

Technical Information

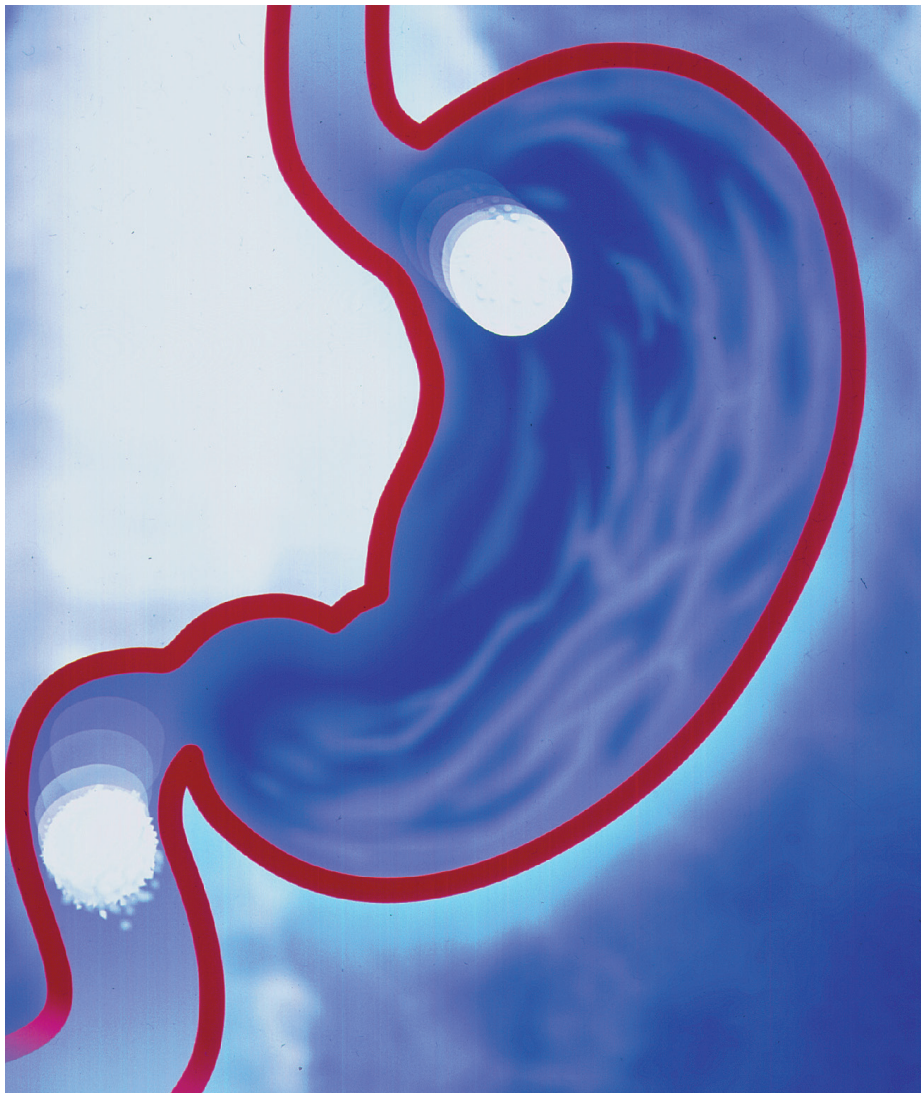
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Kollicoat® MAE 30 DP

® = Registered trademark of BASF group

Methacrylic acid/ethyl acrylate copolymer dispersion for enteric coating



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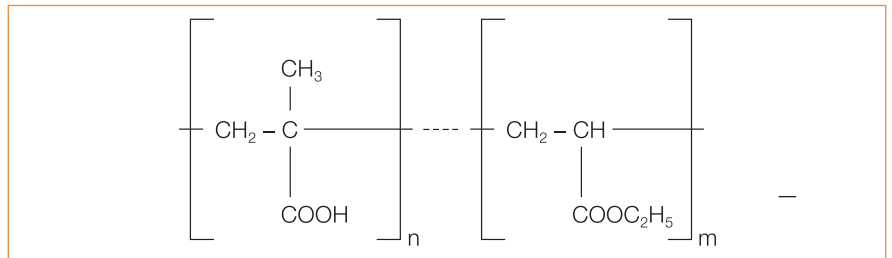
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1. Introduction

1.1 General

Kollicoat® MAE 30 DP is a copolymer derived from methacrylic acid/ethyl acrylate. The copolymer is used as film-former in the pharmaceutical industry for the production of enteric coated solid oral dosage forms.

