

# Breaking new ground in solubilization and bioavailability enhancement.



"Selecting the right solubilization product and technology for a poorly soluble API often involves a lot of trial and error. But thanks to our extensive expertise and cutting-edge tools, we can quickly help our customers find their way out of the solubilization maze, saving them a lot of legwork..."

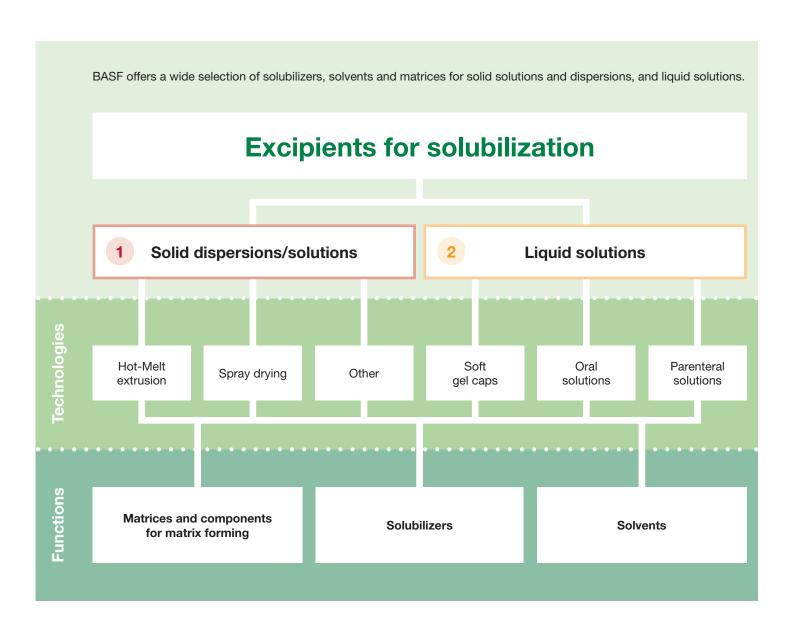
... says Vaishali Tawde, a solubilization expert at BASF. She understands that even the most promising active ingredient is of no use unless it can be effectively solubilized and made bioavailable. This is why she is proud to stand behind our extensive portfolio

of solubilizers, cosolvents and matrices for all common dosage forms, including solids, liquids and semi-solids – a portfolio that includes novel excipients particularly well-suited for poorly soluble drugs.

Vaishali Tawde knows that choosing the right solubilization product and method can be an expensive and time-intensive process.

Which is why the right partner can make all the difference. Vaishali Tawde and her team have extensive solubilization expertise and experience with all key technologies such as hot-melt extrusion, spray drying, and drug layering. What's more, they have access to industry-leading tools such as our high-throughput screening (HTS) robot. This puts them in an excellent position to help customers tackle their solubilization and bioavailability challenges rapidly and efficiently.

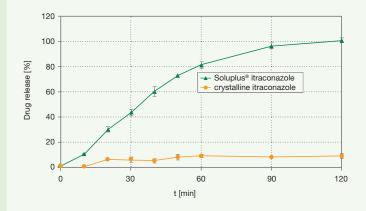
## Our products and services.



## **Soluplus®**

Soluplus® is a leading-edge excipient designed specifically for enhancing solubility and bioavailability of poorly soluble APIs. Thanks to its high flowability and excellent extrudability, Soluplus® exhibits superior performance in forming solid solutions, especially in hot-melt extrusion processes. In addition, it can be used as a matrix former in spray drying processes, a binder in wet or dry granulation, and in drug layering.

#### Improved drug release from Soluplus® extrudates

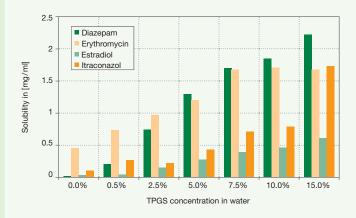


В

## Kolliphor® TPGS

A water-soluble derivative of natural-source vitamin E, Kolliphor® TPGS is suitable for both oral and topical dosage forms. This versatile excipient can be used as a drug solubilizer, absorption enhancer, emulsifier, vehicle for lipid-based drug delivery, source of natural vitamin E, and antioxidant. Based on natural vitamin E manufactured by BASF, Kolliphor® TPGS is produced to the highest quality standards.

