



Chirogate International Inc.
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**LETTER OF DECLARATION OF
MANUFACTURE REGARDING THE RISK
OF
TRANSMITTING AGENTS OF ANIMAL SPONGIFORM
ENCEPHALOPATHIES**

To whom it may concern:

We, Chirogate International Inc., hereby confirm that materials used in the manufacturing process of Misoprostol 1% HPMC Dispersion is not derived from animal or human origin which are susceptible to Transmissible Spongiform Encephalopathy (TSE) / Bovine Spongiform Encephalopathy (BSE) (*cf. Ph. Eur. Chapter 5.2.8 Minimizing the risk of transmitting animal spongiform encephalopathy agents via medicinal products and the related general monograph no. 1483*).

The raw material used in manufacturing process of Misoprostol 1% HPMC Dispersion is purely synthetic chemical and it is not derived product from plant or fermentation/cell culture origin.

Please note that the above information provided is based on the technical knowledge and information possessed by us presently.

Sincerely yours,

Jason Lin
Quality Unit Director
Chirogate International Inc.