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# Technical Information

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## Kollocoat<sup>®</sup> SR 30 D

Poly (Vinyl Acetate) Dispersion 30 per Cent Ph. Eur.

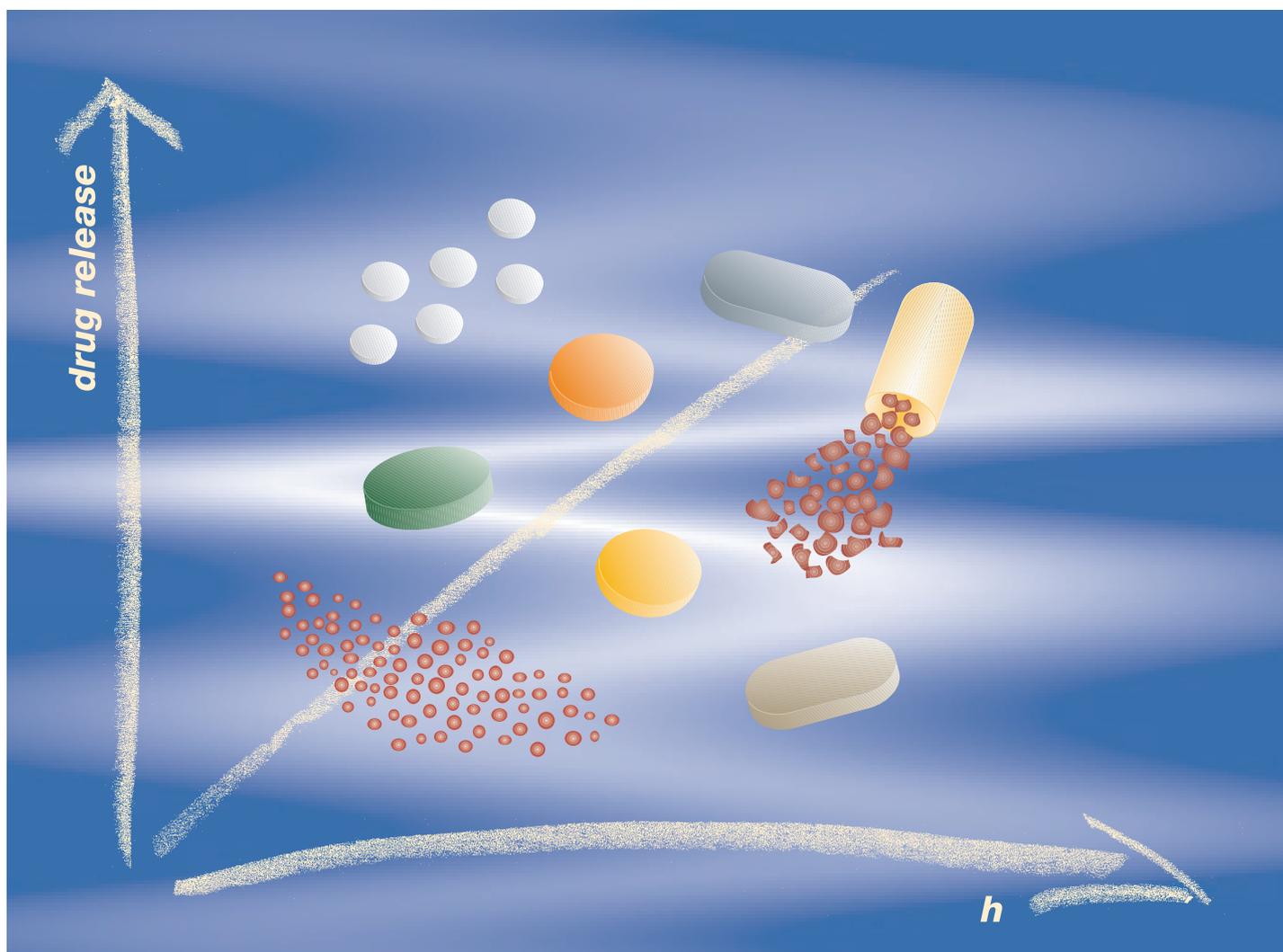
Polyvinyl Acetate Dispersion USP.

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## 1. Introduction

Kollicoat® SR 30 D is a polyvinyl acetate dispersion stabilized with povidone and sodium lauryl sulfate. The dispersion is suitable for the manufacture of pH-independent sustained-release formulations.

