Technical Information

Kollidon® 25
Kollidon® 30
Kollidon® 30 LP
Kollidon® 90 F

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1. Introduction

Historical aspects of polyvinylpyrrolidone

The modern acetylene chemistry was developed at BASF in the 1930s by Reppe. One of the many products that emerged from this work are the soluble polyvinylpyrrolidone grades, obtained by radical polymerization of the monomer unit N-vinylpyrrolidone.

The polymerization can be performed either in water or in organic solutions. Triggered by organic or inorganic radical starters, the polymers span a wide range of molecular weights. Because of its solubility in water and in many organic solvents, its high binding power and its ability to form complexes, soluble polyvinylpyrrolidones are very valuable synthetic polymers for the pharmaceutical industry.

Separate Technical Information Sheets are available for the Povidones with low molecular weights, for the insoluble Kollidon® grades (Crospovidone) and for Kollidon® VA 64, the copolymer consisting of N-vinylpyrrolidone and vinyl acetate (Copovidone).

More information on Kollidon® grades may be found in the book, “Kollidon®, Polyvinylpyrrolidone for the Pharmaceutical Industry”.

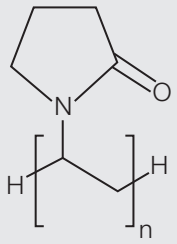
2. Technical properties

Description

The range of medium and high molecular weight Povidones comprises of the grades Kollidon® 25, Kollidon® 30, Kollidon® 30 LP, which are of medium molecular weight and are polymerized in aqueous solution and spray dried. In addition, the high molecular weight grade Kollidon® 90 F, after being polymerized in water achieving a very highly viscous polymer solution, is finally dried using a drum dryer.

The product range comes as white powders with faint, characteristic odor.

Structural formula



Trivial names

Soluble polyvinylpyrrolidone is also known as povidon(e), povidonum, polyvidone, poly(1-vinyl-2-pyrrolidone) and PVP.

CAS number

9003-39-8

Product range and molecular weights

The product range of the medium and high molecular weight Povidones comprises of 4 different products which are, product dependent, manufactured in the production sites in Ludwigshafen, Geismar and/or Shanghai.

The molecular weight of polymers can be expressed in three different forms, as weight average molecular weight, as number average molecular weight and as viscosity average molecular weight.

The molecular weight of povidone is usually expressed as the K-value, from which it is possible to calculate the viscosity average molecular weight (M_v).

However, the weight average molecular weight (M_w) is found more frequently in the literature.

The following M_w values were determined for different grades of Kollidon® in recent measurements. In contrast to former determinations SEC was performed using a detection system not requiring reference standards anymore.

	Nominal K-Value	Compendial range for K-value	M_w [g/mol]
Kollidon® 25	25	24 – 27	28000 – 34000
Kollidon® 30	30	28 – 32	44000 – 54000
Kollidon® 30 LP	30	28 – 32	44000 – 54000
Kollidon® 90 F	90	85 – 95	900000 – 1200000

Table1

Solubility

The solubility of Kollidon® varies considerably from one solvent to another.

In Table 2 below, “soluble” signifies that a solution of at least 10% can be prepared, and “insoluble” signifies that the solubility is less than 1%.

Soluble in:	
chloroform	n-butanol
cyclohexanol	n-propanol
ethanol abs.	polyethylene glycol 300
glycerol	polyethylene glycol 400
isopropanol	propylene glycol
methanol	triethanolamine
methylene chloride	water
Insoluble in:	
cyclohexane	pentane
diethyl ether	carbon tetrachloride
ethyl acetate	toluene
liquid paraffin	xylene

Table 2: Solubility of Kollidon® Grades

Particle size

When analyzed the particle size distribution using a sieving method, particle size distributions of the various polymers can be described with the following typical ranges.

Product	<50 µm	>250 µm
Kollidon® 25	max. 40%	max. 5%
Kollidon® 30	max. 40%	max. 5%
Kollidon® 30 LP	max. 20%	max. 5%
Kollidon® 90 F	max. 10%	max. 25%

Table 3

Bulk density

Bulk density of Kollidon® is determined according to Ph. Eur. current edition, method 2.9.34.

Product	Bulk density
Kollidon® 25/30/30 LP	400 – 600 g/L
Kollidon® 90 F	400 – 550 g/L

Table 4: Bulk density of the Kollidon® grades

Particle size distribution and bulk density are considered characteristic values. They are not part of any specifications.

