

## CERTIFICATE OF GMP COMPLIANCE OF A QUALITY CONTROL LABORATORY

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC and Art. 80(5) of Directive 2001/82/EC as amended and Art. 15 of Directive 2001/20/EC

The competent authority in Sweden confirms the following:

The laboratory: **ALS Scandinavia AB / 556571-8318**

Site address: Aurorum 10  
Luleå

Postal address: Aurorum 10  
SE-977 75 Luleå  
Sweden

has been inspected under the national inspection programme for independent Contract Research Organisation (CRO) which performs quality control testing for pharmaceutical manufacturer in accordance with Art. 40 of Directive 2001/83/EC and Art. 44 of Directive 2001/82/EC and Art. 13 of Directive 2001/20/EC transposed in the following national legislation: LVFS 2004:7.

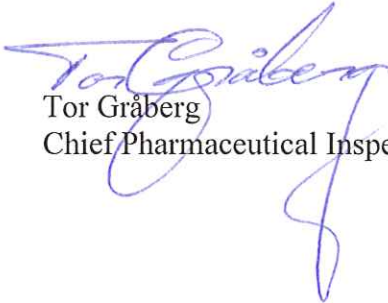
From the knowledge gained during inspection of this laboratory, the latest of which was conducted on 11 December, 2009, it is considered that it complies with the Good Manufacturing Practice requirements referred to in The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.

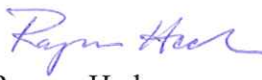
This certificate reflects the status of the laboratory at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted. The authenticity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

### Quality control testing

Chemical/Physical testing for release of Medicinal Products.

On behalf of the Medical Products Agency

  
Tor Gråberg  
Chief Pharmaceutical Inspector

  
Ragnar Hede  
Pharmaceutical Inspector