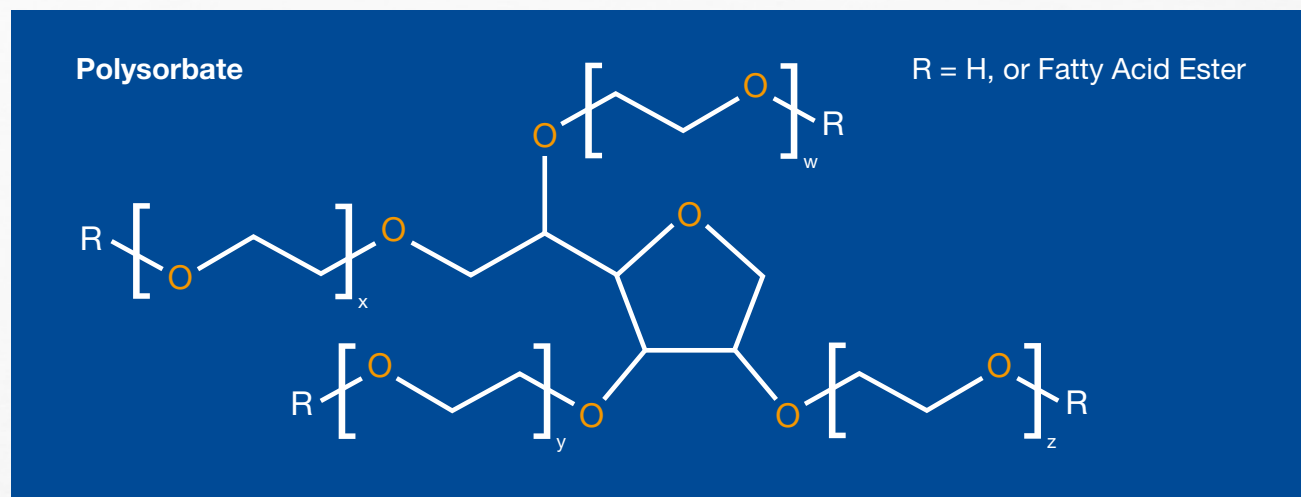
Polysorbates are potent solubilizers, and are often used to deliver poorly water-soluble drugs.<sup>2</sup> As water-miscible surfactants, polysorbates are able to self-assemble and form micelles at concentrations above their critical micelle concentration. Thus, polysorbates can aid in solubilizing drug molecules through either direct cosolvent effect, or by stabilization within micelle structures.

Polysorbates can also be used as emulsifiers in oral applications, such as softgel liquid fills and self-emulsifying drug delivery systems (SEDSS), and topical applications, such as creams and lotions. In these applications, polysorbates may be selected as the single surfactant, or be part of a multi-surfactant system.

Polysorbates are also common wetting agents and dispersants, and can influence release based on their hydrophilic nature.

## Complex chemical structures

**Polysorbates are complex mixtures of ethoxylated partial fatty acid esters of sorbitol and its anhydrides.**<sup>1</sup> The nomenclature of compendial polysorbates (i.e. Polysorbate 20, Polysorbate 80) is based on both the degree of ethoxylation ( $w+x+y+z$ ), as well as the fatty acid composition (Table 2).



For Polysorbate 20, Polysorbate 60, and Polysorbate 80, the degree of ethoxylation sums to 20 total repeat units.

While described by the majority fatty acid component (e.g. polyoxyethylene sorbitan **monolaurate** for Polysorbate 20 and polyoxyethylene sorbitan **monooleate** for Polysorbate 80), the fatty acid composition is often a mixture of species per respective compendial requirements (Table 2). For example, the compendial monolaurate fraction of Polysorbate 20 is 40 to 60 wt% of the fatty acid mixture, and the monooleate fraction of Polysorbate 80 is at least 58 wt% of the fatty acid mixture.