Glass transition temperature Tg_2

Product	Tg_2 [°C]
Kollidon® 25	165
Kollidon® 30	171
Kollidon® 30 LP	171
Kollidon® 90 F	177

The glass transition temperature was determined by DSC as Tg_2, after having eliminated water by heating and finally cooling the dried polymer to room temperature for a second cycle.

Viscosity

Fig. 1 shows the relationship between the viscosity of aqueous solutions of the different grades of Kollidon® and their concentration.

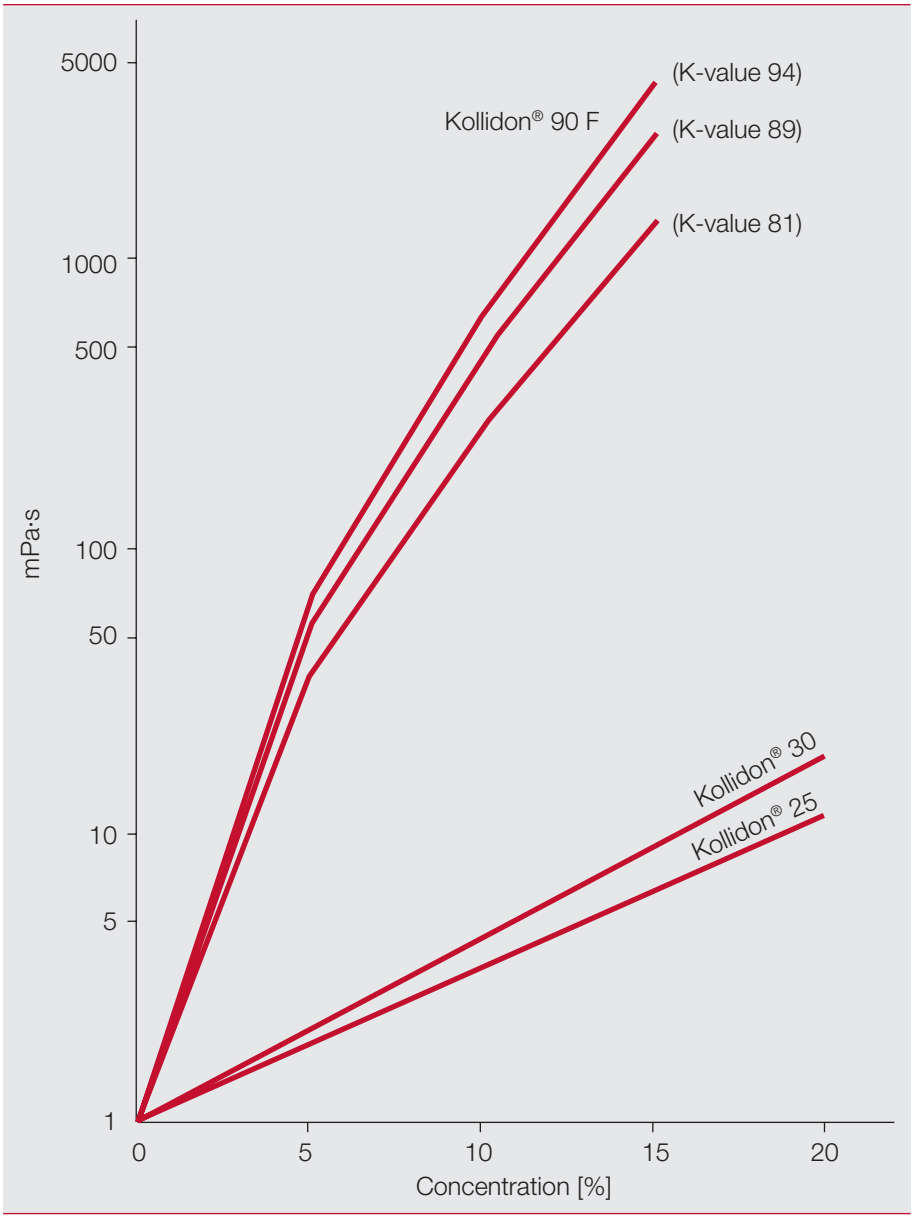


Fig. 1: Viscosity of Kollidon® solutions (Ubbelohde viscometer, 25 °C)

Complexation, chemical interactions

Povidone can form fairly stable association compounds or complexes with a number of active substances. The best known example is PVP-iodine which is the subject of a separate leaflet.

