AquaPolish® MS

Ready-to-use moisture sealing film coating system for solid oral dosage forms

Reliable tablet core protection against humidity. Customized formulation and colouration.
Challenges

Protecting moisture sensitive substances from environmental moisture is one of the biggest challenges in the pharmaceutical and nutritional supplements industry.

Coating the tablet core with a suitable film coating therefore plays an important role in achieving a sufficient moisture barrier. It improves the stability of the tablet and provides protection to prevent degradation of the active ingredients and increases shelf life. Tablet cores with highly hygroscopic active ingredients, such as extracts, or solid dosage forms marketed in countries with high humidity, must be protected from moisture effectively.

The selection of raw materials for the formulation of AquaPolish® MS is adapted to the respective active ingredient and the customer’s requirements. The transparent, white or coloured tailor-made AquaPolish® MS formulations are homogeneous dry milled and easily soluble in water. Ready-to-use in less than one hour.

GLOBAL FORMULATION SUPPORT

BIOGRUND always develops tailor-made compositions according to customer needs, including colour matching. Regional regulatory requirements are taken into account.

Note: This is only an example of a possible clear formulation.
For achieving a reliable moisture sealing a weight gain level of 5% is recommended. Local regulatory restrictions have to be considered. AquaPolish® MS is to be suspended in water up to a 15% solids level.

The solid concentrations and coating conditions were adjusted to the recommended values. The spray process stopped at a weight gain level of 4% to compare all formulations under same conditions. All spray trials were performed on the laboratory drum coater BOSCH SolidLab1.

**MOISTURE BARRIER**

Determination of water absorption: The coated tablets (n=10) were weighed before the start of the measurement, as well as the weight per tablet per day during the time in the climatic chamber (at 40°C, 75% RH). The measured weight difference results from the moisture absorption (shown in % in the graph).

**FILM STRENGTH**

Size of each film sample was 3x3 cm (film thickness 22 μm avg./3 samples). Tested with a Texture Analyzer under compression load.

**DISINTEGRATION**

The disintegration test was carried out according to European Pharmacopeia (EP). Purified water was used as liquid medium (temperature 37 ± 2°C).

### Process Parameter

<table>
<thead>
<tr>
<th>Coating equipment</th>
<th>Conventional Pan</th>
<th>Side vented Pan</th>
<th>Side vented Pan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pan diameter</td>
<td>16”</td>
<td>24”</td>
<td>48”</td>
</tr>
<tr>
<td>Tablet load</td>
<td>2 kg</td>
<td>30 kg</td>
<td>110 kg</td>
</tr>
<tr>
<td>System</td>
<td>Aqueous</td>
<td>Aqueous</td>
<td>Aqueous</td>
</tr>
<tr>
<td>Solid content (%)</td>
<td>12 – 15</td>
<td>12 – 15</td>
<td>12 – 15</td>
</tr>
<tr>
<td>Pan Speed (rpm)</td>
<td>16</td>
<td>10</td>
<td>4</td>
</tr>
<tr>
<td>Baffles</td>
<td>8</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Tablet bed temperature</td>
<td>38 – 42°C</td>
<td>38 – 42°C</td>
<td>38 – 42°C</td>
</tr>
<tr>
<td>Fluid nozzle</td>
<td>1.0 mm</td>
<td>1.2 mm</td>
<td>1.2 mm</td>
</tr>
<tr>
<td>Atomizing air pressure</td>
<td>1.0 – 1.2 bar</td>
<td>1.2 mm</td>
<td>2.4 bar</td>
</tr>
<tr>
<td>Spray procedure</td>
<td>Continuous</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spray rate (g/min)</td>
<td>7 – 12</td>
<td>30 – 40</td>
<td>200 – 300</td>
</tr>
<tr>
<td>Inlet air temperature</td>
<td>50 – 52°C</td>
<td>50 – 52°C</td>
<td>50 – 52°C</td>
</tr>
<tr>
<td>Exhaust air temperature</td>
<td>44 – 46°C</td>
<td>44 – 46°C</td>
<td>44 – 46°C</td>
</tr>
<tr>
<td>Drying air volume</td>
<td>180 m³/h</td>
<td>580 m³/h</td>
<td>2400 m³/h</td>
</tr>
<tr>
<td>Weight gain</td>
<td>5%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**TECHNICAL ASSISTANCE**

You need technical assistance with your film coating process? Please contact us:

technicalservice@biogrund.com

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Logo Definition, Smooth Finish.

A coating needs to adhere well to the tablet surface and have enough flexibility so that the engraving definition of the logo is retained during drying.

The plasticizer amount in AquaPolish® MS formulations is sufficient to ensure a smooth finish with excellent logo definition.

Packaging, Storage, Warranty, Samples.

Standard size: 25 kg carton (tamper evident box), with polyethylene inliner bag. Min. order quantity: 5 kg / max. batch size: 450 kg / max. 450 kg per pallet. Customized packaging available upon request.

Store product at 15-30°C under dry conditions (less than 65 % RH) 24 months from date of manufacture (may vary based on pigment selection). Samples of AquaPolish® MS can be obtained upon request, free of charge. Standard size is 400 g / larger samples are available upon request.

The homogeneous dry powdered compound will be shipped with certificate of analysis, specification, MSDS and processing guide.

Regulatory and quality aspects.

All AquaPolish® MS formulations are developed to meet the official regulatory requirements of the user’s country for pharmaceutical products and nutritional supplements.

BIOGRUND is EXCiPACT™ certified and international standards for quality and environmental management (ISO 9001 & 14001) are implemented as well as a HACCP system. All products are produced in highest quality and a batch-to-batch consistency is guaranteed.

More support?
Contact us!

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General Information on BIOGRUND

Since 1999, the BIOGRUND Group has been the specialist for the homogeneous mixing of excipients and carriers. With locations in Germany, Switzerland, America and Russia, we support the food supplement and pharmaceutical industry in the development, formulation and production of solid oral dosage forms. The tailor-made and ready-to-use special powder mixtures for film coating, sugar-coating, colouring and tabletting enable optimum results in a short time. Easy, fast and reliable!

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