

## Certificate of Analysis

<b>Product: Empty Porcine Hard Gelatin Capsules</b>	Batch No.	VC180745
Capsule Size 07	Color Code Cap/Body	CT/CT
Date of Manufacture JANUARY 2018	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<sup>o</sup>-80<sup>o</sup>F (15<sup>o</sup>-25<sup>o</sup>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 (AA)

Gelatin Porcine	85.500%	No Colorants Used
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Colorant when applicable meets with Directive 78/25/EEC & Council Directive 93/45/EC.

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.

As Permitted in ICH Q3C, USP-467 & Ph. Eur General text 5.4, Class 3 solvents may be used up to 5000 ppm or 0.5 % under Option 1.

### Empty Porcine Hard Gelatin Capsule Specification

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

This product is manufactured from Porcine gelatin certified by USDA or European Union Veterinary Officials processed according Regulation (EC) No. 853/2004 and compliant to 1069/2009 as amended by 142/2011.

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 Transmissible Spongiform Encephalopathy including BSE.

This product meets applicable specifications of US Pharmacopoeia Edition USP39-NF34, Japanese Pharmacopoeia 17<sup>th</sup> Edition and European Pharmacopoeia 9<sup>th</sup> Edition.

GMP+ FSA Assured. This product is manufactured under registration PDV 114350 and can be used in animal feed.

This product meets US Federal Standard 285A and US Federal Specification U-C-115b for acid solubility and water resistance.

This product is GMO free complying with Regulation (EC) No. 1829/2003 and does not require labeling as per 1830/2003.

This product is free from Melamine contamination complying with Commission Regulation (EU) No. 574/2011.

Characteristics (Test)	Specification	Result	
Moisture (loss on drying)	13%- 15% w/w	Complies	13 - 14 %
Disintegration time	Not more than 15 minutes	Complies	08 minutes
Average wt. (Lot of 100 capsules)	192 gms +/- 10%	Complies	193 gms
Total Aerobic microbial count	Not more than 1000 cfu/gm.	Complies	Less than 500cfu/gm.
<i>Escherichia coli</i>	Absent in one gram.	Complies	Absent in one gram.
<i>Salmonella species</i>	Absent in ten grams.	Complies	Absent in ten grams.
<i>Pseudomonas aeruginosa</i>	Absent in one gram.	Complies	Absent in one gram.
<i>Staphylococcus aureus</i>	Absent in one gram.	Complies	Absent in one gram.
Total combined Yeast and Mold count	Not more than 100cfu/gm.	Complies	Less than 100cfu/gm.

The capsules are manufactured under controlled conditions in accordance with cGMP. Continuous control maintained throughout the process guarantees 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 US 46, Fairfield, NJ 07004, USA. Tel.: 1-973-244-1125 Fax: 1-973-244-1365**

**www.torpac.com, e-mail: info37@torpac.com**

This lot of capsules described is hereby certified to you.



**Name: GEETHA KARTHIKEYAN**

**Title: SENIOR MANAGER QA & RA.**

6-Feb.-2018

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.

GRN 21233