The ability of Kollidon® to form a water-soluble complex with insoluble active substances can be used in pharmaceuticals to improve the release rate and solubility of drugs.

There are a few substances such as the polyphenols that form stronger complexes that can precipitate in neutral or acidic media.

It must be noted that if povidone is combined with strongly alkaline substances such as lithium carbonate or sodium hydroxide it can crosslink and become insoluble, particularly at elevated temperatures. In extreme cases, this can increase the viscosity of liquid presentation forms and delay bioavailability in solid presentation forms.

3. Handling

Please refer to the individual Material Safety Data Sheet (MSDS) for instructions on safe and proper handling and disposal.

4. Example application

The main applications of the soluble Kollidon® grades are summarized in Table 6.

Binder	Tablets, capsules, granules
Bioavailability enhancement	Tablets, capsules, granules, pellets, suppositories, transdermal systems
Film formation	Opthalmic solutions, tablets, medical plastics
Solubilization	Oral, parenteral and topical solutions
Lyophilising agent	Injection preparations, oral lyophilisates
Stabilisation of suspensions	Oral and parenteral suspensions
	Oral instant beverage powders and granules for redispersion
Viscosity modifier	Ophthalmic formulations
Adhesives	Transdermal systems, adhesive gels
Drug stabilisation	Enzymes in diagnostics

Table 6: Main applications of the soluble Kollidon® grades of medium and high molecular weight

The adhesive, film-forming, dispersing and thickening properties of the soluble Kollidon® grades are used in the various modifications of granulation technologies for tablet production, film coating and in the preparation of other dosage forms. The improvement in the solubility of active ingredients brought about by complexation or association, and the thickening effect find use mainly in the manufacture of liquid presentation forms.

The grade of Kollidon® that is selected depends mainly on its molecular weight, as this dictates the viscosity, binding effect, the complexation capacity and how readily it is eliminated from the body.

A detailed description of the applications is to be found in the book, “Kollidon®, poly-vinylpyrrolidone for the Pharmaceutical Industry”.

Tablet binding

Kollidon® 25, Kollidon® 30, Kollidon® 30 LP and Kollidon® 90 F

When applied for granulation in high shear mixers or fluid-bed granulators the resulting granules with Kollidon® 25, Kollidon® 30 and Kollidon® 90 F are hard, free flowing with a low proportion of fines. Binding strength is excellent to achieve hard and stable tablets.

Kollidon® 25 and Kollidon® 30 require binder quantities of 2% and 5% related to the tablet weight. As Kollidon® 90 F has a higher binding capacity the required quantities are 2% or even less. The high viscosity of binder solutions of Kollidon® 90 F sometimes requires precautions to ensure the granules to be evenly wetted.

Kollidon® 25, 30 and 90 F are also suitable for the direct compression of tablets without granulation. This technique requires a certain relative humidity, as the powder mixture must have a certain moisture content to bind properly. If Kollidon® is used in addition to microcrystalline cellulose, it not only makes the tablets harder but also gives them stronger edges. For best results in direct compression, all the excipients should have a certain moisture content. This applies to starch, micro- crystalline cellulose and lactose monohydrate as fillers.

It can be seen from Fig. 2 that there is hardly any difference in the hardness of lactose placebo tablets made with Kollidon® 25 and Kollidon® 30. However, the same quantity (3% of the tablet weight) of Kollidon® 90 F almost doubles the hardness, compared with Kollidon® 25.