**Table 2.** Compendial descriptors for polysorbates.

		Kolliphor® PS 20	Kolliphor® PS 60	Kolliphor® PS 80
		Polysorbate 20	Polysorbate 60	Polysorbate 80
Chemical name		Polyoxyethylene (20) sorbitan monolaurate	Polyoxyethylene (20) sorbitan monostearate	Polyoxyethylene (20) sorbitan monooleate
Degree of ethoxylation		20	20	20
Fatty acid ester composition	Carbons in fatty acid chain (optionally ': # of unsaturated bonds')			
Caproic acid	6	≤ 1.0%		
Caprylic acid	8	≤ 10.0%		
Capric acid	10	≤ 10.0%		
<b>Lauric acid</b>	<b>12</b>	<b>40.0 – 60.0%</b>		
Myristic acid	14	14.0 – 25.0%		≤ 5.0%
Palmitic acid	16	7.0 – 15.0%	*	≤ 16.0%
Palmitoleic acid	16:1			≤ 8.0%
<b>Stearic acid</b>	18	7.0%	<b>40.0 – 60.0%</b>	≤ 6.0%
<b>Oleic acid</b>	18:1	≤ 11.0%		<b>≥ 58.0%</b>
Linolenic acid	18:3			≤ 4.0%
Linoleic acid	18:2	≤ 3.0%		≤ 18.0%

\*Polysorbate 60 has ≥ 90% content of stearic acid and palmitic acid.

## Supplier requirements for precision and control

The overall hydrophilic-hydrophobic nature of different polysorbates is a function of both the degree of ethoxylation, as well as the fatty acid composition. Polysorbate 20 is recognized as more hydrophilic than Polysorbate 80, owed to having a higher portion of shorter, saturated fatty acids, whereas Polysorbate 80 has a distribution of longer fatty acid chains and a majority of unsaturated oleic acid.<sup>3</sup>

Because of the fatty acid variability allowed within monograph compliance, the composition and performance of a given polysorbate may vary between vendors, and with lot-to-lot variability largely resultant from different synthesis routes and raw materials sources and grades.<sup>3</sup> Thus, careful selection of a polysorbate manufacturer with a secure and stable supply of high-quality raw materials and precise production control is important for reliable and reproducible polysorbate performance in a given formulation or application. To this end, **BASF offers a range of Kolliphor® PS polysorbates with a commitment to process excellence, consistent supply, and reliable quality**, namely Kolliphor® PS 20, Kolliphor® PS 60, and Kolliphor® PS 80.

### References:

- 1) Sheskey, P. J., Hancock, B. C., Moss, G. P., & Goldfarb, D. J. (2020). Handbook of Pharmaceutical Excipients. London: Pharmaceutical Press.
- 2) Strickley, R. G. (2004). Solubilizing Excipients in Oral and Injectable Formulations. *Pharmaceutical Research*, 21(2).
- 3) Kerwin, B. A. (2008). Polysorbates 20 and 80 Used in the Formulation of Protein Biotherapeutics: Structure and Degradation Pathways. *J. Pharm. Sci.*, 97(8).



# Kolliphor® PS 20

## Product details

Generic name	Polysorbate 20, Polyoxyethylene (20) sorbitan monolaurate
CAS number	9005-64-5
Manufacturing site	Duesseldorf, Germany
Manufacturing process	Semi-synthetic
Regulatory	<ul style="list-style-type: none"> <li>■ USP/NF, Ph. Eur. monographs</li> <li>■ IPEC-PQG GMP for Excipients</li> <li>■ Complete pharma documentation available</li> </ul>
Appearance	Yellow, clear or opalescent liquid
Certified	Kosher, Halal
PRD number	30776820
Packaging and article numbers	190 kg lacquered steel drum (ART 50729141) 25 kg lacquered steel drum (ART 50740624)
Sample and article number	0.5 kg glass bottle (ART 50729142)
Retest period	36 months
Storage and transport	Store in the original packaging and below 30 °C

## Key customer benefits

Supply reliability	<ul style="list-style-type: none"> <li>■ Availability of three different lots with samples for qualification</li> <li>■ Product is globally available in 190 kg and 25 kg drums</li> </ul>
Consistent quality	USP/NF, Ph. Eur. monograph compliance
Sustainability	Roundtable on Sustainable Palm Oil (RSPO) certification available
Technical service	<ul style="list-style-type: none"> <li>■ Deep understanding of excipient science</li> <li>■ Formulation Guidance with Zoomlab™</li> </ul>
BASF Virtual Pharma Assistants	<ul style="list-style-type: none"> <li>■ Regulatory documentation available in RegXcellence®</li> <li>■ Product details available via MyProductWorld</li> <li>■ Full pharma regulatory documentation and submission support</li> </ul>





