VitaCyte®
Unravelling Cell Isolation

CERTIFICATE OF ORIGIN

DE Collagenase 100/10

Version 1 May 2019

COUNTRY OF ORIGIN

DE Collagenase 100, Catalog #011-1010 and DE Collagenase 10, Catalog #011-1110 are manufactured entirely within the United States by VitaCyte LLC.

STATEMENT OF ANIMAL ORIGIN

None of the components used in the formulation of DE Collagenase 100/10 use or come into contact with any ingredient of bovine origin during the manufacturing process. Porcine gelatin peptone is used during the fermentation of the *Clostridium histolyticum* organism to stimulate the collagenase biosynthesis. Prior to inoculation with the organism, the culture media is sterilized for 30 minutes at 121°C, a process shown to inactive many viruses.[1] No animal sourced materials are used during the collagenase purification process which largely removes culture media components. No animal sourced materials are used in the fermentation or purification of the BP Protease. The final product is formulated with a non-mammalian gelatin peptone based excipient.

RISK OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPAHTY

The use of porcine derived components represents a minimal risk of Transmissible Spongiform Encephalopathy (TSE). No evidence exists for naturally occurring TSE in pigs or transmission to pigs from infected tissue.[2]

Signatures:

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[1] International Federation for Animal Health Europe. Viral Inactivation Related to Steam Sterilisation of Biological Products. http://www.ifaheurope.org/ifah-media/publications/215-viral-inactivation-1.html; 2012 (Retrieved 19 Dec 2016)
[2] Wells, G.A.H.; et al. Portrait of experimental BSE in Pigs. In: Hornlimann, B.; Riesner, D.; Kretzschmar, H., eds. Prions in humans and animals. New York/Berlin: Walter de Gruyter; 2007: 275-278.

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