CERTIFICATE OF GOOD MANUFACTURING PRACTICE (GMP) for ACTIVE PHARMACEUTICAL SUBSTANCES

Written confirmation for active substances exported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Confirmation no

1. *Name of Site (including building number, where applicable):* 厂名
   Address: 厂址
2. *Manufacturer's license number*: **Not Applicable**

REGARDING THE MANUFACTURING PLANT UNDER (1) OF THE FOLLOWING ACTIVE SUBSTANCE(S) EXPORTED TO THE EU FOR MEDICINAL PRODUCTS FOR HUMAN USE

Active substance(s) (INN name):	Activity(ies):[1]
品种	

THE REGISTRAR OF MEDICINES, MEDICINES CONTROL COUNCIL, DEPARTMENT OF HEALTH OF THE REPUBLIC OF SOUTH AFRICA, HEREBY CONFIRMS THAT:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (=GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the Registrar of Medicines, South Africa without delay to the EU at email:

3. *Date of the inspection of the plant under (1):* **14 – 17 November 2011**
4. *Name of the inspecting authority if different from the issuing regulatory authority:* **FDA USA**
5. *This written confirmation remains valid until:* **30 June 2016**

The authenticity of this written confirmation may be verified with the Registrar of Medicines, Medicines Control Council, Department of Health, South Africa.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC

Address of the issuing regulatory authority:
REGISTRAR OF MEDICINES, DEPARTMENT OF HEALTH, PRIVATE BAG X828, PRETORIA, 0001

Name and function of the responsible person: **Bafana Malaza, Chief Medicines Control Officer**
E-mail:

SIGN
DATE

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