EUDRAGIT®
Acrylic Polymers for Solid Oral Dosage Forms

EUDRAGIT® Products
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Technical Support
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Formulation Development
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Proof of Concept
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GMP Services
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Advanced Drug Delivery
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Evonik. Power to create.
When it comes to targeted drug release profiles, EUDRAGIT® is the pharmaceutical industry’s preferred choice of product. The range of EUDRAGIT® Poly(meth)acrylate-based products provides full flexibility for your solid oral dosage forms.

**EUDRAGIT® Polymers – Pharmaceutical Properties**

The basis of our offerings are our Poly(meth)acrylates for pharmaceutical applications, which are known worldwide in the industry under the trade name EUDRAGIT®. These polymers allow the active in your solid dosage form to perform during the passage of the human body. The flexibility to combine the different polymers enables you to achieve the desired drug release profile by releasing the drug at the right place and at the right time and, if necessary, over a desired period of time. Other important functions are protection from external influences (moisture) or taste/odor masking to increase patient compliance. The range of our product portfolio provides full flexibility for your targeted drug release profiles by offering best performance for enteric, protective or sustained-release properties.

EUDRAGIT® polymers are copolymers derived from esters of acrylic and methacrylic acid, whose physicochemical properties are determined by functional groups (R). EUDRAGIT® polymers are available in a wide range of different physical forms (aqueous dispersion, organic solution granules and powders).

1. **Poly(meth)acrylates; soluble in digestive fluids by salt formation**
   - EUDRAGIT® L, S, FS and E polymers with acidic or alkaline groups enable pH-dependent release of the active ingredient.
   - **Applications:** from simple taste masking through gastric resistance to controlled drug release in all sections of the intestine.

2. **Poly(meth)acrylates; insoluble but permeable in digestive fluids**
   - EUDRAGIT® RL and RS polymers with alkaline and EUDRAGIT® NE polymers with neutral groups enable controlled time release of the active ingredient by pH-independent swelling.
   - **Applications:** delayed and sustained drug release.

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   - EUDRAGIT® RL and RS polymers with alkaline and EUDRAGIT® NE polymers with neutral groups enable controlled time release of the active ingredient by pH-independent swelling.
   - **Applications:** delayed and sustained drug release.
**EUDRAGIT®** offers valuable advantages for your enteric coatings:

- pH-dependent drug release
- Protection of actives sensitive to gastric fluid
- Protection of gastric mucosa from aggressive actives
- Increase in drug effectiveness
- Good storage stability
- GI and colon targeting

**Gastroresistance and GI Targeting**

If you need to protect your active from the gastric fluid and would like to improve drug effectiveness – EUDRAGIT® L and S polymers are your preferred choice of coating polymers. They enable targeting specific areas of the intestine. Pharma Polymers offers a broad product portfolio of anionic EUDRAGIT® grades which dissolve at rising pH values. In addition, the different grades can be combined with each other, making it possible to adjust the dissolution pH, and thus to achieve the required GI targeting for the drug.

Targeted drug release in the colon is required for local treatment of intestinal disorders such as Crohn’s disease, ulcerative colitis or intestinal cancer. It is also required for drugs that are poorly soluble in the upper gastrointestinal tract. Moreover, the gastroresistance of the coating ensures that the oral dosage form is patient compliant. The preferred coating is EUDRAGIT® FS 30 D, which combines release in the colon with the following technical advantages:

- aqueous processing
- highly flexible coatings
- suitable for multiparticulate tablet preparation

### Enteric Formulations

<table>
<thead>
<tr>
<th>EUDRAGIT® Polymer</th>
<th>Availability</th>
<th>Dissolution Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>L 30 D-55</td>
<td>30 % Aqueous Dispersion</td>
<td>Dissolution above pH 5.5</td>
</tr>
<tr>
<td>L 100-55</td>
<td>Powder</td>
<td>Dissolution above pH 6.0</td>
</tr>
<tr>
<td>L 100</td>
<td>Powder</td>
<td></td>
</tr>
<tr>
<td>L 12.5</td>
<td>12.5 % Organic Solution</td>
<td>Dissolution above pH 7.0</td>
</tr>
<tr>
<td>S 100</td>
<td>Powder</td>
<td></td>
</tr>
<tr>
<td>S 12.5</td>
<td>12.5 % Organic Solution</td>
<td></td>
</tr>
<tr>
<td>FS 30 D</td>
<td>30 % Aqueous Dispersion</td>
<td></td>
</tr>
</tbody>
</table>
EUDRAGIT® offers a strong protection of sensitive contents and improved patient compliance.

