Technical Information

Kollidon® CL

Kollidon® CL-F

Kollidon® CL-SF

Kollidon® CL NT

Crospovidone as excipient for the pharmaceutical industry

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1. Introduction

The Kollidon® CL grades represent a diverse range of insoluble crosslinked polyvinylpyrrolidone products, commonly known as “crospovidone”. These are widely used in the pharmaceutical industry as excipients in solid oral dosage forms, primarily as super disintegrants in tablet formulations due to their unique swelling properties. Crospovidone can enhance the solubility of actives and facilitate complex formation, thereby broadening their utility as pharmaceutical excipients. Additionally, Kollidon® CL grades with smaller particle sizes add dry binding properties in tablet production.

Most pharmacopoeias distinguish between crospovidone Type A and Type B based on particle size distribution (PSD), where Type A has larger particle size then Type B.

BASF portfolio includes the following crospovidone products:

Kollidon® CL	(crospovidone, Type A)
Kollidon® CL NT	(crospovidone, Type A)
Kollidon® CL-F	(F = fine, crospovidone, Type A)
Kollidon® CL-SF	(SF = super fine, crospovidone, Type B)
Kollidon® CL-M	(M = micronized, crospovidone, Type B)

Kollidon® CL NT (NT = nitrite tested) is fully identical to Kollidon® CL but comes with an additional service: each lot is tested for nitrites. While this document discusses Kollidon® CL, the information is therefore equally applicable to Kollidon® CL NT.

Kollidon® CL-M, the micronized crospovidone, has a dedicated Technical Information document detailing its unique properties in dry binding, suspension stabilization and as white pigment.

Kollidon® CL grades come as fine white or nearly white powders (see Fig. 1) that are insoluble in all common solvents. They are practically tasteless and have a slight characteristic odor.

Fig. 1: Kollidon® CL, Kollidon® CL-F and Kollidon® CL-SF powders (left to right)

Separate Technical Information are available for BASF soluble povidone and copovidone products: Kollidon® 12 PF and Kollidon® 17 PF, Kollidon® 25 and Kollidon® 30, Kollidon® 90 Evo, and Kollidon® VA 64.

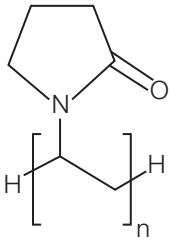
More details on crospovidone and povidone, are described in the books, “Kollidon®, Polyvinylpyrrolidone for the pharmaceutical industry”, published by BASF or “Polyvinylpyrrolidone-Excipients for Pharmaceuticals”, published by Springer-Verlag, ISBN 3-540 23412-8

2. Chemical & Physical Properties

Name

Crospovidone, crospovidonum, insoluble polyvinylpyrrolidone, crosslinked PVP

Chemical Structure



CAS-number

9003-39-08

Raw material and production process

Insoluble Kollidon® CL crospovidone grades are manufactured through a polymerization process known as “popcorn” polymerization.

This process starts with the monomer N-vinyl-pyrrolidone in aqueous solution, which reacts in a unique radical polymerization directly generating the crosslinked insoluble polyvinylpyrrolidone particles. The crosslinking is both chemical and physical, with physical crosslinking - mainly achieved through polymer chain entanglement - playing a dominant role in defining the product's characteristics. Consequently, when analyzed with IR spectroscopy, insoluble crospovidone cannot be distinguished from soluble povidone (linear PVP).

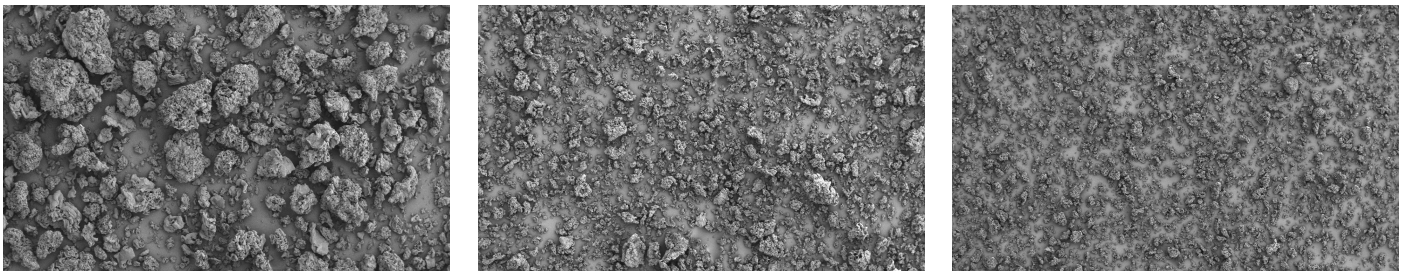


*Fig. 2: Scanning Electron Microscopy Pictures **(magnification: 50)** of Kollidon® CL, Kollidon® CL-F and Kollidon® CL-SF*

