Background Information

AquaPolish® MS

BIOGRUND

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.

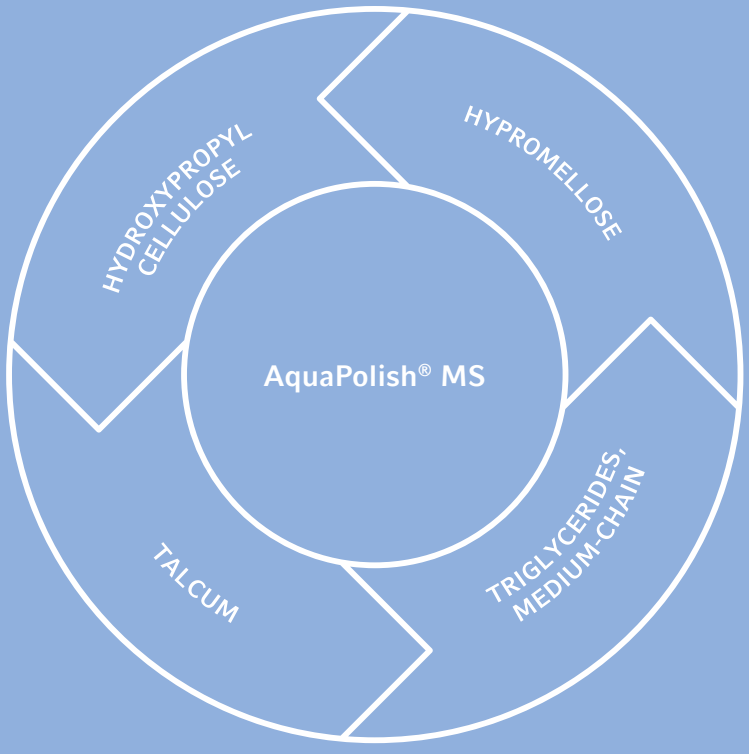
The selection of raw materials for the formulation of AquaPolish® MS is adapted to the respective active ingredient and the customer‘s requirements. The transparent, white or coloured tailor-made AquaPolish® MS formulations are homogeneous dry milled and easily soluble in water. Ready-to-use in less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