1.2 Structural formula



The ratio of the components in the copolymer is roughly 1 : 1. The Kollicoat® MAE 30 DP has an anionic character. The average molecular weight M_w is of the order of 250,000 AMU.

1.3 Trivial names

Methacrylic Acid Copolymer Type C (USP), Methacrylic Acid Copolymer LD (JPE) and Methacrylic Acid-Ethyl Acrylate Copolymer (Ph. Eur.), Methacrylsäure Copolymer.

1.4 Product form

Kollicoat® MAE 30 DP is an aqueous dispersion with a solids content of 30%. The milky white, low-viscosity product has a faint, characteristic odour.

2. Specifications and properties

2.1 Description

Kollicoat® MAE 30 DP contains 0.7% sodium lauryl sulfate and 2.3% Polysorbate 80 as emulsifying agents. (The percentage refers to the solid substances.) The fatty acids used in the manufacture of Polysorbate 80 are of vegetable origin.

Kollicoat® MAE 30 DP is a weakly acidic copolymer that dissolves at a pH above 5.5.

2.2 Specifications

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

2.3 Regulatory status

Kollicoat® MAE 30 DP meets the following current compendial requirements

1. Methacrylic Acid – Ethyl Acrylate Copolymer (1:1) Dispersion 30% (Ph. Eur.)
2. Methacrylic Acid Copolymer Dispersion (USP) *
3. Methacrylic Acid Copolymer LD (JPE)

* The name of this monograph will be modified as of May 1, 2017 as follows:
"Methacrylic acid and Ethyl acrylate Copolymer Dispersion"

3. Applications and typical formulations

3.1 Processing instructions

Plasticizers are essential to improve the flexibility of the films.

Suitable plasticizers or gloss intensifiers are

- 1,2-propylene glycol
- Triethyl citrate
- Polyethylene glycols
- Triacetin

The recommended amount of plasticizer is 10 – 15% relative to the dry matter content of the film former.

Kollicoat® MAE 30 DP is incompatible with magnesium stearate. However, any magnesium stearate in the tablet core to be coated does not represent problems.

1,2-propylene glycol improves the processability 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.
- Formation of foam

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 20%
- Stir the desired auxiliary into the dispersion in form of a dilute 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 30 DP has a high pigment binding capacity: two to three parts of pigments or other auxiliaries may be added for one part of solid polymer.

Use the dispersion under stirring within 24 hours after preparation.

3.2 Coloured enteric film coatings for tablets

Composition of the spray suspension

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

| | Parts by weight, g | % composition |
|--|--------------------|------------------------|
| Polymer suspension | | |
| <i>Alternative I</i> | | |
| Kollicoat® MAE 30 DP | 495.00 | 50.00 |
| Propylene glycol | 22.25 | 2.25 |
| Water | 319.30 | 32.25 |
| Pigment suspension | | |
| Titanium dioxide | 4.95 | 0.50 |
| Sicovit® Red 30 | 4.95 | 0.50 |
| Talc | 39.60 | 4.00 |
| Water | 103.95 | 10.50 |
| | 990.00 | 100.00 |
| Solids content of the spray suspension | | 22.25% |
| Content of polymer dry substance | | 15.0% |
| Polymer applied (as solids) | | 4.0 mg/cm ² |
| Total solids applied | | 5.9 mg/cm ² |

Preparation of the spray suspension

Polymer suspension

Kollicoat® MAE 30 DP: Propylene glycol is first stirred into the specified amount of water. Kollicoat® MAE 30 DP is then stirred in.

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.

