Technical Information

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Kollicoat® MAE 100-55
Kollicoat® MAE 100 P

Methacrylic acid/ethyl acrylate copolymers in powder form for enteric coating

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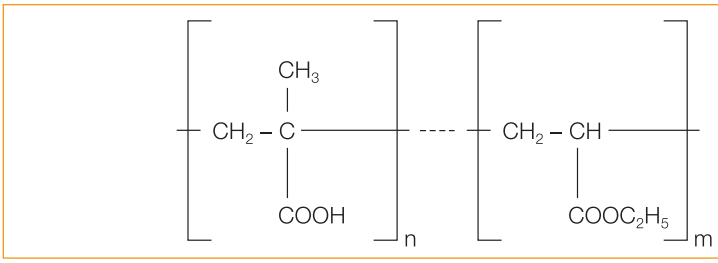
Contents

1. Introduction

1.1 General remarks

Kollicoat® MAE100-55 and Kollicoat® MAE 100 P are spray-dried copolymers consisting of methacrylic acid and ethyl acrylate. They are used as film-formers for enteric coatings of solid dosage forms like crystals, multi-particulates, mini-tablets, tablets soft-gel capsules and others.

1.2 Structural formula



The monomer ratio in the copolymers is 1:1. The average molecular weight M_w is of the order of 250,000 AMU.

Both copolymers have an anionic character.

In contrast to Kollicoat® MAE 100-55 the copolymer in Kollicoat® MAE 100 P is partially neutralized before spray drying.

1.3 Commercial form

Both Kollicoat® MAE 100-55 and Kollicoat® MAE 100 P are white powders with a faint characteristic odour.

In order to apply Kollicoat® MAE 100-55 the powder has to be re-dispersed in water with the addition of a caustic excipient, preferably sodium hydroxide solution.

The pre-neutralized carboxyl groups in the Kollicoat® MAE 100 P powder make it easy to re-disperse in water without further excipients added for partial neutralization.

1.4 Pharmacopoeial situation

The polymers are listed in the three major pharmacopoeias as follows:

Kollicoat® MAE 100-55:

Ph.Eur.: Methacrylic Acid – Ethyl Acrylate Copolymer (1:1) Type A
USP/NF: Methacrylic Acid and Ethyl Acrylate Copolymer NF
JPE: Dried Methacrylic Acid Copolymer LD

Kollicoat® MAE 100 P:

Ph. Eur.: Methacrylic Acid – Ethyl Acrylate copolymer (1:1), Type B
USP-NF: Partially-Neutralized Methacrylic Acid and Ethyl Acrylate copolymer

2. Specifications and properties

2.1 Description

The Kollicoat® MAE grades contain 0.7% sodium lauryl sulfate (USP) and 2.3% Polysorbate 80 (Ph.Eur.) as emulsifying agents. (The percentages refer to the solid substances.)

Polysorbate 80 is manufactured using oil of vegetable origin.

The Kollicoat® MAE grades are weakly acidic copolymers that dissolve at a pH-value above 5.5.

2.2 Specification

See separate document: “Standard Specification (not for regulatory purposes)” available via BASF’s WorldAccount: https://worldaccount.basf.com (registered access).

2.3 Solubility

The Kollicoat® MAE grades are re-dispersible in water. The achieved dispersions regain their milky white appearance either when using a neutralization medium (Kollicoat® MAE 100-55) such as 1 mol/L NaOH or just when mixing it with water (Kollicoat® MAE 100 P).

When treated with higher quantities of dilute alkalis the Kollicoat® MAE powder grades (like the Kollicoat® MAE 30 DP dispersion) become soluble and form clear to slightly cloudy solutions of moderate viscosity.

Kollicoat® MAE 100-55 powder dissolves in alcohols such as methanol, ethanol or i-propanol to yield clear to slightly cloudy solutions

Mixing of the re-dispersed aqueous formulations of Kollicoat® MAE 100-55 or Kollicoat® MAE 100 P with acetone, ethanol or isopropanol in a ratio of 1:5 a faint opalescent or clear, moderately viscous solution is obtained. Upon addition of the organic solvent to the dispersion, the polymer initially precipitates, then re-dissolves as more solvent is added.

3. Processing notes

3.1 Use of plasticizer

Plasticizers are essential to improve the flexibility of the films formed.
Suitable plasticizers or gloss intensifiers are

- 1,2-propylene glycol
- Triethyl citrate
- Polyethylene glycols such as PEG 400

The recommended amounts of plasticizers range from 10% to 25% relative to the amount of polymer dry matter.

The Kollicoat® MAE grades are incompatible with magnesium stearate as part of the coating formulation. However, any magnesium stearate present in the cores to be coated does not present problems.

1.2-propylene glycol improves the processibility and barrier properties of the film coatings.

A number of factors may cause aqueous dispersions to coagulate during processing, rendering them unusable:

- Addition of finely divided pigments
- High shear gradients on stirring and grinding
- Addition of emulsifying agents, stabilizers or wetting agents
- Changes in pH
- Cationic additives
- Organic solvents.
- Foam formation

Foam formation during processing can be prevented by adding a silicone antifoam such as Pharsil 21046.

Flat-plate stirrers have proved suitable for the production of spray suspensions.

Spray suspensions with a 15 – 30% solids content give good results and save time in spraying.

To avoid problems in incorporating auxiliaries in the aqueous suspensions, we recommend to:

- Dilute the dispersion to a solids content of 15% to 20%
- Stir the desired auxiliary into the dispersion in the form of a diluted solution.

