Appendix 2: Table of information required in applications for evidentiary documents for good manufacturing practices for medicinal products

I. Western medicinal products

The following application documents shall be submitted when applying for evidentiary documents for good manufacturing practices for medicinal products:

- (1) An application form for evidentiary documents.
- (2) The manufacturing license for domestically produced medicinal products, or photocopies of the approval document showing conformity by a foreign manufacturer of imported medicinal products with the Pharmaceutical Good Manufacturing Practice Regulations.
- (3) Evidentiary documents showing the manufacturer's registration.
- (4) A photocopy of the pharmaceutical firm license.

II. Chinese herbal medicine products

The following application documents shall be submitted when applying for "Evidentiary documents for good manufacturing practices for medicinal products":

- (1) An application form for evidentiary documents.
- (2) A photocopy of the manufacturing license for domestically produced medicinal products or the approval document for a foreign manufacturer of imported medicinal products in conformity with the Pharmaceutical Good Manufacturing Practice Regulations.
- (3) Evidentiary documents showing the manufacturer's registration.
- (4) A photocopy of the pharmaceutical firm license.

III. Medical devices

The following application documents shall be submitted when applying for "evidentiary documents for good manufacturing practices for medical devices":

- (1) An application form for evidentiary documents for good manufacturing practices for medical devices.
- (2) The manufacturing license for domestically produced medical devices or a photocopy of the approval document showing conformity by a foreign manufacturer of imported medical devices with the Pharmaceutical Good Manufacturing Practice Regulations.