

#### **Kollisolv<sup>®</sup> PEGs**

Polyethylene glycols for pharmaceutical applications

**Technical Presentation** 

# BASF has a portfolio of Kollisolv<sup>®</sup> PEG offerings to support pharmaceutical oral and topical dosage forms.

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STANDARD	Liquid	Semi-solid	Solid	USP-NF	Ph. Eur.
Kollisolv <sup>®</sup> PEG 300 G	•			•	•
Kollisolv® PEG 400 G	•			•	•
Kollisolv® PEG 600	•			•	•
Kollisolv® PEG 1000		•		•	•
Kollisolv® PEG 1450			•	•	
Kollisolv® PEG 3350 USP LAX			•	•	•
Kollisolv <sup>®</sup> PEG 8000			•	•	•
LOW ALDEHYDE	Liquid	Semi-solid	Solid	USP-NF	Ph. Eur.
Kollisolv® PEG 400 LA	•			•	•
Kollisolv® PEG 600 LA	•			•	•

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# Kollisolv<sup>®</sup> PEGs can be used in liquid, semi-solid, and solid dosage forms, in combination with other PEGs or other excipients and APIs.



# Typical properties of liquid and solid Kollisolv<sup>®</sup> PEGs allow for a variety of uses.

	Kollisolv® PEG 300 G	Kollisolv <sup>®</sup> PEG 400 G	Kollisolv <sup>®</sup> PEG 400 LA	Kollisolv <sup>®</sup> PEG 600	Kollisolv® PEG 600 LA	Kollisolv® PEG 1000	Kollisolv® PEG 1450	Kollisolv® PEG 3350 LAX	Kollisolv <sup>®</sup> PEG 8000
Appearance	Colorless, almost odorless, and tasteless liquid at room temperature				White to almost white solid with a waxy or paraffin-like appearance				
Average molecular weight (g/mol)	285 to 315	380 to 420	380 to 420	570 to 630	570 to 630	900 to 1100	1305 to 1595	3015 to 3685	7000 to 9000
Melting point (°C)	-15 to -8	4 to 8	4 to 8	15 to 25	15 to 25	35 to 40	42 to 46	53 to 57	55 to 62
lydroxyl value (mg KOH/g)	340 to 394	264 to 300	264 to 300	178 to 197	178 to 197	107 to 118	70 to 86	30 to 38	12 to 16
/iscosity at 25 °C (mPa.s)	80 to 105	105 to 130	105 to 130	Solid	Solid	Solid	Solid	Solid	Solid
/iscosity at 99 °C (mm²/s)	5.4 to 6.4	6.8 to 8.0	6.8 to 8.0	9.9 to 11.3	9.9 to 11.3	16.0 to 19.0	25 to 32	76 to 110	470 to 900
Solubility	Very soluble in water and alcohol, practically insoluble in oils and fats				Very soluble in water, freely soluble in alcohol, practically insoluble in oil and fats.		Very soluble in water, slightly soluble in alcohol, practically insoluble in oils and fats.		
ōtal aldehydes			≤ 10 ppm		≤ 10 ppm	-			

### Low Aldehyde Kollisolv<sup>®</sup> PEGs are perfectly suited for softgel fill applications.

Kollisolv<sup>®</sup> PEG 400 LA PRD 30607819

Commercial 204 kg Steel Drums: ART 50382500 Sample 1 kg glass bottle: ART 50784432 Kollisolv<sup>®</sup> PEG 600 LA PRD 30607821

Commercial 204 kg Steel Drums : ART 50382526 Sample 1 kg glass bottle: ART 50784433

- 10 ppm maximum total aldehyde specification
- Include measures in manufacturing to minimize peroxide and formaldehyde formation
- Overlayed in N<sub>2</sub>, to ensure long-term stability
- Eliminate cross-linking that inhibits disintegration
- Support solubilization of poorly soluble APIs in combination with other BASF solubilizers
- Can be paired with crystallization inhibitors and ingredients



# Kollisolv<sup>®</sup> PEGs are versatile and can be used in combination with other chemistries in tablet and capsule formulations for large volume markets.