The following excipients can be included in a film-coating formulation:

- Talc
- Syloid
- Aerosil and
- Kaolin as release and smoothing agents;
- Pigments

The Kollicoat® MAE grades have a high pigment binding capacity: two to three parts of pigments or other auxiliaries may be added for one part of solid polymer.

3.2 Re-dispersion of Kollicoat® MAE 100-55

The proper use of Kollicoat® MAE 100-55 comprises of two steps:

1. Re-dispersion of Kollicoat® MAE 100-55 powder to form an aqueous latex dispersion

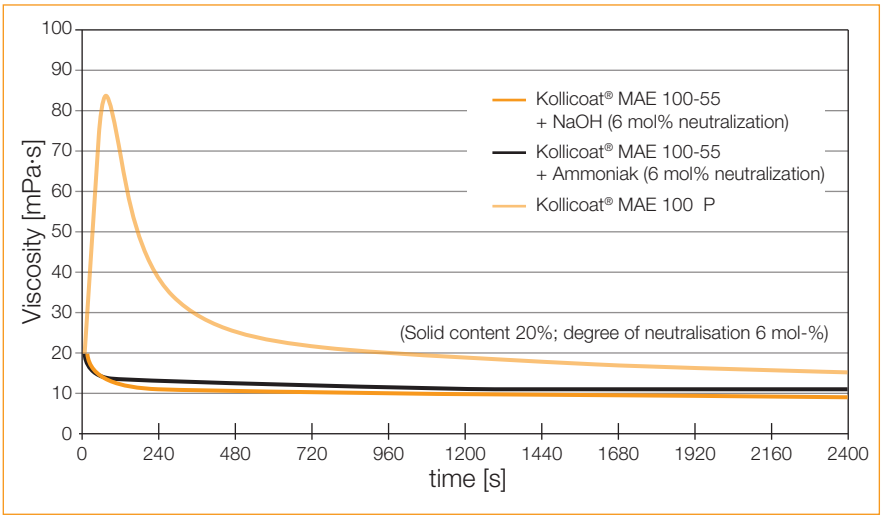
2. Addition of plasticizer

To achieve a proper re-dispersion the polymer powder has to be incorporated in water in combination with a caustic compound to achieve the requested degree of neutralization of around 6 mol-percent of the methyacrylic acid moieties in the polymer. This neutralized polymer dispersion can be further processed by adding the required additives such as plasticizer, colorants etc. to generate a coating dispersion of an appropriate concentration.

For the re-dispersion step a number of caustic excipients can be used for neutralization. The compounds proposed in the following list are applied in a 1 mol/L aqueous solution if not otherwise stated. Sodium hydroxide (NaOH) is the most recommended compound. Others are

- Potassium hydroxide (KOH)
- Ammonia (NH_3 in water)
- Ammonium bicarbonate $(NH_4)HCO_3$
- Ammonium carbonate $(NH_4)_2CO_3$
  (to be applied in a concentration of 0.5 mol/L

The following graph shows the viscosity determination for a 20% dispersion of Kollicoat® MAE 100 P and the situation for Kollicoat® MAE 100-55 after its re-dispersion using a 1 mol/L solution of sodium hydroxide and ammonia, respectively to achieve a 6 mol-% neutralization of the methacrylic acid moiety.



Shortly after the addition of the caustic compound the viscosity of the re-dispersed enteric polymer reaches already its minimum level. Different neutralization media have only little influence on the finally achievable viscosity. The following graph shows the resulting viscosities for the 6 mol-% neutralization of Kolllicoat® MAE 100-55 using either a solution of 1 mol/L NaOH, of 1 mol/L ammonia, of 1 mol/L ammonium hydrogen carbonate or of 0.5 mol/L ammonium carbonate solution, respectively. To manufacture 1 kg of a Kollicoat® MAE-enteric coating dispersion the following procedure has to be followed:

Processing recommendations

Function	Compound	Required Quantity	Dry matter content
		[g]	[g]
Kollicoat® MAE 100-55 suspension			
Polymer	Kollicoat® MAE 100-55	300.0	300.0
Suspension media	Water	600.0	
Kollicoat® MAE 100-55 dispersion			
Neutralizing agent	NaOH (1 mol/L)	100.0	4.0
Total		**1000.0**	**304.0**

Instead of adding 100 ml of a 1 mol/L NaOH solution the alternative neutralizing agents mentioned above can be applied. The dry matter content has to be adjusted accordingly.

3.3 Re-dispersion of Kollicoat® MAE 100 P

When stirring the powder into water an aqueous dispersion is achieved with processing properties similar to those of Kollicoat® MAE 100-55 or Kollicoat® MAE 30 DP-dispersions.

Procedure:
Add the powder to the specified quantity of water with stirring. During stirring, ensure that

- the powder does not form lumps
- the powder is immediately wetted
- the speed of the stirrer always matches the viscosity
- not too much foam is being formed.

To avoid lump formation and deposits on the stirrer, a stirrer with no horizontal surfaces, e.g. a bar or gate-type should be used.

When the powder has been incorporated, the viscosity initially rises and then decreases on further stirring. The dispersion should be stirred for 2 – 4 hours to ensure complete re-dispersion. It must be ensured that not too much air is entrained in the dispersion when it thickens.

A concentration of 20% has been found to be the optimum. The further steps in the preparation of a suitable dispersion are essentially the same as for Kollicoat® MAE 30 DP.

