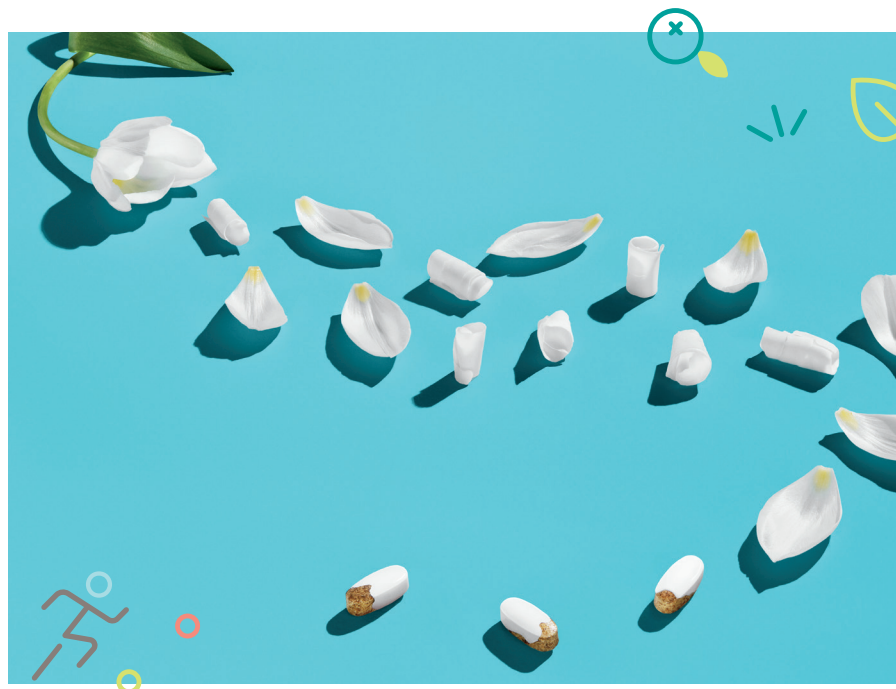


aquarius™ film coating systems for nutraceutical applications

easily dispersed and ready-to-use aquarius™ film coating systems have a range of functions to suit almost any core

key features and benefits

- provides superior aesthetics
- reduces rework
- color matching available
- available with naturally derived light-stable pigments, synthetic colors, and iron oxides
- taste and odor masking alternatives
- titanium dioxide free alternatives
- organic alternatives

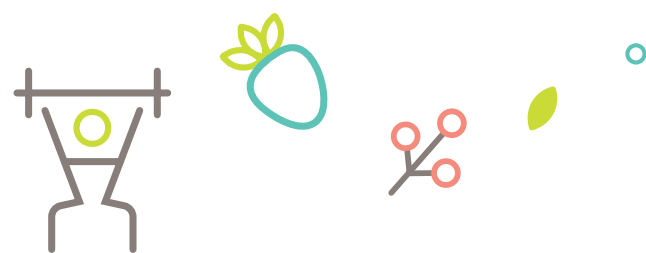


aquarius™ nutra film coating systems

Aquarius™ Nutra are fully formulated, immediate release, aqueous film coating systems made specifically for nutritional and dietary supplement products. Aquarius™ Nutra film coating systems are available as clear, white, or pigmented.

description

Achieving the desired appearance and performance of film coatings, while minimizing the potential for processing problems, requires balancing and optimizing both ingredient selection and ingredient use levels. The selection of specific ingredients and their use levels will impact film strength, film adhesion, film flexibility and opacity. This balance is particularly difficult to achieve with many dietary supplements. Ashland offers several products to answer the call for more health-conscious coating choices and to protect sensitive nutraceutical tablet cores.



aquarius™ nutra tf film coating systems

Due to the re-evaluation of TiO_2 as a food additive in the European Union (E171), Ashland is committed to offering titanium dioxide-free film coating formulations to our customers in the nutraceutical space. Aquarius™ Nutra TF is a TiO_2 -free film coating system that provides a comparable white film coating for oral solid dosage forms. Aquarius™ Nutra TF aqueous film coating options are available as white or pigmented systems.

figure 1. aquarius™ nutra tf, formulated without TiO_2 , provides a comparable white film coating for oral solid dosage forms



figure 2. multivitamin tablets coated with label-friendly and high gloss aquarius™ organic coating



aquarius™ organic film coating systems

Aquarius™ Organic is a clear, fully formulated, certified organic and non-GMO project verified, aqueous film coating system.

features:

- made with non-allergenic, label-friendly ingredients
- vegetarian, Kosher and Halal certified
- an aqueous-based alternative to animal-derived, shellac-based systems
- provides exceptional gloss, and improved slip for packaging while preventing dusting
- quick to disperse and easy to apply

aquarius™ protect film coating systems

Many nutraceutical formulations are sensitive to moisture or can possess unpleasant odors or tastes. Aquarius™ Protect film coating systems provide a range of barrier coatings for moisture, taste or odor.

Aquarius™ Protect is a premium multi-functional barrier coating system that effectively reduces moisture uptake and masks against offensive taste and odor.

features:

- fully formulated, ready-mixed systems disperse quickly in water or solvent
- clears:** 10–12% solids
- white and colors:** can be sprayed up to 20% solids while remaining non-tacky, achieving significant process savings
- composed of cellulose derivatives and natural wax blend delivering superior barrier properties, efficient processing, and flexibility without compromising drug release
 - easy and efficient application using standard spray equipment and process conditions
 - all ingredients have FDA and EU direct food additive and/or Generally Recognized as Safe (GRAS) status; compliance for specific formulations listed on the certificate of analysis

benefit to formulators and purchasers:

- superior moisture barrier protection vs. competitor PVA coating system
- especially useful in high humidity environments, including climate zones 4 and 5
- for use with dietary supplements looking to prevent black spots on multivitamins
- more label friendly than PVA (natural wax)
- potential for faster processing times or lower processing temperatures



aquarius™ film coating systems formulated with naturally derived colors

The inactive ingredients in nutraceutical formulations are subject to food regulations, which, compared with their pharmaceutical counterparts, are more restrictive about the range of permitted colorants and maximum use levels. The Aquarius™ film coating systems, natural colors palette addresses the needs of the nutraceutical industry with formulations that clearly designate compliance by region.

Some important features of our Aquarius™ film coating systems formulated with naturally derived colors are:

- o designed to meet the regulatory requirements of the European Union and the United States
- o stable color performance—tested for light and storage stability
- o easy-to-use, high-solids formulations

As a remedy for the well-known light and color instability of naturally derived colors, our scientists performed extensive tests using the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines for stability testing to select light-stable colors. The proposed formulations were exposed to simulated daylight for 1.2 million lux-hours under stringent conditions for direct light exposure.

For color storage stability testing, we again followed ICH guidelines. We used an accelerated stability test that is run at 40 °C and 75% relative humidity. Coated tablets were placed in HDPE bottles for up to 3 months and measurements were taken with a spectrophotometer at 1-, 2- and 3-month intervals. Because these conditions for light and color stability are extreme, Ashland's scientists are confident in the stability of our broad portfolio of naturally derived colors. Please contact your Ashland sales representative for more information about color choices.

Figure 3. Milk thistle tablets coated with aquarius™ protect film coating systems.

Left to right: Uncoated tablet, tablet coated with Aquarius™ Protect film coating system, uncoated tablet after 48 hours at room temperature and 75% relative humidity (RH), coated tablet after 48 hours at room temperature and 75% RH.



uncoated

coated with aquarius™ protect

uncoated after 48 hours at room temperature, 75% RH

coated after 48 hours at room temperature, 75% RH