# Kolliphor® PS 60

## Product details

Generic name	Polysorbate 60, Polyoxyethylene (20) sorbitan monostearate
CAS number	9005-67-8
Manufacturing site	Duesseldorf, Germany
Manufacturing process	Semi-synthetic
Regulatory	<ul style="list-style-type: none"><li>■ USP/NF, Ph. Eur., JPE monographs</li><li>■ IPEC-PQG GMP for Excipients</li><li>■ Complete pharma documentation available</li></ul>
Appearance	Colorless or yellow, clear liquid with a faint characteristic odor
Certified	Kosher, Halal
PRD number	30554490
Packaging and article numbers	190 kg lacquered steel drum (ART 50278844)
Sample and article number	0.5 kg plastic bottle (ART 50259497)
Retest period	36 months (Full 36-month stability report available)
Storage and transport	Store in the original packaging and below 30 °C

## Key customer benefits

Supply reliability	<ul style="list-style-type: none"><li>■ Product is globally available in 190 kg drums</li></ul>
Consistent quality	USP/NF, Ph. Eur., JPE monograph compliance
Sustainability	Roundtable on Sustainable Palm Oil (RSPO) certification available
Technical service	<ul style="list-style-type: none"><li>■ Deep understanding of excipient science</li><li>■ Formulation Guidance with Zoomlab™</li></ul>
BASF Virtual Pharma Assistants	<ul style="list-style-type: none"><li>■ Regulatory documentation available in RegXcellence®</li><li>■ Product details available via MyProductWorld</li><li>■ Full pharma regulatory documentation and submission support</li></ul>

# Kolliphor® PS 80

## Product details

Generic name	Polysorbate 80, Polyoxyethylene (20) sorbitan monooleate
CAS number	9005-65-6
Manufacturing site	Duesseldorf, Germany
Manufacturing process	Semi-synthetic
Regulatory	<ul style="list-style-type: none"> <li>■ USP/NF, Ph. Eur., JP monographs</li> <li>■ IPEC-PQG GMP for Excipients</li> <li>■ Complete pharma documentation available</li> </ul>
Appearance	Colorless or yellow, clear liquid with a faint characteristic odor
Certified	Kosher, Halal
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)
Retest period	36 months
Storage and transport	Store in the original packaging and below 30 °C



## Key customer benefits

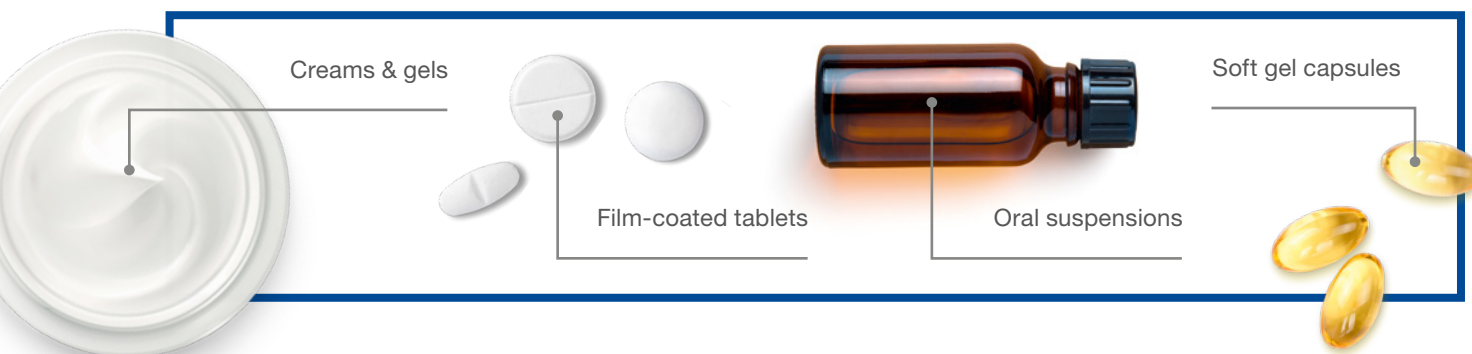
Supply reliability	<ul style="list-style-type: none"> <li>■ Availability of three different lots with samples for qualification</li> <li>■ Product is globally available in 190 kg and 25 kg drums</li> </ul>
Consistent quality	USP/NF, Ph. Eur., JP monograph compliance
Sustainability	Roundtable on Sustainable Palm Oil (RSPO) certification available
Technical service	<ul style="list-style-type: none"> <li>■ Deep understanding of excipient science</li> <li>■ Full pharma regulatory documentation and submission support</li> </ul>
BASF Virtual Pharma Assistants	<ul style="list-style-type: none"> <li>■ Regulatory documentation available in RegXcellence®</li> <li>■ Formulation Guidance with ZoomLab™</li> <li>■ Product details available via MyProductWorld</li> </ul>