Moisture Protection and Odor/Taste Masking

Do you need to protect your active from moisture or light and would like to increase patient compliance? EUDRAGIT® E polymers help you to seal sensitive actives and increase patient compliance by masking tastes and odors. Even thin layers of EUDRAGIT® provide the desired effect, making it an extremely economical application. Pharma Polymers offer various cationic EUDRAGIT® E grades for protective coatings.

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<th>EUDRAGIT® Polymer</th>
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<tr>
<td>E 100</td>
<td>Granules</td>
<td>Soluble in gastric fluid up to pH 5.0</td>
</tr>
<tr>
<td>E 12.5</td>
<td>12.5 % Organic Solution</td>
<td>Swellable and permeable above pH 5.0</td>
</tr>
<tr>
<td>E PD</td>
<td>Powder</td>
<td></td>
</tr>
</tbody>
</table>

Our protective polymers are suitable for aqueous or organic coatings and can be applied in a melt extrusion process. During the melt extrusion process the cationic EUDRAGIT® E polymer interacts with the anionic active which provides excellent taste masking properties.

Take advantage of protective EUDRAGIT® coatings:
- pH-dependent drug release
- Protection of sensitive actives
- Taste and odor masking
- Moisture protection
- Economical application
- Improved passage of the dosage form
- Smooth and glossy surfaces, good color coating
Controlled release: EUDRAGIT® enables formulations which allow customer-tailored release profiles and releases over a specific period of time.

**Time-Controlled Drug Release**

Whether you need your drug to release over a specific period of time or would like to benefit from the advantages of multiparticulate or matrix formulations – EUDRAGIT® can help you achieve your desired release profile. Drug delivery can be controlled throughout the entire gastrointestinal tract to increase the therapeutic effect and patient compliance. Different polymer combinations of EUDRAGIT® RL and RS grades allow custom-tailored release profiles to achieve the desired drug delivery performance. EUDRAGIT® NE and NM grades are neutral ester dispersions which do not require addition of plasticizer.

**EUDRAGIT® Polymer Availability Dissolution Properties**

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<tr>
<td>RL 100</td>
<td>Granules</td>
<td>Insoluble High permeability pH-independent swelling</td>
</tr>
<tr>
<td>RL PO</td>
<td>Powder</td>
<td></td>
</tr>
<tr>
<td>RL 30 D</td>
<td>30% Aqueous Dispersion</td>
<td></td>
</tr>
<tr>
<td>RL 12,5</td>
<td>12.5% Organic Solution</td>
<td></td>
</tr>
<tr>
<td>RS 100</td>
<td>Granules</td>
<td>Insoluble Low permeability pH-independent swelling</td>
</tr>
<tr>
<td>RS PO</td>
<td>Powder</td>
<td></td>
</tr>
<tr>
<td>RS 30 D</td>
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</tr>
<tr>
<td>RS 12,5</td>
<td>12.5% Organic Solution</td>
<td></td>
</tr>
<tr>
<td>NE 30 D</td>
<td>30% Aqueous Dispersion</td>
<td></td>
</tr>
<tr>
<td>NE 40 D</td>
<td>40% Aqueous Dispersion</td>
<td></td>
</tr>
<tr>
<td>NM 30 D</td>
<td>30% Aqueous Dispersion</td>
<td></td>
</tr>
</tbody>
</table>

EUDRAGIT® serves as a matrix within which the active ingredient is embedded. The matrix structure is obtained by direct compression, granulation, or melt extrusion. EUDRAGIT® NM 30 D is particularly suitable for granulation processes in the manufacture of matrix tablets.

