

(LETTERHEAD OF COMPETENT AUTHORITY)

Certificate No: ___/___/___

**CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER
ISSUED UNDER THE PROVISIONS OF THE MUTUAL RECOGNITION AGREEMENT
BETWEEN THE EC AND [MRA partner]**

As requested by on/...../.....
(date), the competent authority of.....(Country) confirms the following:

The company,
whose legally registered address is:
.....
.....
.....

has been authorised, in accordance to Directive 2001/83/EC, Article 40, or Directive 2001/82/EC,
Article 44, or Directive 2001/20/EC, Article 13 (delete as appropriate)
transposed in the following national legislation:

.....
.....
.....

under the authorisation reference number,
covering the following sites of manufacture:

- 1.....
- 2.....

to carry out the following operations:

+ manufacture of (investigational^{*}) medicinal products for human use / veterinary use
(*)

+ total/partial manufacture
of the following (investigational^{*}) medicinal product or group of products for human use /
veterinary use (*):

.....
.....

in the following dosage forms: (see overleaf).

(*): delete that which does not apply

From the knowledge gained during inspection 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 of Mutual Recognition between the European Community and
[MRA partner].

This certificate remains valid for three years from the date of last inspection.

...../...../..... (date) Name and signature of the authorised person of the Competent Authority of
(country)

.....
(name, title, national authority, phone & fax numbers)

Dosage forms of which manufacture is authorized (*):

Sterile products:

- Liquid dosage forms (Large Volume Parenterals)
 - aseptically prepared
 - terminally sterilized
- Liquid dosage forms (Small Volume Parenterals)
 - aseptically prepared
 - terminally sterilized
 - eye drops
- Semi-solid dosage forms
- Solid dosage forms
 - solid fill
 - freeze-dried

Non-sterile products:

- Liquid dosage forms
- Semi-solid dosage forms
- Solid dosage forms
 - unit dose form (tablets, capsules, suppositories, pessaries)
 - multi dose form (powders, granules)

Biological products:

- Vaccines
- Sera
- Blood products
- Allergens
- Other (describe: e.g. hormones, enzymes of human or animal origin, genetically engineered products)

Packaging only:

- Liquid dosage form
- Semi-solid dosage form
- Solid dosage form

(*: delete that which does not apply).