### Solubilization capacity of Kolliphor® TPGS

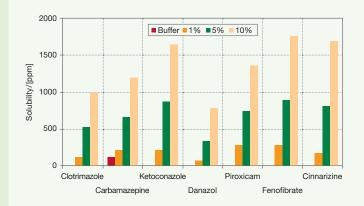


# C

# Kolliphor® HS 15

Kolliphor® HS 15 is a potent non-ionic solubilizer with low toxicity. It is used for manufacturing aqueous parenteral preparations with vitamins A, D, E and K, plus lipophilic APIs such as propanidid, miconazole, alfadolone, alfaxalone, nifedipine, and piroxicam. Kolliphor® HS 15 is soluble in water, ethanol, and 2-propanol.

#### Solubility enhancement with Kolliphor® HS 15

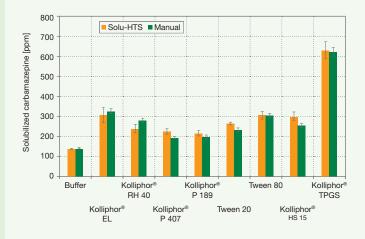


# D

## Solu-HTS

Identifying the right solubilization method for a poorly soluble API can be a time-consuming and expensive process. This is where Solu-HTS, our industry-leading high-throughput screening robot, comes in. It helps customers identify the most suitable solubilizer or combination of solubilizers for their needs – rapidly and reliably. What's more, it can be used to examine structure-property relationships.

#### Comparison of test methods: Manual vs. Solu-HTS



### **Technical services**

Selecting the right solubilization product and method for your API does not have to be a matter of trial and error – thanks to our extensive experience and industry-leading tools. For example, Solu-HTS, our high-throughput screening (HTS) robot, helps customers efficiently and reliably identify the most suitable solubilizer or combination of solubilizers for their needs, and examine structure-property relationships. This significantly reduces development time and costs. And you can always tap into our specialists' expertise for advice on leveraging technologies such as hot-melt extrusion.

1

## **Excipients for solid dispersions and solutions**

When working with poorly soluble APIs, solid dispersions and solutions are often the answer. We have extensive expertise in this area – and our portfolio has a variety of products well-suited for corresponding processes such as hot-melt extrusion, spray drying and drug layering. Soluplus® and Kollidon® VA 64 fine, for example, are matrix-forming polymers, and the various Kolliphor® grades – Kolliphor® TPGS in particular – can be used in combination with matrix formers or matrices.

2

## **Excipients for liquid solutions**

BASF's portfolio includes products suitable for oral solutions and parenteral applications, for both traditional and complex solubilization methods. The Kolliphor® range includes non-ionic solubilizers ideal for solubilizing low-solubility actives in microemulsions. Kolliphor® ELP and Kolliphor® HS 15 are suitable for parenteral applications. Plus, we offer both hydrophilic and lipophilic cosolvents.

# Our cutting-edge excipients for solubilization.

Function	New name	Former name	Compendial name	Standard package (kg)			
Kolliphor®: Innovative solubilizers – for a whole new world of possibilities.							
Solubilizer	Kolliphor® EL	Cremophor® EL Castor Oil	51 5 M 11 15 1 1 1 25 1/20/M5 5 1 1 1 25 0 1 27	00			
	Kolliphor® ELP	Cremophor® ELP	Ph. Eur.: Macrogolglycerol Ricinoleate 35; USP/NF: Polyoxyl 35 Castor Oil	60			
	Kolliphor® RH 40	Cremophor® RH 40	Ph. Eur.: Macrogolglycerolhydroxystearate 40; USP/NF, Polyoxyl 40 Hydrogenerated Castor Oil	60			
	Kolliphor® CS 12	Eumulgin® B 1 PH	Ph. Eur.: Macrogol Cetostearyl Ether 12	20			
	Kolliphor® CS 20	Eumulgin® B 2 PH	Ph. Eur.: Macrogol Cetostearyl Ether 20; USP/NF: Polyoxyl 20 Cetostearyl Ether	25			
	Kolliphor® CS B	Lanette® 20 PH	Ph. Eur.: Cetostearylalcohol (Type B), Emulsifying	20			
	Kolliphor® CS S	Lanette® E PH	Ph. Eur.: Sodium Cetostearyl Sulphate	12			
	Kolliphor® CS A	Lanette® N PH	Ph. Eur.: Cetostearylalcohol (Type A), Emulsifying	20			
	Kolliphor® CS L	Lanette® SX PH	Not monographed	20			
	Kolliphor® P 407 micro	Lµtrol® micro 127	Ph. Eur., USP/NF, JP: Poloxamer 407	25			
	Kolliphor® P 188 micro	Lµtrol® micro 68	Ph. Eur., USP/NF, JP: Poloxamer 188	25			
	Kolliphor® P 338	Lutrol® F 108	Ph. Eur., USP/NF: Poloxamer 338	18/80			
	Kolliphor® P 407	Lutrol® F 127	Ph. Eur., USP/NF, JP: Poloxamer 407	25/90			
	Kolliphor® P 188	Lutrol® F 68	Ph. Eur., USP/NF, JP: Poloxamer 188	25/102			
	Kolliphor® P 237	Lutrol® F 87	Ph. Eur., USP/NF: Poloxamer 237	25			
	Kolliphor® PS 20	Polysorbate 20 PH	Ph. Eur., USP/NF: Polysorbate 20	200			
	Kolliphor® PS 60	Polysorbate 60 PH	Ph. Eur., USP/NF: Polysorbate 60	200			
	Kolliphor® PS 80	Polysorbate 80 PH	Ph. Eur., USP/NF: Polysorbate 80	200			
	Soluplus®	Soluplus®	Not monographed	25			
	Kolliphor® HS 15	Solutol® HS 15	Ph. Eur.: Macrogol 15 Hydroxystearate; USP/NF: Polyoxyl 15 Hydroxystearate	50			
	Kolliphor® TPGS	Speziol® TPGS PHARMA	USP/NF: Vitamin E Polyethylene Glycol Succinate	05, 10, 50			
	Kolliphor® SLS 1216	Speziol® V 95 G	Ph. Eur., USP/NF, JP: Sodium Lauryl Sulfate	25/600			
	Kolliphor® SLS	Texapon® K 12 G PH		25			
	Kolliphor® SLS Fine	Texapon® K 12 P PH		15			

