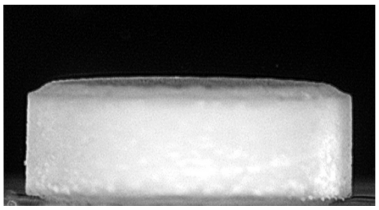
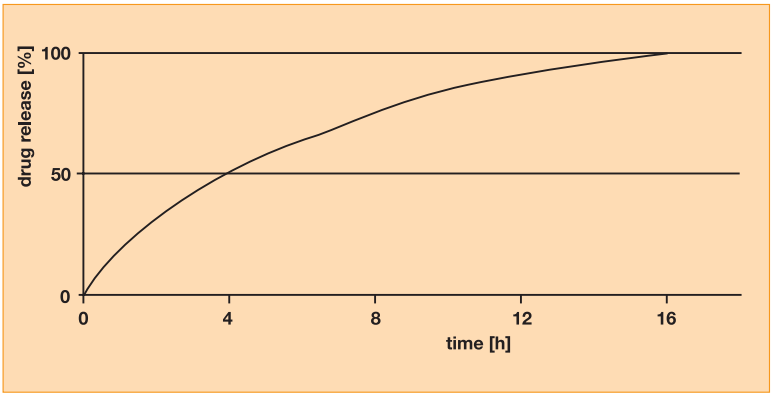
Technical Information

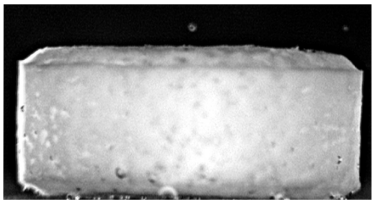
Kollidon® SR

Polyvinyl acetate and povidone based matrix sustained release excipient

August 2024 | **Supersedes issue dated September 2015** | **Last change DAWF-2024-0703**







BASF
We create chemistry

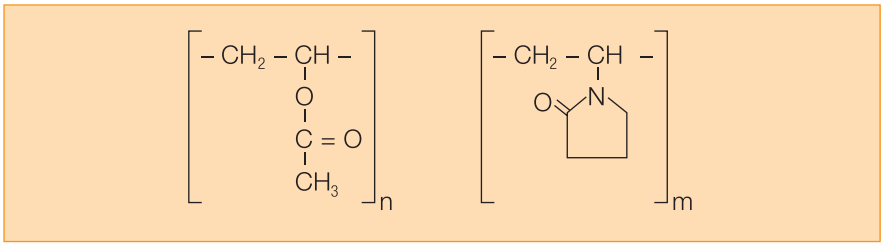
Contents

1. Introduction

1.1 General

Kollidon® SR is a polyvinyl acetate and povidone based matrix retarding agent. It is particularly suitable for the manufacture of pH-independent sustained-release matrix tablets by direct compression. Polyvinyl acetate is a very plastic material that forms a coherent matrix even under low compression forces. When the tablets are introduced into gastric or intestinal fluid, the water soluble povidone is leached out to form pores allowing the active ingredient to diffuse. Kollidon® SR does not contain ionic groups and therefore does not show interactions with drug substances. The sustained-release properties are unaffected by ions or salts.

1.2 Chemical structure



1.3 Trivial name

Polyvinyl acetate/polyvinylpyrrolidone

2. Compositions

Kollidon® SR is a co-processed excipient consisting of polyvinyl acetate (from Kollicoat® SR 30 D) as a major component and povidone (from Kollidon® 30) as pore former. For the exact composition please refer to the product specification.

3. Specifications and methods

3.1 Specification

The current version of the product specification is available on RegXcellence.

3.2 IR-spectra

The IR-spectra is measured in potassium bromide and a typical spectra is given in the following figure 1.

