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*ExActConcepts*

Example: **Omega 3 (Fish) oil**

## Gastric-resistant coating of soft gelatin capsules

This formulation concept effectively combines

### **No fish burp**

Coating excipients, which ensure enteric properties, are applied to soft gelatin capsules so that the capsules remain intact in the stomach.

Through the stability in gastric fluid, fish burps are avoided.

### **Fast release in the gastro intestinal tract**

Quick dissolution and thus fast release of the capsule content in the intestine is achieved by the opening pH of the enteric coating polymer.

## Task:

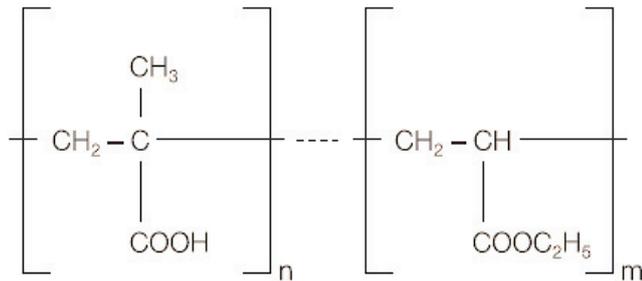
Obtain a formulation with a reliable enteric property of soft gelatin capsules

## Concept:

Coating with gastric-resistant excipient

## Enteric release

Polymer structure of Kollicoat® MAE



1:1 Methacrylic Acid - Ethyl Acrylate Copolymer

## Kollicoat® MAE 30 DP\*

a film-forming aqueous dispersion applicable for solid dosage forms, ensures gastric resistance and immediate enteric release on grounds of insolubility and stability in the stomach's gastric fluid with pH values of 1<sup>\*2</sup> and fast dissolution in pH values > 5.5 in the intestine.

\* Kollicoat® MAE is also available as partially neutralized powder as Kollicoat® MAE 100 P.

<sup>\*2</sup> If a stomach is in fed state, pH values increase to pH 5–6 and consequently stability of the coating in the stomach is no longer assured.

# Example formulation

## Enteric coating of Soft Gelatin Capsules

### Composition

Enteric Coating		Quantity [%]
Ingredient	Function	
Kollicoat® MAE 30 DP	Coating agent	55.5
Plasacryl T20	Coating agent	8.3
Water		34.5
Triethyl citrate (TEC)	Plasticizer	1.7
<b>→ 20% solid content</b>		

### Parameter set

Coating	
Coater	Compulab
Drum	19" Perforated
Drum speed	16 rpm
Nozzle	1 mm
Batch size	5.0 kg
Inlet air temp.	40 °C
Inlet air quantity	210 CFM
Spray rate	20 g/min

### Manufacturing instructions

Disperse TEC in water. Stir resulting dispersion into Kollicoat® MAE 30 DP dispersion. Add Plasacryl. Continue stirring for 2h with low shear mixer.

Spray resulting 20% final dispersion on soft gelatin capsules.

**Coating level of 4% will lead to satisfying release profile.**



The Chemical Company

## Analytical results

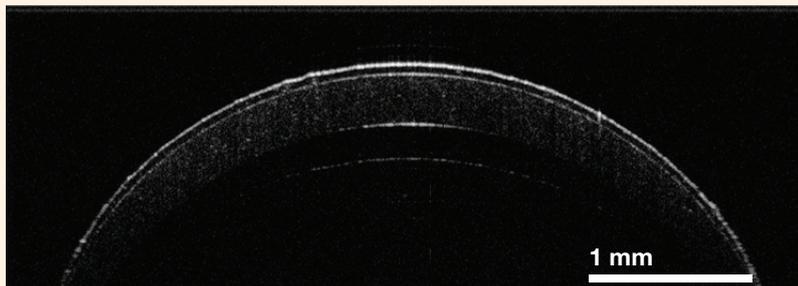
### Disintegration test

SGC (1 hour, 37 °C)

No oil leakage from  
the coated capsules



### OCT image



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