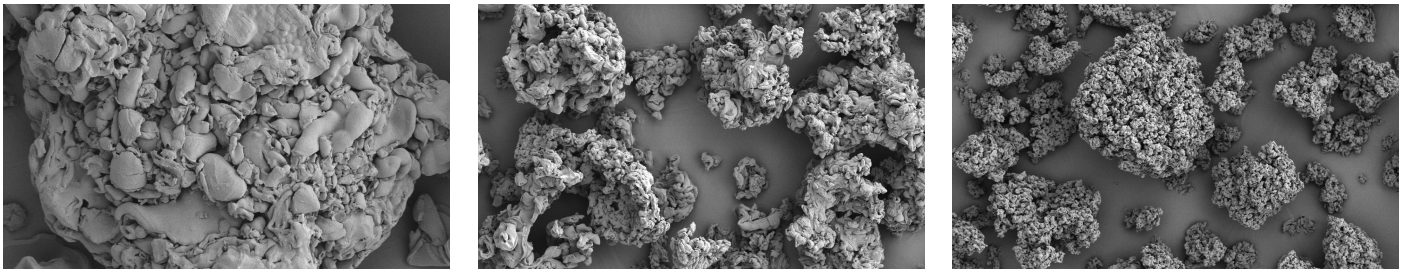


*Fig. 3: Scanning Electron Microscopy Pictures **(magnification: 500)** of Kollidon® CL, Kollidon® CL-F and Kollidon® CL-SF*

The particle size distribution and particle morphology of the final products is controlled in the polymerization step. The resulting particles are irregular in shape and show a characteristic surface structure, which can be visualized by Scanning Electron Microscopy (SEM, Fig. 2 and 3).

In the high quality-controlled production processes for all Kollidon® CL grades there are no known risks for nitrite presence as described in the respective Risk Assessment statements that are available in RegXcellence®. High lot-to-lot consistency is demonstrated for all Kollidon® CL grades with no quantifiable levels of nitrites detected, based on the LOQ of respective fully validated nitrite test methods.

Kollidon® CL NT (Nitrite Tested) is produced with identical manufacturing process, raw materials and with the same equipment as Kollidon® CL. However, Kollidon® CL NT is offered with the additional service of testing the nitrite content for every lot and reporting the result on the CoA. All the information and data in this document is therefore equally applicable to Kollidon® CL and Kollidon® CL NT.

Hygroscopicity

Kollidon® CL grades show unique hygroscopic properties that are particularly important to their application as disintegrant. The diagram (Fig. 4) shows the amount of water absorbed after seven days' exposure to different conditions of relative humidity: there is hardly any difference between the individual grades, that can all be represented by a single curve.