It is not necessary to add any other auxiliaries such as alkali to re-disperse Kollicoat® MAE 100 P. The powder contains already the necessary percentage of neutralized methacrylic acid groups for easy re-dispersion.

4. Applications and typical formulations using Kollicoat® MAE 100-55

Formulations with Kollicoat® MAE 100-55

For the proper handling of Kollicoat® MAE 100-55 it is recommended to follow the instructions given for the re-dispersion of the polymer in section 3.2. Thorough calculation of the dry matter content of the polymer dispersion after addition of the selected neutralisation compound is essential.

4.1 Enteric coated acetyl salicylic acid crystals

The crystals were enteric coated using a Kollicoat® MAE 100-55-formulation without pigments. The ASS-crystals were coated in a Glatt WSG fluid-bed coater with a 7" Wurster insert.

Acetyl salicylic acid crystals with Kollicoat® MAE 100-55

Re-dispersion of the polymer powder

For the preparation of an appropriate polymer dispersion follow the recommendations in chapter 3.2.

An aqueous polymer dispersion containing 600 g of Kollicoat® MAE 100-55 with the appropriate amount of triethyl citrate as plasticizer are prepared as follows:

Ingredients	Parts by weight [g]	Composition [%]
Kollicoat® MAE 100-55	600.0	18.00
Triethyl citrate (10% relative to polymer weight)	60.0	1.80
NaOH (1 mol/L)	204.0	0.25
Demineralized Water	2460.0	-
Total	**3224.0**	**20.10**

Preparation of the coating formulation

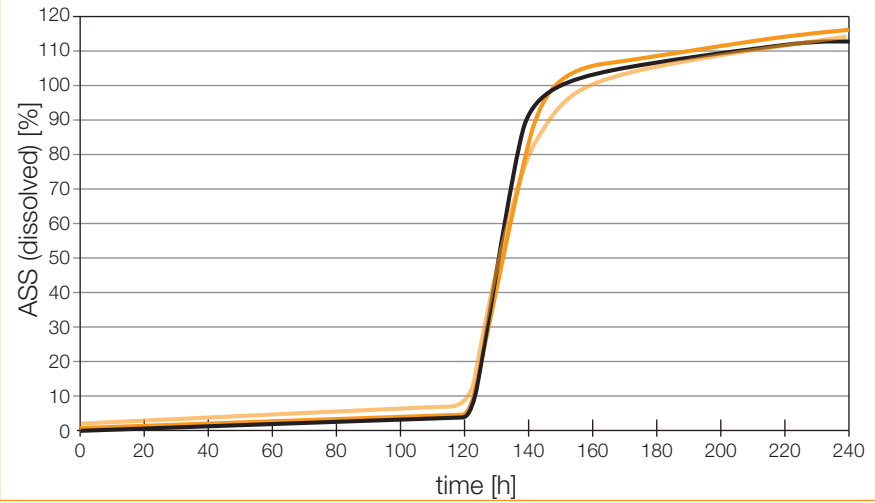
The polymer powder is stirred into 2200 g of water. The required quantity of NaOH-solution is added and the re-dispersion is performed for 30 minutes under stirring while the triethyl citrate is dispersed in the remaining volume of water in a separate beaker.

The plasticizer dispersion is combined with the polymer dispersion and stirred for 2 hours.

Coating equipment and process parameters

Coating equipment	Glatt GPCG 3.1 with Wurster insert (7 “)	
Batch size	kg	1.0
Number of nozzles		1
Nozzle diameter	mm	0.8
Total applied quantity (for 50% weight gain)	g	2750
Spraying rate	g/min	20.0
Spraying pressure	bar	1.0
Spraying time	min	~ 140
Air supply	m^3/h	90 …130
Inlet air temperature	°C	60
Drying time	min	8
Weight gain	%	20 to 50

Release testing



Kollicoat® MAE 100-55 coating levels:
- 20% weight gain
- 40% weight gain
- 50% weight gain

At the recommended minimum coating level of 20% weight gain the release level of acetyl salicylic acid crystals of less than 10% within the 2 h residence time in 0.08N HCl can be achieved.

4.2 Enteric coated acetyl salicylic acid tablets (100 mg/tablet)

Composition of the tableting mixture

Ingredients	Parts by weight [g]	Composition [%]
Acetyl salicylic acid	285.7	28.6
Ludipress®	704.3	70.4
Stearyl fumarate-Na (Pruv®)	10.0	1.0
Total	**1000.0**	**100.0**

Processing of the tableting mixture

The ingredients except the sodium stearyl fumarate are blended in a Turbula blender for 10 minutes and passed through an 800 µm-sieve. The lubricant is added and the resulting blend is additionally mixed for 1 minute.

Tableting equipment

Rotary press	Korsch XL 100
Tablet shape	concave
Tablet weight	350 mg
Tablet diameter	9 mm
Compression force	6 kN

Enteric coating with Kollicoat® MAE 100-55

Re-dispersion of the polymer powder

For the preparation of an appropriate polymer dispersion follow the recommendations in chapter 3.2.

Prepare around 1200 g of a dispersion containing around 220 g of Kollicoat® MAE 100-55

Composition of the coating formulation

Ingredients	Parts by weight [g]	Composition [%]	Dry matter [%]
Kollicoat® MAE 100-55	218.0	18.2	18.2
Triethyl citrate (10% relative to polymer weight)	21.8	1.8	1.8
NaOH (1 mol/L)	75.2	6.3	0.3
Demineralized Water	887.0	73.7	-
Total	**1200.0**	**100.0**	**20.2**

Prepartion of the coating formulation

Around 200 g of the water is used to disperse the triethyl citrate.

