

Enteric Coating: Protecting your Product



Enteric Coating: Protecting your Product

Enteric Coating - Necessary

Benefits of Enteric Coating

Proof that Enteric Coating Works

Enteric Coating - Necessary

Our digestive system contains very harsh conditions that enable it to break down food efficiently.



Enteric Coating - Necessary

When we take a typical supplement:

- The capsule or tablet is swallowed and travels down the esophagus to the stomach.
- In the stomach the tablet or capsule is churned and gyrated in highly acidic digestive secretions with **pH 1-4**, for 45 minutes to 2 hours.
- If there is anything left of the tablet or capsule (and its contents), it will be passed through the duodenum to the small intestine.



Highly Acidic Environment

Enteric Coating - Necessary

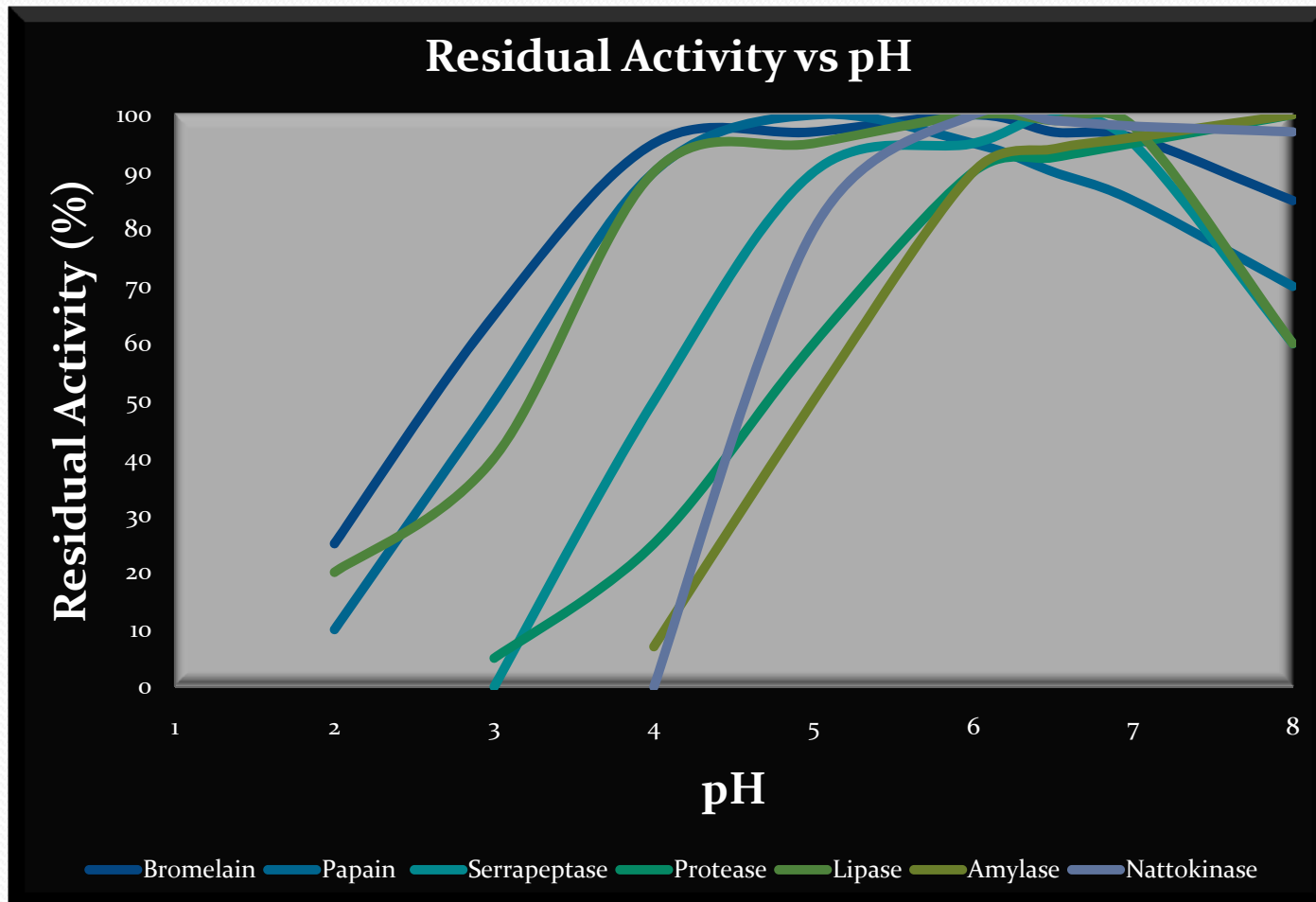
What happens to uncoated tablets and capsules?

