# Technical Information

# Kollidon® 12 PF
# Kollidon® 17 PF



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## 1. Introduction

Povidone, soluble polyvinylpyrrolidone (PVP), is one of the most widely utilized excipients in the pharmaceutical industry.

The history of Povidone dates back to the 1930s when chemist Walter Reppe first synthesized polyvinylpyrrolidone polymers in BASF laboratories. As the originator of Povidone, BASF continues to market these products under the Kollidon® brand.

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.

In the Pharmacopoeias, Povidone grades are typically characterized by the K-value which correlates to the relative viscosity of the polymer in water and therefore, to the mean molecular weight of the polymer chains. BASF Kollidon® portfolio offers a comprehensive selection of Povidone grades, encompassing low, medium, and high molecular weight products to meet various formulation needs.

This Technical Information covers products in the low molecular weight range: Kollidon® 12 PF and Kollidon® 17 PF.

The two products are white powders (Fig. 1) with a faint, characteristic odor.

*Fig. 1: Kollidon® 12 PF powder (identical to Kollidon® 17 PF)*

Dedicated 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).

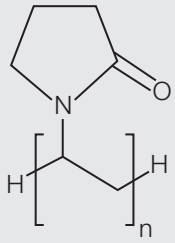
More information on Kollidon® grades may be found in the book, “Kollidon®, Polyvinylpyrrolidone for the Pharmaceutical Industry”, published by BASF or “Polyvinylpyrrolidone-Excipients for Pharmaceuticals”, published by Springer-Verlag, ISBN 3-540 23412-8.

## 2. Chemical and Physical Properties

### Production Process

Kollidon® 12 PF and Kollidon® 17 PF are produced by polymerization of the monomer N-vinyl-pyrrolidone in organic solution followed by solvent exchange and spray drying.

## 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

As inherent to polymers, soluble Kollidon® grades have polymer chains of different lengths and can thus be described by their respective molecular weight distribution curve.

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 ($M_n$) or as viscosity average molecular weight.

The viscosity average molecular weight finds application in the Pharmacopoeias for the characterization of povidone. The K-value of aqueous Povidone solutions is calculated from viscosity, measured via a capillary viscometer, and relates to the molecular weight of the polymers.

The weight average molecular weight ($M_w$) is determined by methods such as size exclusion chromatography (SEC) using light scattering detection, a method to determine an absolute molecular weight without the need to apply a reference material.

| Table 1: | Nominal K-Value | K-Value Range | $M_w$ Range [g/mol] |
|---|---|---|---|
| Kollidon® 12 PF | 12 | 10.2 - 13.8 | 2000 - 4000 |
| Kollidon® 17 PF | 17 | 15.3 – 18.4 | 6000 - 7000 |

## Solubility

Kollidon® 12 PF and Kollidon® 17 PF are highly soluble in water and many polar solvents like isopropanol, methanol, or propylene glycol but show limited solubility in hydrocarbon solvents.

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%.

*Table 2: Solubility of low molecular weight Kollidon® 12 PF and 17 PF.*

| **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 |

### Glass transition temperature Tg

Glass transition temperature (Tg) of a polymer is the temperature at which the material transitions from a brittle, glassy state to a more flexible, rubbery state. Upon approaching Tg, polymer chains gain mobility, leading to increased flexibility and ductility. The Tg can vary based on factors like molecular weight of the polymer chains, composition and impurities, and the presence of plasticizers.

Due to higher molecular weight, Kollidon® 17 PF has a higher Tg than Kollidon® 12 PF.

The glass transition temperatures (Tg2) given below are determined by means of differential scanning calorimetry (DSC). To exclude the water content impacting the result by acting as a plasticizer, two heating cycles are conducted for the measurement. The first heating cycle ensures the elimination of water from the sample. After cooling the dried polymer to room temperature, the Tg2 is then determined in a second cycle.

| **Table 3: Glass transition temperature** | **Tg [°C]** |
|---|---|
| Kollidon® 12 PF | ~ 103 |
| Kollidon® 17 PF | ~ 138 |

## 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):

| **Table 4:** | **d(0.1), µm** | **d(0.5), µm** | **d(0.9), µm** |
|---|---|---|---|
| Kollidon® 12 PF | 10 +/- 3 | 35 +/- 5 | 80 +/- 10 |
| Kollidon® 17 PF | 10 +/- 3 | 33 +/- 5 | 75 +/- 10 |

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.

| Table 5: Bulk density | |
|---|---|
| Kollidon® 12 PF | 400 – 600 g/L |
| Kollidon® 17 PF | 400 – 600 g/L |

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 tested for bacterial endotoxins by method 2.6.14 d as published in the latest edition of the Ph. Eur.

## Solution Viscosity

The curves shown in Fig. 2 represent typical values for the solution viscosity of Kollidon® 12 PF and Kollidon® 17 PF measured in water and isopropanol with a rotation rheometer.