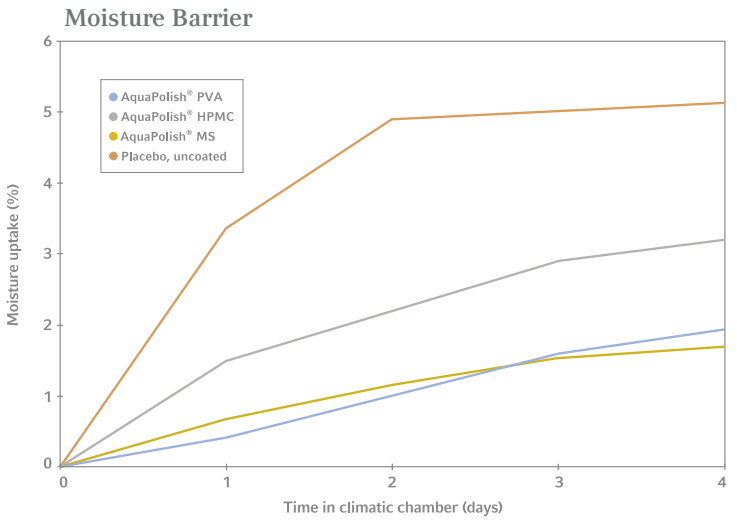
Characteristics/Benefits

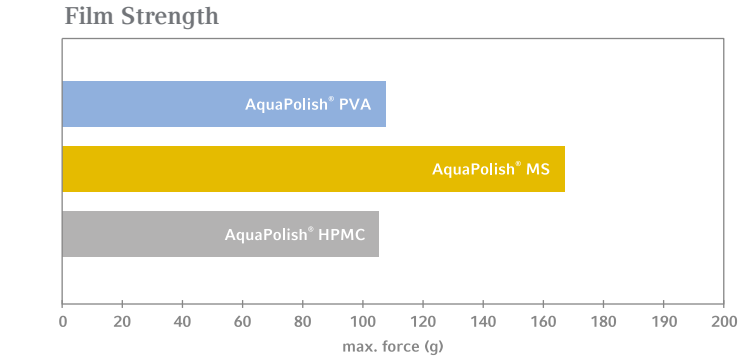
Qualitative Composition

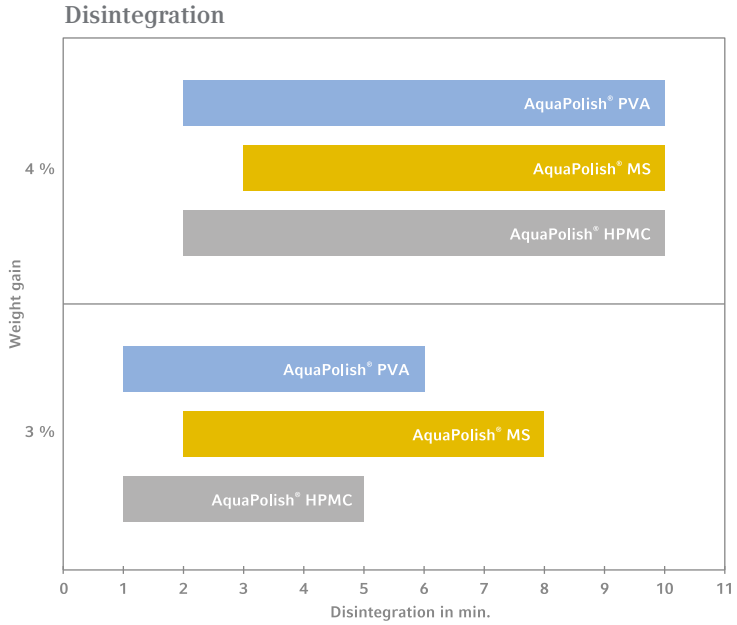


Note: This is only an example of a possible clear formulation.

Film Properties







For the following data collection placebo tablets* were coated with three different white formulations (AquaPolish® MS, AquaPolish® based on HPMC, AquaPolish® based on PVA).

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 moisture absorption – differential weighing: Before the coated tablets were placed in the climatic chamber, they were weighed. During the time in the climatic chamber (conditions: 40°C, 75% RH), the tablets were weighed every 24 hours to determine the moisture absorption. The results are shown in the graph „Moisture Barrier“ (in %).

FILM STRENGTH

Size of each film sample was 3 x 3 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).

* Size: 9 mm, round biconvex | Ingredients: Microcrystalline Cellulose, Dicalcium Phosphate, Magnesium Stearate

Process Parameter

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.

Coating equipment	Conventional Pan	Side vented Pan	Side vented Pan
Pan diameter	16''	24''	48''
Tablet load	2 kg	30 kg	110 kg
System		Aqueous	
Solid content (%)		12 – 15	
Pan Speed (rpm)	16	10	4
Baffles	8	4	4
Tablet bed temperature		38 – 42°C	
Fluid nozzle	1.0 mm	1.2 mm	1.2 mm
Atomizing air pressure	1.0 – 1,2 bar	2,4 bar	2,4 bar
Spray procedure		Continuous	
Spray rate (g/min)	7 – 12	30 – 40	200 – 300
Inlet air temperature		50 – 52°C	
Exhaust air temperature		44 – 46°C	
Drying air volume	100 m^3/h	500 m^3/h	2400 m^3/h
Weight gain		5 %	

TECHNICAL ASSISTANCE

You need technical assistance with your film coating process? Please contact us:
technicalservice@biogrund.com
T +49 6126 952-63 0

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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.

AquaPolish® MS can be used for pharmaceutical products and for nutritional or dietary 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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© 2023 BIOGRUND GmbH | Printed in Germany 08/2023 | EN 300 | Order no.: 70000

General Information on BIOGRUND

Since 1999, **BIOGRUND** 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, coloring and tableting enable optimum results in a short time. Easy, fast and reliable!

Locations

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