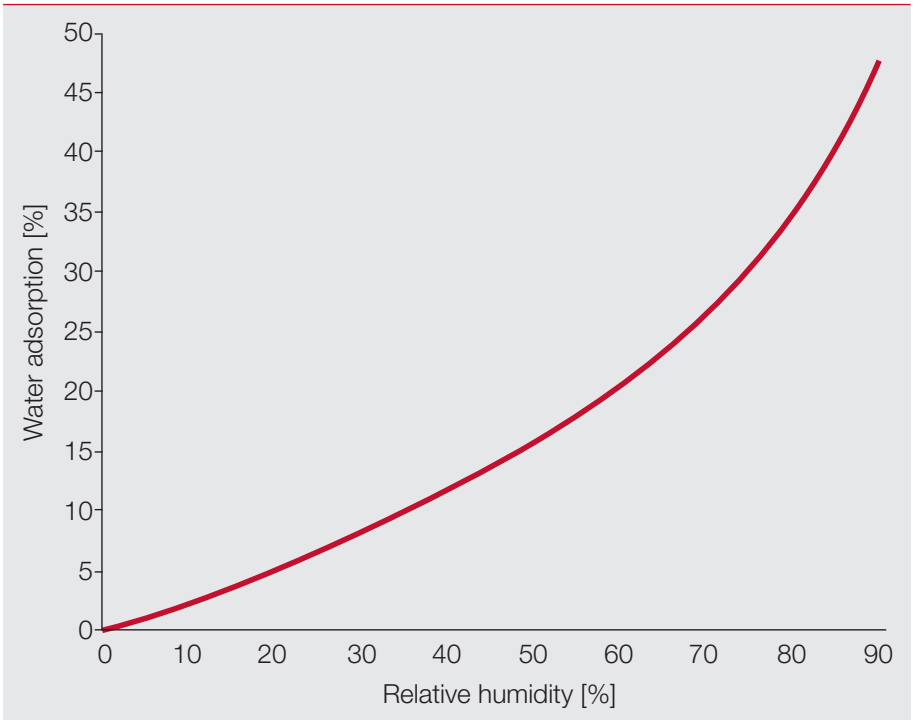


Fig. 4: Hygroscopicity of the Kollidon® CL-grades

Bulk and Tap Density

The following table show typical results of bulk and tap density measured with EN ISO 60 method for the Kollidon® CL grades.

Table 1:	Bulk Density [g/ml]	Tap Density [g/ml]
Kollidon® CL	0.28 – 0.42	0.40 – 0.50
Kollidon® CL-F	0.18 – 0.32	0.25 – 0.35
Kollidon® CL-SF	0.10 – 0.20	0.18 – 0.25

3. Functionality

Functionality-related characteristics are “not a mandatory requirement” as explained in the General Notices of Ph.Eur. and USP-NF.

The products are not tested on regular basis for all functionality-related characteristics. In this chapter exemplary results are described.

Particle Size Distribution

Particle size distribution is an essential characteristic of crospovidone. Most pharmacopoeias differentiate between crospovidone Type A and Type B based on particle size, determined through sieving of particles suspended in water. Type A has a larger particle size compared to Type B.

Table 2 presents historical ranges for particle size distribution of Kollidon® CL grades, as measured by wet sieving according to compendial method.

Table 3 shows ranges for particle size distribution of Kollidon® CL grades, measured by laser diffraction of the powders dispersed in water. More details on the test method are provided in RegXcellence®.

Table 2: PSD by wet sieving	Ratio of particles > 63µm [%]
Kollidon® CL	35 – 85
Kollidon® CL-F	15 - 60
Kollidon® CL-SF	1 - 15

Table 3: PSD by laser diffraction	d (0.1) [µm]	d (0.5) [µm]	d (0.9) [µm]
Kollidon® CL	8 - 35	45 – 180	130 - 370
Kollidon® CL-F	5 - 17	35 - 95	100 - 220
Kollidon® CL-SF	1 - 12	20 - 50	20 - 50

Flowability

Kollidon® CL is the crospovidone with largest particle size and the only product in the crospovidone portfolio that is free flowing and thus allows for a proper determination of the flow characteristics, measured according to Ph.Eur. Monograph Crospovidone (see Table 4).

The different flowing properties of the three grades are qualitatively described by the pictures of the powders (Fig. 1).

Table 4: Flowability	Angle of repose [°]	Flow time [s]
Kollidon® CL	32 - 38	< 25

Hydration and swelling properties

The most important property of the insoluble Kollidon® CL-grades for their application as tablet disintegrants is their property to adsorb water very fast and predictably without any gel formation.

The properties in aqueous media can be described by different means. The hydration capacity of the grades, which is the amount of water uptake per weight of material, measured according to the Ph.Eur. Monograph Crospovidone is given in Table 5.

Table 5: Hydration capacity [g water/g polymer]

Kollidon® CL	3.5 – 5.5
Kollidon® CL-F	5.6 – 6.6
Kollidon® CL-SF	5.9 – 8.5

Alternatively, the swelling of crospovidone can be investigated by comparing the particle size of the materials in the dry state with the particle size in the swollen state after dispersion in water. Figures 5 to 7 show the increase of the particle sizes upon swelling for each Kollidon CL grade. Measurements of the PSD of dry and wet particles were conducted by means of laser diffraction on a Malvern Mastersizer 2000.

