European Medicines Agency
Inspections

London, 4 March 2005
Doc. Ref. EMEA/INS/GMP/15331/2005

(LETTERHEAD OF COMPETENT AUTHORITY)

Certificate No: _ _ _/_ _ _/_ _

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER
Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC or Art. 80(5) of Directive 2001/82/EC.*

or

Issued under the provisions of the Mutual Recognition Agreement between the European Community and *[MRA Partner].**

The competent authority of.....*[Member State]* confirms the following:
The manufacturer……..
Site address…….
……..

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. …… in accordance with Art. 40 of Directive 2001/83/EC/ Art. 44 of Directive 2001/82/EC/ Art. 13 of Directive 2001/20/EC* transposed in the following national legislation:
….....……*

or

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 8(2)/33(2)/19(3)/44(3)* of Regulation (EC) 726/2004* or Art. 111(4) of Directive 2001/83/EC/Art. 80(4) of Directive 2001/82/EC transposed in the following national legislation:
….....……*

*and/or**

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC/ Art. 80(1) of Directive 2001/82/EC* transposed in the following national legislation:
….....….....……*

or

Other (please specify):……*

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on …../...…/..…. *[date],* it is considered that it complies with the Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Community and *[MRA partner]/*The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC/Directive 91/412/EC/The principles of GMP for active substances.*

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted.

The authenticity of this certificate may be verified with the issuing authority.

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Part 2

Human Medicinal Products*
Veterinary Medicinal Products*
Human Investigational Medicinal Products* for phase I, II, III clinical trials*

1 Manufacturing operations authorised/subject to inspection*	
- importation, partial manufacturing, quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant section. - if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other potentially hazardous active ingredients this should be stated under the relevant product type and dosage form.	
1.1	Sterile Products 1.1.1 aseptically prepared (list of dosage forms) 1.1.2 terminally sterilised (list of dosage forms) 1.1.3 testing or batch release only (list of dosage forms)
1.2	Non-sterile products (list of dosage forms) 1.2.1 testing and batch release only (list of dosage forms)
1.3	Biological medicinal products (specify product types under the relevant sections eg. allergens, antibodies, vaccines, viral vaccines, rDNA etc.) 1.3.1 Blood products 1.3.2 Immunological products 1.3.3 Cell therapy products 1.3.4 Gene therapy products 1.3.5 Biotechnology products 1.3.6 Human or animal extracted products 1.3.7 testing and batch release only (list of product types/ dosage forms)
1.4	Other products or manufacturing activity (any other relevant manufacturing activity/ product type that is not covered above e.g. sterilisation of active substances, manufacturing of biological active starting materials, medicinal gases, herbal or homoeopathic products, bulk or partial manufacturing etc.)
1.5	Packaging only 1.4.1 Primary packing (list of product types/dosage forms) 1.4.2 Secondary packing
1.6	Quality Control testing (optional list of analysis techniques)
1.7	Blinding

Manufacture of active substance. Names of substances subject to inspection*:
……
……

Any restrictions or clarifying remarks related to the scope of this certificate*:
……
……
……

…../……/..... *[date]*

Name and signature of the authorised person of the Competent Authority of *[country]*[1]

……
[name, title, national authority, phone & fax numbers]

(*): delete that which does not apply.

[1] The signature, date and contact details should appear on each page of the certificate.