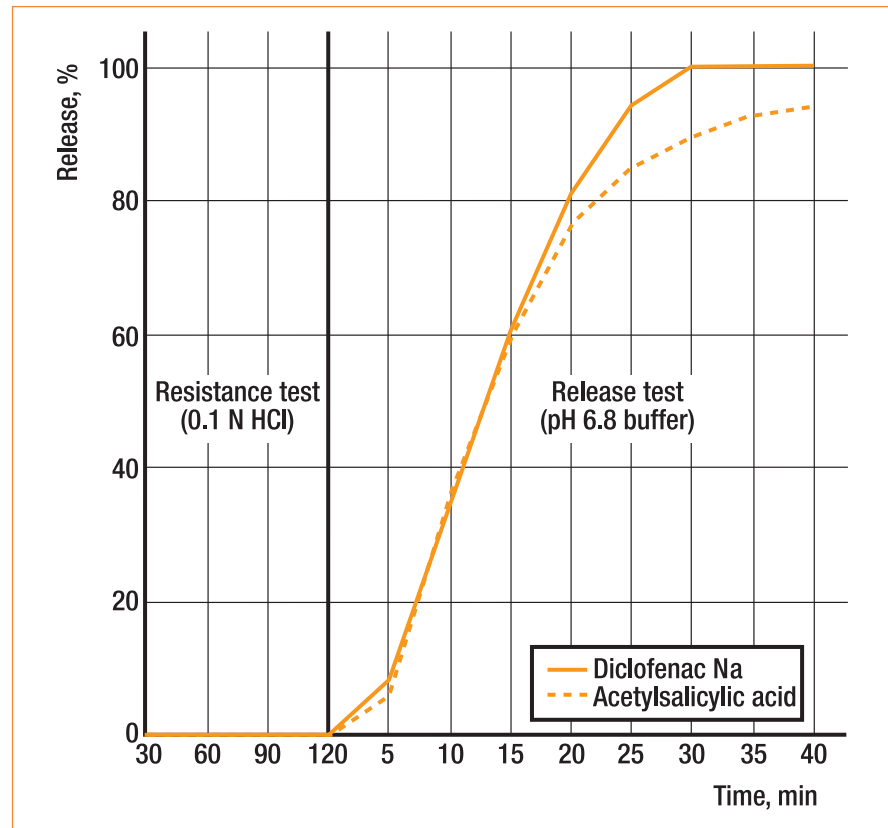
Coating equipment and parameters

| | |
|-------------------------|---------------------------|
| 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 |

Release rates of diclofenac Na and acetylsalicylic acid tablets

The tablets were made with the following formulations:

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



3.3 Coloured enteric film coatings for pellets and crystals

Composition of the spray suspension

The formulation has been calculated for 500 g of crystals (diameter 0.3 – 1.0 mm)

| | Parts by weight, g | Proportion, % |
|--|--------------------|------------------------|
| Polymer suspension | | |
| Alternative I | | |
| Kollicoat® MAE 30 DP | 495.00 | 50.00 |
| Propylene glycol | 22.28 | 2.25 |
| Water | 319.27 | 32.25 |
| Pigment suspension | | |
| Titanium dioxide | 4.95 | 0.5 |
| Sicovit Red 30 | 4.95 | 0.5 |
| Talc | 39.60 | 4.0 |
| Water | 103.95 | 10.5 |
| | 990.00 | 100,0 |
| Solids content of the spray suspension | | 22.25% |
| Solid polymer in the spray suspension | | 15.0% |
| Solid polymer applied | | 4.0 mg/cm ² |
| Total solids applied | | 5.9 mg/cm ² |

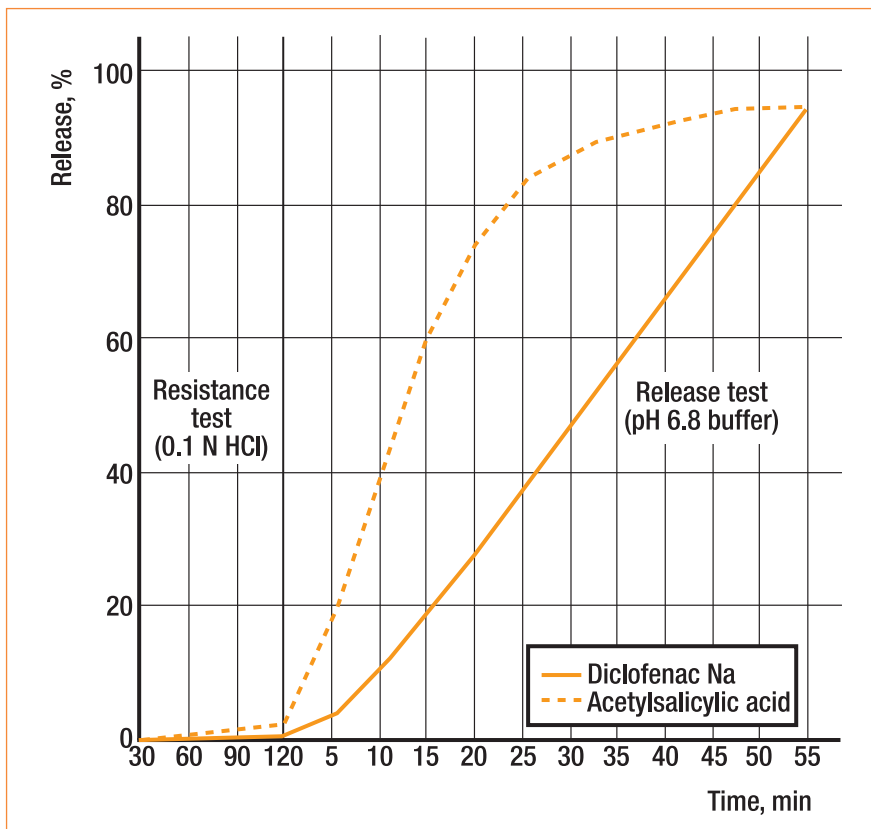
Preparation of the spray suspension

See the processing notes under 3.2

Coating equipment and 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 pellets and acetylsalicylic acid crystals