Kollicoat® MAE 100-55 is added to the remaining quantity of water and dispersed after the addition of the required quantity of 1 mol/L NaOH-solution. After 30 minutes of permanent stirring the plasticizer dispersion is added.

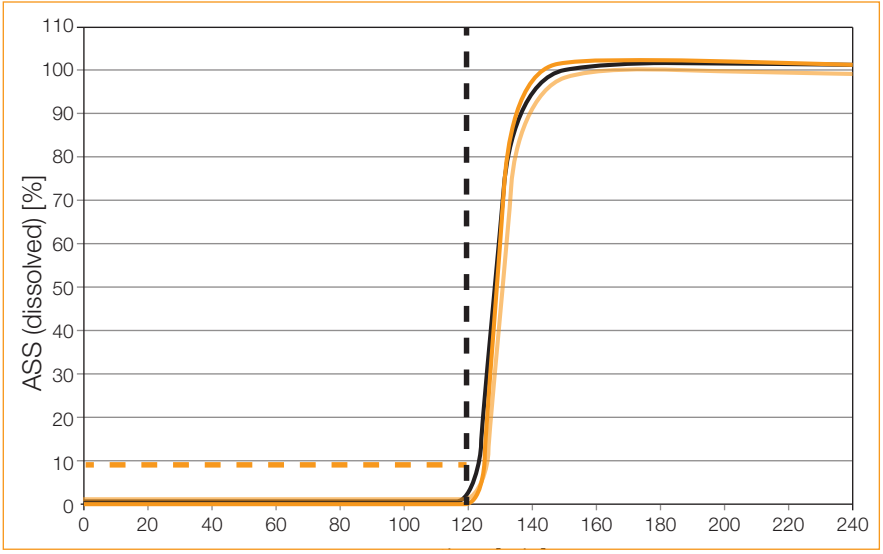
The resulting coating suspension is stirred for 2 h prior to use.

The recommended conditions are shown in the following. The cores were heated to 50 °C for 30 minutes before applying the coating formulation.

Coating equipment and process parameters

Coating equipment	Manesty Coater XL Lab 01	
Batch size	kg	4.0
Number of nozzles		1
Nozzle diameter	mm	0.8
Spraying rate	g/min	20
Application quantity	mg/cm²	3 to 6
Spraying time	min	32
Air supply	m³/h	400
Pan speed	rpm	25
Inlet air temperature	°C	55
Drying time	min	5

Release testing



Kollicoat® MAE 100-55 coating levels:
- 3 mg /cm²
- 4 mg/cm²
- 6 mg/cm²
- allowance limit
- buffer change

4.3 Enteric coated Diclofenac-Na tablets (50 mg/tablet)

Composition of the tableting mixture

Ingredients	Parts by weight [g]	Composition [%]
Diclofenac-Na	181.8	18.2
Ludipress®	738.2	73.8
Kollidon® VA 64 Fine	50.9	5.1
Kollidon® CL	18.2	1.8
Aerosil 200	3.6	0.4
Magnesium stearate	7.3	0.7
Total	**1000.0**	**100.0**

Processing of the tableting mixture

The ingredients except the Mg-stearate are blended in a Turbula T2C blender for 10 minutes and passed through an 800 µm-sieve. Finally the magnesium stearate is added and the resulting blend is mixed for 1 minute.

Tableting equipment
Tableting

Rotary press	Korsch XL 100
Tablet shape	concave
Tablet weight	275 mg
Tablet diameter	9 mm
Compression force	15 kN

Enteric coating with Kollicoat® MAE 100-55

Re-dispersion of the polymer powder

For the preparation of an appropriate polymer dispersion follow the recommendations in chapter 3.2.

Composition of the coating formulation

Ingredients	Parts by weight [g]	Composition [%]	Dry matter [%]
Kollicoat® MAE 100-55	451.5	18.1	18.1
Triethyl citrate (10% relative to polymer weight)	45.0	1.8	1.8
NaOH (1 mol/L)	153.5	6.1	2.5
Demineralized Water	1850.0	74.0	-
Total	**2500.0**	**100.0**	**22.3**

Prepartion of the coating formulation

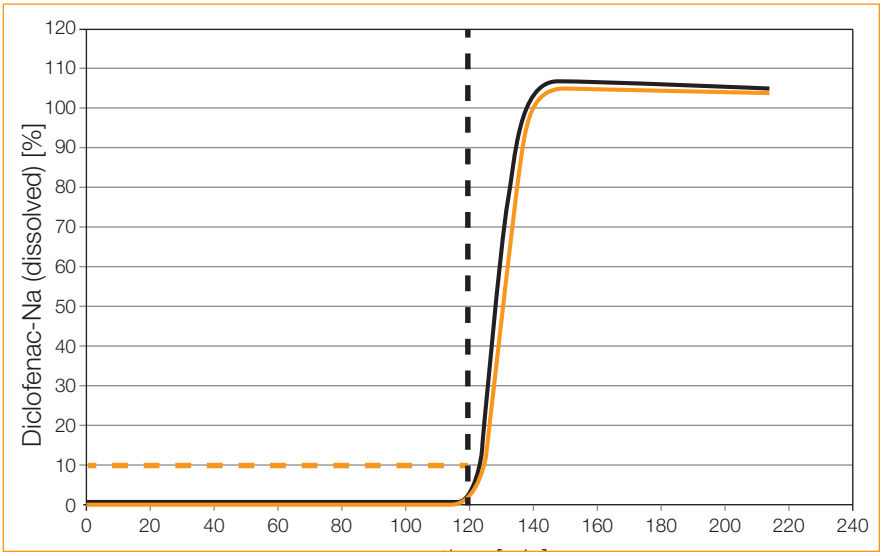
Around 200 g of the water is used to disperse the triethyl citrate. Kollicoat® MAE 100-55 is added to the remaining quantity and dispersed after the addition of the 1 mol/L NaOH-solution. After 30 minutes of permanent stirring the plasticizer-dispersion is added.