Function	New name	Former name	Compendial name	package (kg)			
Kollisolv®: Premium solvents, manufactured to the highest standards.							
Solvent	Kollisolv® PG	Propylenglycol	Ph. Eur., USP/NF, JP: Propylene Glycol	220			
	Kollisolv® PEG 300	Lutrol® E 300	Ph. Eur.: Macrogols; USP/NF: Polyethylene Glycol; JPE: Macrogol 300	130			
	Kollisolv® PEG 400	Lutrol® E 400	Ph. Eur.: Macrogols; USP/NF: Polyethylene Glycol; JPE: Macrogol 400	130			
	Kollisolv® P 124	Lutrol® L 44	Ph. Eur., USP/NF, JPE: Poloxamer 124	18/200			
	Kollisolv® MCT 60	Myritol® 312 PH	Ph. Eur., USP/NF, JP: Triglycerides medium-chain	850			
	Kollisolv® MCT 70	Myritol® 318 PH	Ph. Eur., USP/NF, JP: Triglycerides medium-chain	190/850			
	Kollisolv® CAP	Speziol® CAP	Not monographed	175			
	Kollisolv® G 85	Speziol® G 86% PF	Ph. Eur.: Glycerol 85 per cent	250			
	Kollisolv® G 99	Speziol® G 99.8% PF	Ph. Eur.: Glycerol; USP/NF: Glycerin	250			
	Kollisolv® GTA	Speziol® GTA	Ph. Eur., USP/NF: Triacetin	235			
	Kollisolv® PYR	Soluphor® P	Ph. Eur.: Pyrrolidone	200			
Function	Product name		Application				
Matrices and components for matrix forming	Soluplus <sup>®</sup>		Solubilizing agent, dispersant, crystallization inhibitor, immediate release matrix				
	Kollidon® VA 64 / VA 64 fine						
	Kollidon® 12 PF						
	Kollidon® 17 PF						
	Kollidon® 30						
	Kollidon® 90 F						
	Kollidon® SR		Controlled release matrix systems, also suitable for poorly soluble drugs				
	Kollicoat® MAE 100 P		For enteric matrices, solid solutions for delayed release drug delivery systems	delivery systems			

For immediate release matrices

Compendial name

Function

New name

Kollicoat® IR

Kollicoat® Protect

Former name

Standard

### Pharma Ingredients & Services. Welcome to more opportunities.

### **Custom Synthesis | Excipients | Active Ingredients**

BASF's vast solubilization expertise opens new horizons in solubility and bioavailability.

- Broad portfolio for all common dosage forms
- Innovative excipients for poorly soluble APIs
- Proven performance and safety
- Experience with key technologies such as hot-melt extrusion

Contact us to see how Vaishali Tawde and her colleagues around the globe can help you tackle your solubilization challenges, or visit www.pharma-ingredients.basf.com

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