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STATE ADMINISTRATION OF UKRAINE ON MEDICINAL PRODUCTS (SAUMP)

WRITTEN CONFIRMATION FOR ACTIVE SUBSTANCES

exported to 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 and address of site (including building number, where applicable):

廠名 + 廠址

2. Manufacturer's licence number(s):

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):[1]	Activity(ies):[2]
品項名稱	

STATE ADMINISTRATION OF UKRAINE ON MEDICINAL PRODUCTS (SAUMP) HEREBY CONFIRMS THAT:

The standards of good manufacturing practice applicable to this manufacturing plant are equivalent to those laid down in the EU;

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 a protection of public health equivalent to that in the EU;
and
In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.[3]

Date of inspection of the plant under:

This written confirmation remains valid until:

The authenticity of this written confirmation may be verified with the SAUMP.

Address of the SAUMP:

E-mail, Telephone no., and Fax no.:

Name and function of responsible person:

Head of State Administration of Ukraine on Medicinal Products

Stamp

[1] Identification of the specific active substances through an internationally-agreed terminology (preferably international nonproprietary name).
[2] For example. 'Chemical synthesis', 'Extraction from natural sources', 'Biological processes', 'Finishing steps'.
[3] qdefect@ema.europa.eu