## 2. Technical properties

### Description

The dispersion consists of about 27% polyvinyl acetate, 2.7% povidone and 0.3% sodium lauryl sulfate. The low viscosity product has a weak characteristic odor and a milky white or slightly yellowish appearance.

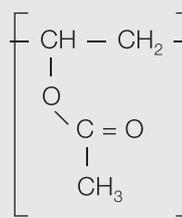
### Trivial name

Poly (Vinyl Acetate) Dispersion 30 per cent

### CAS-number

9003-20-7

### Structural formula



### Solubility

Kollicoat® SR 30 D is miscible with water in any ratio while retaining its milky-white appearance. Mixing the product with ethanol or isopropyl alcohol in a 1 : 5 ratio produces a slightly turbid and somewhat viscous solution; a solution in acetone is more turbid. When organic solvents are added, the polymer precipitates at first, but then dissolves when further solvent is added.

Kollicoat® SR 30 D is insoluble in dilute alkaline or acidic solutions.

### 3. Handling

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

### 4. Example application

#### Application

##### Sustained-release coated formulations

Kollicoat® SR 30 D is used mainly for the manufacture of sustained-release dosage forms. Very effective control of drug release is achieved by coating pellets, granules and crystals.

##### Sustained-release matrix formulations

Matrix tablets can be produced by granulating active ingredients, for example in the fluidized bed process, followed by compression.

#### Processing information

The dispersion is not particularly vulnerable to external influences.

Nevertheless, the following factors could result in coagulate formation that precludes further use of the dispersion:

- addition of finely dispersed pigments
- high shear gradients in stirrers and mills
- addition of emulsifiers, stabilizers or wetting agents
- pH changes
- organic solvents
- foaming

The minimum film-forming temperature (MFT) of the pure dispersion is 18 °C. It can be lowered by adding plasticizers.

The dispersion can theoretically also be used without plasticizers, but these additives enhance film formation and the flexibility of the films.

The following are suitable as plasticizers or gloss enhancers:

- 1,2-propylene glycol
- triethyl citrate
- polyethylene glycols and
- triacetin

The recommended plasticizer content is 0 – 10% with reference to the dried polymer substance.

1,2-Propylene glycol offers advantages for processing the dispersion and for film properties.

Plasticizer supplement	MFT
2.5% propylene glycol	18 °C
5% propylene glycol	16 °C
10% propylene glycol	14 °C
15% propylene glycol	12 °C
2.5% triethyl citrate	10 °C
5% triethyl citrate	8 °C
10% triethyl citrate	1 °C
15% triethyl citrate	< 0 °C

Triethyl citrate lowers the MFT more than propylene glycol.

Kollicoat® SR 30 D films without plasticizer are relatively brittle in the dry state; when wet, however, they are very flexible (elongation at break > 100%).

A small plasticizer supplement also increases the flexibility of the polymer in the dry state. Elongation at break values of more than 250% can be achieved using 5% triethyl citrate or 10% propylene glycol. Crack formation in coats, due for example to pronounced swelling of the core, is thereby prevented.

