Background Information

Functional Coating

Easy, fast and reliable enteric protection? Why not!

- High performance protection against acidic conditions
- Suitable for granules, pellets, tablets and capsules
- For pharmaceutical and nutraceutical applications

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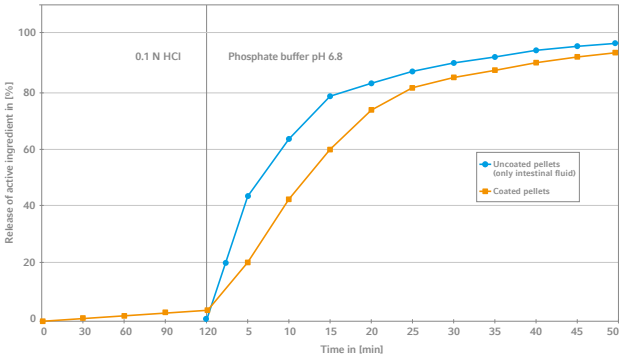
Why enteric protection?

There are active ingredients that have to be protected from the stomach acids (pH 1-4). Thus, they should not be released before reaching the small intestine (pH 5-7). Reasons for that can be the sensibility of the active ingredient to the acidic environment in the stomach. Hence, therapeutic effects can be reduced or neutralized by the acid. Also, some active compounds should first be released in the small intestine to yield better adsorption or they should first have an effect there, like intestinal antiseptics that should not be diluted in the stomach. Moreover, some active agents can cause gastric mucos irritations and therefore need enteric protection to prevent irritations.

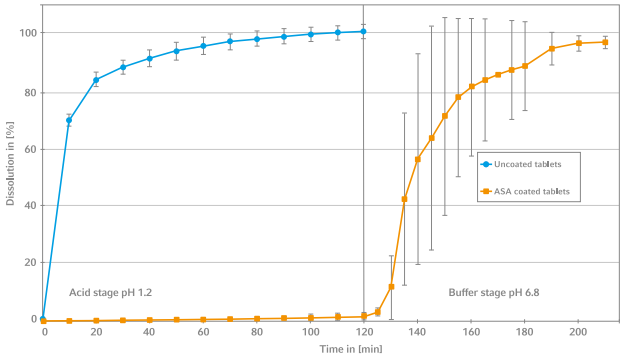
The dissolution behavior of the coating is dependent on the pH value, so that the active ingredient is specifically released only in the section of the intestine whose milieu corresponds to this value. With **AquaPolish® E** and **BonuLac® E**, **BIOGRUND** has the right solution for the pharmaceutical and nutraceutical industry. These enteric ready-to-use film coatings are formulated for actives that must reliably pass through the stomach.

Release of Acetylsalicylic Acid from Coated Pellets



The release of the active ingredient was tested using the coated pellets by placing them in 0.1 N HCl for a period of 2 hours and afterwards in phosphate buffer (pH 6.8). Pellets coated with **AquaPolish® E** based on methacrylic acid-ethyl acrylate copolymer type B.

Release of Acetylsalicylic Acid from Tablets (n=6)



The ASA-tablets were coated with **AquaPolish® E** based on HPMC-AS. Full enteric resistance was observed at 9% weight gain. For the measurement, the dissolution half buffer change method from USP was chosen.

AquaPolish® E
This ready-to-use film coating system provides a protective film with excellent enteric properties. And with its superior light, oxygen and moisture protection, it is recommended for tablets, pellets, capsules and granules. Regardless of whether a pharmaceutical or nutraceutical grade is required, **AquaPolish® E** can be formulated with the appropriate polymers (acrylic acid copolymer, HPMC AS or sodium alginate). For pharmaceutical applications, polymers are chosen which complies with the USP/EP/JP pharmacopeia criteria.

BonuLac® E
An enteric film coating based on natural shellac which can be used for pharmaceutical and nutraceutical applications. The protective film provides good odor and taste masking. Therefore, **BonuLac® E** is recommended for coating natural extracts, fatty oils and substances with bad taste or odor. It is a combination of natural shellac with plasticisers, color additives and additional auxiliary substances. **BonuLac® E** is water soluble and a reproducible high quality coating is guaranteed.

Ready-to-Use Enteric Protection Film Coating Sytems

	AquaPolish® E			BonuLac® E
Quality	**Pharma**	**Pharma**	**Food/Nutra**	**Pharma/Food/Nutra**
Polymer basis	Metacrylic acid-ethyl acrylate copolymer (1:1) Type B	Hypromellose Acetate Succinate	Sodium Alginate	Natural Shellac
Pharmacopeia Criteria fulfilled/ Compendial status	EP/USP	JP/NF	E401	E904
Dissolution at pH-level	>5.5	LF*≧5.5 MF*≧6.0 HF*≧6.5	–	–
Disntegration time at pH 6.8	>10 min	10 min (aqueous) 9 min (ethanol/water)	>10 min	10-30 min
Weight gain level:	–	–	–	–
On tablets	10-12 %	8-10 %	8-12 %	4-7 %
On capsules	12-20 %	10-15 %	10-15 %	4-12 %
On pellets (depending on form/application)	MIN 15-25 %	MIN 15-25 %	MIN 15-25 %	MIN 4-15 %
Solid content in spray suspension	22 %	15 %	12 %	18 %
Application	- Aqueous/cold - Plasticizer added by customer - 45 min preparation	- Aqueous/cold - Plasticizer added by customer - 45 min preparation	- Aqueous/cold - 45 min preparation	- Aqueous/warm - Plasticizer added by customer - 45 min preparation
Advantages	- Cost effective coating process - Protect actives against light decomposition, oxidation and moisture	- Cellulose derivate, made from highly purified pulp - 3 different types for 3 different release points (ph-values)	- For probiotics - Vegan - Non-animal - Light glossy effect - Clean label	- Recommended for coating of natural extracts, fatty oils, substances with bad taste/odor - Moisture protection

* Different types of HPMC-AS

All film coating systems can be used for pharmaceutical products and for nutritional or dietary supplements.

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!

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