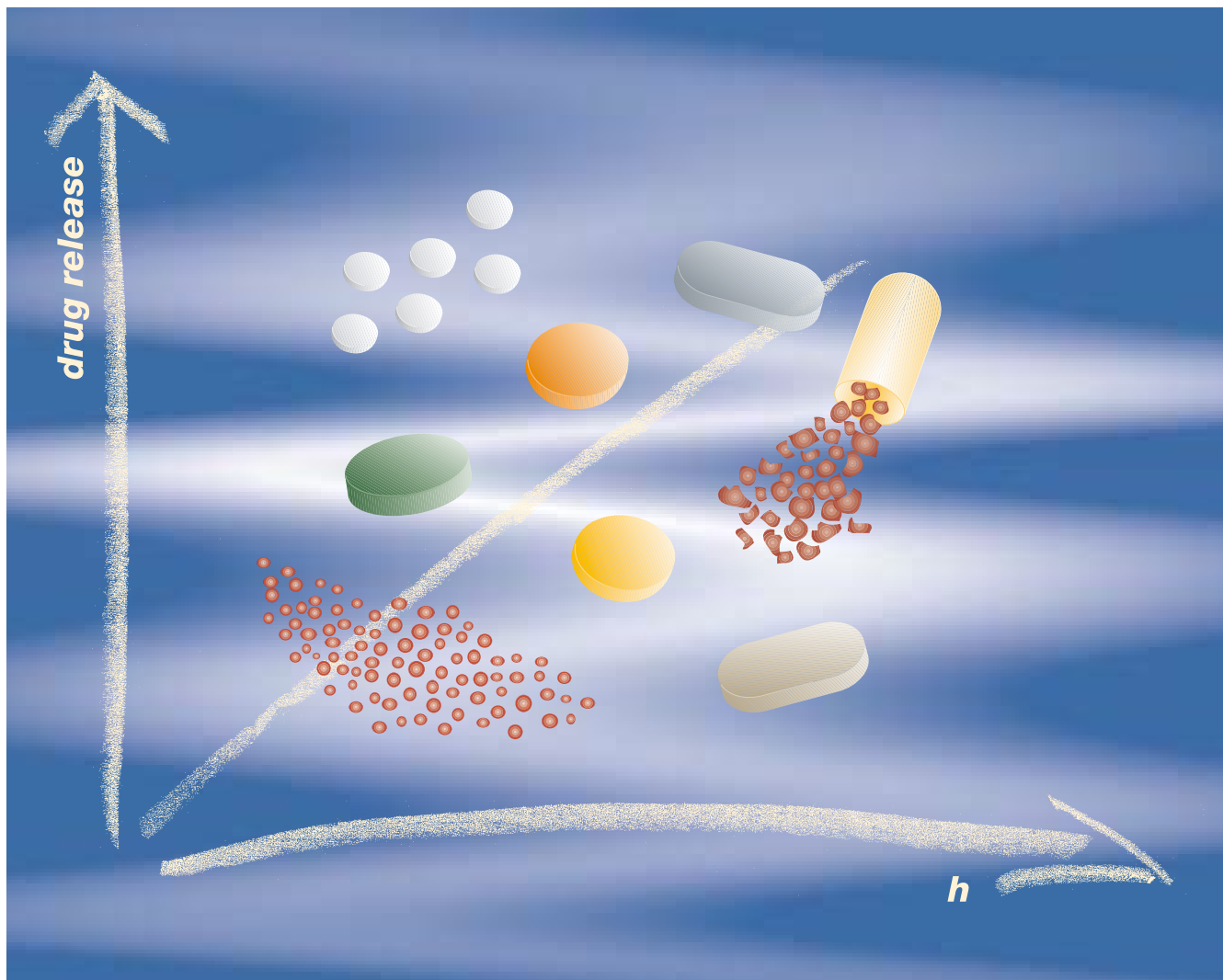


# Kollicoat® SR 30 D

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

® = Registered trademark of BASF SE

Polyvinyl acetate dispersion for sustained-release  
pharmaceutical formulations



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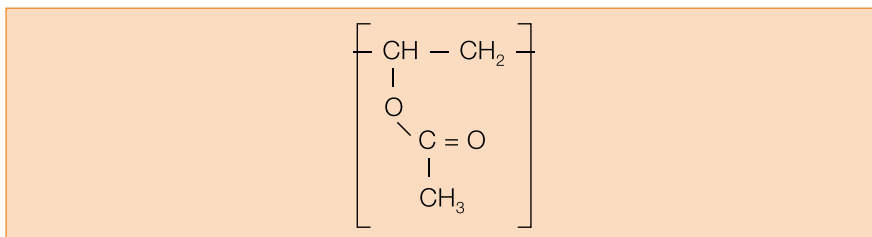
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## 1. Introduction

### 1.1 General

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. The dispersion can also be used for taste masking.

