

## Steps before prequalification

### I. BACKGROUND INFORMATION ON THE PROCEDURE

#### 1. Submission of the dossier

The company Medopharm Private Limited submitted in 2021 an application for [NT012 trade name]\* (NT012) to be assessed with the aim of including [NT012 trade name] in the list of prequalified medicinal products for neglected tropical diseases.

[NT012 trade name] was assessed according to the ‘*Procedure for Assessing the Acceptability, in Principle, of Pharmaceutical Products for Purchase by United Nations Agencies*’ by the team of WHO assessors. The assessors are senior experts, mainly from national authorities, invited by WHO to participate in the prequalification assessment process.

#### 2. Steps taken in the evaluation of the product

|                         |  |
|-------------------------|--|
| July 2021               | During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested             |
| July and September 2021 | During the meetings of the assessment team the quality data were reviewed and further information was requested.                       |
| September 2021          | The applicant’s response letter was received.  |
| September 2021          | During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested. |
| October 2021            | The applicant’s response letter was received.  |
| November 2021           | The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.                                     |
| November 2021           | The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.  |
| January 2022            | The applicant’s response letter was received.  |
| January 2022            | During the meeting of the assessment team the additional quality data were reviewed and further information was requested.             |
| March 2022              | The applicant’s response letter was received.  |
| March 2022              | During the meeting of the assessment team the additional quality data were reviewed and further information was requested.             |
| May 2022                | The applicant’s response letter was received.  |
| May 2022                | During the meeting of the assessment team the additional quality data were reviewed and further information was requested.             |
| June 2022               | The applicant’s response letter was received.  |
| July 2022               | During the meeting of the assessment team the additional quality data were reviewed and further information was requested.             |
| September 2022          | The manufacturer of the API was inspected for compliance with WHO requirements for GMP.  |
| September 2022          | The applicant’s response letter was received.  |

\* Trade names are not prequalified by WHO. This is the national medicines regulatory authority’s responsibility.

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| September and November 2022 | During the meetings of the assessment team the additional quality data were reviewed and further information was requested.   |
| December 2022               | The applicant's response letter was received.   |
| December 2022               | The additional quality data were reviewed and further information was requested.  |
| December 2022               | The applicant's response letter was received.   |
| December 2022               | The additional quality data were reviewed and further information was requested.  |
| January 2024                | A desk review for evaluation of compliance for the bioequivalence study for GCP/GLP met WHO requirements.   |
| October 2024                | The applicant's response letters were received.   |
| October 2024                | The additional quality data were reviewed and further information was requested.  |
| November 2024               | Due to concerns regarding GCP compliance, a new bioequivalence study was submitted. The safety and efficacy data were reviewed and further information was requested. |
| December 2024               | The applicant's response letters were received.   |
| December 2024               | The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.  |
| December 2024               | The quality data were reviewed and found to comply with the relevant WHO requirements.  |
| December 2024               | Product dossier accepted (quality assurance)  |
| 25 December 2024            | [NT012 trade name] was included in the list of prequalified medicinal products.   |

## II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

### 1. Manufacturer and Inspection status

#### Manufacturer of the finished product and responsible for batch release

Medopharm Private Limited

Unit II, No. 50, Kayarambedu Village

Guduvanchery - 603 202

Tamil Nadu,

India.

#### Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP.

A desk review for evaluation of compliance for the bioequivalence study for GCP/GLP met WHO requirements.

### 2. (Advice on) Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.

Further information is available at:

<https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>