



# 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

<b>Product:</b>	EMPTY HARD GELATIN CAPSULE SHELLS
<b>Supplier Information:</b>	
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>
<b>Manufacturer Information:</b>	
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>
<b>Is the product produced or derived from any constituent of animal origin?</b>	YES
<b>Does the equipment used in the manufacturing process of the product come into contact with a substance derived from animal origin?</b>	YES
<b>The materials concerned by this declaration are materials used for the preparation of</b>	
	<b><u>EMPTY HARD GELATIN CAPSULE SHELLS</u></b>
<b>Details on the Material of animal origin (GELATIN)</b>	
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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<b>Only for Ruminant Materials:</b> (for gelatin)		
<b>Origin of Ruminant Animals:</b>	INDIA	
<b>Source animals (Section 3.2)</b>	YES, the animals used are fit for human consumption	
<b>Animals as Source of Material Comply with EMEA/410/01</b>	Section 3.2.1.1	Section 3.2.2. Closed Bovine Herds
	GBR Assessment: '2'	YES
<b>Parts of Animal According to EMEA/410/01 (Chapter 3.3)</b>	Category - C, Bovine Bones	
<b>Material Processing - Description of Manufacturing Process including in process controls (Chapter 3.5)</b>	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.	
<b>Cleaning Process, Removal/Inactivation Validation, According to EMEA/410/01 (Chapter 3.5)</b>	Yes Cleaning process applies as low infectivity tissues from category - C are used.	
<b>Quantity of Tissue Used for Manufacturing of 1kg of the Above Mentioned Product</b>	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.		
<b>Name:</b>	Amit Jain	
<b>Position:</b>	Director	
<b>Date:</b>	July 18, 2008	
<b>Signature:</b>		