### 1.2 Chemical structure



### 1.3 Trivial name

Poly (Vinyl Acetate) Dispersion 30 per cent

## 2. Specifications and properties

### 2.1 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.

### 2.2 Physical and chemical properties

#### 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.

#### Specification

See separate document: "Standard Specification (not for regulatory purposes)" available via BASF's WorldAccount: <https://worldaccount.basf.com> (registered access).

### 2.3 Regulatory status

Meets current Poly (Vinyl Acetate) Dispersion 30 Per Cent Ph. Eur monograph.

### 2.4 Marketing authorization

Polyvinyl acetate is described, with reference to oral administration, in Japanese Pharmaceutical Excipients (JPE) 1993. Polyvinyl acetate is used in a variety of medicinal products for oral administration in numerous countries including Germany, France and the USA.

Polyvinyl acetate is also used in the food industry, for example as a chewing gum base or for coating fruits and vegetables. It is listed, for example, in Germany in the Regulations for Marketing Authorization of Food Additives for Technological Purposes, in the USA in the Code of Federal Regulations, Section 172.615, in South Korea in the Public Code on Food Additives 1995 and in Japan in the Japanese Standard for Food Additives, March 1997.

### 3. Application and Processing

#### 3.1 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.

##### **Protective coats**

Applied in small quantities or with hydrophilic additives, Kollicoat SR 30 D provides good protection against odour or taste. It can also be used, for example as a subcoating, for isolating active ingredients to prevent interactions.

##### **Sustained-release matrix formulations**

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

#### 3.2 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

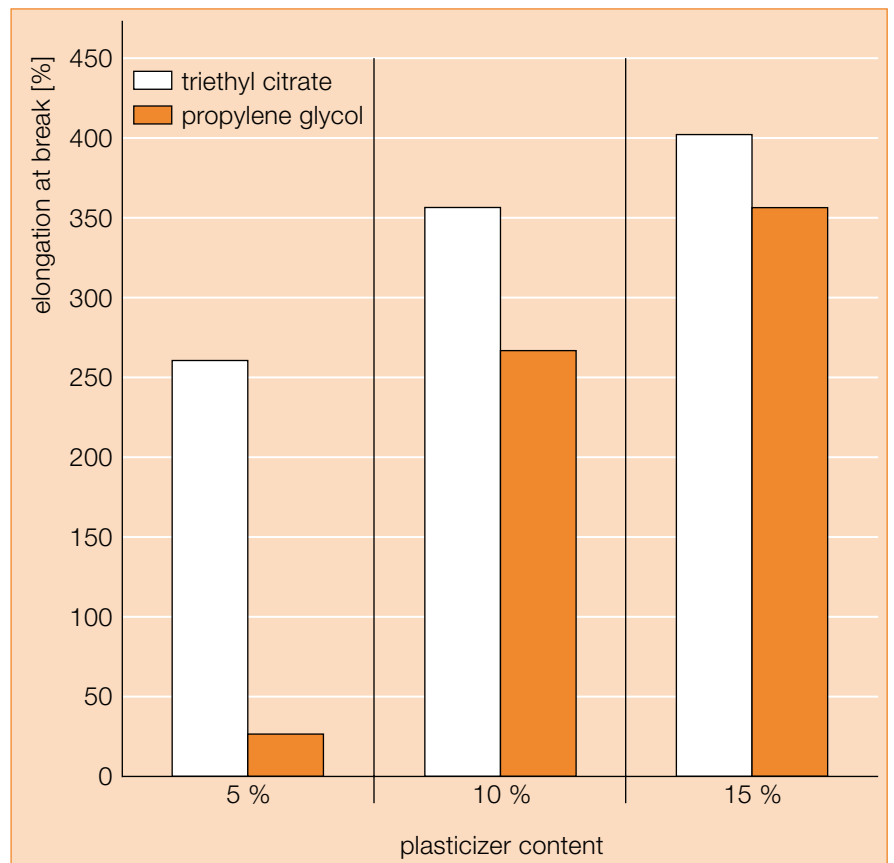
1,2-Propylene glycol offers advantages for processing the dispersion and for film properties.