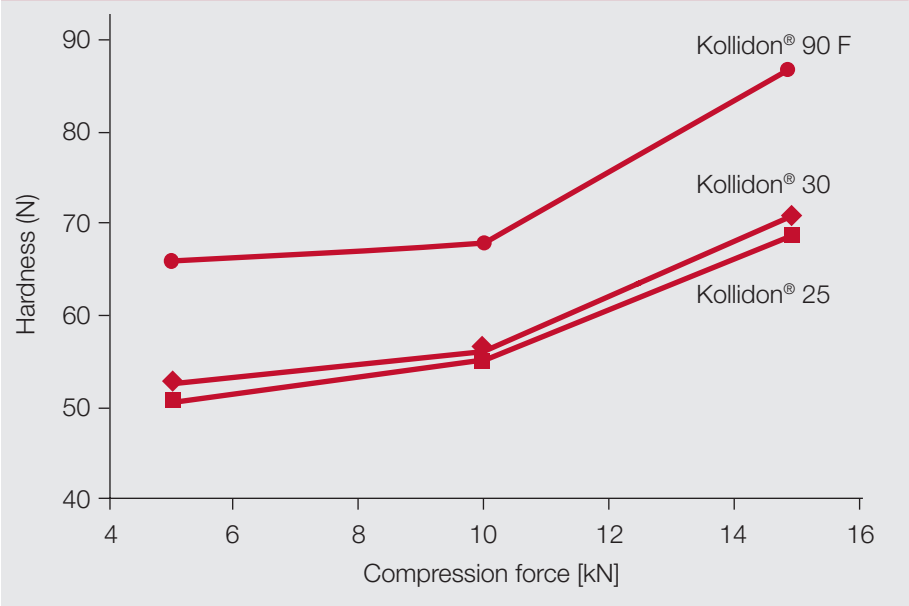


Fig. 2: Lactose monohydrate tablets with 3% Kollidon® (wet granulation)

Kollidon® is also suitable as a binder in fluidized-bed granulation processes. Thanks to their relatively low viscosity, solutions of Kollidon® 25 and Kollidon® 30 can be prepared relatively quickly, and sprayed easily, to quickly give stable granules.

Co-precipitation, co-milling

Kollidon® 25, 30

The dissolution rate and therefore the absorption rate of drugs that do not dissolve readily in water can be greatly improved by co-milling or coprecipitation with Kollidon® 25 or Kollidon® 30, as the complex formed is, in effect, a solid solution of the drug in the Kollidon®. This requires an excess of Kollidon® to maintain the (partially) amorphous form of the active substance. Suitable processes include mixing, co-milling or melt extrusion of the Kollidon®-drug mixture, or coprecipitation, granulation onto a carrier, or spray-drying a solution containing the drug and Kollidon®.

The literature contains hundreds of publications on this application. The most frequently tested active substance mentioned is probably nifedipine.

Stabilizers of suspensions

Kollidon® 25, 30, 90 F

These grades can be used to stabilize oral and topical suspensions with a wide range of active ingredients, e.g. acyclovir, ibuprofen, magaldrate, nystatin, phenytoin, trimethoprim, sulfonamides and antibiotics, as well as sugar-coating suspensions. Combinations of Kollidon® 90 F with Kollidon® CL-M have often given very good results.

Thickener

Kollidon® 90 F

Because of its good solubility in water and alcohol, Kollidon® 90 F can be used as a thickener for aqueous or aqueous-alcoholic solutions for oral application (viscosity curve, see Figure 1).

5. Safety data sheet

Safety data sheets are available on request and are sent with every consignment.

6. Retest date and storage conditions

Please refer to Quality & Regulatory Product Information (QRPI).

7. Specification

For current specification, please speak to your local BASF sales or technical representative.

8. Regulatory status

Please refer to Quality & Regulatory Product Information (QRPI).

9. Toxicological data

For information on toxicological issues please refer to the tox abstract which can be supplied on request.

More/detailed toxicological information for Kollidon® grades is available on request under Secrecy Agreement.

10. PRD and Article numbers

PRD-No.*	Product name	Article numbers	Packaging
30034967	Kollidon® 25	57254799	25 kg Cardboard boxes
		50348143	0.5 kg Plastic pail
30697299	Kollidon® 25	50574244	50 kg Plastic drums
		50574245	0.5 kg Plastic pail
30034974	Kollidon® 30 Origin Germany	57254693	25 kg Cardboard boxes
		50347950	0.5 kg Plastic pail
30525451	Kollidon® 30 Origin Germany	50022331	50 kg Plastic drums
		50347978	0.5 kg Plastic pail
30403404	Kollidon® 30 Origin USA	55238758	1 kg PE-Bottle
		55087337	50 kg PE-Drum, removable head
30660388	Kollidon® 30 Origin China	50486018	50 kg Plastic drums
		50498559	0.5 kg Plastic pail
30255812	Kollidon® 30 LP	50347979	0.5 kg Plastic pail
		50796353	25 kg Cardboard boxes
30034978	Kollidon® 90 F	50347976	0.5 kg Plastic pail
		51031936	25 kg Cardboard boxes

* BASF's commercial product number.

11. Publications

http://pharmaceutical.basf.com/en.html

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