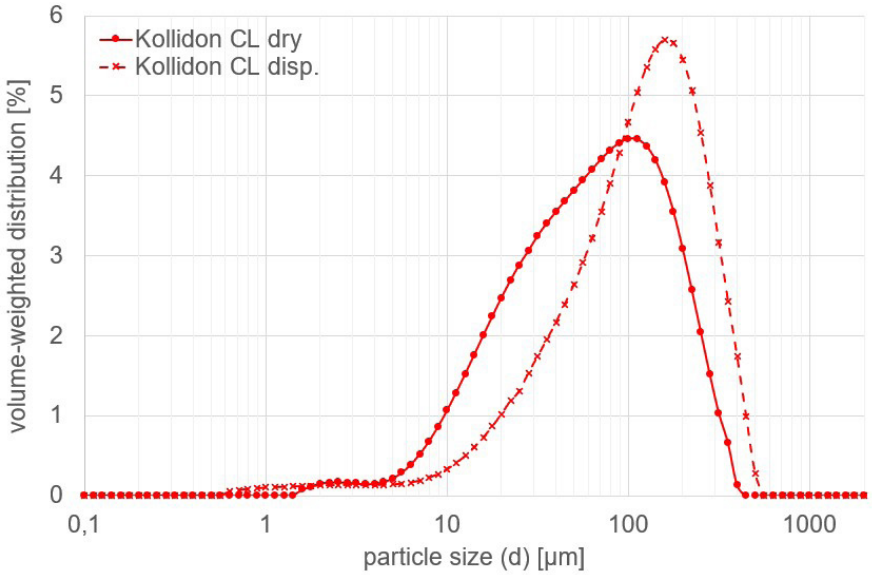


Fig. 5: Comparison of particle size distribution of Kollidon® CL: dry and wet (Qualitative example).

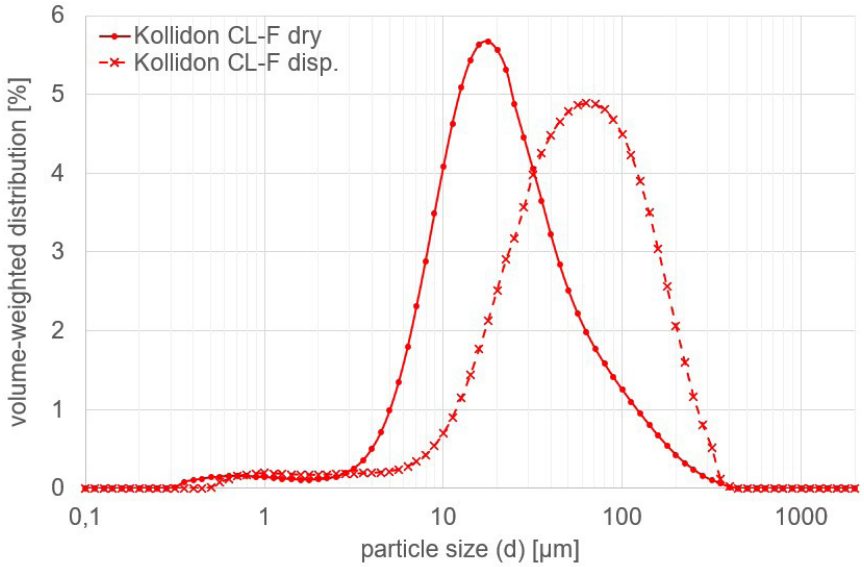


Fig. 6: Comparison of particle size distribution of Kollidon® CL-F: dry and wet (Qualitative example).