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.



#### *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.

### **3.3 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.

## 4. Formulation examples

### 4.1 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]	Co mposition [%]
<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
	447.35	100.0

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:*

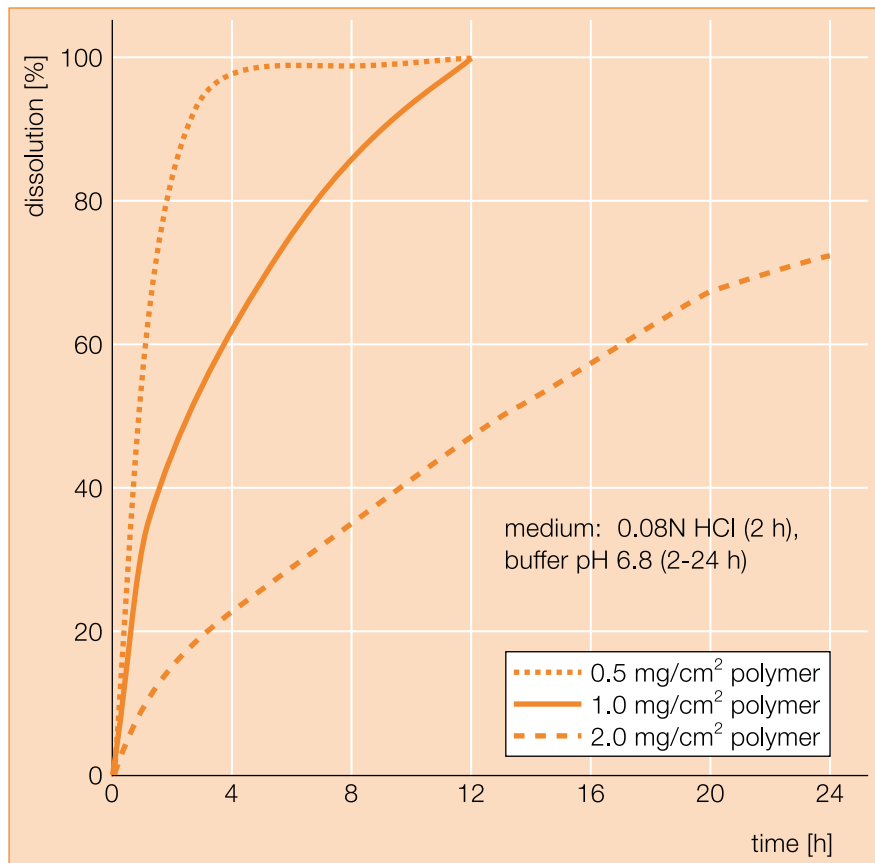
The pigment suspension is incorporated into the polymer suspension with stirring. The suspension must be stirred during the spray process to prevent settling.

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.



