

土耳其 ->

REPUBLIC OF TURKEY
MINISTRY OF HEALTH
TURKISH MEDICINES AND MEDICAL DEVICES AGENCY

Written confirmation for active substances imported 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. (given by the Issuing regulatory authority):

1. Name and address of site:

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

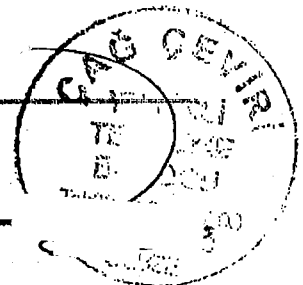
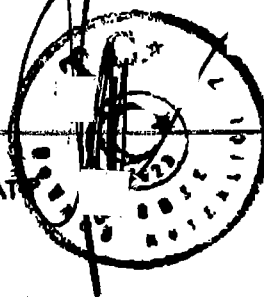
Active substance(s):	Activity(ies):
• <u>2</u> <u>20</u>	Chemical Synthesis
•	Chemical Synthesis, Purification, Milling
•	Chemical Synthesis, Purification, Milling
•	Chemical Synthesis, Purification, Milling, Micronization
•	Chemical Synthesis, Milling, Micronization
•	Chemical Synthesis, Purification
•	Chemical Synthesis, Purification Milling
•	Chemical Synthesis, Purification, Milling
•	Chemical Synthesis, Purification, Milling
•	Chemical Synthesis, Purification, Milling
•	Chemical Synthesis
•	Chemical Synthesis

HEREBY CONFIRMS THAT:

The standards of good manufacturing practice applicable to this manufacturing plant are at least 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 at least equivalent to that in the EU; and

Gebze J. Nöbetçi
SERPİL BİÇİCİ
Yerine İmzaya Yetkili BAŞKAT
JÜLİDE KOŞTU



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.

Date of Inspection of the plant under (1).

The Written Confirmation remains valid until

The authenticity of this written confirmation may be verified with the issuing regulatory authority.

Address of the issuing regulatory authority:

Name and function of responsible person:

YILDIZ YILDIZIN
Kurum Başkanı / President

Signature

Stamp of the authority and date



Gebze 3. Noteri
SERPİL BIÇICI
Yerine İmzaya Yetkili BAŞKATİP
JÜLİDE KOŞTU