The resulting coating suspension is stirred for 2 h prior to use.

Coating equipment and process parameters

Coating equipment	Manesty Coater XL Lab 01	
Batch size	kg	4.0
Number of nozzles		1
Nozzle diameter	mm	0.8
Spraying rate	g/min	20
Application quantity	mg/cm²	3 – 4
Spraying time	min	40
Air supply	m³/h	400
Inlet air temperature	°C	55
Drying time	min	5

Release testing



Kollicoat® MAE 100-55 coating levels:
- 3 mg /cm²
- 4 mg/cm²
- allowance limit
- buffer change

4.4 Enteric coated pantoprazol-Na mini-tablets (6.4 mg tablet weight)

The mini-tablets were coated using an aqueous solutions of Kollicoat® MAE 100-55 in a fluid bed coater. A a sub-coat is applied to prevent the API from degradation caused by interacting with water.

Composition of the tableting mixture

Ingredients	Parts by weight [g]	Composition [%]
Pantoprazole Na hydrate	242.4	12.12
Ludipress® LCE	1547.6	77.38
Kollidon® VA 64 fine	100.0	5.00
Kollidon® CL-F	100.0	5.00
Mg-stearate	10.0	0.50
Total	**2000.0**	**100.00**

Processing of the tableting mixture

Prior to use all ingredients were sieved through an 800µm-sieve. After sieving the ingredients with the exception of Mg-stearate were blended in a Turbula T2C blender for 8 minutes. Finally the magnesium stearate was added and the tableting mixture is achieved after 2 minutes additional blending.

Coating equipment and process parameters

Korsch XL 100 4 micro punches, no engravings	
Tablet diameter	2 mm
Tablet shape	concave
Tableting speed	30 rpm
Agitator filling shoe	5 rpm
Compression force	1,5 kN
Tablet weight	6.4 mg

Around 312,000 mini-tablets were achieved. At a tablet weight of 6.4 mg one tablet contains 0.78 mg of pantoprazole Na.

Enteric coating with Kollicoat® MAE 100-55

1. Sub-coating

To prevent the API in the mini-tablets to interact with the aqueous coating formulation a sub-coat consisting either of Kollicoat® IR White II, Kollicoat® IR or Kollidon® VA 64 can be applied. The latter one has the advantage that the polymer can be applied using an organic solvent e.g. i-propanol.

Ingredients and composition

Ingredients	Parts by weight [g]	Composition [%]
Kollicoat® IR White II	199.3	19.9
FD&C Blue No.1	0.7	0.1
Water	800.0	80.0
Total	**1000.0**	**100.0**

Coating equipment and process parameters

Glatt GPCG 3.1, Granu 5l, Nozzle position 1: top spray		
Nozzle	mm	0.8
Mini tablet load	g	1500
Sub-coat dispersion	g	825
Spray rate	g/min	20
Atomization air	bar	2.0
Air volume rate	m³/h	206
Inlet air temperature	°C	60
Product temperature	°C	48

2. Enteric coating

Re-dispersion of the polymer powder

For the preparation of an appropriate polymer dispersion follow the recommendations in chapter 3.2.

Ingredients and composition

Ingredients	Parts by weight [g]	Composition [%]
Kollicoat® MAE 100-55	600.0	18.0
Triethyl citrate (10% relative to polymer weight)	60.0	1.8
NaOH (1 mol/L)	207.0	0.2
Water	2470.0	
Total	**3337.0**	**20.0**

Preparation of the coating formulation

Around 1800 ml of water is used to re-disperse the Kollicoat® MAE 100-55 while the 1 mol/L NaOH-solution is added. The mixture is stirred for 30 minutes. In parallel the plasticizer is dispersed in the remaining quantity of water.

After adding the dispersed plasticizer to the polymer dispersion this is stirred for 2 hours.

Enteric coating formulation is applied until a coating level of 4.5 mg/cm² was achieved.