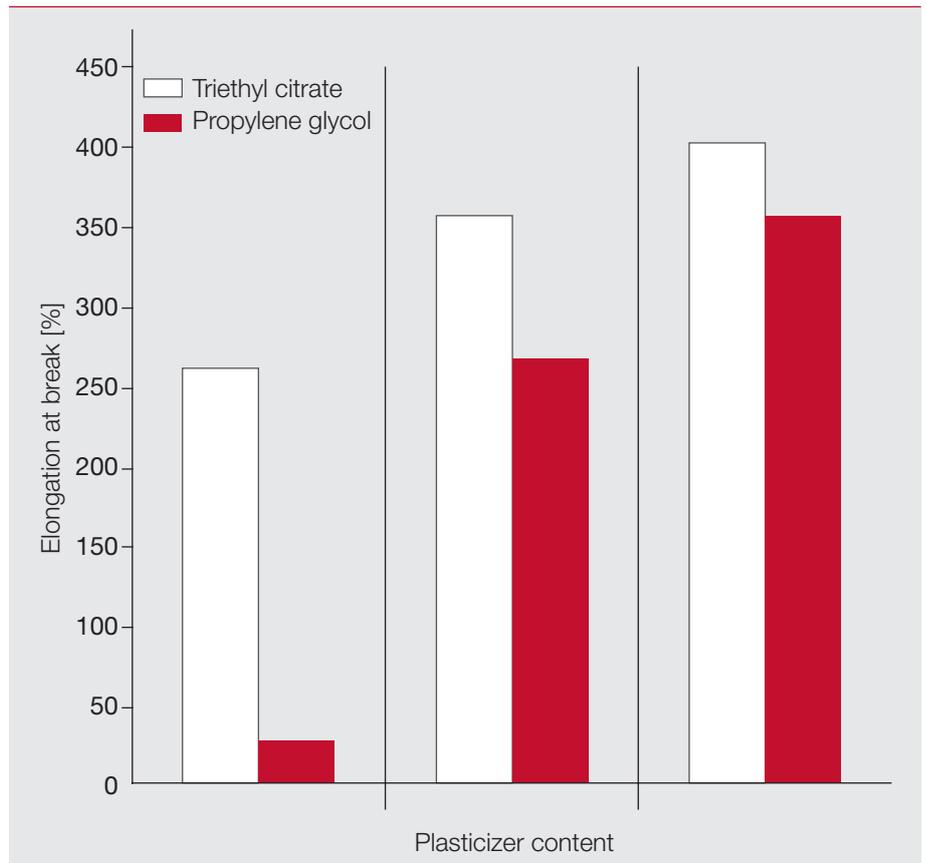


Fig. 1: Correlation of elongation at break of isolated films and plasticizer content

The permeability of the water-insoluble but swellable films can be varied by:

- the layer thickness of the coat
- the use of pore formers (Kollidon® VA 64, Kollidon® 30, HPMC, Avicel PH 105).  
The required content depends on the desired release profile.

The layer thickness should not be less than 1.5 mg/cm<sup>2</sup> (= about 15 µm) since otherwise film defects and burst effects are to be expected. Kollicoat® SR 30 D can be applied using either a top spray or bottom spray in the fluidized-bed coater.

Kollicoat® SR 30 D has no charged or ionizable groups and consequently results in pH-independent film coats.

Using talc in the spray formulations reduces the sticking tendency thereby preventing agglomeration of small particles in the fluidized bed as well as adhesion effects. Mixing the coated particles with 0.1 – 0.5% Aerosil® 200 prevents cohesion during storage even at elevated temperatures.

### Cleaning recommendation

As polyvinyl acetate is insoluble in water, acid and alkali, residues cannot simply be removed with aqueous solutions. However, they can be soaked in hot water until they swell and then removed with high pressure or hot water cleaners or mechanically with brushes and conventional cleansers.

As polyvinyl acetate is soluble in ethanol and 2-propanol, these alcohols can also be used. This is of particular interest for the cleaning of smaller apparatus parts such as nozzles and tubes.

## Formulation examples

### Theophylline sustained-release pellets

#### Composition of spray suspension

The formulation is designed for 500 g pellets (diameter 0.8 – 1.3 mm)

	Parts by weight [g]	Composition [%]
<b>Polymer suspension</b>		
Kollicoat® SR 30 D	223.67	50.0
Propylene glycol	6.71	1.5
Water	149.86	33.5
<b>Pigment suspension</b>		
Kollidon® 30	2.24	0.5
Titanium dioxide	2.24	0.5
Sicovit® Red 30	2.24	0.5
Talc	15.66	3.5
Water	44.73	10.0
	<b>447.35</b>	<b>100.0</b>

### Preparation of spray suspension

#### Polymer suspension

Propylene glycol followed by Kollicoat® SR 30 D are added to the stated quantity of water with stirring.

#### Pigment suspension

Kollidon® 30 is dissolved in the stated quantity of water. Sicovit® Red 30, titanium dioxide and talc are added with vigorous stirring and the mixture is homogenized with a corundum disk mill.

#### Spray suspension

The pigment suspension is incorporated into the polymer suspension with stirring. The suspension must be stirred during the spray process to prevent settling.

#### Machine parameters

Machine	Aeromatic Strea-1 fluidized bed granulator
Batch size	500 g
Inlet air temperature	60 °C
Outlet air temperature	37 °C
Product temperature	38 °C
Air flow	80 m <sup>3</sup> /h
Spraying pressure	1 bar
Spraying rate	11.5 g/min
Spraying time	39 min
Secondary drying	45 °C/5 min
Coating level	2 mg film former/cm <sup>2</sup>

The spray suspension is sprayed continuously onto the fluidized, pre-heated pellets by the top spray method.

