

**STATEMENT ON GOOD MANUFACTURING PRACTICES FOR
PHARMACEUTICAL STARTING MATERIALS (API)**

This one-page certificate conforms to the format recommended
by the World Health Organization

On the basis of our inspection carried out on: January 14 and 15; 2008

we certify that the site indicated on this certificate complies with Good Manufacturing Practices for active pharmaceutical ingredients according to The Rules governing Medicinal Products in the European Union, Volume 4 Part 2, for the dosage forms, categories and activities listed in Table 1.

Name and address of site:

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H5-206
CGMP-API-IV
Bio

Table 1

Product / Product category:

Ramipril	Salmeterol Xinafoate	Carbamazepine
Quinapril Hcl	Ipratropium Bromide	Oxcarbazepine
Benazepril Hcl	Gemcitabine Hcl	Bupropion Hydrochloride
Perindopril tert-butylamine	Bicalutamide	Fluticasone Propionate
Ranolazine Di- Hcl / Base	Ifosfamide	Mometasone Furoate
Lacidipine	Mesna	Desonide
Budesonide	Mercaptopurine	Triamcinolone acetonide
R-Salbutamol Sulphate	Irinotecan Hydrochloride	Adapalene
Levalbuterol Tartrate	Venlafaxine Hcl	Aminophylline
Levalbuterol Hcl	Quetiapine Hemifumarate	

Dosage form(s):

Bulk

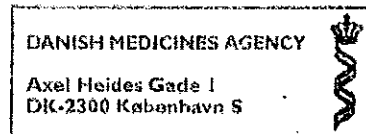
Activity(ies):

Manufacturing of API, Quality Control

The responsibility for the purity and quality of the individual batches of the active pharmaceutical ingredients manufactured through the process lies with the manufacturer.

This certificate remains valid for three years from the date of last inspection.

This certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.



Doris Heideberg Lyndby
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