# Kolliphor® PS Polysorbate applications

## General information on applications of Kolliphor® PS Polysorbates

### Kolliphor® PS Polysorbates can be used in a range of oral and topical dosage forms:

- Oral tablets can utilize polysorbates as plasticizing agents to reduce the melting temperature of drug molecules, and improve processing during manufacturing.
- Oral suspensions show improved oral bioavailability of poorly water-soluble drug molecules in a range of dosage forms, and polysorbates can be used to improve stability of solution formulations.
- Soft gelatin capsules can be filled with oral liquids or self-emulsifying drug delivery systems using Kolliphor® PS Polysorbates as solubilizers or surfactants.
- Topical dosage forms including, but not limited to, creams, ointments, gels, and shampoos utilize polysorbates as solubilizers and surfactants.



Depending on the HLB value and the miscibility in water of the product, they either act more as a solubilizer or emulsifier. Products like Kolliphor® PS 20 and Kolliphor® PS 80 are more suitable for use as a solubilizer of poorly water-soluble drug substances in either liquid or solid oral dosage forms.

Kolliphor® PS 60 is more likely to be used as an emulsifier in topical applications like creams and lotions; however, Kolliphor® PS 20 and 80 can also be formulated in conjunction with sorbitan esters to enhance emulsion stability.

	Kolliphor® PS 20	Kolliphor® PS 60	Kolliphor® PS 80
	Polysorbate 20	Polysorbate 60	Polysorbate 80
Emulsifier	●	●	●
Solubilizer	●		●
Suspension stabilizer	●		●
Oral solid dosage forms	●	●	●
Semi-solid dosage forms	●	●	●
Cold processing		●	
Skin penetration enhancer	●		●
Liquid dosage forms	●	●	●
Broad pH ranges	●	●	●



# Application as solubilizer for liquid, solid, and semi-solid dosage forms

## Liquid formulations: Performance of Kolliphor® PS Polysorbates based on model APIs

Pharmaceutical scientists increasingly face the challenge of formulating poorly water soluble active pharmaceutical ingredients (API). This is likely to increase, as new APIs in pharmaceutical research become more and more lipophilic and complex molecules. A high-throughput screening robot was established at BASF SE to reduce development time and formalize early solubilizer screening activities. The aim of this study is to screen the solubilizing performance of three Kolliphor® PS Polysorbate grades based on model APIs with different physico-chemical profiles. The solubilizer concentration with max. 20% exceeds the typical usage levels in standard pharmaceutical liquid or solid formulations in order to assess a potential saturation effect.

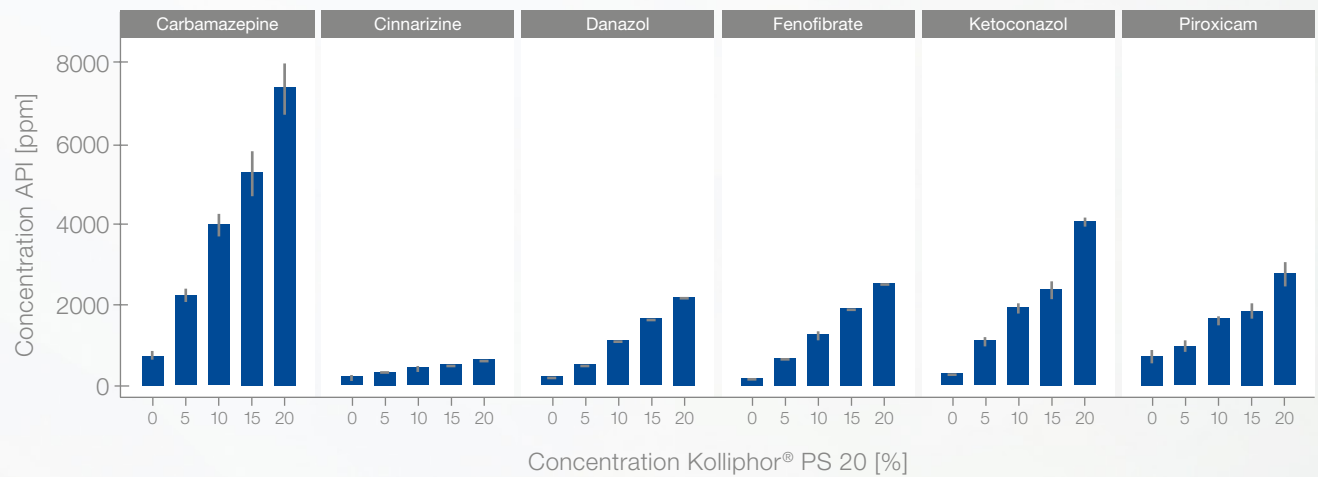
The selected model APIs differ in molecular weight, estimated logP values, estimated water solubility and melting point. Table 3 shows an overview of these attributes for all selected model compounds.

