Technical Information

Kollidon® 12
Kollidon® 12 PF
Kollidon® 17 PF

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1. Introduction

Historical aspects of polyvinylpyrrolidone

The modern acetylene chemistry was developed at BASF by Reppe in the 1930s. 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.

Separate Technical Information Sheets are available for the Povidones with the medium and high 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”.

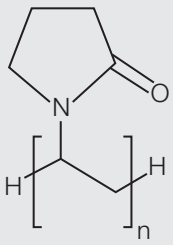
2. Technical properties

Description

The low molecular weight Povidones grades Kollidon® 12, Kollidon® 12 PF and Kollidon® 17 PF are polymerized and finally spray dried polymer powders.

They come 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

Molecular weights

In general, the average molecular weight of polymers can be expressed in three different ways, either as weight average molecular weight (M_w), as number average molecular weight (Mn) or as viscosity average molecular weight (M_v).

The molecular weight of povidones is usually expressed as 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. It is determined by methods such as size exclusion chromatographie (SEC) using light scattering detection, a method to determine an absolute molecular weight without the need to apply a reference material.

For different grades of Kollidon® the following M_w values were determined in as shown in table 1:

	M_w [AMU]
Kollidon® 12	2000 – 3000
Kollidon® 12 PF	2000 – 3000
Kollidon® 17 PF	7000 – 11000

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
glycerine	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 low molecular weight Kollidon® grades Grades (12, 12 PF and 17 PF)

Glass transition temperature Tg

Product	Tg [°C]
Kollidon® 12	102
Kollidon® 12 PF	102
Kollidon® 17 PF	138

Table 3

Particle size

The particle size distributions of the spray dried polymers can be described with the following ranges **(to be considered as characteristic values only)**:

Product	d(0.1), µm	d(0.5), µm	d(0.9), µm	D[4.3], µm
Kollidon® 12 PF	10 +/- 3	35 +/- 5	80 +/- 10	42 +/- 5
Kollidon® 17 PF	10 +/- 3	33 +/- 5	75 +/- 10	38 +/- 5

Table 4

The determination was performed with a Malvern Mastersizer 2000. The air pressure was set to 1 bar.

Bulk density

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

Product	Bulk density
Kollidon® 12	400 – 600 g/L
Kollidon® 12 PF	400 – 600 g/L
Kollidon® 17 PF	400 – 600 g/L

Table 5: Bulk density of the Kollidon® grades

Particle size distribution and bulk density are considered characteristic values. They are not part of the product specification.

Endotoxin testing

Kollidon® 12 PF and Kollidon® 17 PF are intended for the use in parenteral pharmaceutical formulations and thus tested for bacterial endotoxins.