Dissolution of Theophylline sustained-release pellets

#### 4.2 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
	547.99	100.0

## Preparation of spray suspension

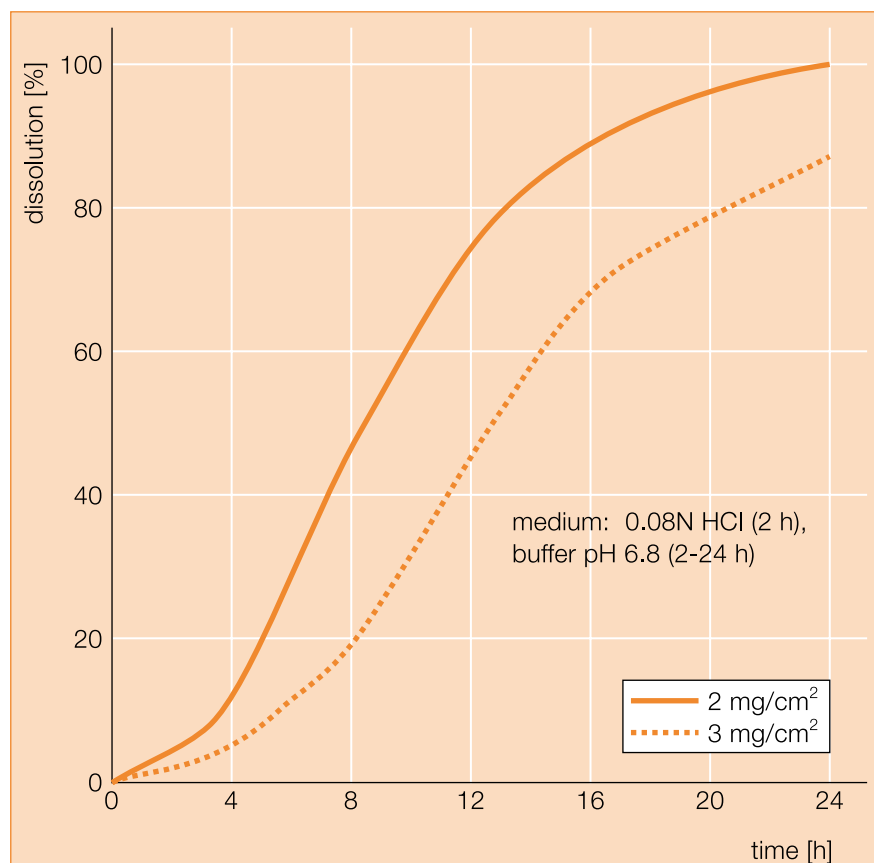
*See Working Procedure 4.1*

## 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.

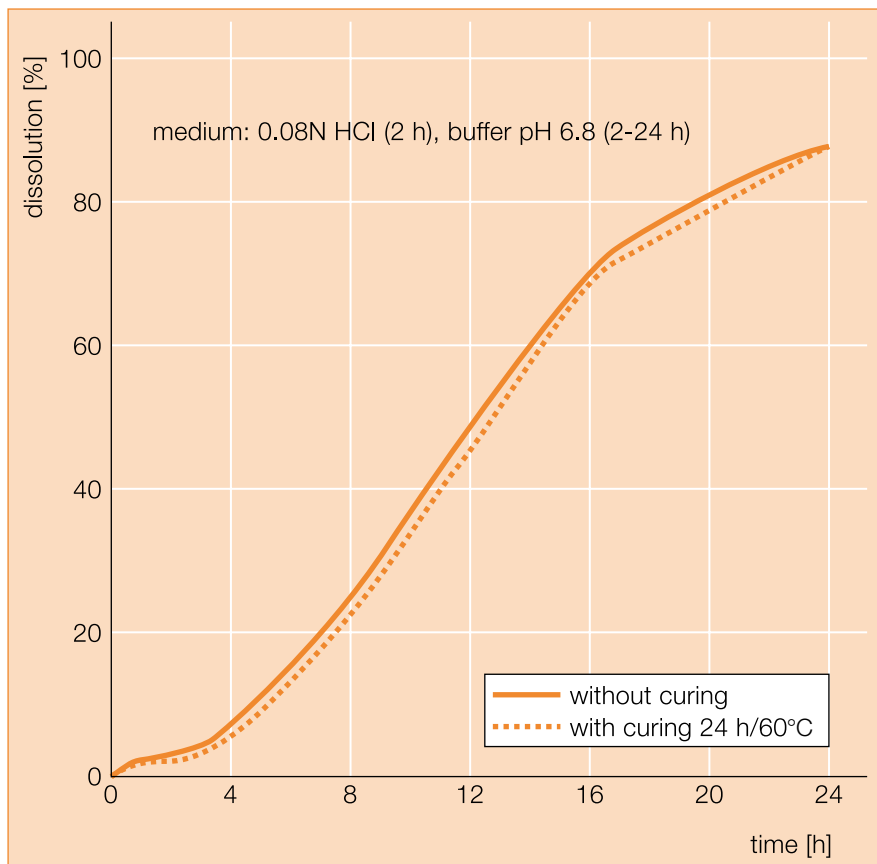
The coating level of 3 mg film former/cm<sup>2</sup> stated here was established for the pellets by surface area determination. Since the particle size distribution and surface structure influence the required polymer quantity, calculating the surface area is recommended as a means of estimating the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