**Table 3.** Overview of physico-chemical properties of the selected model APIs.

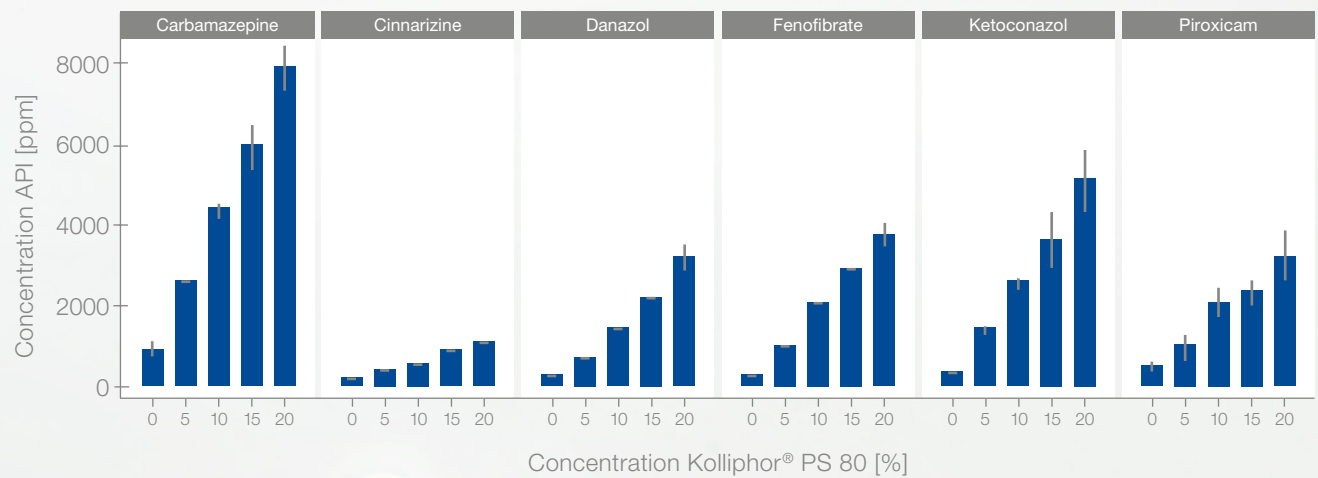
	Molecular weight g/mol	logP	Water solubility mg/mL	T <sub>m</sub> °C
Carbamazepin	236.27	2.1	1.52 x 10 <sup>-1</sup>	201 – 206
Cinnarizin	368.514	5.19	1.72 x 10 <sup>-3</sup>	117 – 120
Danazol	337.455	3.62	7.07 x 10 <sup>-4</sup>	224 – 227
Fenofibrate	360.831	4.86	1.76 x 10 <sup>-2</sup>	80.5
Ketoconazol	531.431	4.3	9.31 x 10 <sup>-3</sup>	146
Piroxicam	331.346	2.2	1.43 x 10 <sup>-1</sup>	198 – 200

Both Kolliphor® PS 20 and PS 80 form clear solutions in water at concentration levels ranging from 1 – 20%. Therefore, these substances are adequate for the evaluation of a potential saturation effect by solubilizer concentration. The results of figure 1 and 2 support this and show, that the solubility enhancement of all substances increase with solubilizer concentration.