Coating equipment and process parameters

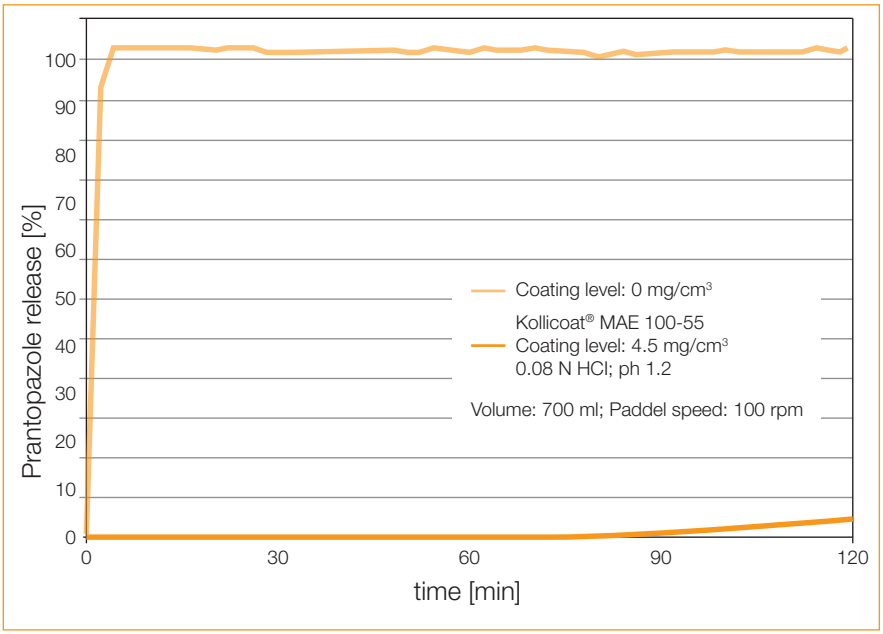
Glatt GPCG 3.1, Granu 5l, nozzle position 1: top spray		
Batch size	kg	1.37
Number of nozzles		1
Nozzle diameter	mm	0.8
Spraying rate	g/min	20
Atomization air	bar	2.0
Air supply	m³/h	206
Inlet air temperature	°C	50
Product temperature	°C	39
Drying time	min	5

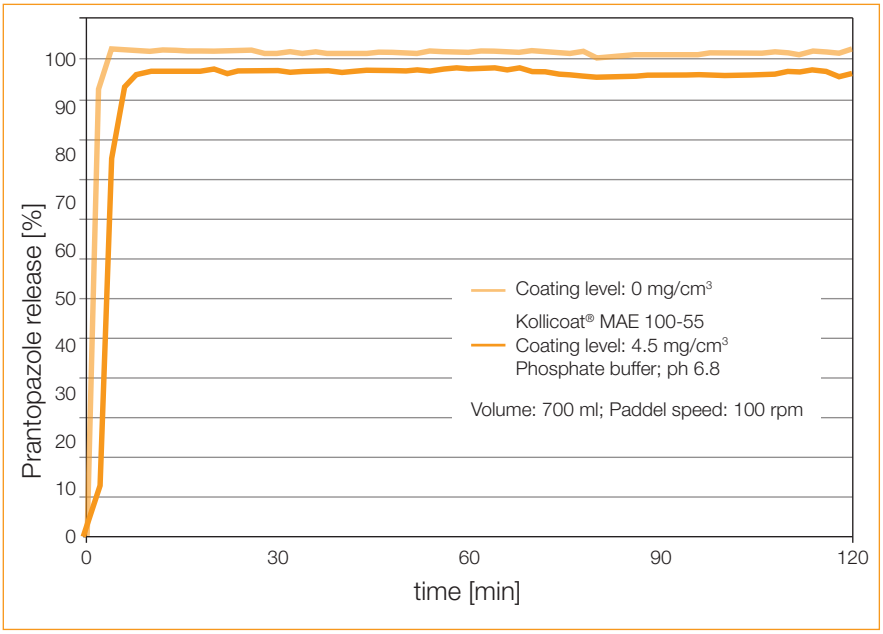
Finished dosage form

The coated mini-tablets are filled in hard-gel capsules. To achieve the claimed API concentration of 40 mg per capsule 52 mini-tablets are required.

Release testing

Due to the sensitivity of the API release testing with a buffer change is not opportune. The tests at pH 1.2 and pH 6.8 have to be performed separately.





4.5 Enteric Coated Propranolol tablets (30 mg/tablet)

Composition of the tableting mixture

Ingredients	Parts by weight [g]	Composition [%]
Propranolol	300.0	16.7
Ludipress® LCE	1383.0	76.8
Kollidon® VA 64 Fine	54.0	3.0
Kollidon® CL-F	54.0	3.0
Magnesium stearate	9.0	0.5
Total	**1800.0**	**100.00**

Processing of the tableting mixture

The ingredients except the Mg-stearate are blended in a Turbula blender for 10 minutes and passed through an 800 µm-sieve. Finally the magnesium stearate is added and the resulting blend is mixed for 1 minute.

Coating equipment and process parameters

Rotary press Korsch XL 100	
Tablet shape	7 mm concave, engraved
Tableting speed	5 rpm
Tablet weight	180 mg
Tablet diameter	7 mm
Compression force	5 kN
Tablet hardness	85 – 110 N
Friability	0.02%

Enteric coating with Kollicoat® MAE 100-55

Re-dispersion of the polymer powder

For the preparation of an appropriate polymer dispersion follow the recommendations in chapter 3.2.

