INGENIØRFORENINGEN I DANMARK

Certificate

13th and 14th June, 2003

BASIC GMP

Good Manufacturing Practice

Christian Boldsen Knudsen

has attended this GMP course

The content was related to the requirements given by the Pharmaceutical Industry based upon EUDRALEX vol. 4 1998, cGMP for Bulk Pharmaceutical Ingreedients 1996 and ICH-API guide 2000. The following GMP subjects were explained. Validation topics and type of documents were discussed in working groups.

GMP principles and guidelines

Administration and Personnel

Premises and Equipment

Maintenance and Calibration

GMP production

Cross-contamination and Cleaning Validation

User Requirement Specification

Validation Terms and Documentation

Documentation

Quality Assurance / Quality Control

Selfinspection

GMP versus ISO 9000

QC laboratory

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