Appendix 7

CERTIFICATE OF PHARMACEUTICAL MANUFACTURER IN THE FRAMEWORK OF THE AGREEMENT ON MUTUAL RECOGNITION BETWEEN CANADA AND THE EUROPEAN COMMUNITY, SECTORAL ANNEX ON MEDICINAL PRODUCTS GMP INSPECTION AND BATCH CERTIFICATION

As requested by the .....
(*) on ...../...../..... (date) (reference: .....), the Competent Authority of ..... (**) confirms the following:

The company .....
whose legally registered address is: .....
.....
.....
has been authorized, under Directive 75/319/EEC, Article 16, and Directive 81/851/EEC, Article 24, transposed in the national legislation of ..... (**), under the authorization reference number .....
covering the following site(s) of manufacture (and contract testing laboratories, if any):
1 .....
.....
2 .....
.....
3 .....
.....
to carry out the following manufacturing operations:

+ complete manufacture (***)

+ partial manufacture (***), i.e. (detail of manufacturing 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 between Canada and the European Community.

..../..../.... (date) For the Competent Authority,

(Name and signature of the officer responsible)

(*) : insert exporting or importing firm or Health Canada
(**) : insert European Community Member State or European Community as required
(***) : delete that which does not apply