Composition of the coating formulation

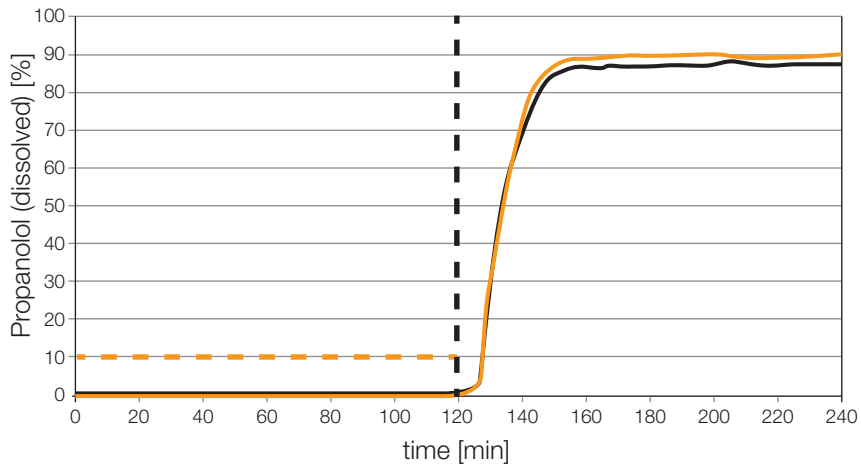
Ingredients	Parts by weight [g]	Composition [%]	Percentage
Kollicoat® MAE 100-55	172.0	172.0	17.9
Triethyl citrate	17.2	17.2	1.8
NaOH-solution; (1 mol/L)	59.4	2.5	0.3
Water	710.0	-	-
Total	**958.4**	**191.7**	**20.0**

Coating equipment and process parameters

Coating equipment Manesty XL Lab01		
Batch size	kg	4.0
Number of nozzles		1
Nozzle diameter	mm	0.8
Pan speed	rpm	25
Spraying rate	g/min	20
Spraying pressure	bar	1.8
Air supply	m^3/h	400
Inlet air temperature	°C	55
Drying time	min. 55 °C	5

Release testing

Erweka Dissolution Tester	
Medium	0.08N HCl Phosphate buffer pH 6.8
Volume	880 ml
Stirrer	50 rpm
Temperature	37 °C



Kollicoat® MAE 100-55 coating levels:
- 5 mg /cm²
- 6 mg/cm²
- allowance limit
- buffer change

5. Applications and typical formulations using Kollicoat® MAE 100 P

5.1 Coloured enteric film coatings for tablets

The formulation below is for 5 kg of propranolol cores coatings for tablets (diameter 9 mm;weight 330 mg)

Re-dispersion of coating polymer

See 3.3 Processing notes

Composition of the spray suspension

Polymer suspension	Parts by weight [g]	Composition [%]
Kollicoat® MAE 100 P	148.50	15.00
1,2-propylene glycol	22.28	2.25
Water	665.77	67.25
Pigment suspension		
Titanium dioxide	4.95	0.5
Sicovit® Red 30	4.95	0.5
Talc	36.60	4.0
Water	103.95	10.5
Total	**990.00**	**100.0**

Solids content of the spray suspension	22.25%
Content of polymer dry substance	15.0%
Polymer applied (as solids)	4.0 mg/cm²
Total solids applied	5.9 mg/cm²

Preparation of the spray suspension

Polymer suspension

Kollicoat® MAE 100 P is dispersed in the specified amount of water. When completely dispersed, the plasticizer is incorporated.

Pigment suspension

Sicovit® Red 30, titanium dioxide and talc are intensively stirred into the specified amount of water and homogenized in a corundum disk mill.

Spray suspension

The pigment suspension is stirred into the coating suspension. The spray suspension must be stirred during spraying to prevent the solid substances settling out.

Coating equipment and process parameters

Coating pan:	Accela Cota 24” (Manesty)
Size of batch:	5 kg
Air supply temperature:	60 °C
Product temperature:	32 – 35 °C
Spraying pressure:	2 bar
Spraying rate:	40 g/m
Spraying time:	25 – 30 min

5.2 Coloured enteric film coatings for pellets and crystals

Re-dispersion of coating polymer

See 3.3 Processing notes

Composition of the spray suspension

The following formulation is calculated for 500 g of ASS-crystals spray suspension (diameter 0.3 – 1.0 mm)

Polymer suspension	Parts by weight [g]	Composition [%]
Kollicoat® MAE 100 P	148.5	14.9
1,2-propylene glycol	22.3	2.2
Water	675.8	67.6
Pigment suspension		
Titanium dioxide	5.0	0.5
Sicovit® Red 30	5.0	0.5
Talc	39.6	4.0
Water	104.0	10.4
Total	**1000.0**	**100.0**

Solids content of the spray suspension
Solid polymer in the spray suspension
Solid polymer applied
Total solids applied

Coating equipment and process parameters

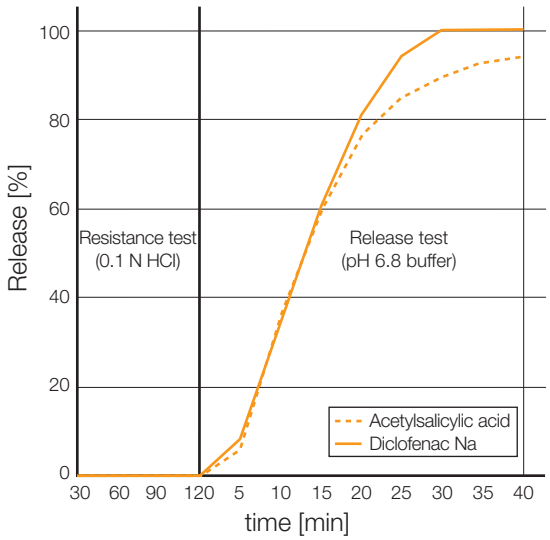
Coating pan:	WSG Aeromatic Strea 1
Size of batch:	500 g
Air supply temperature:	60 °C
Exhaust air temperature:	35 °C
Spraying pressure:	1 bar
Spraying time:	100 min