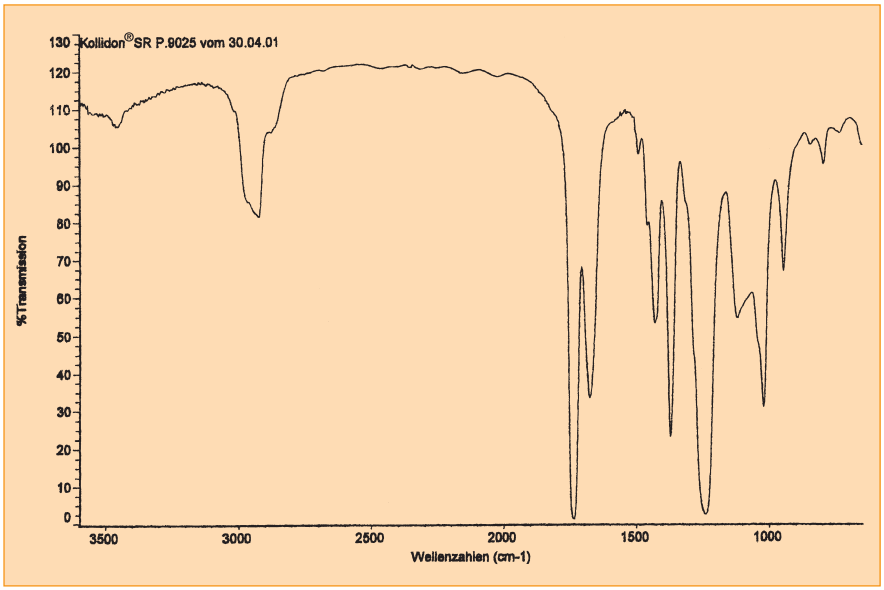


Fig. 1: IR-spectra of Kollidon® SR

4. Properties

Description	White or slightly yellowish, free-flowing powder.
Solubility	Insoluble in water (The povidone part is soluble but the polyvinyl acetate part is insoluble). It is very soluble in N-methylpyrrolidone.
Particle size distribution	The average particle size is about 50-70 µm.
Glass transition temperature	The glass transition temperature Tg of the anhydrous material is about 35 °C.
Bulk density	About 0.45 g/ml.
Flowability	Kollidon® SR has outstanding flow properties with a angle of repose well below 30 °. It can enhance the flowability of other components added for a tablet formulation.
Hygroscopicity	The water uptake is much less than that of povidone or copovidone. Figure 2 shows the water sorption and desorption isotherms at room temperature.

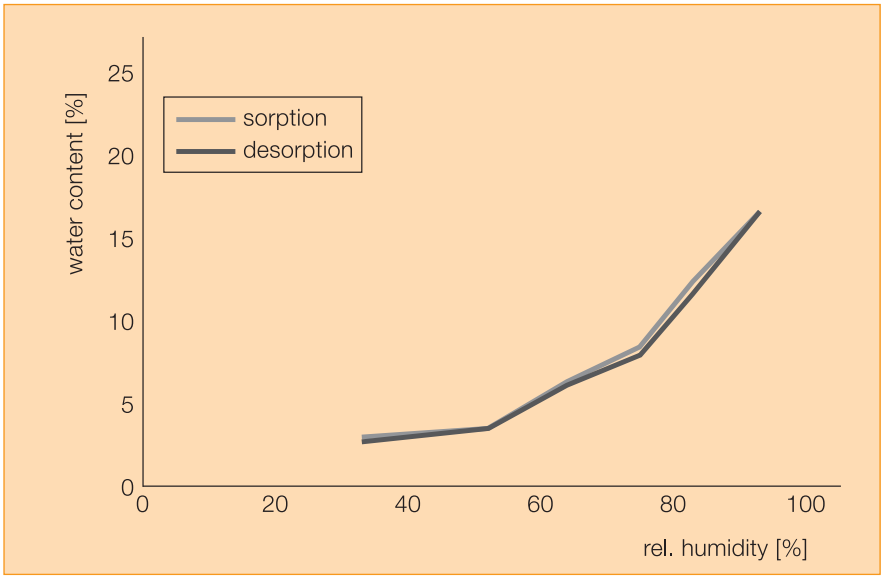


Fig. 2: Sorption isotherms of Kollidon® SR

Compressibility	Kollidon® SR has excellent compressibility and endows tablets with enormous hardness and low friability. This is due to the combination of the very plastic polyvinyl acetate and the also strongly binding povidone.