EUDRAGIT® is employed as a coating material, usually for the coating of pellets or particles that are filled into capsules or compressed into tablets. These pellets or particles act as diffusion cells in the digestive tract and release a constant drug quantity per unit of time (multi-unit dosage forms).

**Benefit from EUDRAGIT® coatings with sustained release:**
- Time-controlled release of active ingredients
- Therapeutically customized release profiles
- Higher patient compliance due to reduced number of doses to be taken
- Cost-effective processing
Pharma Polymers, a business line of Evonik Industries, offers the complete line of EUDRAGIT® products and related services along the value chain of our customers. For over 50 years we have proven our reliability as a quality partner to the pharmaceutical industry. Our state of the art services cover various stages of the development processes, including

- advanced technical support
- formulation development
- proof of concept
- GMP services.

Our customers see us as a strategic partner for their developments of solid oral dosage forms with a targeted drug release profile. By using our value adding business model our customers get:

- increased efficiency in their R&D and manufacturing processes
- new drug delivery technologies
- reduction of the time to market for their developments
- professional management of their product’s life cycle

Market Strength by means of Strategic Partnership

Our contribution to your value chain

**Value Chain**

1. EUDRAGIT® Products
   - Unique drug release functionality
   - Flexible toolbox (enteric, protective & time control)

2. Technical Support
   - Technical training
   - On site scale-up & production support
   - Feasibility testing

3. Formulation Development
   - Matching desired release profiles by various process technologies
   - One source from feasibility to clinical sample

4. Proof of Concept
   - Efficient development to reduce time to market
   - Customer tailored formulation concept

5. GMP Services
   - Clinical batch manufacturing
   - EUDRAGIT® expertise for various process technologies

6. Advanced Drug Delivery
   - Highly sophisticated drug release profiles
   - Transfer of enabling concepts
   - IP protection & exclusivity
EUDRAGIT®

Versatile Polymers for Oral Solid Dosage Formulations

- Jejunum pH 6-7
  - Sustained-Release Formulations
  - EUDRAGIT® S 30 D-55
  - EUDRAGIT® S 100-55
- Ileum, Colon delivery pH > 7.0
  - EUDRAGIT® L 30 D-55
  - EUDRAGIT® L 100-55
- Duodenum pH > 5.5
  - EUDRAGIT® L 100
  - EUDRAGIT® L 12,5
- Stomach pH 1 - 5
  - EUDRAGIT® E 100
  - EUDRAGIT® E 12,5
- Time controlled release pH independent
  - EUDRAGIT® BL 30 D
  - EUDRAGIT® BL 100
  - EUDRAGIT® BL 30 D
  - EUDRAGIT® RS 30 D
  - EUDRAGIT® RS 50 D
  - EUDRAGIT® RS 100
  - EUDRAGIT® RL 30 D
  - EUDRAGIT® RL 100
  - EUDRAGIT® RL 12,5
  - EUDRAGIT® NE 30 D
  - EUDRAGIT® NE 40 D
  - EUDRAGIT® NE 50 D
  - EUDRAGIT® NE 100

Stomach pH 1 - 5

Protective Formulations

EUDRAGIT® at a glance

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EUDRAGIT®

Versatile Polymers for Oral Solid Dosage Formulations

Duodenum pH > 5.5
- EUDRAGIT® L 30 D-55
- EUDRAGIT® L 100-55

Jejunum pH 6-7
- EUDRAGIT® S 100
- EUDRAGIT® S 12,5
- EUDRAGIT® FS 30 D
- EUDRAGIT® L 100
- EUDRAGIT® L 12,5

Ileum, Colon delivery pH > 7.0
- EUDRAGIT® S 100
- EUDRAGIT® S 12,5
- EUDRAGIT® FS 30 D
- EUDRAGIT® L 100
- EUDRAGIT® L 12,5