Release rates of diclofenac Na and acetylsalicylic acid tablets

The tablets were made with the following formulations:

a.) Acetylsalicylic acid
Acetylsalicylic acid 100 mg, Ludipress® 148.5 mg, Avicel PH 102 50.0 mg, magnesium stearate 1.5 mg

b.) Diclofenac Na
Diclofenac Na 49.7 mg, Ludipress® 201.4 mg, Kollidon® VA 64 14.9 mg, Kollidon® CL 5.0 mg, Aerosil 200 1.2 mg, magnesium stearate 2.8 mg



5.3 White enteric film coatings for pellets

Re-dispersion of coating polymer

See 3.3 Processing notes

Composition of the spray suspension

The following formulation is calculated for 5 kg of pellets (diameter 0.8 – 1.2 mm)

Polymer suspension	Parts by weight [g]	Composition [%]
Kollicoat® MAE 100 P	675.0	15.0
1,2-propylene glycol	67.5	1.5
Water	3.010.0	66.9
Pigment suspension		
Kollidon®	22.5	0.5
Titanium dioxide	45.0	1.0
Talc	180.0	4.0
Water	500.0	11.1
Total	**4500.0**	**100.0**

Solids content of the spray suspension	22.0%
Polymer (solids) in the spray suspension	15.0%
Polymer (solids) applied	mg/cm²
Total solids applied	mg/cm²

Preparation of the spray suspension

Polymer suspension

Dissolve Kollidon 100 P in the specified amount of water. Proceed as usual.

Pigment suspension

Spray suspension

See suggested method under 3.3.

Coating equipment and process parameters

Coating pan:	Hüttlin Kugelcoater HKC 5 TJ
Size of batch:	5 kg
Air supply temperature:	60 °C
Exhaust air temperature:	32 – 35 °C
Spraying rate:	45 g/m
Spraying time:	100 min

5.4 Colourless enteric coatings for soft-gel capsules

Re-dispersion of coating polymer

See 3.3 Processing notes

Composition of the spray

The following formulation is intended for 5 kg of soft-gel capsules

Coating suspension	Parts by weight [g]	Composition [%]
Kollicoat® MAE 100 P	500.0	21.0
1,2-propylene glycol	100.8	4.2
Water	1,795.2	74.8
Total	**2400.0**	**100.0**

Solids content of the spray suspension	25.2%
Content of polymer dry substance	21.0%
Polymer applied (as solids)	10.0 mg/cm²
Total solids applied	12.0 mg/cm²

Preparation of the spray suspension

Polymer suspension

Polypropylene glycol is first dissolved in the specified amount of water. Then Kollicoat® MAE 100 P is stirred in until completely redispered. The blend is stirred for 3 hours.

Coating equipment and process parameters

Coating pan:	Accela Cota 24 ” (Manesty)
Size of batch:	5 kg
Inlet air temperature:	50 °C
Product temperature:	30 – 32 °C
Spraying rate:	30 – 35 g/min
Spraying time:	70 min

5.5 Seal-coating of tablet cores

Some tablet cores contain a water-sensitive drug or a highly effective tablet disintegrant, e.g. Kollidon® CL. Before they can be coated with aqueous solutions a seal coat has to be applied. The same applies if the cores are too soft, or if an aqueous coating will not take to theirsurface. In such cases, heating the cores to about 35 °C and spraying them with a 10% solution of Kollidon® VA 64, e.g. in isopropanol has given good results. Experience indicates that an adequate sub-coating film is built up when small amounts of Kollidon® VA 64 are applied, i.e. approx. 0.4 mg/cm².

Alternatively seal-coating can be performed using Kollicoat® IR or even Kollicoat® IR White II. When using aqueous seal-coats a hydrophobic plasticizer can be used. In order to prevent interactions with hydrophilic or water-absorbing components present in the core low spray rates have to be used in the initial stage of the seal-coat application.

5.6 Further applications

Coatings levels of 0.5 – 2.0 mg/cm² can be applied for the following purposes:

- To mask unpleasant tastes and odours
- To protect the tablet core against atmospheric humidity
- As a barrier between incompatible active substances

6. Equipment Cleaning Recommendations

Kollicoat® MAE 100-55 and Kollicoat® 100 become water-soluble after neutralizing the majority of the polymer's methacrylic acid moiety. To achieve this level cleaning is thus best performed using dilute NaOH-solutions containing small amounts, e.g. 0.5 – 1% of a surfactant such as sodium lauryl sulfate (SLS).

7. Storage

The powder products Kollicoat® MAE 100-55 and Kollicoat® MAE® 100 P should be stored at temperatures below 25 °C. In contrast to the Kollicoat® MAE 30 DP dispersion the powder grades do not require transportation and storage above 0 °C.

8. Shelf life

Kollicoat® MAE 100-55 and Kollicoat® MAE 100 P are stable for at least 18 months in the unopened original drums at room temperature.

After re-dispersion to aqueous forms the exposure to heat or frost, as well as foam formation have to be avoided. These effects may cause coagulation and turn the products defective.

Once a drum has been opened the contents it is recommended to use the contents within a few weeks.

9. PRD Numbers

Kollicoat® MAE 100-55	30638896
Kollicoat® MAE 100 P	30070095

10. Packaging

Kollicoat® MAE 100-55	20 kg polyethylene drums with a PE inner liner.
Kollicoat® MAE 100 P	20 kg polyethylene drums with a PE inner liner.

Note

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