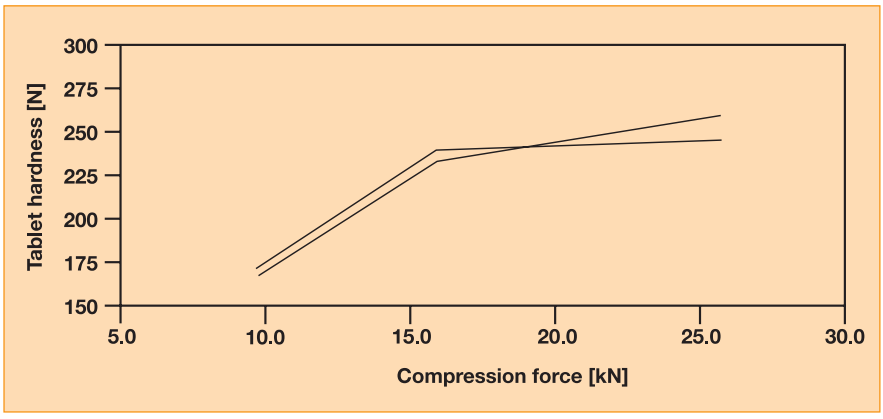


Fig. 3: Hardness-compression force profile of propranolol sustained release tablets containing 50% of Kollidon® SR (2 Lots, Formulation see chapter 6.2)

5. Registration

5.1 Regulatory status

The product is a co-processed excipient. Thus monographs for Kollidon® SR do not exist.

5.2 Drug Master File

For registration purposes a US-DMF was prepared.

5.3 Use of polyvinyl acetate in drugs and food

Polyvinyl acetate is used in a variety of drugs for oral administration in numerous countries including Germany, France, Japan and USA.
Polyvinyl acetate also is allowed in the food industry in several countries like Germany, USA and Japan.

6. Applications

6.1 General Information

Kollidon® SR can be used for the production of the following sustained release matrix dosage forms: Tablets, pellets and granules.

Different technologies to obtain such dosage forms can be applied:
Direct compression, roller compaction, wet granulation and extrusion.

The excellent flowability and compressibility of Kollidon® SR makes this excipient particulary suitable for the manufacture of sustained release tablets obtained by **direct compression**.

The required content of Kollidon® SR in the tablet depends on the solubility of the active ingredient. The following table gives an information about the usual amounts of Kollidon® SR to obtain a sustained release during 12 – 24 hours.

Solubility of the active ingredient	Kollidon® SR in the tablet
Very slightly soluble to practically insoluble	15 – 25%
Sparingly soluble to slightly soluble	25 – 40%
Soluble to freely soluble	40 – 55%

The sustained release characteristics can be modified by varying the Kollidon® SR content in the formulation. Figure 4 shows the influence of the amount of Kollidon® SR on the release of caffeine as a example of a soluble active ingredient.

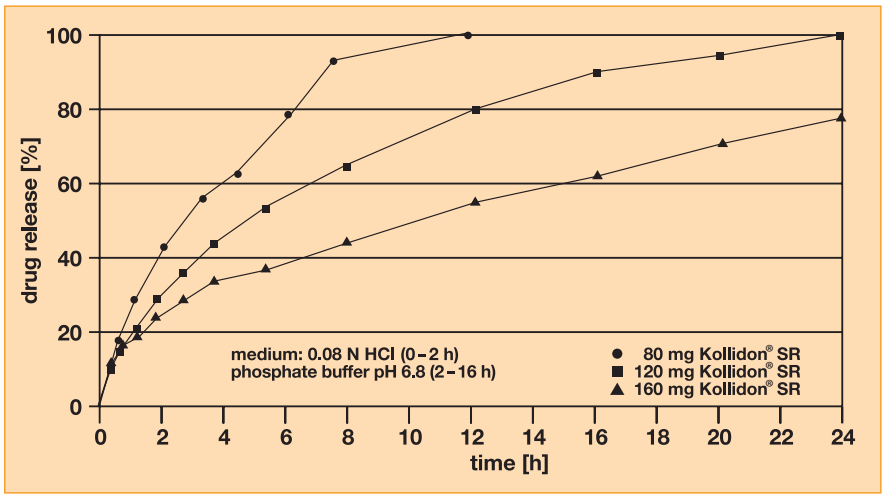


Fig. 4: Influence of the amount of Kollidon® SR on the drug release in a caffeine sustained release tablet (160 mg Caffeine)

In the case of slightly soluble or practically insoluble drug substances the release can be accelerated not only by reducing the content of Kollidon® SR but also by the addition of hydrophilic substances like lactose, Kollidon® 30 or Kollidon® CL-M which act as pore former.