The coating level of 2 mg film former/cm<sup>2</sup> stated here was established for the pellets by surface area determination. Since the particle size distribution and surface structure influence the required polymer quantity, calculating the surface area is recommended as a means of estimating the required coating level in each specific case.

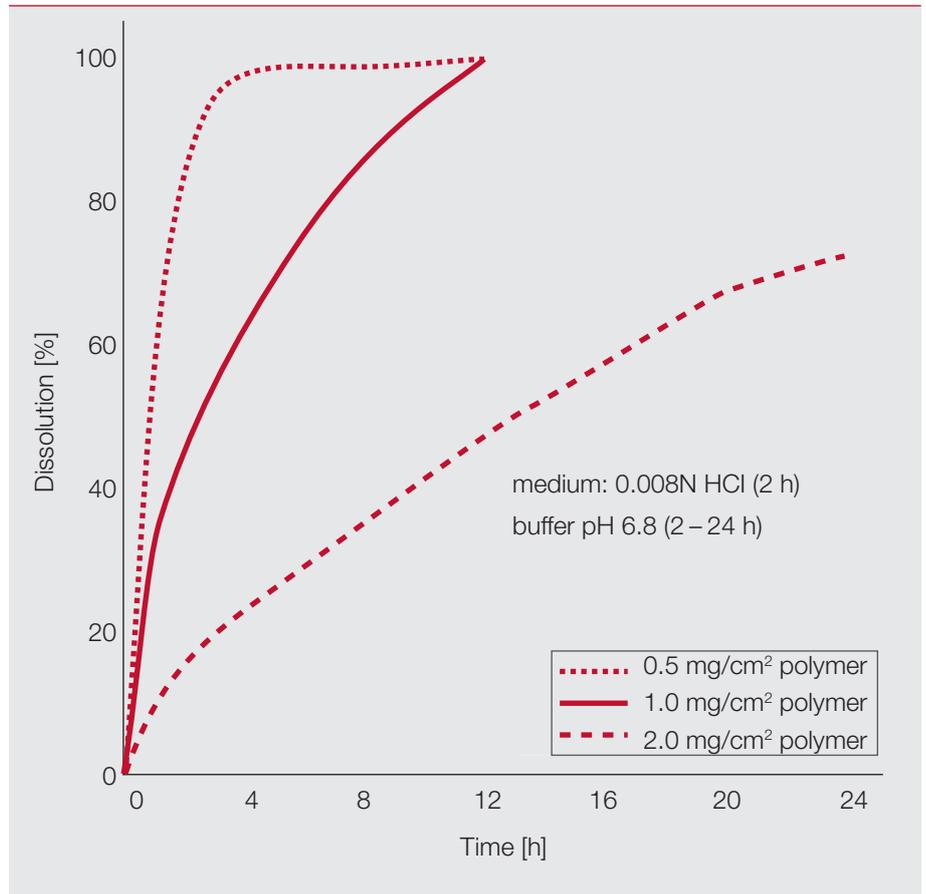


Fig. 2: Dissolution of Theophylline sustained-release pellets

## Caffeine sustained-release pellets

### Composition of pellets

10% caffeine, 43.75% Avicel PH 101, 43.75% lactose, 2.5% Kollidon® VA 64

### Composition of spray suspension

The formulation is designed for 500 g pellets (diameter 0.7 – 1.4 mm)

	Parts by weight [g]	Composition [%]
<b>Polymer suspension</b>		
Kollicoat® SR 30 D	269.44	49.3
Propylene glycol	8.09	1.5
Water	188.61	34.5
<b>Pigment suspension</b>		
Kollidon® 30	2.7	0.5
Titanium dioxide	2.7	0.5
Sicovit® Red 30	2.7	0.5
Talc	18.87	3.4
Water	53.89	9.8
	<b>547.99</b>	<b>100.0</b>

### Preparation of spray suspension

See Working "Theophylline sustained-release pellets" (page 5).

### Machine parameters

Machine	Aeromatic Strea-1 fluidized bed granulator
Batch size	500 g
Inlet air temperature	60 °C
Outlet air temperature	36 °C
Product temperature	37 °C
Air flow	80 m <sup>3</sup> /h
Spray pressure	1 bar
Spraying rate	12 g/min
Spraying time	45 min
Secondary drying	45 °C/5 min
Coating level	3 mg film former/cm <sup>2</sup>

The spray suspension is sprayed continuously onto the fluidized, pre-heated pellets by the top spray method.