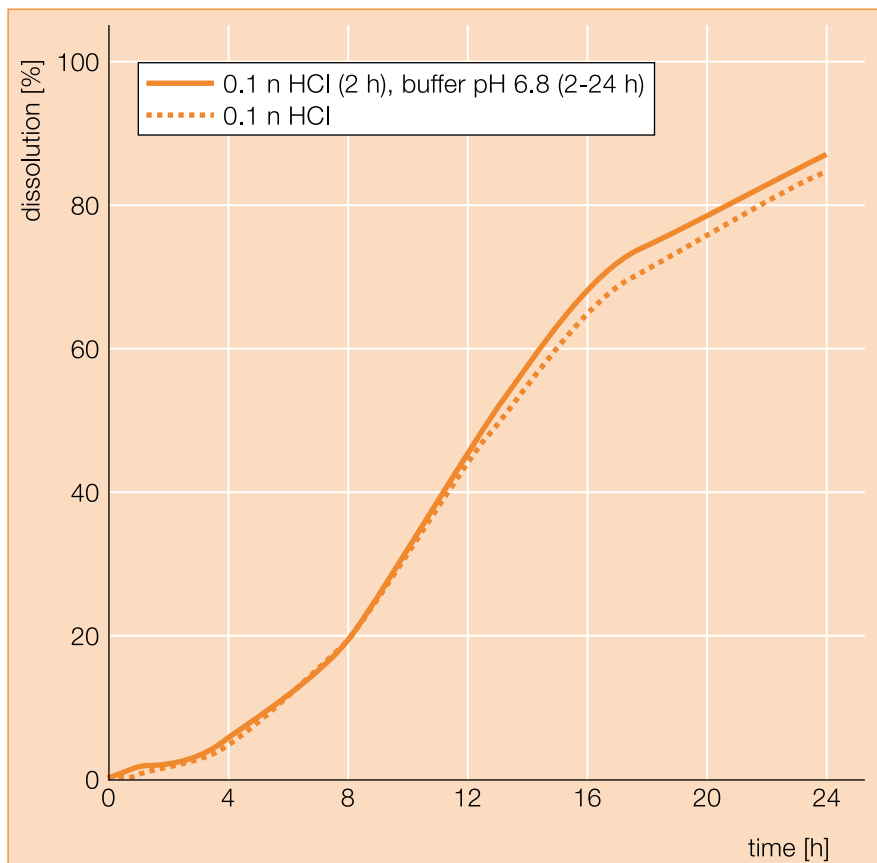
*Dissolution rate of Caffeine sustained-release pellets at different coating levels*



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



Dissolution rate of Caffeine sustained-release pellets with and without curing



Dissolution rate of Caffeine sustained-release pellets in different media

The release of caffeine pellets is pH independent.

### 4.3 Propranolol sustained-release pellets

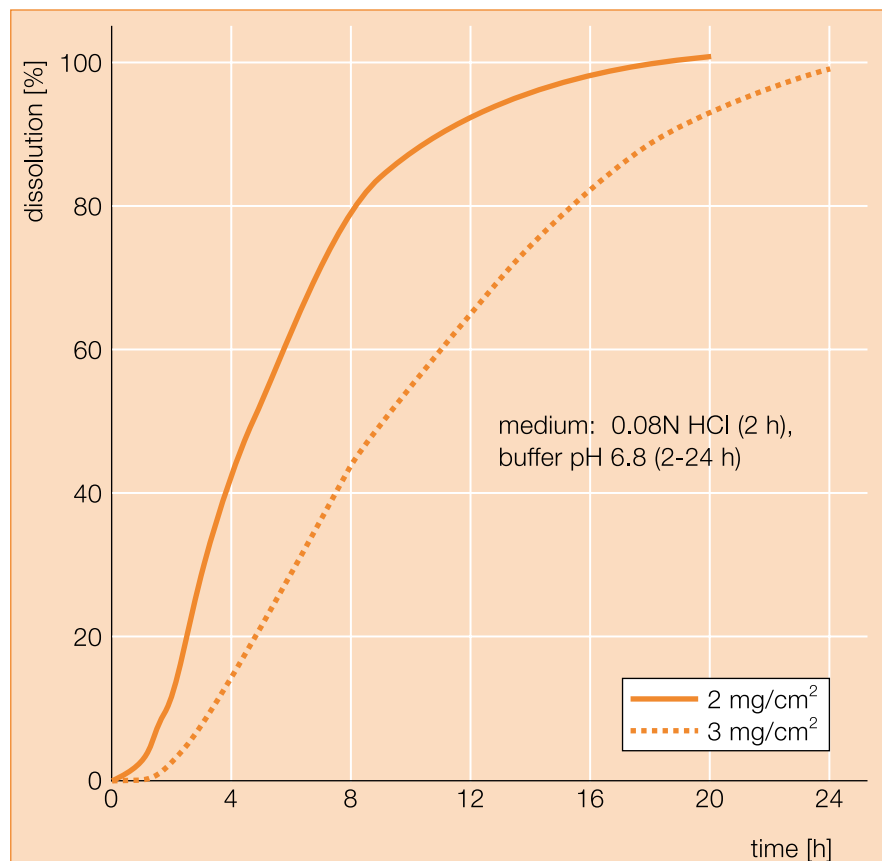
Composition of pellets: 20.0% propranolol, 51.66% Avicel PH 101, 25.84% lactose, 2.5% Kollidon VA 64

