



Erawat Pharma Limited

MANUFACTURERS OF EMPTY HARD GELATIN CAPSULES

DECLARATION OF COMPLIANCE WITH EMEA 410/01 TSE/BSE DOCUMENT

NOTE FOR GUIDANCE ON MINIMISING THE RISK OF TRANSMITTING ANIMAL ENCEPHALOPATHIES VIA HUMAN AND VETERINARY MEDICINAL PRODUCTS

Product:	EMPTY HARD GELATIN CAPSULE SHELLS
Supplier Information:	
Name of company:	<u>ERAWAT PHARMA LIMITED</u>
Address of company:	<u>302, ANU APARTMENT, 21-22 SHANKAR NAGAR, SAKET, INDORE - 452 018, MP - INDIA</u>
Telephone number:	<u>0091-731-4259107</u>
Manufacturer Information:	
Name of company:	<u>ERAWAT PHARMA LIMITED</u>
Address of company:	<u>512, IND AREA NO. 3, PITHUMPUR, SAGORE, DISTRICT DHAR 454 774, M.P., INDIA</u>
Telephone number:	<u>0091-7292-256243</u>
Is the product produced or derived from any constituent of animal origin?	YES
Does the equipment used in the manufacturing process of the product come into contact with a substance derived from animal origin?	YES
The materials concerned by this declaration are materials used for the preparation of	
	<u>EMPTY HARD GELATIN CAPSULE SHELLS</u>
Details on the Material of animal origin (GELATIN)	
Bovine (Section 3.2.1.1 of the guide)	YES
Small Ruminants (Section 3.2.1.2 of the guide)	NO
Non-Ruminant	NO





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Only for Ruminant Materials: (for gelatin)		
Origin of Ruminant Animals:	INDIA	
Source animals (Section 3.2)	YES, the animals used are fit for human consumption	
Animals as Source of Material Comply with EMEA/410/01	Section 3.2.1.1	Section 3.2.2. Closed Bovine Herds
	GBR Assessment: '2'	YES
Parts of Animal According to EMEA/410/01 (Chapter 3.3)	Category - C, Bovine Bones	
Material Processing – Description of Manufacturing Process including in process controls (Chapter 3.5)	We purchase gelatin from manufacturer sourcing bones which are controlled under Category - C tissues only. We take relevant certificates and documents from our supplier on this. The bones are subjected to a process of Degreasing, acid demineralisation, alkaline treatment, filtration, sterilization at > 138° C for a minimum of 4 sec.	
Cleaning Process, Removal/Inactivation Validation, According to EMEA/410/01 (Chapter 3.5)	Yes Cleaning process applies as low injectivity tissues from category - C are used.	
Quantity of Tissue Used for Manufacturing of 1kg of the Above Mentioned Product	7 Kgs of bones are required to manufacture 1 Kg gelatin.	

We purchase Gelatin only from suppliers who follow quality assurance systems and are ISO 9000, HACCP & GMP compliant.

Name: Amit Jain
Position: Director
Date: July 18, 2008
Signature: *Amit Jain*

