

Certificate of Analysis

Product: Empty Porcine Hard Gelatin Capsules		Batch No.	2256
Capsule Size	Su07	Color Code Cap / Body	CT/CT CT= Clear Transparent
Date of manufacture	MAY 2009	Expiration Date For Use Outside India*	
		Expiration Date For Use In India**	

*Based on real-time stability data customers outside India can use an expiration date of 7 years from the Date of Manufacture. **Expiration Date in India is 5 years as Indian FDA regulations classify capsules as a drug and specify a maximum shelf life of 5 years for drugs if packed cartons stored under the following conditions:

- a) At 60-80 F (15-25 C) and 40-60% Relative Humidity b) Away from any direct source of heat (e.g. radiators, sunlight, etc.)
c) Protected from moisture.

Ingredients & Composition

Gelatin Porcine	85.640%	No Colorants Used	
Methyl Paraben	0.574%	No Colorants Used	
Propyl Paraben	0.143%	No Colorants Used	
Sodium Lauryl Sulphate	0.143%	No Colorants Used	

Porcine gelatin and other raw materials used meet applicable US, European and Japanese Pharmacopoeia specifications for the use in manufacture of empty porcine hard gelatin capsules.

Due to the nature of raw material, their sourcing and technology improvements, the colorant composition data indicated are target values and actual values may vary to insure the consistency of capsule color.

Empty Porcine Hard Gelatin Capsule Specification

This product does not contain and is not derived from any ruminant (including bovine) materials. Therefore, it does not contain any materials that may present a risk of Transmitting Spongiform Encephalopathy including BSE.

This product was manufactured from Porcine gelatin certified by USDA or European Union Veterinary officials to be in compliance with EU Regulation 2002/1774.

This product was manufactured in compliance with the monograph Pharmacopoeia Europe Vth Edition. 01/2005:50208.

Finished capsules meet applicable US, European and Japanese Pharmacopoeia specifications.

Finished capsules meet US Federal Standard 285A and US Federal Specification U-C-115b for acid solubility and water resistance.

Characteristics (Test)	Specification	Result	
Moisture (Loss on drying)	12.5%-16% w/w	Complies	13 - 14 %
Disintegration Time	Less than 15 minutes	Complies	09 minutes
Average Wt. (Lot of 100 capsules)	208 gms +/- 10%	Complies	208 gms
Total microbial Count for 48-72 Hrs (30-35C)	Less than 1000 cfu/gm	Complies	Less than 500 cfu/gm.
<i>Escherichia Coli</i>	Absent in ten grams	Complies	Absent in ten grams.
<i>Salmonella species</i>	Absent in ten grams	Complies	Absent in ten grams.
<i>Pseudomonas aeruginosa</i>	Absent in ten grams	Complies	Absent in ten grams.
<i>Staphylococcus aureus</i>	Absent in ten grams	Complies	Absent in ten grams.
Yeast and Mold count for 120 Hrs. (20-25 C)	Less than 100 cfu/gm	Complies	Less than 100 cfu/gm.

The capsules are manufactured under carefully controlled conditions in accordance with c-GMP. Continuous control maintained throughout the process and guarantee that capsules conform to the highest quality standard.

World Sales & Service:

For further information on capsules, filling machines, dosing devices or assistance with research or other industrial uses contact:
Torpac Inc., 333 Route 46, Fairfield, NJ 07004, USA. Tel.: 1-973-244-1125 Fax : 1-973-244-1365
www.torpac.com E-mail: info@torpac.com

This lot of capsules described is hereby certified to you.

Name: 
MINAL BABREKAR
22-June- 2009

Title: Q. A. Officer

Manufactured for Torpac Inc. under exclusive contract by Custom Capsules Pvt. Ltd., B-8/1, Tarapur MIDC, Boisar-401 506, Maharashtra, India. Manufacturing Licence No. KD/33.