The coating level of 3 mg film former/cm<sup>2</sup> stated here was established for the pellets by surface area determination. Since the particle size distribution and surface structure influence the required polymer quantity, calculating the surface area is recommended as a means of estimating the required coating level in each specific case.

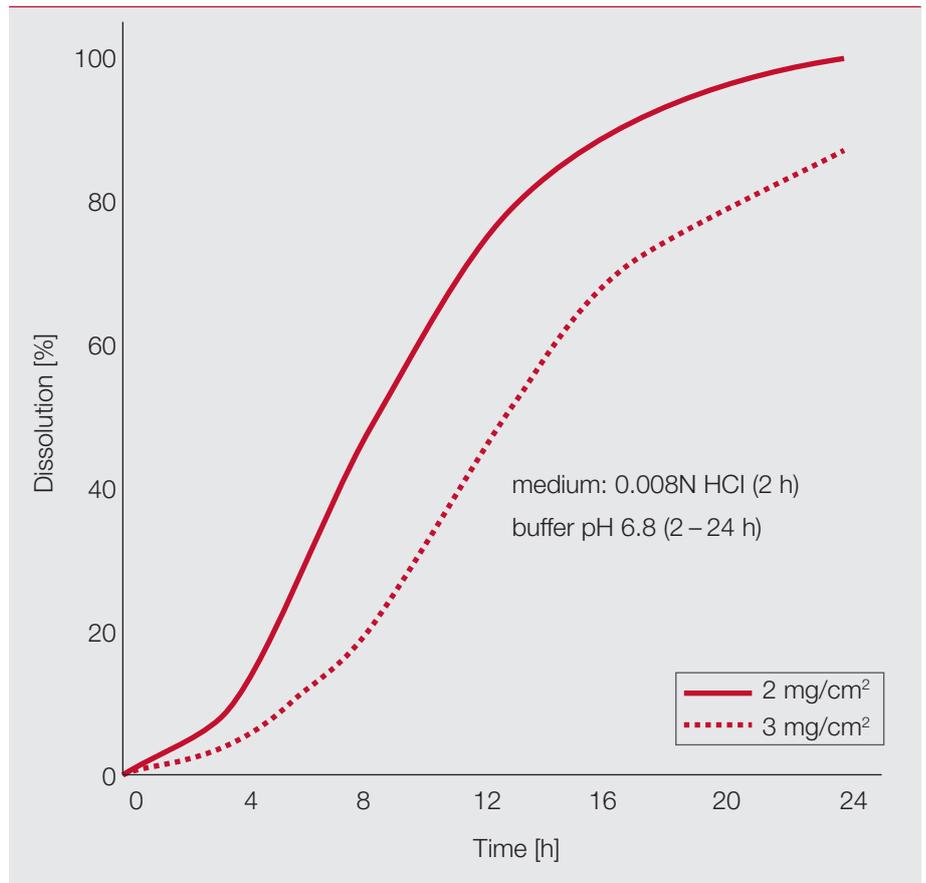


Fig. 3: Dissolution rate of Caffeine sustained-release pellets at different coating levels

Curing (Thermal postcoating treatment) of the pellets is not necessary.