**Figure 1.** Solubility enhancement of model APIs by using Kolliphor® PS 20 (Polysorbate 20).



**Figure 2.** Solubility enhancement of model APIs by using Kolliphor® PS 80 (Polysorbate 80).



## Solid oral dosage application: Kolliphor® PS Polysorbates based on Hot Melt Extrusion (HME)

All Kolliphor® PS Polysorbates are easy to handle in HME applications. No significant difference can be observed in handling compared to other semi-solid solubilizers such as Kolliphor® RH 40.

### Formulation

API	Ritonavir
Polymer	Kollidon® VA 64
Solubilizer	Kolliphor® PS 20 / Kolliphor® PS 20 / Kolliphor® RH 40

### API

30.0%

30.0%

30.0%

30.0%

### Polymer

70.0%

67.5%

65.0%

62.5%

### Solubilizer

-

2.5%

5.0%

7.5%

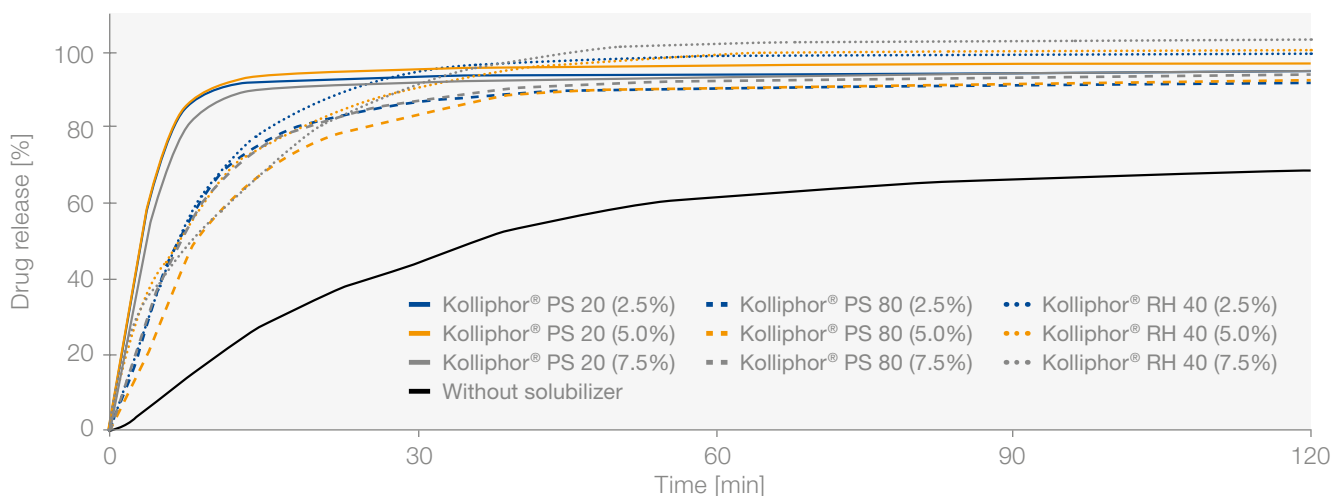
### Process

16 mm Twin Screw Extruder PTW Thermo Fisher

Troughput	1 kg/h
Screw speed	200 rpm
Extrusion temperature	135 °C
Pelletizing	1.5 mm
Dissolution	0.8 M HCL pH = 1.2 (2 h)



**Figure 3.** Ritonavir release from HME extrudates based on surfactants Kolliphor® PS 20, Kolliphor® PS 80, and Kolliphor® RH 40.



