

**WHO Prequalification Programme**  
**WHO PUBLIC ASSESSMENT REPORT (WHOPAR)**

**[MA151 trade name]\***

**Dihydroartemisinin /Piperaquine phosphate 60 mg/480 mg Tablets**

[MA151 trade name], manufactured at Guilin Pharmaceutical Co., Ltd, Guilin, Guangxi, China, was included in the WHO list of prequalified medicinal products for the treatment of Malaria on 16 September 2020.

[MA151 trade name] is currently indicated for uncomplicated malaria in adults, children and infants. Detailed information on the use of this product is described in the summary of product characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredient(s) of [MA151 trade name] are Dihydroartemisinin and Piperaquine phosphate.

The efficacy and safety of Dihydroartemisinin and Piperaquine phosphate are well established based on extensive clinical experience in the treatment of malaria.

For details on the uses of this product and for side effects and warnings, see Part 4 of this WHOPAR (summary of product characteristics).

On the basis of data submitted and public information on the use of Dihydroartemisinin and Piperaquine phosphate, the team of assessors advised that [MA151 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA151 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [MA151 trade name]:**

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

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

<b>Initial acceptance</b>	<b>Date</b>	<b>Outcome</b>
<b>Status on PQ list</b>	16 September 2020	listed
Pharmaceutical quality	08 September 2020	MR
Bioequivalence	04 September 2020	MR
Safety, efficacy	NA	NA
<b>GMP (re-)inspection</b>		
API	04 May 2018	MR
FPP	19 October 2019	MR
<b>GCP/GLP (re-)inspection</b>	NA	NA
API: active pharmaceutical ingredient FPP: finished pharmaceutical product GCP: good clinical practice [quality standard] GLP: good laboratory practice [quality standard]	GMP: good manufacturing practice [quality standard] MR: meets requirements MR*: desk review (based on recent inspection reports) NA: not applicable, not available PQ: prequalification	