I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Guilin Pharm Co Ltd submitted in 2011 an application for Artesun® 30mg [*] (MA089) to be assessed with the aim of including Artesun® 30mg in the list of prequalified medicinal products for the treatment of tuberculosis.

Artesun® 30mg 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. The countries of origin of the assessors involved with Artesun® 30mg were Canada, Ethiopia, Germany, South Africa, Switzerland and Zimbabwe.

Licensing status:

Artesun® 30mg has been licensed / registered in countries:

Country Name	Registration number
Benin	N°6769/13
Burkina Faso	0744220122C000000
Cameroon	7451302
Cote d'ivoire	E-2013-085
Democratic Republic of the Congo (DRC)	1253/10/05/DGM/0055/2014
Gabon	5155/2013
Ghana	FDB/SD.133-12855
Guinea	2013/4554
Kenya	CTD388
Madagascar	27.1.1.129
Malawi	PMPB/PL397/4
Mali	2013-1348/MS-SG
Niger	14-5141-01
Nigeria	A4-9524
Sierra Leone	14-249
Tanzania	TZ12H036
Togo	SG.TG4350
Uganda	7590-6-11
Zambia	043/008

[*] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

2. Steps taken for the assessment of the product

Sept 2011	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Nov 2011	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Nov 2011	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Jan 2012	The company's response letter was received.
Jan 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2012	The company's response letter was received.
May 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2012	The company's response letter was received.
July 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2012	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Oct 2012	The company's response letter was received.
Nov 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Dec 2012	The company's response letter was received.
Jan 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2013	The company's response letter was received.
March 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2013	The company's response letter was received.
April 2013	The quality data were reviewed and found to comply with the relevant WHO requirements
April 2013	Product dossier accepted (quality assurance)
23 May 2013	Artesun® 30mg was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Guilin Pharmaceutical Co., Ltd.
No. 43 Qilidian Road
Guilin,
Guangxi,
China

Commitments for Prequalification

None which has an impact on the benefit-risk profile of the medicinal product.

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP and GLP.
Not inspected for GCP. Previous inspections by a stringent regulatory authority showed acceptable outcome.

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

Medicinal product subject to medical prescription.

Further information is available at:
www.who.int/prequal/