WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA479 trade name][1]

Ceftriaxone (sodium) 1 g powder for solution for injection

Abstract

[HA479 trade name] manufactured at Egyptian International Pharmaceutical Industries Company, Egypt was included in the WHO list of prequalified medicinal products for the treatment of bacterial infections in Human Immunodeficiency Virus (HIV)/AIDS patients on 16 May 2014.

[HA479 trade name] is indicated for the treatment of bacterial infections. 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 of [HA479 trade name] is ceftriaxone.

The efficacy and safety profile of ceftriaxone is well established based on extensive clinical experience in the treatment of bacterial infections.

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 ceftriaxone in bacterial infections, the team of assessors advised that [HA479 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA479 trade name] in the list of prequalified medicinal products.

[1] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

Summary of Prequalification Status for [HA479 trade name]:
The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

Initial acceptance	**Date**	**Outcome**
Status on PQ list	16 May 2014	listed
Pharmaceutical quality	07 April 2014	MR
Bioequivalence	28 April 2014	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	NA	NA
FPP	04 March 2013	MR
GCP/GLP (re-)inspection	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

Requalification	17 February 2023