Stomach acid breaks down tablets and capsules to prematurely release active ingredients (enzymes).

The highly acidic environment of the stomach destroys the majority of the enzymes' activities. (see graph next slide)

If the tablet is of poor quality (contains binders and fillers) the product may pass through both the stomach and intestine with no absorption.

Notice Lack of Enzyme Activity in Harsh Stomach Conditions (pH 1-4)



Enzyme Effectiveness

- Determined by amount of activity level in bloodstream after the enzyme has been absorbed from the small intestine.
- Enzymes lose activity in low pH(1-3) of the stomach.
- Studies show unprotected enzymes can lose up to 100% of their activity in 30 min or less!
- Only reliable method is ensure 100% of the enzymes are not destroyed is to enteric coat the enzymes.

How Enteric Coating Evolved:

The Evolution of Systemic Enzyme Delivery Systems



Animal derived enzymes are combined with fillers and excipients to form a tablet. High doses are required for therapeutic effects.



Acid-tolerant vegetarian enzyme powders are available in capsule form. High doses are required for therapeutic effects.



Capsules containing coated enzymes allow for increased enzyme absorption. Lower doses required for therapeutic effects.



Liquid filled gencaps are introduced with full enteric coating. Smaller capsules, smaller doses, higher potency. A first in the industry.

1960's

1990's

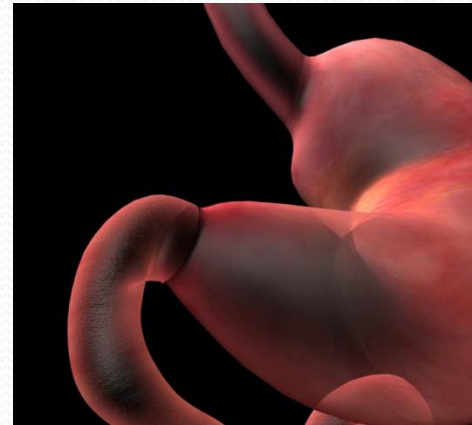
2000's

2010

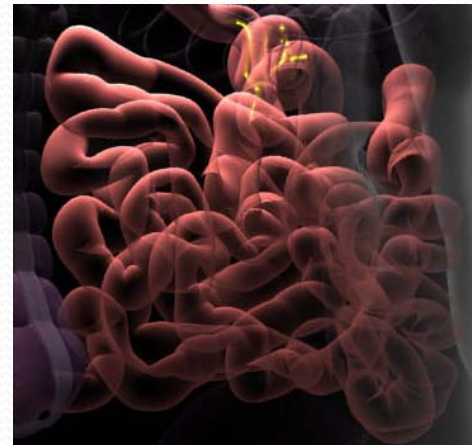
Benefits of Enteric Coating

- Protects capsule or tablet contents from acidic environments of stomach
- After passing through the stomach allows capsule or tablet to break down easily in pancreatic juices in the Duodenum* (pH 6-8)
- Enables absorption of enzymes, at their highest activity levels, in the small intestine

* (approximately 1st 10" of small intestine)



Duodenum



Small
Intestine

Proof that Enteric Coating Works

Conducted “Disintegration Tests (Enteric Coated Capsules)”
following procedures from Japanese Pharmacopeia
(General Tests, 15th Edition)

Two Test Conditions

- First test simulates gastric fluid (harsh stomach conditions):
pH 1.2 for 120 minutes at 37 °C (98.6 ° F)
- Second test simulates intestinal fluid (duodenum):
pH 6.8 for 60 minutes at 37 °C (98.6 ° F)

Test Results for Enteric Coated Capsules

- Stomach Conditions – Capsules did not disintegrate
- Intestinal (duodenum) Conditions – Capsules disintegrated completely

Proof that Enteric Coating Works

Certificate of Analysis – With Enteric Coating



Japan Food Research Laboratories
Authorized by the Japanese Government
52-1 Motoyoyogi-cho, Shibuya-ku, Tokyo 151-0062, Japan

No. 09030524001-01 1/1
December 07, 2009

CERTIFICATE OF ANALYSIS

Requested by: World Nutrition, Inc.
7001 North Scottsdale Road, Suite 2000, Scottsdale, Arizona 85253, U.S.A.

Sample name: Vitalzym X
Lot#: B09A
Manufacturing factory: Sun Capsule Co., Ltd.
533-2 Oiwa, Fujinomiya, Shizuoka 418-0013, Japan
Received date: December 02, 2009

This is to certify that the following result(s) have been obtained from our analysis on the above-mentioned sample(s) submitted by the client.

