

Nutrateric[™] Nutritional Enteric Coating System for Nutritional Supplements

INTRODUCTION

Enteric coating systems for drug products have been long established¹. However, polymers commonly used for enteric coating of drug products, such as phthalates and acrylates, are not approved for use in nutritional or food applications.

A new enteric coating formulation that is suitable for these applications has been developed and is now commercially available.

This coating system, Nutrateric, complies with the US regulations for nutritional supplements. It is based on Surelease[®], aqueous ethylcellulose dispersion E-7-19010 and NS Enteric[™], nutritional enteric component 29Z19241.

The system is shown to provide good enteric properties on garlic tablets and fish oil soft gelatin capsules and meets enteric specifications after storage at 40°C/75%RH for three months.

METHODOLOGY

The enteric coating system was prepared by mixing the NS Enteric 29Z19241 powder in water for 45 minutes. Surelease E-7-19010 was added to the dispersion, and mixing was continued for an additional 30 minutes before application. Final dispersion solids content was 10%. The dispersion viscosity was measured using a Brookfield viscometer model DV-II.

The formulation was coated onto 1kg of garlic tablets in a Thomas Engineering Compu-Lab 15" side-vented coating pan using one Spraying Systems 1/8" VAU nozzle. Coating conditions: 43-46°C tablet bed temperature, 30 psi atomizing air pressure, 30 psi pattern air pressure, 6 inches gun-to-bed distance, 15 grams/minute spray rate, and 18 RPM pan speed.

Fish oil soft gelatin capsules were coated in an O'Hara Labcoat II 19" side-vented coating pan using one Spraying Systems 1/8" VAU nozzle. Coating conditions: 38-40°C bed temperature, 30 psi atomizing air pressure, 40 psi pattern air pressure, 4 inches gun-to-bed distance, 20 grams/minute spray rate, and 12 RPM pan speed.

Testing of coated dosage forms utilized the six-tablet basket-rack disintegration apparatus as described in USP test method 701. Samples were required to be intact with no ruptures after a 60 minute test in 0.1N HCl (pH 1.2). Pass/fail was reported. Plastic disks were then placed on top of the samples and the basket transferred to a pH 6.8 tribasic sodium phosphate buffer solution for disintegration testing. The disintegration time of each tablet was recorded.

Coated dosage forms were required to disintegrate within 120 minutes. They were tested one day after coating (storage at ambient conditions) and again after storage at 40°C/75%RH for 3 months in an induction-sealed HDPE bottle without desiccant.

Film tensile testing was conducted using an Instron Mini 44 universal testing machine and Instron Series IX data acquisition and analysis software. Dispersions of each were prepared as described above and cast on a Teflon substrate using a BYK-Gardner film casting knife with a targeted dry film thickness of 100 microns. Films were dried at 70°C for two hours.

After drying, films were removed from the substrate and allowed to equilibrate at 23°C/55%RH for 24 hours prior to testing. Sample dimensions were 25mm x 10mm x 100mm+/-10mm (length x width x thickness), and the test was conducted at a displacement rate of 1.0 inch/minute. The tensile strength(s), elastic modulus (E) and energy to break (EtB) were recorded for 10 samples of each formulation². The average values and standard deviation were reported.

RESULTS AND DISCUSSION

The 10% solids content dispersion viscosity was 560 cP at 23.0°C.

The formulation provided both dosage forms with 60 minutes of protection in the gastric test at both the one-day and three-month time points (A, B). All tablets and soft gelatin capsules were intact with no ruptures. In the phosphate buffer medium, both dosage forms disintegrated well within the 120 minute specification at both the one-day and three-month time points (C, D).

Table 1. Enteric Testing Results

	Tablets*	Soft Gelatin Capsules
A	Intact	Intact
B	Intact	Intact
C	79:50 +/- 6:25	13:00 +/- 3:06
D	82:20 +/- 9:58	18:42 +/- 4:06

*The uncoated tablets disintegrated in 41 minutes in pH 6.8 phosphate buffer solution

A: 60 minute gastric testing results – 1 day

B: 60 minute gastric testing results – 3 months, 40°/75%RH

C: Average disintegration time (minutes) after 1 day, n=6

D: Average disintegration time (minutes) after 3 months, 40°/75%RH, n=6

Film tensile properties of each formulation are given in the following table. Though energy to break is reduced, the tensile strength and elastic modulus of the US-compliant Nutrateric formulation do not differ significantly from commercially available Surelease E-7-19010, its parent formulation.

Table 2. Film Properties: Nutrateric vs. Surelease

	Nutrateric Formulation	Surelease E-7-19010
σ (MPa)	3.12 +/- 0.45	3.92 +/- 0.46
E (MPa)	171.06 +/- 15.5	157.26 +/- 12.96
EtB (mJ)	0.98 +/- 0.31	10.36 +/- 2.92

Key: σ = Tensile Strength E = Elastic Modulus EtB = Energy to Break Point

CONCLUSIONS

A new enteric coating formulation that meets the US regulatory requirements for nutritional supplements has been developed and is now commercially available. Coated garlic tablets and fish oil soft gelatin capsules maintain their properties during stability testing, with no significant change in enteric protection through three months of storage at 40°C/75%RH. The formulation has film properties comparable to its commercially available parent formulation and can provide enteric protection for a variety of dosage forms while allowing timely disintegration in pH 6.8 buffer medium.

REFERENCES

1. Porter, S.C. "Coating of Pharmaceutical Dosage Forms," Remington: The Science and Practice of Pharmacy, 20th ed., Lippincott Williams & Wilkins, 897-898. (2000)
2. Parikh, N.H., Porter, S.C. and Rohera, B.D. "Tensile Properties of Free Films Cast from Aqueous Ethylcellulose Dispersions," Pharmaceutical Research 10(6), 811-812. (1993)

This ADS has been adapted from the following Controlled Release Society poster:
 Martin L, Simon B, Farrell T. New Enteric Coating System (Nutrateric™) for Nutritional Supplements.
 Poster presented at: CRS, June 2005.

The information contained herein, to the best of Colorcon, Inc.'s knowledge is true and accurate. Any recommendations or suggestions of Colorcon, Inc. with regard to the products provided by Colorcon, Inc. are made without warranty, either implied or expressed, because of the variations in methods, conditions and equipment which may be used in commercially processing the products, and no such warranties are made for the suitability of the products for any applications that you may have disclosed. Colorcon, Inc. shall not be liable for loss of profit or for incidental, special or consequential loss or damages.

Colorcon, Inc. makes no warranty, either expressed or implied, that the use of the products provided by Colorcon, Inc., will not infringe any trademark, trade name, copyright, patent or other rights held by any third person or entity when used in the customer's application.

For more information, contact your Colorcon representative or call:

North America
 +1-215-699-7733

Europe/Middle East/Africa
 +44-(0)-1322-293000

Asia Pacific
 +65-6438-0318

Latin America
 +54-11-4552-1565

You can also visit our website at www.colorcon.com



© BPSI Holdings LLC, 2010. The information contained in this document is proprietary to Colorcon, Inc. and may not be used or disseminated inappropriately.

All trademarks, except where noted, are property of BPSI Holdings LLC.