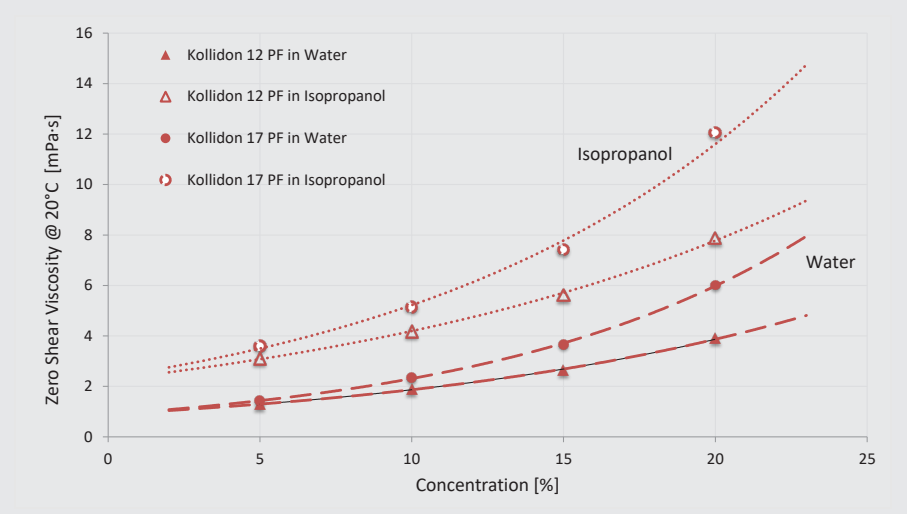



*Fig. 2: Viscosity of Kollidon® 12 PF and Kollidon® 17 PF in water and isopropanol (20 °C)*

### 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. 3).

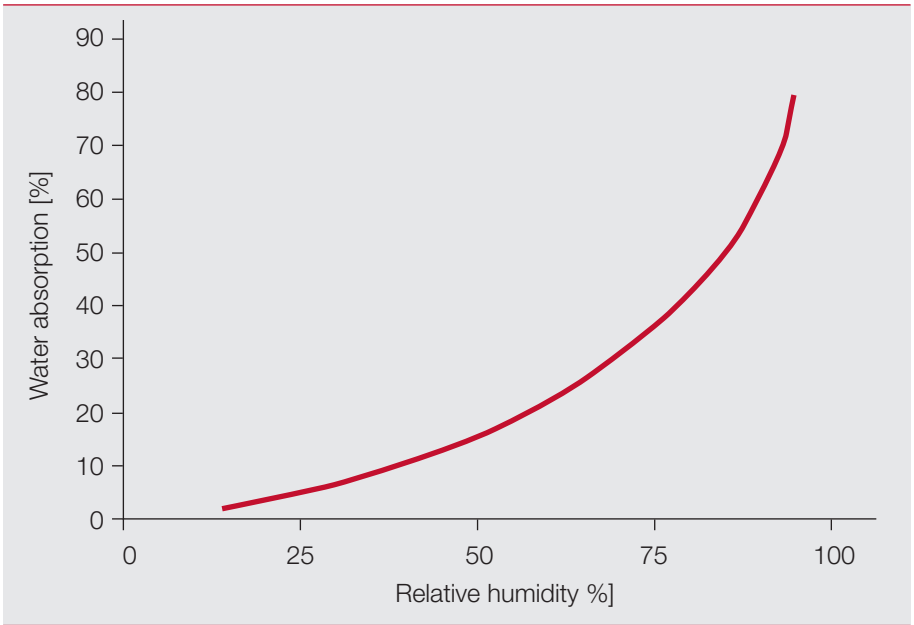



*Fig. 3: Hygroscopicity of soluble Kollidon®*

## 3. Handling and processing instruction

Kollidon® 12 PF and Kollidon® 17 PF are packaged using PeroXeal® concept to minimize peroxide formation by eliminating, as far as possible, oxygen in the packaging. BASF´s PeroXeal® concept includes filling the product powder using inert gas, filling into a liner with oxygen barrier properties and heat-sealing this liner for proper closure. Please note the protection provided by PeroXeal® is only intact until the first opening of the original sealed packaging.

For sensitive applications, BASF recommends proper reclosure, fast consumption, and/or peroxide monitoring.

## 4. Example application

Solubilizing agents, dispersants and crystallization inhibitors in solutions or lyophilisates for injection. The low-molecular grades, Kollidon® 12 PF and Kollidon® 17 PF are used as solubilizing agents, dispersants and crystallization inhibitors in injectables.

The low-molecular weight endotoxin tested products can be used to stabilize parenteral suspensions.

Furthermore, liquid formulations for soft gel capsules contain the low-molecular weight grade Kollidon® 12 PF as solubilizer.

## 5. Stability & Safety

The products are typically stable for 3 years after date of production provided storage under recommended conditions. The actual retest period and storage conditions can be found in RegXcellence®.

Please refer to the material safety data sheet (MSDS) for instructions on safe and proper handling and disposal. MSDS are sent with every consignment. In addition they are available on BASF RegXcellence® or from your local BASF sales representative.

## 6. Documents, Quality & Regulatory Information

MyBASFWorld: article numbers, sample order, safety data sheet, sustainability information

RegXcellence®: specification, compliance documents, regulatory product summary

ZoomLab®: formulation assistance to predict starting formulations and expedite drug development.

## 7. Available Articles and Packaging

| Product name | PRD number* | Article number | Article | Packaging |
|---|---|---|---|---|
| Kollidon® 12 PF | 30034972 | 50444166 | 50 kg commercial article | HDPE drum with liner |
| | | 50348141 | 0.5 kg non-commercial technical sample | HDPE pail with liner |
| Kollidon® 17 PF | 30034981 | 50029276 | 50 kg commercial article | HDPE drum with liner |
| | | 50348142 | 0.5 kg non-commercial technical sample | HDPE pail with liner |

* BASF's commercial product number.

## 8. Publications

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

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