



CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

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

The competent authority of *Denmark* confirms the following:

The manufacturer **Akzo Nobel Salt A/S**
Site address **Hadsundvej 17**
DK-9550 Mariager

is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation: (*Consolidated*) *Medicinal Products Act, 2005, as amended* *

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **September 30th 2010**, it is considered that it complies with the Good Manufacturing Practice requirements referred to in:

The principles of GMP for active substances referred to in Article 47 of Directive 2001/83/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.

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

Sanal P
Sanal P+
Sanal SQ

Any restrictions or clarifying remarks related to the scope of this certificate: **None**

Date: *November 8th 2010*

Name and signature of the authorised person of the competent authority of Denmark:

Poul Vibholm Petersen

The Danish Medicines Agency

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