Interesting and important properties of sustained release matrix tablets based on Kollidon® SR are the following:

1. **The drug release is independent of the pH (see figure 5).**
2. **The drug release is independent of the ionic strength of the dissolution medium (see figure 5, addition of 2.5% of NaCl).**
3. **The drug release is independent of the usual compression force and tablet hardness (see figure 6).**

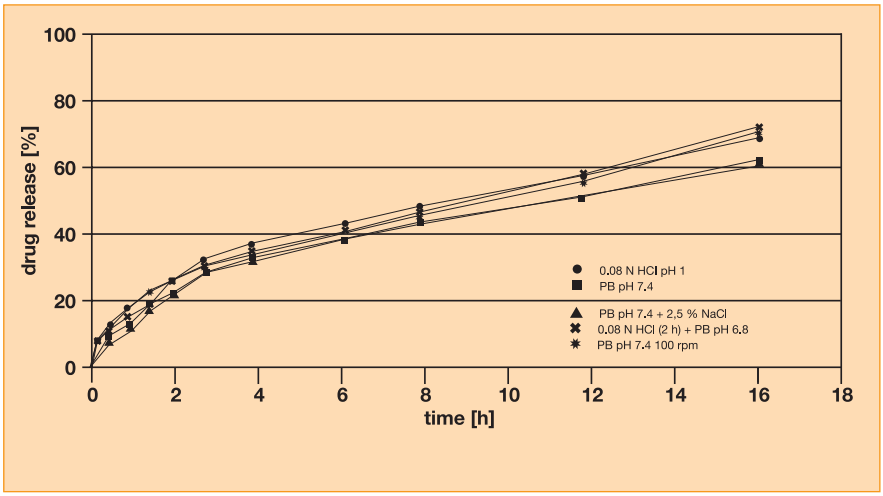


Fig. 5: Influence of the pH and the ionic strength of the dissolution medium on the release of caffeine tablets (Caffeine + Kollidon® SR 1+1)

It is recommended to store the matrix tablets containing Kollidon® SR at temperatures below 30 °C and in tightly closed containers to avoid the uptake of humidity which could modify the release profile of formulations containing a higher percentage of Kollidon® SR.

In the following chapters three typical examples of soluble and practically insoluble active ingredients are given in form of sustained release tablets.

6.2 Propranolol Sustained Release Matrix Tablets

Formulation

	Parts by weight [g]	Composition [%]
Propranolol-HCl	160.0	49.23
Kollidon® SR	160.0	49.23
Silicon dioxide, colloidal	3.4	1.05
Magnesium stearate	1.6	0.49
Total	325.0	100.00

Manufacture

Tablet properties

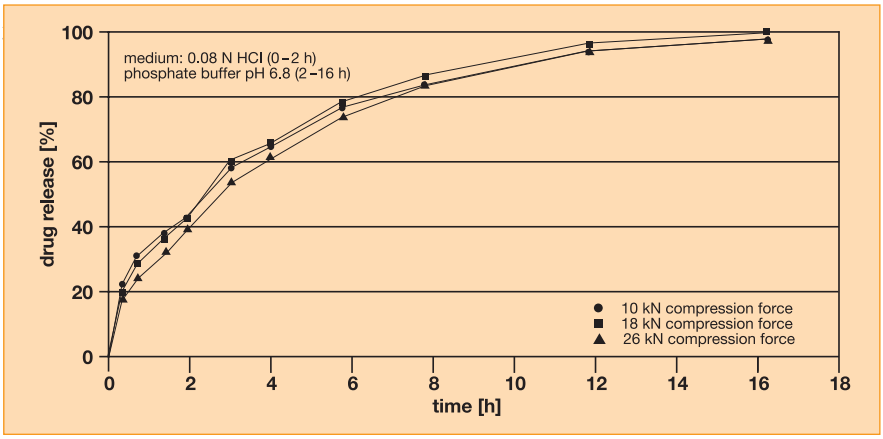


Fig. 6: Propranolol sustained release tablets: Influence of the compression force on the drug release

6.3 Diclofenac Sustained Release Matrix Tablets

Formulation

	Weight	Percent
Diclofenac sodium	100 g	48.4
Kollidon® SR	100 g	48.4
Aerosil 200	3.4 g	1.6
Magnesium stearate	3.4 g	1.6

Manufacture

All ingredients are mixed, passed through a 0.8 mm sieve and pressed with a medium compression force on a rotary press.