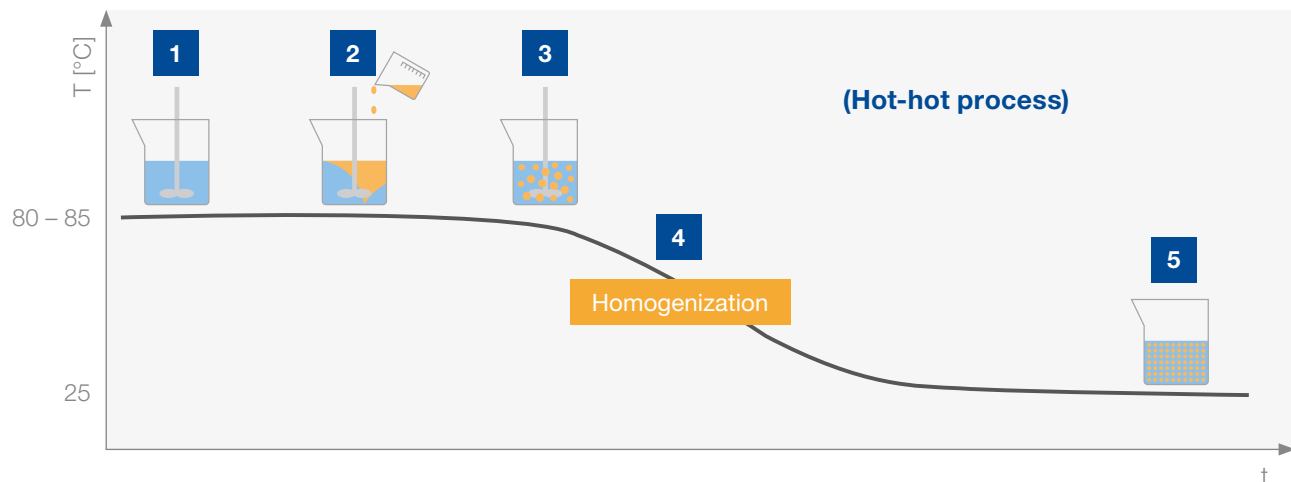
## Semi-solid application: Emulsifier for semi-solid topical forms

Topical formulations are complex mixtures composed of ingredients with varying functionalities. When formulating semi-solid dosage forms, achieving stability through the strategic selection of excipients is of the utmost importance.

In addition to delivering both water and oil soluble active ingredients through the stratum corneum, topical formulations should also preferentially control the penetration of these substances to the epidermis and dermis. To maintain the physical stability of these systems, consistency factors and emulsifiers are necessary to build robust lamellar structures.

The choice of emulsifiers for specific applications depends on the desired properties of the formulation (i.e., stability, viscosity, skin feel, etc.), or on the desired processing technology (i.e., phase inversion technology or PIT, hot processing, or cold processing).

### Hot-hot processing:



1. Mix water phase and oil phase separately.
2. Add oil phase very slowly while stirring.
3. Allow to cool while stirring (approx. 50 – 60 °C).
4. If necessary homogenisation (e.g. Ultra Turrax).
5. Finished emulsion.

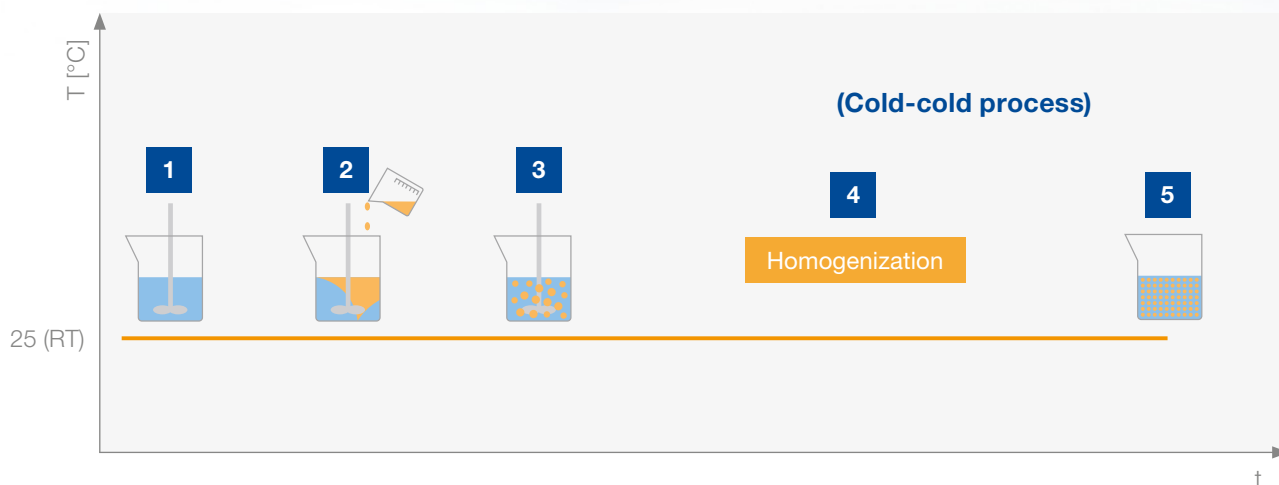
Hot-hot processing is the mostly utilized common method when formulating topical emulsions. When processing oil-in-water (O/W) emulsions, both phases are typically heated to 70 – 80 °C and then mixed under shear to disperse the inner oil phase within the external water phase. As the formulation comes to room temperature, a semi-solid results to allow for easy, local application to the affected area.

