



IRISH MEDICINES BOARD

Certificate No: 2006-220

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER Part 1

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

The competent authority of *Republic of Ireland* confirms the following:

The manufacturer: *Charles River Laboratories BioLabs Europe Limited*

Site address: *Carrentrila, Ballina, Co. Mayo*

Has been inspected under the national inspection programme in connection with laboratory authorisation no. *L006* in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:

Medical Preparations, (Licensing of Manufacture) Regulations 1993-1996

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on *13th September 2006*, it is considered that it complies with the Good Manufacturing Practice requirements referred to in the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.

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.

Part 2

Human Medicinal Products*

1 MANUFACTURING OPERATIONS *

- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary;

- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;

- 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 or potentially hazardous active ingredients this should be stated under the relevant product type and dosage form.

1.6

Quality control testing

1.6.1 Microbiological: sterility

1.6.2 Microbiological: non-sterility

1.6.4 Biological

6th March 2007

Name and signature of the authorised person of the
Competent Authority of *Republic of Ireland*

Patrick Keating, Irish Medicines Board

Bord Leigheasra na hÉireann

Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2. Tel: 353-1-676 4971 Fax: 353-1-676 7836
Website: www.imb.ie

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