Test Item	Result	QL	N	M
Disintegration test			1	
Time of disintegration 1	None of six dosage units was disintegrated for 120 minutes.	---	2	
Time of disintegration 2	Six dosage units were disintegrated for 60 minutes.	---	3	

QL: Quantitation limit N: Notes M: Method

Notes

- 1: "Disintegration Test (Enteric coated capsule)", General Tests, The Japanese Pharmacopoeia, Fifteenth Edition.
- 2: First fluid for disintegration test was used.
- 3: Second fluid for disintegration test was used.



N. Imaizumi
Noriko Imaizumi
Principal Investigator
Japan Food Research Laboratories

Sample name: Vitalzym X
Lot#: B09A
Manufacturing factory: Sun Capsule Co., Ltd.
533-2 Oiwa, Fujinomiya, Shizuoka 418-0013, Japan
Received date: December 02, 2009

This is to certify that the following result(s) have been obtained from our analysis on the above-mentioned sample(s) submitted by the client.

Test Result(s)

Test Item	Result	QL	N	M
Disintegration test			1	
Time of disintegration 1	None of six dosage units was disintegrated for 120 minutes.	-----	2	
Time of disintegration 2	SIX dosage units were disintegrated for 60 minutes.	-----	3	

Capsule Remained Intact

QL: Quantitation limit N: Notes M: Method

Notes

- 1: "Disintegration Test (Enteric coated capsule)", General Tests, The Japanese Pharmacopoeia, Fifteenth Edition.
- 2: First fluid for disintegration test was used.
- 3: Second fluid for disintegration test was used.

Highlighted Area

Proof that Enteric Coating Works

Certificate of Analysis – No Enteric Coating



Japan Food Research Laboratories

Authorized by the Japanese Government

62-1 Motoyoyogi-cho, Shibuya-ku, Tokyo 151-0062, Japan

No.09027385002-01 1/1
December 07, 2009

CERTIFICATE OF ANALYSIS

Requested by: World Nutrition, Inc.
7001 North Scottsdale Road, Suite 2000, Scottsdale, Arizona 85253, U.S.A.

Sample name: Neprinol AFD

Received date: November 24, 2009

This is to certify that the following result(s) have been obtained from our analysis on the above-mentioned sample(s) submitted by the client.

Test Result(s) Test Item	Result	QL	N	M
Disintegration test	---	---	1	---
Time of disintegration 1	Six dosage units were disintegrated for 120 minutes.	---	2	---
Time of disintegration 2	Six dosage units were disintegrated for 60 minutes.	---	3	---

QL: Quantitation limit N: Notes M: Method

Notes

1:"Disintegration Test (Enteric coated capsule)", General Tests, The Japanese Pharmacopoeia, Fifteenth Edition.

2:First fluid for disintegration test was used.

3:Second fluid for disintegration test was used.



N. Imaizumi
Noriko Imaizumi
Principal Investigator
Japan Food Research Laboratories

Sample name: Neprinol AFD

Received date: November 24, 2009

This is to certify that the following result(s) have been obtained from our analysis on the above-mentioned sample(s) submitted by the client.

Test Result(s)

Test Item	Result	QL	N	M
Disintegration test	---	---	1	---
Time of disintegration 1	Six dosage units were disintegrated for 120 minutes.	---	2	---
Time of disintegration 2	Six dosage units were disintegrated for 60 minutes.	---	3	---

Capsule Was Compromised

QL: Quantitation limit N: Notes M: Method

Notes

1:"Disintegration Test (Enteric coated capsule)", General Tests, The Japanese Pharmacopoeia, Fifteenth Edition.

2:First fluid for disintegration test was used.

3:Second fluid for disintegration test was used.

Highlighted Area

Enteric Coating State of the Art

- Revolutionary process for Enzymes; similar to enteric coating process used in today's most advanced products.
- All natural shell that withstands pH levels found in Stomach.
- Designed to pass USP (United States Pharmacopeia) and JP (Japanese Pharmacopeia) disintegration tests.
- Every batch is tested to ensure it meets agency guidelines before export to U.S.



Benefits of Enteric Coating: Summary

- Uncoated Capsules and Tablets lose the effectiveness of their enzymes when passing through the stomach (Enzymes are destroyed)
- Enteric Coating protects a capsule's contents in the highly acidic environments of the Stomach
- Enteric Coating breaks down completely in neutral pH environments of the Duodenum
- Enteric Coating enables delivery of enzymes for absorption with maximum activity levels intact into the Small Intestine