

Excipients for Parenteral Use

Application and
Sterilization Data



BASF Excipients for Parenteral Use



✓ Kollidon® 12 PF and Kollidon® 17 PF: The endotoxin-controlled PVP-based solubilizers for parenteral and oral formulations



✓ Kolliphor® HS 15: The potent IID listed nonionic solubilizer



✓ Kolliphor® ELP: The highly purified solubilizer for oral, parenteral and topical applications



BASF's quality and regulatory standards for excipients for parenterals:

- Manufacturing according to IPEC-PQG GMP
- Compendial compliance covering current and proposed major global pharmacopoeia standards
- Endotoxin and microbial testing
- Elemental impurity limits according to ICH Q3D
- Regulatory documentation
- Registration and submission support
- Non-clinical safety data available



Kollidon® 12 PF and Kollidon® 17 PF

Sterilization test

Sterile filtration pre- and post sterilization

Test parameters

20% aqueous solution	20% aqueous solution
Autoclaving (121°C, 20 minutes)	0.20 µm filter (cellulose acetate)

Test results*

	Kollidon® 12 PF			Kollidon® 17 PF		
	Blank sample	Filtered sample	Autoclaved sample	Blank sample	Filtered sample	Autoclaved sample
pH	4.0	4.0	4.0	3.9	3.9	4.0
Dynamic viscosity [mPas]	4.1	4.0	3.9	5.1	5.2	5.0
K value	13.3	13.6	13.4	17.4	17.9	17.4
Molecular weight [g/mol]						
Mw	2910	2820	2830	7320	7050	7240
Mn	1040	1030	1040	2070	2020	2060
Aldehyde [ppm]						
Formaldehyde	<1	1	<1	1	2	1
Acetaldehyde	1	<1	4	1	1	<1
Propionaldehyde	<1	<1	<1	<1	<1	<1
Hydrazine [ppm]	<1	<1	<1	<1	<1	<1
Peroxide value [meq/kg]	4	<2	<2	6	4	2

* Tested parameters are considered stability indicating. For more information please contact your local BASF representative.

Kolliphor® HS 15

	Sterilization test	Sterile filtration pre- and post sterilization	Heat stress test
Test parameters	20% aqueous solution	20% aqueous solution	100% product as supplied
	Autoclaving (121°C, 20 minutes)	0.20 µm filter (cellulose acetate)	20 heat-cool cycles Each cycle started by heating to 65°C, holding for 24 hours; cooled to 4°C, held for 24 hours prior to repeating the cycle.

Test results*

	Blank sample	Filtered sample	Autoclaved sample	Stress test
pH (20% aq. solution)	6.64	6.62	6.29	5.6
Viscosity [mPas], 25°C @1000 1/s	5.45	5.61	5.28	5.8
Aldehyde [mg/kg]				
Formaldehyde	<1	<1	2	3
Acetaldehyde	4	4	3	4
Propionaldehyde	<1	<1	<1	1
Peroxide value [meq/kg]	<2	<2	<2	1
Hydroxyl value [mg KOH/kg]	27	23	23	33
Iodine value [g I2/100g]	0.3	0.4	0.3	0.2
Acid value [mg KOH/g]	0.1	0.1	0.1	0.2

* Tested parameters are considered stability indicating. For more information please contact your local BASF representative.

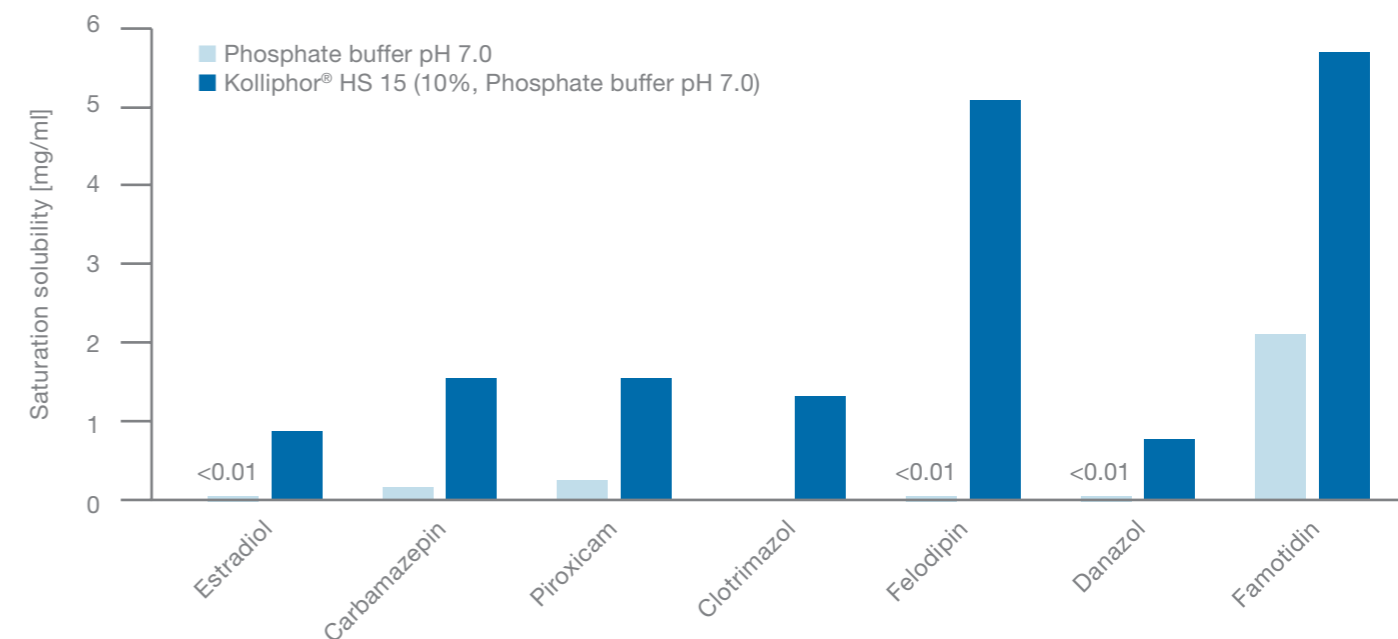
Kolliphor® HS 15: Low histamine release for fewer side effects