Crospovidone Kollidon<sup>®</sup> CL / CL-F / CL-SF / CL-M

Povidone Kollidon<sup>®</sup> 12 PF, 17 PF, 25, 30

> Methacrylic acid Kollicoat<sup>®</sup> MAE 100-55

Copovidone Kollidon<sup>®</sup> VA 64 Triacetin Kollisolv® GTA

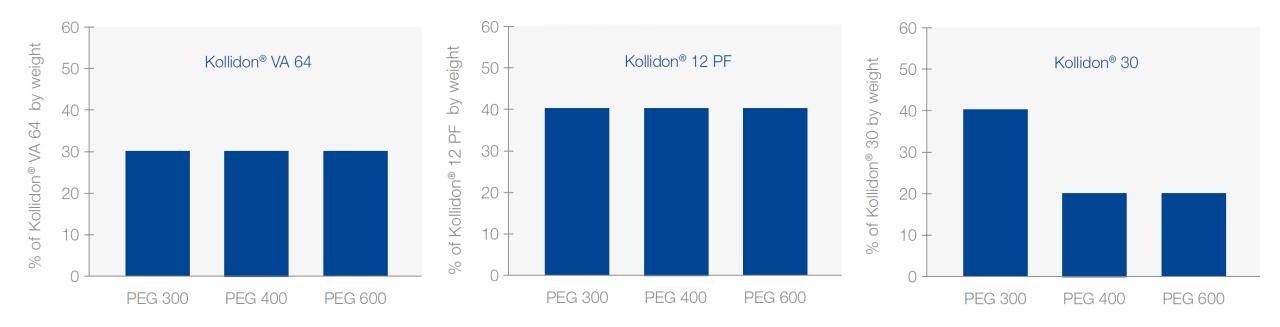
> Polysorbate 20, 60, 80 Kolliphor® PS 20 / 60 / 80

Sodium lauryl sulfate Kolliphor<sup>®</sup> SLS / SLS fine

Poloxamer Kolliphor<sup>®</sup> 188 / 338 / P407

 Operating at global-supply scale, BASF Pharma Solutions offers an unparalleled portfolio of quality PEG materials, and a complementary broader portfolio of supporting pharmaceutical ingredients.

# BASF PVP-based crystallization inbitors are soluble in low molecular weight, liquid PEGs at high concentrations up to 40 wt%.



- PVP-based Kollidon<sup>®</sup> VA 64, Kollidon<sup>®</sup> 12 PF, and Kollidon<sup>®</sup> 30 are soluble at room temperature up to 40 wt% in liquid Kollisolv<sup>®</sup> PEGs.
- BASF's deep expertise in solubilization and crystallization inhibition, coupled with a wide portfolio offering of chemistries perfectly fit for use, positions us as a reliable and versatile supplier.



# Geismar Kollisolv<sup>®</sup> PEGs are overlayed with nitrogen for stability, and purified post-production for removal of trace impurities.

	Kollisolv <sup>®</sup> PEG 400 LA	Market Leading Low Aldehyde PEG 400
	Ph. Eur., USP	Ph. Eur., USP
ppm Acetic Acid*	12	27
ppm Acetate*	12	27
ppm Formic Acid*	49	96
ppm Formate*	49	98
Ethylene Glycol (wt%)	<0.01	0.02
Diethylene Glycol (wt%)	0.02	0.04
ppm Fe**	<1	<1
ppmMn**	<1	<1
ppm K**	8	10
ppm P**	<1	10

\* In-house Gradient Ion Chromatography Analysis.

\*\* In-house Inductively Coupled Plasma (ICP) metal analysis against 4-point calibration.

 PEGs are generally considered stable, however even trace impurities of species like acids and metals (below compendial requirements) can trigger oxidative degradation of the excipient and/or drug formulations.

- Geismar Kollisolv<sup>®</sup> PEGs blanketed with nitrogen, and refined through a proprietary purification step.
- Purification post-production of Geismar Kollisolv<sup>®</sup> PEGs achieves best-in-class profile of residuals, on par with market-leading pharmaceutical PEGs.



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