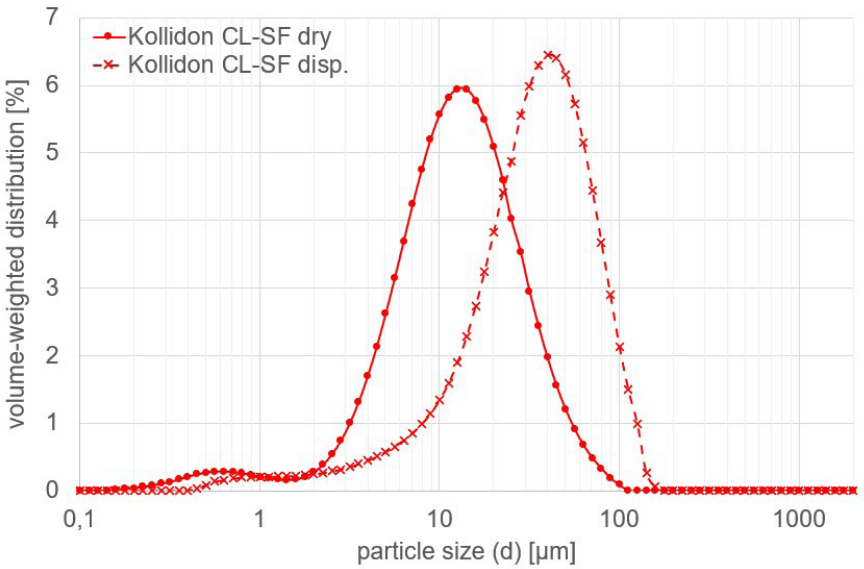


Fig. 7: Comparison of particle size distribution of Kollidon® CL-SF: dry and wet (Qualitative example).

Settling volume

Kollidon® CL, CL-F and CL-SF have all a settling volume < 60 ml, measured according to Ph.Eur. Monograph Crospovidone. The settling volume is a parameter of interest for the application as suspension stabilizer. The results show that this is no relevant application for the above-mentioned products, and only relevant for Kollidon® CL-M which has separate Technical Information document.

4. Handling & processing instructions

Kollidon® CL, Kollidon® CL NT, Kollidon® CL-F and Kollidon® CL-SF 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.

Please refer to the individual material safety data sheet (MSDS) for instructions on safe and proper handling and disposal. Material safety data sheets are sent with every consignment.

5. Example Application(s)

The Kollidon® CL grades possess several unique properties that make their application as excipients essential in various pharmaceutical formulations. An overview is summarized in Table 6.

Table 6: Main applications of Kollidon® CL grades

Super disintegrant	All cCL grades provide predictable swelling without gel formation for fast disintegration
Dissolution	All Kollidon® CL grades can support drug dissolution
Dry binder	Kollidon® CL-SF is a valuable dry binder by combining small particle sizes with good compactability
Complex former	Kollidon® CL grades show selective adsorption of e.g. polyphenols and certain endotoxins by complex formation
Stabilizer	Due to their hygroscopicity and the ability to absorb water, Kollidon® CL grades can act as stabilizers for water sensitive compounds as e.g. in in vitamin formulations

The primary application of the Kollidon® CL grades is as super-disintegrant. For this application, crospovidone are usually employed at concentrations between 2% and 8% of the total tablet weight.

As there is no universal ideal disintegrant, the best matching disintegrant needs to be selected individually and need-based for each formulation. To facilitate disintegrant selection, Table 7 provides a qualitative comparison of the properties of Kollidon® CL grades.

Table 7:	Disintegration	Drug dissolution	Mouthfeel (ODTs)	Smooth tablet surface	Dry binding
Kollidon® CL	++	++	-	-	+/-
Kollidon® CL-F	+	+	+	+/-	+
Kollidon® CL-SF	+	+/-	++	+	++

Whilst their disintegration property directly correlates with the particle size of the products, the dry binding properties are inversely proportional to the particle size, making Kollidon® CL-SF super fine particles the best selection for dry binding. For the same reason, Kollidon® CL-SF is the ideal disintegrant for orally disintegrating tablets (ODTs): the fine particles contribute to a creamy mouthfeel upon disintegration. Kollidon® CL-F and CL-SF finer particles ensure smooth and even tablet surfaces where humidity control is difficult.

Disintegrant and Dry Binding Properties

Below, two formulations with respectively 2.5% and 5% disintegrant content demonstrate the excellent functionality of Kollidon® CL grades as disintegrant and dry binder in placebo tablets obtained by direct compression.

For each formulation, Ludipress® LCE is blended with the respective Kollidon® CL grade in a tubular mixer. After blending, magnesium stearate is added as lubricant and round shaped tablets of 10 mm diameter are prepared on a Compaction Simulator applying different compression forces.

Table 8: Placebo blends	Formulation (1) [g/100g]	Formulation (2) [g/100g]
Kollidon® CL grade	2.5	5.0
Ludipress® LCE*	97.0	94.5
Magnesium Stearate	0.5	0.5

* coprocessed excipient consisting of lactose monohydrate and Kollidon® 30 (Povidone)

All placebo tablets show very fast disintegration: on average less than two minutes even with low content (2.5%) of the respective Kollidon® CL grade. Tablets with higher amount of disintegrant (5%) have shorter disintegration times. For comparison, Ludipress® LCE based placebo tablets without disintegrant take more than 5 minutes to disintegrate.