Stomach pH 1-5
- EUDRAGIT® E 100
- EUDRAGIT® E 12,5
- EUDRAGIT® PO
- EUDRAGIT® L 100
- EUDRAGIT® L 12,5

Time controlled release pH independent
- EUDRAGIT® RL 30 D
- EUDRAGIT® RL PO
- EUDRAGIT® RL 100
- EUDRAGIT® RL 12,5
- EUDRAGIT® RS 30 D
- EUDRAGIT® RS PO
- EUDRAGIT® RS 100
- EUDRAGIT® RS 12,5

Enteric Formulations

Protective Formulations

Sustained-Release Formulations

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®
= registered trademark
EUDRAGIT = registered Trademark of Evonik Röhm GmbH, Darmstadt, Germany

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eudragit.japan@evonik.com

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### EUDRAGIT® Versatile Polymers for Oral Solid Dosage Formulations

**Applications**

<table>
<thead>
<tr>
<th>Drug delivery in duodenum</th>
<th><strong>EUDRAGIT®</strong> Grades</th>
<th>Product Form</th>
<th>Functionality</th>
<th>Dissolution Properties</th>
<th>Advantages</th>
<th>Monographs + DMFs</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUDRAGIT® L 100-55 Powder</td>
<td>Anionic polymers with methacrylic acid as a functional group</td>
<td>Dissolution above pH 5.5</td>
<td>Effective and stable enteric coatings with a broad dissolution in the upper bowel</td>
<td>Ph. Eur., USP/NF, JPE, BP 2008</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EUDRAGIT® L 30 D-55 Aqueous Dispersion 30%</td>
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<td></td>
</tr>
</tbody>
</table>

**Colonic delivery**

<table>
<thead>
<tr>
<th>Drug delivery in jejunum</th>
<th><strong>EUDRAGIT®</strong> Grades</th>
<th>Product Form</th>
<th>Functionality</th>
<th>Dissolution Properties</th>
<th>Advantages</th>
<th>Monographs + DMFs</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUDRAGIT® L 30 D-55 Aqueous Dispersion 30%</td>
<td>Anionic polymers with methacrylic acid as a functional group</td>
<td>Dissolution above pH 6.0</td>
<td>Site-specific drug delivery in relation to the combination of EUDRAGIT® L/S grades</td>
<td>DMP 1242</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EUDRAGIT® L 100 Powder</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Colon delivery**

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<th>Product Form</th>
<th>Functionality</th>
<th>Dissolution Properties</th>
<th>Advantages</th>
<th>Monographs + DMFs</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUDRAGIT® S 100 Powder</td>
<td></td>
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</tbody>
</table>

### Protective Formulations

<table>
<thead>
<tr>
<th>Insulating coatings</th>
<th><strong>EUDRAGIT®</strong> Grades</th>
<th>Product Form</th>
<th>Functionality</th>
<th>Dissolution Properties</th>
<th>Advantages</th>
<th>Monographs + DMFs</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUDRAGIT® E 100 Granules</td>
<td>Cationic polymer with dimethylaminoethyl methacrylate as a functional group</td>
<td>Soluble in gastric fluid up to pH 5.0</td>
<td>Swellable and permeable above pH 5.0</td>
<td>DMP 1242</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EUDRAGIT® E 12,5 Organic Solution 12.5%</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

### Sustained-Release Formulations

<table>
<thead>
<tr>
<th>Sustained release formulations</th>
<th><strong>EUDRAGIT®</strong> Grades</th>
<th>Product Form</th>
<th>Functionality</th>
<th>Dissolution Properties</th>
<th>Advantages</th>
<th>Monographs + DMFs</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUDRAGIT® RL 30 D Aqueous Dispersion 30%</td>
<td>Meth-/acrylate copolymers with trimethylammonioethyl methacrylate as a functional group</td>
<td>Insoluble</td>
<td>High permeability, pH-independent swelling</td>
<td>DMP 1242</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EUDRAGIT® RL PO Powder</td>
<td></td>
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</tr>
</tbody>
</table>