Kolliphor® PS 20, PS 60 and PS 80 are suitable for this processing method.





### Cold-cold processing:



1. Mix water phase and oil phase separately.
2. Add oil phase very slowly while stirring.
3. Stirring.
4. If necessary homogenisation (e.g. Ultra Turrax).
5. Finished emulsion.

Besides the well-known emulsifying process with two hot phases there is also the possibility to formulate an emulsion at room temperature. The processing of O/W emulsions at room temperature has several significant benefits. For example, it is no longer necessary to heat the water and oil phase to 70 – 80 °C. This saves considerable amounts of energy and reduces the production time as the cooling step is eliminated. Another very important advantage is that heat-sensitive APIs can be added to the emulsions at any point.

Kolliphor® PS 60 is very suitable for this kind of application.

## Semi-solid formulation examples (hot-hot processing)

Phase	Ingredients	Chemical name	Wt%					
A	Kollicream® OD	Octyldodecanol	20	20	20	0	0	0
	Kollisolv® MCT 70	Triglycerides medium-chain	0	0	0	20	20	20
	Koliwax® CA	Cetyl alcohol	3	0	0	3	0	0
	Koliwax® S	Stearic acid	0	3	0	0	3	0
	Koliwax® SA	Stearyl alcohol	0	0	3	0	0	3
	Koliwax® GMS II	Glyceryl monostearate 40-50 (typ II)	1.25	1.25	1.25	2.08	2.08	2.08
	Kolliphor® PS 60	Polysorbate 60	3.75	3.75	3.75	2.92	2.92	2.92
B	Deionized water		69.8	69.8	69.8	69.8	69.8	69.8
	Carbopol® ETD 2020 polymer	Acrylates/C <sub>10-30</sub> alkyl acrylate crosspolymer	0.2	0.2	0.2	0.2	0.2	0.2
C	Triethanolamine		1	1	1	1	1	1
D	Germaben		1	1	1	1	1	1



HLB can be lowered by mixing with Koliwax® GMS II to achieve stable and aesthetically acceptable cream or lotion emulsions with Kollicream® IPM.

Phase	Ingredients	Chemical name	Wt%	
A	Kollicream® IPM	Isopropylmyristate	20	20
	Koliwax® GMS II	Glyceryl monostearate 40-50 (typ II)	1.45	1.45
	Kolliphor® PS 60	Polysorbate 60	3.55	0
	Kolliphor® PS 80	Polysorbate 80	0	3.55
B	Deionized water		72.8	72.8
	Carbopol® ETD 2020 polymer	Acrylates/C <sub>10-30</sub> alkyl acrylate crosspolymer	0.2	0.2
C	Triethanolamine		1	1
D	Germaben II	Propylene glycol (and) diazolidinyl urea (and) methylparaben (and) propylparaben	1	1

Kollicream® 3 C has demonstrated excellent mildness in clinical studies. Kolliphor® PS 60 or PS 80 can be used to make very stable, aesthetically acceptable, emulsion creams with Kollicream® 3 C.

Phase	Ingredients	Chemical name	Wt%	
A	Kollicream® 3C	Cocoyl caprylocaprate	20	20
	Kolliwax® GMS II	Glyceryl monostearate 40-50 (typ II)	2.5	2.5
	Kolliphor® PS 60	Polysorbate 60	2.5	0
	Kolliphor® PS 80	Polysorbate 80	0	2.5
B	Deionized water		72.8	72.8
	Carbopol® ETD 2020 polymer	Acrylates/C <sub>10-30</sub> alkyl acrylate crosspolymer	0.2	0.2
C	Triethanolamine		1	1
D	Germaben II	Propylene glycol (and) diazolidinyl urea (and) methylparaben (and) propylparaben	1	1

**The following processing steps apply in all of the above formulations:**

#### Procedure

1. Phase A was weighed in a clean beaker and heated until the waxes melted.
2. In another beaker, water was heated to 80 °C and sprinkled with Carbopol while stirring.
3. Phase A was added into phase B with stirring and then neutralized with TEA.
4. The mixture was homogenized for about 2 minutes.
5. Mixture was allowed to cool under mild shear. Germaben II (Phase D) was added during cooling mixing step.



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