Table 9: Disintegration times of formulation (1) tablets [min]

Compression force [kN]	Kollidon® CL	Kollidon® CL-F	Kollidon® CL-SF
5	~ 1	~ 1	~ 1
10	~ 1.5	~ 1.5	~ 1.5
15	~ 1.5	~ 2	~ 2
20	~ 1.5	~ 2	~ 3

Table 10: Disintegration times of formulation (2) tablets [min]

Compression force [kN]	Kollidon® CL	Kollidon® CL-F	Kollidon® CL-SF
5	~ 0.5	~ 0.5	~ 0.5
10	~ 1.0	~ 1.0	~ 1.0
15	~ 1.0	~ 1.5	~ 1.5
20	~ 1.5	~ 1.5	~ 2.0

The tabletability plots (Fig. 8 and Fig 9) show the increasing dry binding effect that is observed when Kollidon® CL is substituted by the finer Kollidon® CL-F or the super fine Kollidon® CL-SF: the smaller PSD grades allow for increased tablet tensile strength while still providing excellent disintegration.

The differences in tabletability and increase of tablet strength directly correlates with the relative content of disintegrant in the formulations.

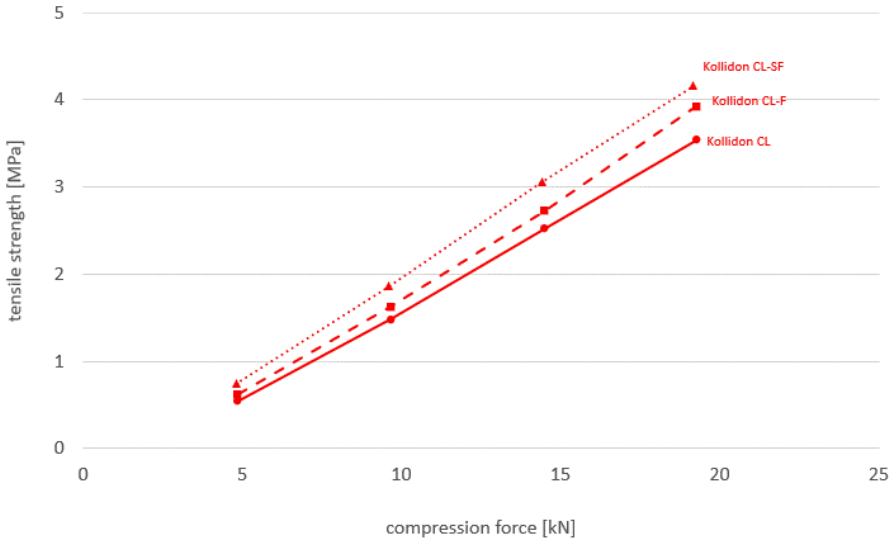


Fig. 8: Tabletability Plot of Formulation (1) tablets containing 2.5% Kollidon® CL grade (300 mg round shape)

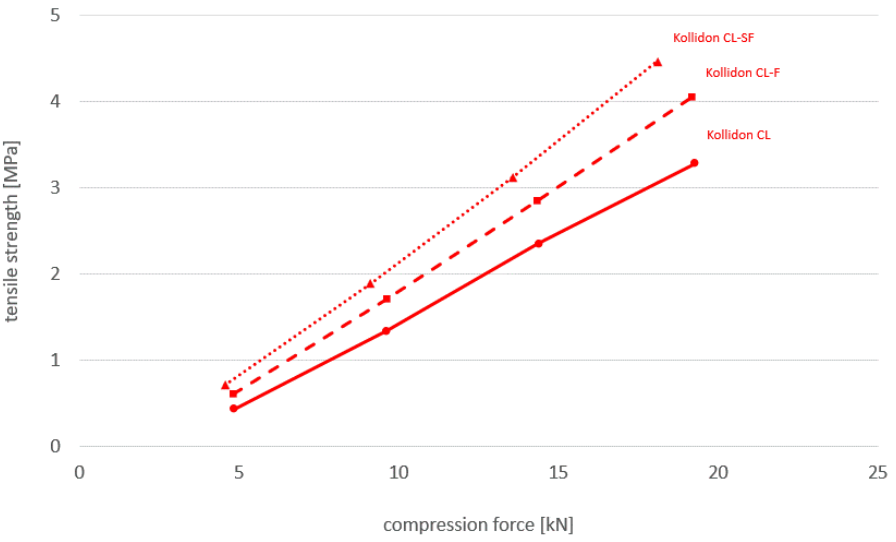


Fig. 9: Tabletability Plot of Formulation (2) tablets containing 5% Kollidon® CL-grade (300 mg round shape)