### Delivery and Packaging

<table>
<thead>
<tr>
<th>Grade</th>
<th>Unit (kg, net)</th>
<th>Packaging</th>
<th>Storage</th>
<th>Flash Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUDRAGIT® L 100</td>
<td>5, 30, 600**</td>
<td>Polyethylene canister</td>
<td>Protect from freezing, Store at controlled room temperature.</td>
<td>Not Flammable</td>
</tr>
<tr>
<td>EUDRAGIT® L 100-55</td>
<td>5, 20 PP box with polyethylene inner bag</td>
<td>Store at controlled room temperature. Protect against moisture.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EUDRAGIT® NE 30 D</td>
<td>5, 30</td>
<td>Steel drum with exterior lacquer coat and polyethylene lining</td>
<td>Protect from freezing and do not store above 25 °C (77 °F).</td>
<td>-15 °C (5 °F)</td>
</tr>
<tr>
<td>EUDRAGIT® NE 40 D</td>
<td>5, 20</td>
<td>Steel drum with exterior lacquer coat and polyethylene lining</td>
<td>Protect from freezing and do not store above 25 °C (77 °F).</td>
<td>-15 °C (5 °F)</td>
</tr>
</tbody>
</table>

### Stability:

Minimum stability dates are stated on the product labels and batch related certificates of analysis. Storage stability data is available upon request.
EUDRAGIT®
Versatile Polymers for Oral Solid Dosage Formulations

Applications | EUDRAGIT® Grades | Product Form | Functionality | Dissolution Properties | Advantages | Monographs + DMFs
--- | --- | --- | --- | --- | --- | ---
Drug delivery in duodenum | EUDRAGIT® L 100-55 | Powder | Dispersions above pH 5.5 | Effective and stable enteric coatings with a broad dissolution in the upper bowel | Ph. Eur., USP, JP, EP, BP 2008

Enteric Formulations
Drug delivery in duodenum | EUDRAGIT® L 100 Powder | Dispersions above pH 5.5 | Enteric formulations | Dissolution above pH 5.5 | Effective and stable enteric coatings with a fast dissolution in the upper bowel | DMP 1242

EUDRAGIT® L 100-55 Powder | Anionic polymers with methacrylic acid as a functional group | Dissolution above pH 5.5 | Effective and stable enteric coatings with a fast dissolution in the upper bowel | Ph. Eur., USP/NF, JPE, DMF 2584

EUDRAGIT® L 30 D-55 Aqueous Dispersion 30 % | Dissolution above pH 5.5 | Effective and stable enteric coatings with a fast dissolution in the upper bowel | Ph. Eur., USP/NF, JPE, DMF 1242

EUDRAGIT® L 100 | Dissolution above pH 6.0 | Granulation of drug substances from the enterally released coating | DMP 1242

EUDRAGIT® L 12,5 Organic Solution 12.5 % | Dissolution above pH 6.0 | Low viscosity, high pigment binding capacity, good adhesion, low polymer weight gain | DMP 1242

Colonic delivery | EUDRAGIT® FS 30 D Aqueous Dispersion 30 % | Variable release profiles | Sustained-Release Formulations

EUDRAGIT® FS 30 D | Insoluble, low permeability, pH-independent swelling | Customized release profiles by combination of RL and RS grades in different ratios | USP/NF, DMF 1242

Protective Formulations
Insulating coatings:
- Taste masking
- Odor masking
- Moisture protection
- Light protection

Protection and Packaging
Grade | Unit (kg, net) | Packaging | Storage | Flash Point
--- | --- | --- | --- | ---
EUDRAGIT® L 30 D-55 | 5, 30, 200*, 1000** | Polyethylene canister | Protect from freezing. Store at controlled room temperature. | Not flammable

EUDRAGIT® NE 30 D | 5, 30, 600** | Polyethylene drum* | Protect from freezing and do not store above 25 °C (77 °F). | Not flammable

EUDRAGIT® NE 40 D | 5, 30 | Steel drum with exterior lacquer coat and polyethylene lining | Protect from warm temperatures. Store at controlled room temperature. | -15 °C (5 °F)

Stability:
- Minimum stability dates are stated on the product labels and batch related certificates of analysis.
- Storage stability data is available upon request.
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