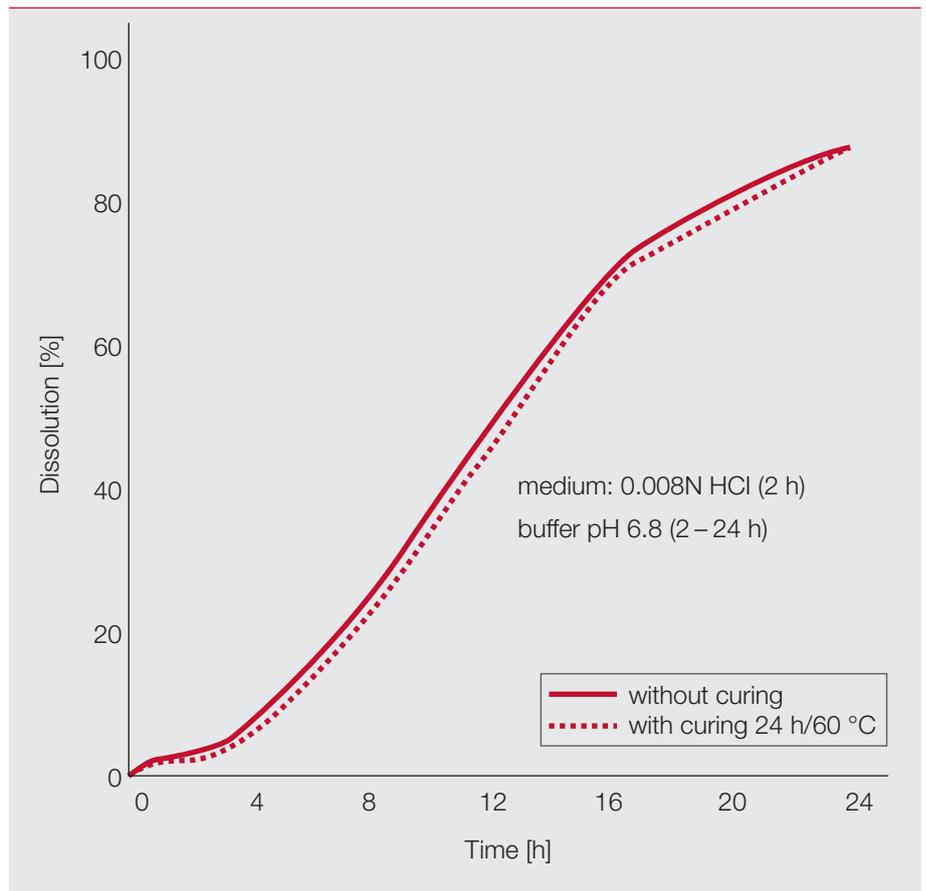


Fig. 4: Dissolution rate of Caffeine sustained-release pellets with and without curing

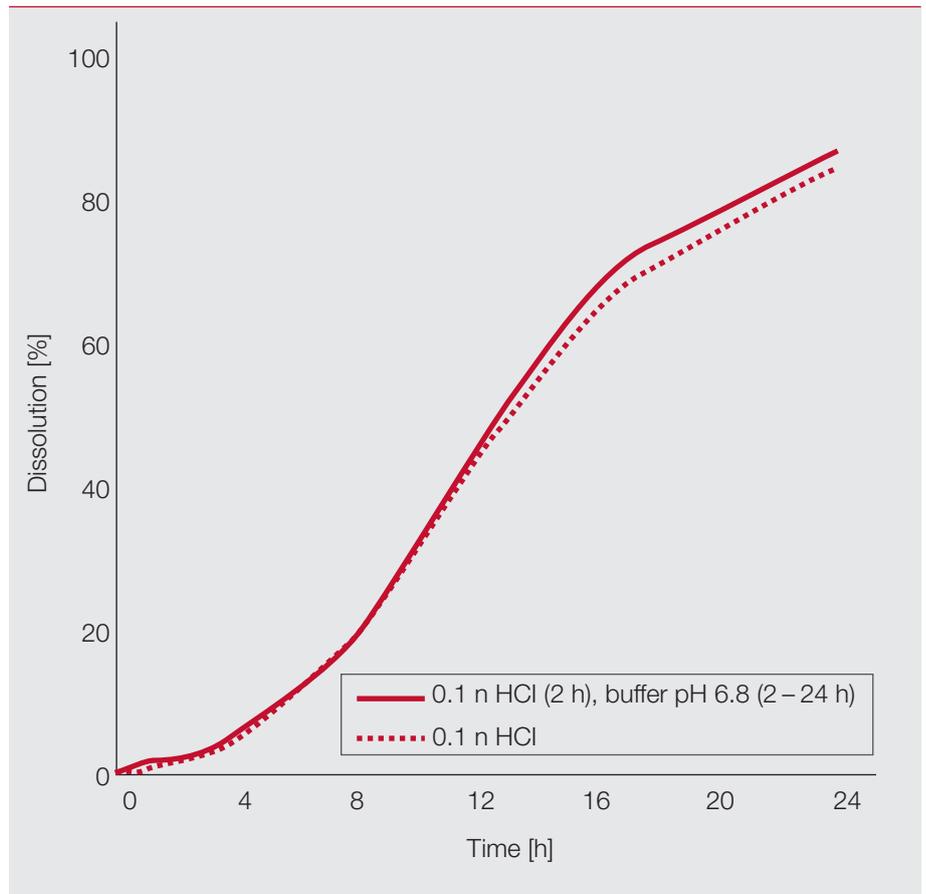


Fig. 5: Dissolution rate of Caffeine sustained-release pellets with and without curing

The release of caffeine pellets is pH independent.