*I*n the following example, the performance of Kollidon® CL grades is compared to alternative disintegrants in an analgesic tablet formulation. The granulates are prepared by mixing I with II and sieving, they are then mixed with III and compressed into tablets (598.5 weight each). The tablets containing one of the Kollidon® CL grades prove to show the faster disintegration compared to alternative disintegrants (Table 12).

Table 11: Analgesic tablet composition [mg]		
I	Paracetamol cryst.	250
	Acetylsalicylic acid cryst.	250
	Caffeine cryst.	50
II	Kollidon® 30 (dissolved in water)	27.5
III	Magnesium stearate	5
	Disintegrant	16

Table 12: Disintegration time of analgesic tablets in synthetic gastric juice [min]	
No disintegrant	>70
Kollidon® CL	9
Kollidon® CL-F	11
Kollidon® CL-SF	9
Croscarmellose	24
Sodium carboxy methyl starch	34

Disintegration and Drug dissolution

While the disintegration time of a tablet is crucial, the dissolution rate of the active ingredient is equally significant. Selecting the right disintegrant can improve the dissolution and bioavailability of actives, as demonstrated in the following example.

The acetylsalicylic acid formulations containing alternative disintegrants are pressed with a laboratory rotary tablet press (direct compression, 8 kN). The tablets have different physical properties depending on the disintegrant.

The notably poor dissolution rate of acetylsalicylic acid in the absence of a disintegrant is improved with a disintegrant and the fastest dissolution is achieved with Kollidon® CL (Fig. 10).

Table 13: Acetylsalicylic acid tablet composition [g/100 g]	
Acetylsalicylic acid cryst.	78
Ludipress®	19
Stearic acid	0.2
Disintegrant	2.8

Table 14: Properties of Acetylsalicylic acid tablets			
	Hardness [N]	Disintegration time - gastric juice	Friability [%]
No disintegrant	95	22 min	0.4
Kollidon® CL	90	30 s	0.4
Croscarmellose	84	48 s	0.3
Sodium carboxy-methyl starch	89	50 s	0.3

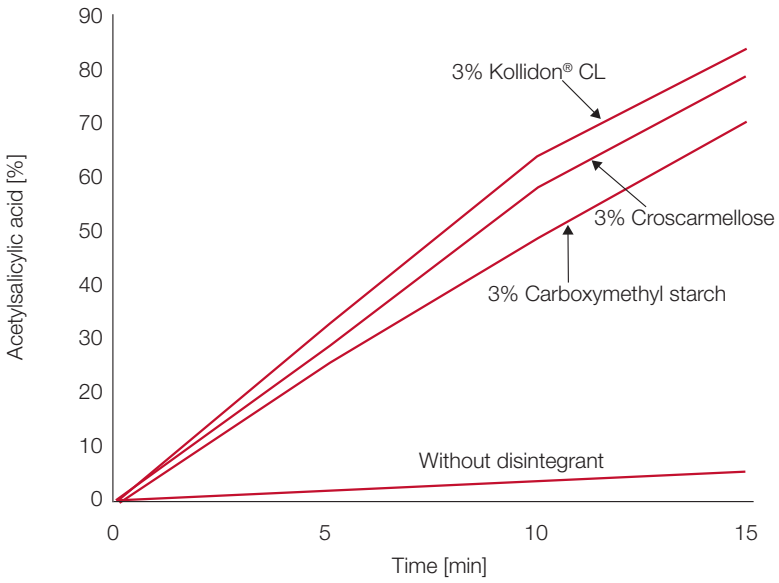


Fig. 10: Dissolution of the acetylsalicylic acid tablets described in Table 14 (USP method)

Tablets Storage

Due to the hygroscopic properties and swelling of the disintegrants, it is important to assess the effect of water absorption on the tablets surface during storage.

The tables 15 and 16 present a qualitative evaluation of disintegrant's impact on tablets appearance when stored under controlled temperature and humidity. The composition of the tablets tested is described in Table 11.