Viscosity

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

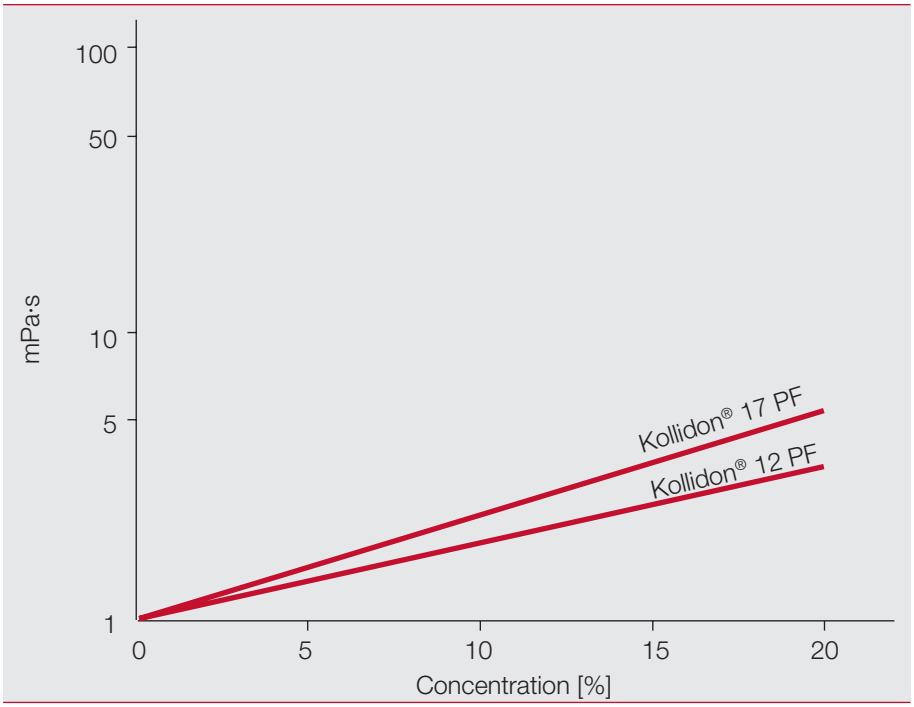


Fig. 1: Viscosity of Kollidon® solutions (Ubbelohde viscometer, 25 °C)

Hygroscopicity

The hygroscopic nature of Kollidon® is important in many applications. There is hardly any difference between the individual grades so that the same curve applies to all Povidone grades (Fig. 2).

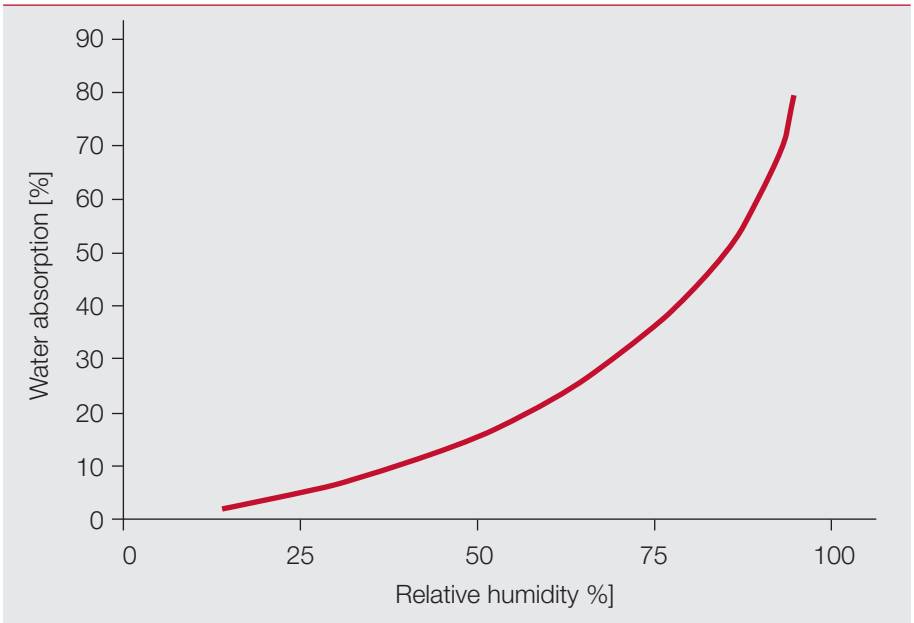


Fig. 2: Hygroscopicity of soluble Kollidon®

3. Handling

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

4. Example application

Kollidon® 12 PF, 17 PF

Solubilizing agents, dispersants and crystallization inhibitors in solutions or lyophilisates for injection. The low-molecular grades, Kollidon® 12 PF and Kollidon® 17 PF are intended for use as solubilizing agents, dispersants and crystallization inhibitors particularly for injectables. These properties are of particular interest for antibiotics in *solution or in lyophilized powder form*.

Stabilizers for parenteral suspensions

The low-molecular weight endotoxin tested grades of Kollidon® can be used to stabilize *parenteral suspensions*. This applies in particular for formulations of antibiotics.

Kollidon® 12

Solubilisation of APIs in soft-gels

Furthermore, liquid formulations for soft gel capsules contain the low-molecular weight grade Kollidon® 12 as solubilizer. Like in other formulations for oral application, a grade tested for endotoxins is not required.

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

Toxicological and biochemical studies have been carried out with the individual Kollidon® grades. Abridged reports summarizing the toxicological results are available on request. The original reports can be provided when secrecy agreements are in place.

10. PRD and Article numbers

PRD-No.*	Product name	Article numbers	Packaging
30553394	Kollidon® 12	50269252	100 kg PE drum with PE-inliner
30034972	Kollidon® 12 PF	50444166	50 kg PE drum with EVOH-inliner
30034981	Kollidon® 17 PF	50029276	50 kg PE drum with EVOH-inliner

* BASF's commercial product number.

11. Publications

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

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