

Certificate of Analysis

Product: Empty Porcine Hard Gelatin Capsules	Batch No. 2852
Capsule Size 11	Color Code Cap / Body CT/CT CT= Clear Transparent
Date of Manufacture NOVEMBER 2012	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 are 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 / Methyl -4- hydroxybenzoate	0.574%	No Colorants Used
Propyl Paraben / Propyl -4- hydroxybenzoate	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 ensure 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 processed according to 853/2004 and compliant to 1069/2009 as amended by EU Regulation 142/2011.

This product was manufactured in compliance with the European Pharmacopoeia monograph.

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	Not more than 15 minutes	Complies	07 minutes
Average Wt. (Lot of 100 capsules)	117 gms +/- 10%	Complies	114 gms
Total Aerobic microbial Count	Not more than 1000 cfu/gm	Complies	Less than 500 cfu/gm.
<i>Escherichia Coli</i>	Absent in one grams	Complies	Absent in one grams.
<i>Salmonella species</i>	Absent in ten grams	Complies	Absent in ten grams.
<i>Pseudomonas aeruginosa</i>	Absent in one grams	Complies	Absent in one grams.
<i>Staphylococcus aureus</i>	Absent in one grams	Complies	Absent in one grams.
Total combined Yeast and Mold count	Not more than 100 cfu/gm	Complies	Less than 100 cfu/gm.

The capsules are manufactured under 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.

(Handwritten Signature)

Name: H.R.PATIL

Title: Officer QA

15-Dec-2012

Manufactured for Torpac Inc. under exclusive contract by Custom Capsules Pvt. Ltd., B-8/1, Tarapur MIDC Boisar-401506, and Maharashtra, India. Manufacturing License No. KD/33.