## Propranolol sustained-release pellets

### Composition of pellets

20.0% propranolol, 51.66% Avicel PH 101, 25.84% lactose, 2.5% Kollidon® VA 64

### Composition of spray suspension

The formulation is designed for 500 g pellets (diameter 0.4 – 1.5 mm)

	Parts by weight [g]	Composition [%]
<b>Polymer suspension</b>		
Kollicoat® SR 30 D	249.41	49.2
Propylene glycol	7.49	1.5
Water	174.59	34.5
<b>Talc suspension</b>		
Talc	29.94	5.9
Water	44.91	8.9
	<b>506.34</b>	<b>100.0</b>

### Preparation of spray suspension

See Working "Theophylline sustained-release pellets" (page 5).

**Machine parameters**

Machine	Aeromatic Strea-1 fluidized bed granulator
Batch size	500 g
Inlet air temperature	60 °C
Outlet air temperature	35 °C
Product temperature	36 °C
Air flow	80 m <sup>3</sup> /h
Spray pressure	1 bar
Spraying rate	13 g/min
Spraying time	39 min
Secondary drying	45 °C/5 min
Coating level	3 mg film former/cm <sup>2</sup>

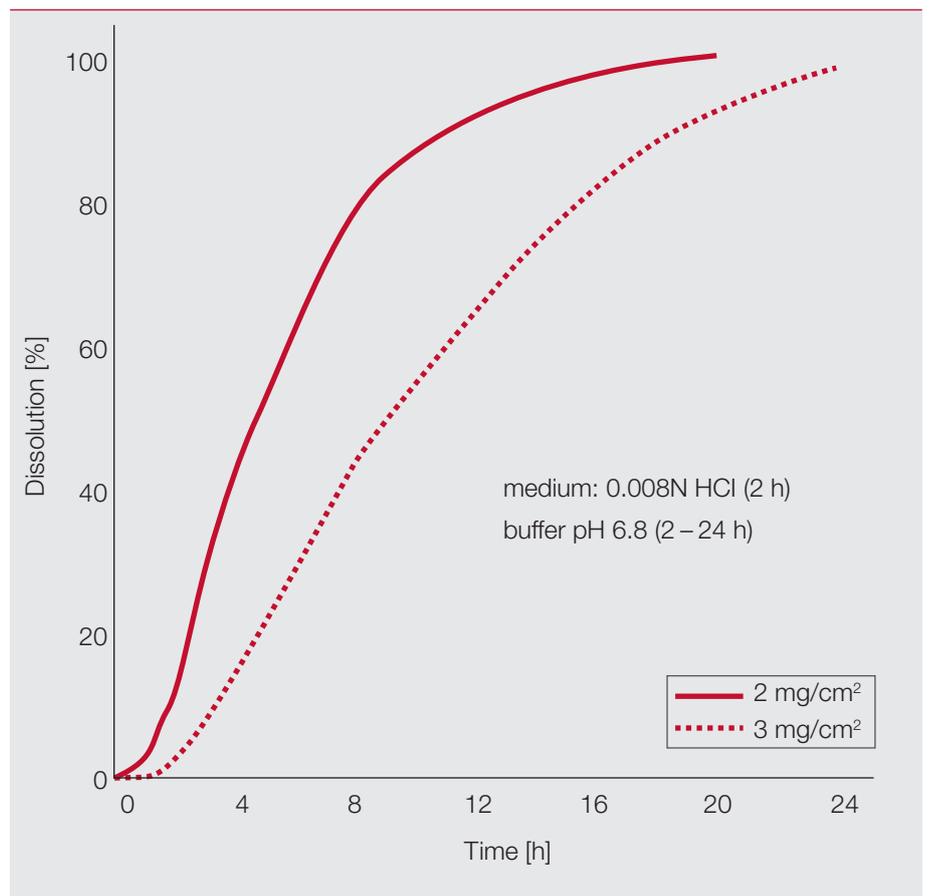


Fig. 6: Dissolution rate of Propranolol sustained-release pellets

## 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

The toxicological abstract is available on request.

## 10. PRD and Article numbers

PRD-No.*	Product name	Article numbers	Packaging
30067541	Kollicoat® SR 30 D	51597817	1 kg Plastic bottle
		50893290	25 kg Plastic jerricans

\* BASF's commercial product number.

## 11. Publications

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

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