Table 15:
Evaluation of tablets surface after storage at 23 °C, 65% relative humidity

Storage time	1 day	3 days	7 days
Kollidon® CL	5	5	5
Kollidon® CL-F	3	4-5	4-5
Kollidon® CL-SF	2	2	2
Croscarmellose	3*	3*	3*
Sodium carboxymethyl starch	3*	3*	3*

* Tablets show light brown discoloration as of day 1 and the color intensifies throughout storage.

Table 16:
Evaluation of tablets surface after storage at 23 °C, 75% relative humidity

Storage time	1 day	3 days	7 days
Kollidon® CL	6	6	6
Kollidon® CL-F	4	5	5
Kollidon® CL-SF	2	3	4
Croscarmellose	3*	3*	3*
Sodium carboxymethyl starch	3-4*	3-4*	3*

* Tablets show light brown discoloration as of day 1 and the color intensifies throughout storage.

Qualitative rating of results (Tables 15 and 16):

smooth	1
small unevenness on the tablet surface	2
small unevenness, rough tablet surface	3
remarkable unevenness, formation of “pimples” begins	4
slight formation of “pimples”	5
medium formation of “pimples”	6
strong formation of “pimples”	7
strong formation of “pimples”/tablet fragile and swollen	8

Tablets with Kollidon® CL-SF show only a moderate decrease in smoothness upon storage, whilst Kollidon® CL and Kollidon® CL-F tablets become rougher. Moisture-proof packaging is therefore always recommended for tablets and capsules that contain the Type A grades (Kollidon® CL and Kollidon® CL-F).

Coating tablet cores containing Kollidon® CL grades

When tablet cores containing a high concentration of crospovidone are sugar- or film coated with aqueous coating formulations, there is an inherent risk of crospovidone particles swelling, leading to rough tablet surfaces. To mitigate this issue, it is advisable to use crospovidone with smaller particle sizes, such as Kollidon® CL-F or Kollidon® CL-SF. Upon coating tablet cores that contain high amounts of Kollidon® CL, careful attention must be paid in selecting the appropriate coating parameters and equipment. To prevent or minimize swelling, it is advisable to enhance the drying efficiency during the coating process. Alternatively, a sub-coating layer can be applied using a polymer dissolved in an organic. A 10% solution of Kollidon® VA 64 in isopropanol, ethanol, or ethyl acetate serves as an effective sub-coating. The sub-coating can typically be sprayed onto pre-warmed tablet cores in the same coating pan prior to the application of the aqueous coating (refer to the Technical Information document on “Kollidon® VA 64” for further details).

Complex Formation

The insoluble crosslinked Kollidon® CL grades, like the soluble Kollidon® grades, form chemical complexes or associate with several actives. The formation of such complexes occurs in alkaline media and is reversible. Whether complexes are formed or not, depends very much on the chemical structure of the individual active: e.g. complexes are more readily formed with aromatic compounds.

The ability to form complexes finds application in. e.g. adsorbing and removing polyphenols and tannins from tinctures and herbal extracts and to improve the taste of azithromycin, paracetamol and vitamins.

6. Stability & Safety

The product is typically stable for 36 months after date of production provided storage under recommended conditions. The actual retest period and storage conditions can be found in RegXcellence®.

The actual version of the safety data sheet is accessible via MyProductWorld and sent with every consignment.

7. Articles and Packaging

Product name	PRD number	Article number	Description	Packaging
Kollidon® CL	30034964	50000695	40 kg commercial article	HDPE drum with liner
		50347948	0.5 kg non-commercial technical sample	HDPE pail with liner
Kollidon® CL-F	30274401	53216545	30 kg commercial article	HDPE drum with liner
		50539226	0.25 kg non-commercial technical sample	HDPE pail with liner
Kollidon® CL-SF	30034964	52595650	30 kg commercial article	HDPE drum with liner
		50348145	0.25 kg non-commercial technical sample	HDPE pail with liner
Kollidon® CL NT	30034964	50866347	40 kg commercial article	HDPE drum with liner
		No separate sample article is offered for Kollidon® CL NT as the product is fully identical to Kollidon® CL standard grade.		

8. Documents, Quality & Regulatory Information

Visit our BASF website to learn about the benefits of Kollidon® CL grades:

Meet your Virtual Pharma Assistants!

MyProductWorld, RegXcellence® and ZoomLab™

www.virtualpharmaassistants.basf.com

MyProductWorld: 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.

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