

Dear Sir or Madam,

Re: Comment on the consultation paper for Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Type of the company: API manufacturer/Big-sized enterprise/P.R.China

We have the following comments on the consultation letter:

1. If a company has an EU GMP certificate, we don't think it is necessary to issue the confirmation letter. The GMP certificate can be an evidence that the API be manufactured in accordance with EU GMP.
2. According to the local legislation, the local authority can only ensure API manufactured in accordance with the local GMP. It is not the responsibility of local authority to confirm the other GMP compliance of the API.

Sincerely yours

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