

## Steps before prequalification

### I. BACKGROUND INFORMATION ON THE PROCEDURE

#### 1. Submission of the dossier

The company UNIVERSAL FARMA, S.L submitted in 2018 an application for Itraconazole 100 mg capsules, hard\* (HA704) to be assessed with the aim of including Itraconazole 100 mg capsules, hard in the list of prequalified medicinal products the treatment of HIV/AIDS related conditions.

Itraconazole 100 mg capsules, hard 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

March 2018	During the meeting of the assessment team the quality data were reviewed and further information was requested.
May 2018	The applicant’s response letter was received.
May 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2018	The applicant’s response letter was received.
July 2018	The quality data were reviewed and found to comply with the relevant WHO requirements
17 July 2018	Itraconazole 100 mg capsules, hard was included in the list of prequalified medicinal products.

Further information is available at:

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

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\* Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority’s responsibility Throughout this WHOPAR the proprietary name is given as an example only.

\*Formerly: “UNIVERSAL FARMA, S.L”