	Haemolytic activity [% Haemolysis]			Serum histamine level (beagle dogs) [nM]		
	0.1%	1%	10%	0 min	15 min	60 min
Kolliphor® HS 15	0	0	8.7	5	220	8
Polysorbate 80	0	0	11.1	3	>50,000	247

The haemolytic activity of Kolliphor® HS 15 is much lower than for other polyoxyethylene-based surfactants.

While its performance is comparable to Polysorbate 80, however it shows a much lower histamine release making it ideal for parenteral applications.

Potent solubilizer for poorly water soluble drugs



Comparison of saturation solubility of representative poorly water soluble APIs.

Kolliphor® ELP

	Sterilization test	Sterile filtration pre- and post sterilization	Heat stress test
Test parameters	20% aqueous solution	20% aqueous solution	20 heat-cool cycles Each cycle started by heating to 65°C, holding for 24 hours; cooled to 4°C, held for 24 hours prior to repeating the cycle.
	Autoclaving (121°C, 20 minutes)	0.20 µm filter (cellulose acetate)	20 heat-cool cycles

Test results*

	Blank sample	Filtered sample	Autoclaved sample	Stress test
pH (20% aq. solution)	6.03	5.88	4.92	6.1
Viscosity [mPas], 25°C @1000 1/s	7.44	7.31	7.06	7.05
Aldehyde [mg/kg]				
Formaldehyde	<1	1	4	2
Acetaldehyde	4	4	3	4
Propionaldehyde	<1	<1	<1	<1
Peroxide value [meq/kg]	5	2	2	1
Hydroxyl value [mg KOH/kg]	21	18	19	28
Iodine value [g I ₂ /100g]	6.3	6.3	6.5	6.1
Acid value [mg KOH/g]	0.1	0.1	0.1	<0.1

* Tested parameters are considered stability indicating. For more information please contact your local BASF representative.

Application Data Highlights

More products to come!

Kollidon® 12 PF and 17 PF

- ✓ Proven stability after sterile filtration and autoclave sterilization
- ✓ The endotoxin-controlled PVP-based solubilizers for parenteral and oral formulations
- ✓ Low viscosity for easy filtration

Kolliphor® HS 15

- ✓ Proven stability after sterile filtration, autoclave sterilization and heat stress cycling
- ✓ Potent non-ionic solubilizer
- ✓ Recently approved (FDA IID) in parenteral and ophthalmic drug formulations
- ✓ Extremely low histamine release compared to standard parenteral excipients

Kolliphor® ELP

- ✓ Proven stability after sterile filtration, autoclave sterilization and heat stress cycling
- ✓ Highly purified and endotoxin controlled version of Kolliphor® EL – particularly suitable for parenteral formulations
- ✓ Widely used in approved drug formulations worldwide
- ✓ Tightly controlled water, potassium and free fatty acid content for particularly sensitive API formulations



We create chemistry

Our service offer

For our parenteral excipients we provide comprehensive documentation including toxicological assessments, regulatory & quality packages, certificates and more.

Please contact us regarding your specific applications and needs:

North America

Shaukat Ali
shaukat.ali@basf.com

South America

Joao Marcos Assis
joao-marcos.assis@basf.com

Asia-Pacific

Rajkiran Narkhede
rajkiran.narkhede@basf.com

Europe, Middle East, Africa

Nadezhda Romanova
nadezhda.romanova@basf.com

For more information visit us on
www.pharma.basf.com

For sample requests contact us at
pharma-solutions@basf.com