Accreditation Category

1. Category of Accreditation of Foreign Manufacturers

Under the provision of Article 36 of the Pharmaceutical Affairs Law Enforcement Regulations, the category of the accreditation of a foreign manufacturer shall be as specified below.

(1) Drugs (excluding *in vitro* diagnostic reagents)

Articles	
Article 36, Paragraph 1, Item 1	Accreditation for all or part of the manufacturing process of the drugs specified under Article 80, Paragraph 2, Item 3-A, 3-C and 3-D of the Ordinance (e.g. biologics, drugs with national certificate, drugs produced by recombinant DNA technology, drugs using cell culture technology, cell/tissue therapy drugs, and specified biological products)
Article 36, Paragraph 1, Item 2	Accreditation for all or part of the manufacturing process of radiopharmaceuticals (excluding drugs indicated in the preceding item)
Article 36, Paragraph 1, Item 3	Accreditation for all or part of the manufacturing process of sterile drugs (excluding manufacturing processes indicated in Item 5)
Article 36, Paragraph 1, Item 4	Accreditation for all or part of the manufacturing process of drugs other than those indicated in the preceding three items (excluding manufacturing processes indicated in the next item)
Article 36, Paragraph 1, Item 5	Accreditation for only the process of packaging, labeling or storage among the manufacturing processes indicated in the preceding two items

(2) *In vitro* Diagnostic Reagents

Articles	
Article 36, Paragraph 2, Item 1	Accreditation for all or part of the manufacturing process of radiopharmaceuticals
Article 36, Paragraph 2,	Accreditation for all or part of the manufacturing

Item 2	process of drugs other than those indicated in the preceding item (excluding manufacturing processes indicated in the next item)
Article 36, Paragraph 2, Item 3	Accreditation for only the process of packaging, labeling or storage among the manufacturing processes of the drugs specified in the preceding item

(3) Quasi-drugs

Articles	
Article 36, Paragraph 3, Item 1	Accreditation for all or part of the manufacturing process of sterile quasi-drugs (excluding manufacturing processes indicated in Item 3)
Article 36, Paragraph 3, Item 2	Accreditation for all or part of the manufacturing process of quasi-drugs other than those indicated in the preceding item (excluding manufacturing processes indicated in the next item)
Article 36, Paragraph 3, Item 3	Accreditation for only the process of packaging, labeling or storage among the manufacturing processes of quasi-drugs

(4) Medical Devices

Articles	
Article 36, Paragraph 4, Item 1	Accreditation for all or part of the manufacturing process of the medical devices designated by the Minister pursuant to the provisions of Article 43, Paragraph 2 of PAL as well as of the medical devices designated by the Minister as requiring due caution to be exercised in their manufacturing control and quality control pursuant to the provisions of Article 80, Paragraph 2, Item 3 of the Ordinance (e.g. cell/tissue therapy drugs, and specified biological products)
Article 36, Paragraph 4, Item 2	Accreditation for all or part of the manufacturing process of sterile medical devices (excluding manufacturing processes indicated in the Item 4)
Article 36, Paragraph 4,	Accreditation for all or part of the manufacturing

Item 3	process of medical devices other than those indicated in the preceding two items (excluding manufacturing processes indicated in the next item)
Article 36, Paragraph 4, Item 4	Accreditation for only the process of packaging, labeling or storage among the manufacturing processes of medical devices indicated in the preceding two items

Note: When a foreign manufacturer takes part of the manufacturing process of sterile medical devices but has no facilities for sterilization in their establishment, the accreditation category is not sterile medical devices (Article 36-4 (2) of the PAL Enforcement Regulations), but general medical devices (Article 36-4 (3) of the Regulations).