Tablet properties

Diameter	8 mm
Weight	206 mg
Compression force	medium
Hardnes	195 N
Friability	<0.1%
Drug release	See Figure 7

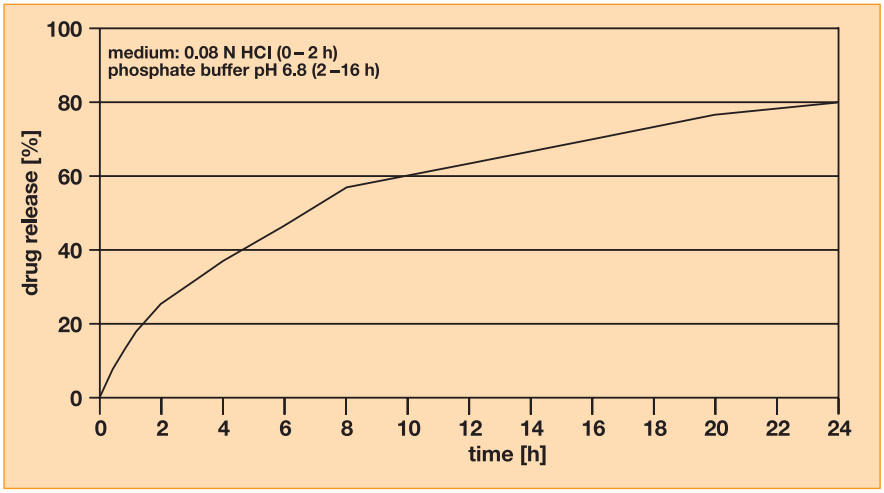


Fig. 7: Dissolution of Diclofenac sustained release tablets

6.4 Theophylline Sustained Release Matrix Tablets

Formulation

	Parts by weight [g]	Composition [%]
Theophylline gran.	500.0	53.9
Kollidon® SR	200.0	21.6
Ludipress® LCE	225.0	24.2
Magnesium stearate	3.0	0.3
Total	**928.0**	**100.00**

Manufacture

All ingredients were passed through a 0.8 mm sieve, blended for 10 min in a Turbula mixer and then pressed on a rotary press.

Tablet properties

Diameter	19.0 x 8.5 mm (football shape)
Weight	928 mg
Compression force	11 kN
Hardness	172 N
Friability	<0.1%
Drug release	See Figure 8

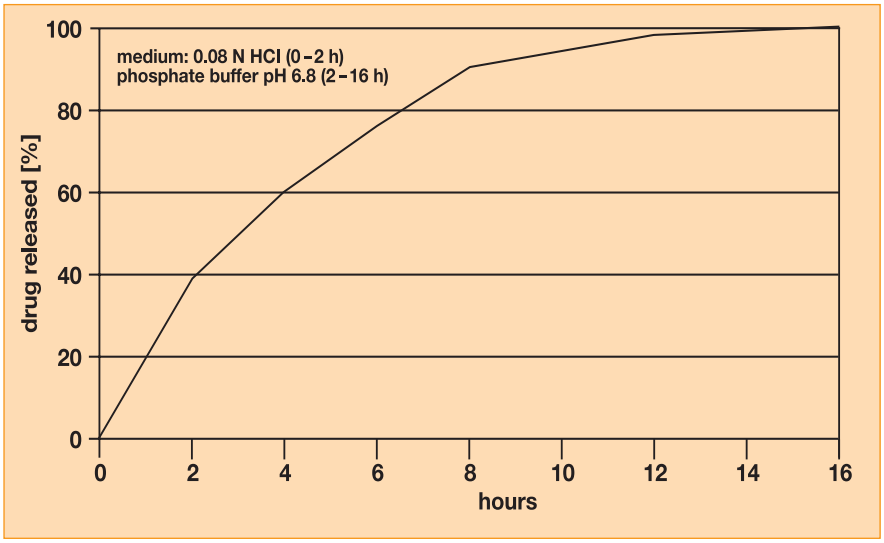


Fig. 8: Dissolution of theophylline sustained release tablets

7. Stability & Safety

The product is typically stable for 48 months after date of production provided storage under recommended conditions. The actual retest period and storage conditions can be found in the document “Quality & Regulatory Product Summary” in RegXcellence.

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

8. Available Articles and Packaging

Product name	PRD number*	Article number	Packaging
Kollidon® SR	30071321	52622254	20 kg plastic drums

*BASF´s commercial product number

9. Documents, Quality & Regulatory Information

Virtual Pharma Assistants

Meet your Virtual Pharma Assistants! MyProductWorld, RegXcellence® and ZoomLab™

www.virtualpharmaassistants.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 formulations.

Disclaimer