



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

1. Name and address of site: M/s. Quantum Drugs & Chemicals,  
C-21, SIPCOT Industrial Complex,  
Manamadurai - 630606, Sivaganga District,  
Manamadurai.

2. Manufacturer's licence number: 936/2012

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

List of API(s):

| S. No. | Active substance(s)      | Activity(ies)           |
|--------|--------------------------|-------------------------|
| 1      | CHLORPROPAMIDE BP/USP/EP | Manufacturing & Packing |
| 2      | TOLBUTAMIDE BP/USP/EP    | Manufacturing & Packing |

ITEM(s) Two (02) Only  
And as per annexure(s) enclosed

The issuing Regulatory Authority 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 (= 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 a 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 exporting third country without delay to the EU.

Date of Inspection of the plant: 02.12.2024 & 03.12.2024

The Written Confirmation remains valid until: Three years from the date of issue

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

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: Central Drugs Standard Control Organisation  
FDA Bhawan, Kotla Road,  
New Delhi- 110 002, India

Name and function of responsible person: Ranga Chandrashekar,  
Joint Drugs Controller (India)

E-mail: ranga.cs@cdsco.nic.in;

Telephone no.: +91-11-23236965

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Signature

*Chandrashekar Ranga*  
चंद्रशेखर रंगा/Chandrashekar Ranga  
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)  
केन्द्रीय औषधि अधिकारिका संगठन (संयुक्तता), स्वास्थ्य सेवा महानिदेशालय  
C.D.S.C.O.(Hq), Dte. General of Health Services  
स्वास्थ्य और परिवार कल्याण विभाग / Ministry of Health and Family Welfare  
एन.डी.ए. भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date



04 JUL 2025