3.4 White enteric film coatings for pellets

Composition of the spray suspension

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

| | Parts by Weight, g | Composition, % |
|--|--------------------|------------------------|
| Polymer suspension | | |
| <i>Alternative 1</i> | | |
| Kollicoat® MAE 30 DP | 2250.0 | 50.0 |
| Propylene glycol | 67.5 | 1.5 |
| Water | 1435.0 | 31.9 |
| Pigment suspension | | |
| Kollidon 30 | 22.5 | 0.5 |
| Titanium dioxide | 45.0 | 1.0 |
| Talc | 180.0 | 4.0 |
| Water | 500.0 | 11.1 |
| | 4500.0 | 100.0 |
| Solids content of the spray suspension | | 22.0% |
| Dry polymer content | | 15.0% |
| Solid polymer applied | | 2.0 mg/cm ² |
| Total solids applied | | 2.9 mg/cm ² |

| | |
|-------------------------------------|--|
| Preparation of the spray suspension | Polymer suspension |
| | See the processing notes under 3.2. |
| | Pigment suspension |
| | Dissolve Kollidon 30 in the specified amount of water. Proceed as usual. |
| Spray suspension | See suggested method under 3.2. |

| | | |
|----------------------------------|--------------------------|------------------------------|
| Coating equipment and 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 |

3.5 Colourless enteric coatings for soft gelatin capsules

Composition of the spray

The formulation below is intended for 5 kg of soft gelatin capsules

| | Parts by weight, g | Composition, % |
|--|--------------------|----------------|
|--|--------------------|----------------|

Polymer suspension

Alternative I

| | | |
|--|---------------|-------------------------|
| Kollicoat® MAE 30 DP | 1680.0 | 70.0 |
| Propylene glycol | 100.8 | 4.2 |
| Water | 619.2 | 25.8 |
| | 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/cm ² |
| Total solids applied | | 12.0 mg/cm ² |

| | |
|-------------------------------------|--|
| Preparation of the spray suspension | Polymer suspension |
| | Kollicoat® MAE 30 DP: polypropylene glycol is first dissolved in the specified amount of water. Then Kollicoat® MAE 30 DP is stirred in. |

| | | |
|----------------------------------|------------------------|---------------------------|
| Coating equipment and parameters | Coating pan: | Accela Cota 24" (Manesty) |
| | Size of batch: | 5 kg |
| | Inlet air temperature: | 50 °C |
| | Product temperature: | 30 – 32 °C |
| | Spraying pressure: | 2 bar |
| | Spraying rate: | 30 – 35 g/m |
| Spraying time: | 70 min | |

3.6 Subcoating of tablet cores

Some tablet cores contain either a water-sensitive drug or a highly effective tablet disintegrant, e. g. Kollidon® CL. To prevent interactions with an aqueous coating formulation a polymeric water barrier must be applied first. The same applies if the cores are too soft, or if an aqueous coating will not adhere on their surface. 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 subcoating film is built up when small amounts of Kollidon® VA 64 or Kollidon® IR are applied, i. e. approx. 0.5 mg/cm².

3.7 Further applications

Fine coatings of 0.5 – 2.0 mg/cm² (solids), can be applied for the following purposes:

- Masking unpleasant tastes and odours,
- As a barrier between incompatible active substances,
- Protection against atmospheric humidity.

3.8 Patents

EP 152 038 and EP 208 213 concerning aqueous dispersions for coating pharmaceutical products containing dispersed latex particles (A) of a polymer that contains carboxyl groups soluble in water between pH 5.0 and 8.0 and (B) a film-forming polymer (of great elasticity) that is insoluble in water, in which the weight ratio of the total amount of latex particles A and B lies between 60:40 and 5:95.

4. Storage

Kollicoat® MAE 30 DP should be protected from frost and kept below 30 °C.

5. Stability

Kollicoat® MAE 30 DP (aqueous dispersion) is stable for at least 18 months in the unopened original containers and storage conditions below 30 °C. The dispersion must be protected from heat or frost. Once a drum has been opened, care must be taken to avoid contamination and the content must be used within a few weeks.

6. PRD-Nos.

30057597

7. Packaging

Kollicoat® MAE 30 DP:
25 l polyethylene drums. Also available in 1,000-l IBCs.

Note

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