Sectoral Annex

Medicinal Products/ Drugs Good Manufacturing Practices (GMP)

to carry out the following operations:

+ complete manufacture (***)

+ partial manufacture (***), i.e. (detail of operations authorized):

for the following medicinal product:

for human use/use in animals (***).

From the knowledge gained during inspections of this manufacturer, the latest of which was conducted on/.... (date), it is considered that the company complies with the Good Manufacturing Practice requirements referred to in the Agreement on Mutual Recognition relating to Conformity Assessment between Canada and the EEA EFTA States.

..../.... (date)

For the Competent Authority,

(Name and signature of the office responsible)

| (*) | : | insert exporting or importing firm or requesting authority |
|-------|---|--|
| (**) | : | insert name and country of the Competent Authority |
| (***) | : | delete that which does not apply |

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