WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB351 trade name]*

Linezolid 600 mg Tablets

[TB351 trade name], manufactured at Celltrion Pharma Inc., Chungcheongbuk-do, Republic of Korea was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 6 February 2019

[TB351 trade name] is indicated in combination with other anti-tuberculosis agents for the treatment of tuberculosis caused by *Mycobacterium tuberculosis*. 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 ingredients of [TB351 trade name] is linezolid.

The efficacy and safety profile of [TB351 trade name] is well established based on extensive clinical experience in the treatment of tuberculosis.

On the basis of data submitted and public information on the use of [TB351 trade name] in tuberculosis, the team of assessors advised that [TB351 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB351 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB351 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	06 Feb 2019	listed
Quality	30 Jan 2019	MR
Bioequivalence	24 Jan 2019	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	18 Aug 2016	MR
FPP	July 2018	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	

The table represents the status of relevant completed activities only.

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