A written GMP confirmation of Japanese authorities is required.

As Japan is included in a list of third countries ensuring a level of protection of public health equivalent to that of EU (on and after 2 July 2013):

- Under the Pharmaceutical Affairs Law (PAL), when a manufacturer in Japan exports an API to overseas markets, it is required that the API and its manufacturing site are complied with Japanese GMP requirements, but it does not guarantee those are complied with the EU GMP requirements.
- The EU has not control any APIs exported from foreign countries.

※APIs: active pharmaceutical ingredients are regulated as drugs under PAL in Japan