WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA515 trade name]*

Ganciclovir (as sodium) 500mg powder for injection

[HA515 trade name], manufactured at Hainan Poly Pharm Co Ltd, Guilinyang Economic Development Area, Haikou, Hainan Province, China was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS related conditions on 20 December 2012

[HA515 trade name] is indicated for the treatment of sight-threatening or life-threatening cytomegalovirus (CMV) infection in HIV-infected patients. 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 [HA515 trade name] is ganciclovir (as sodium).

The efficacy and safety of ganciclovir (as sodium) are well established based on extensive clinical experience in the treatment of cytomegalovirus (CMV) infection in HIV-infected patients.

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 ganciclovir (as sodium) in tuberculosis, the team of assessors advised that [HA515 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA515 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA515 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	20 Dec 2012	listed
Quality	19 Dec 2012	MR
Bioequivalence	10 Dec 2012	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
API	23 Nov 2011	MR
FPP	16 May 2011	MR
GCP (re-)inspection	NA	NA
Batch Analysis	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 NA: not applicable, not available PQ: prequalification

The table represents the status of relevant completed activities only.

Requalification	17 May 2021

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