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
	506.34	100.0

Preparation of spray suspension *See Working Procedure 4.1.*

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
Spraying 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>



*Dissolution rate of Propranolol sustained-release pellets*

**4.4 Taste-masked acetaminophen**

Acetaminophen granules. (Knoll AG)

Smaller quantities have to be applied for taste masking since otherwise drug release characteristics would be excessively altered.

Crystalline acetaminophen is coated with 4% Kollocoat SR 30 D.

*The formulation is designed for 500 g powder.*

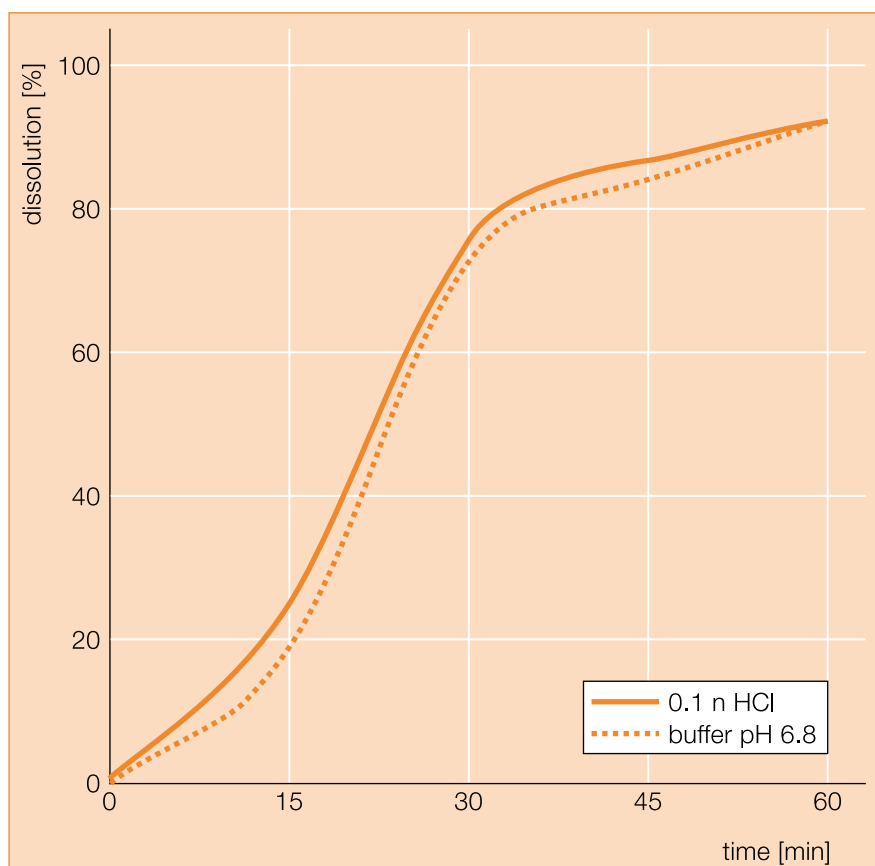
	Parts by weight [g]	Composition [%]
<b>Polymer suspension</b>		
Kollocoat SR 30 D	73.33	100.0

Machine parameters

Machine	Aeromatic Strea-1 fluidized bed granulator
Batch size	500 g
Inlet air temperature	60°C
Outlet air temperature	40°C
Product temperature	41°C
Air flow	80 m <sup>3</sup> /h
Spraying pressure	1 bar
Spraying rate	9 g/min
Spraying time	9 min
Secondary drying	45°C/5 min
Coating level	4%

Taste masking

No bitter taste



*Dissolution rate of taste-masked acetaminophen*

**5. Storage**

Protect from frost and store below 25°C

**6. Stability**

At least 18 months in the unopened original container. On exposure to heat and frost and if foaming occurs, aqueous dispersions may form coagulates that preclude further use of the product.

**7. PBG-No.**

10201076

**8. PRD-No.**

30067541

**9. Packaging**

25-l polyethylene container. The product can also be filled into larger containers.

**Note**

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