Prequalified Medicinal Products

Reference Number: HA098 (a)

Date of prequalification: 20 March 2002

Basis of listing: Prequalified by WHO

Status: Active

INN: Lopinavir/Ritonavir

Therapeutic area: HIV/AIDS

Dosage form & strength: Solution, Oral 80mg/mL/20mg/mL

Storage condition: Store in a refrigerator (2 °C to 8 °C)

Shelf life (months): 24

Packaging: Bottle PET: 60mL

Applicant:
AbbVie LTD., Deutschland GmbH and Com KG, Knollstrasse 67061, Ludwigshafen, Germany

FPP Manufacturing Site:
AbbVie Inc., 1 N Waukegan Road, IL 60064, North Chicago, United States of America
Aesica Queenborough Limited, North Road, Queenborough, Kent, ME11 5EL, United Kingdom of Great Britain and Northern Ireland
UPS SCS B.V., Marco Poloweg 22-24, 5928 LE Venlo, Netherlands

FPP WHO Public Inspection Reports:

API Manufacturing Site:
AbbVie S.r.L, S.R. 148 Pontina, Km 52 snc, Campoverde di Aprilia (LT), 04011, Italy

API WHO Public Inspection Reports:

WHO Public Assessment Reports

Part 1, Part 2a, Part 2b, Part 7

Part 1 - Abstract
Part 2a - All accepted presentations
Part 2b - Visual appearance of the product
Part 3 - WHO-PQ recommended patient information leaflet*
Part 4 - WHO-PQ recommended summary of product characteristics*

Part 5 - Label
Part 6 - Discussion (status at the time of prequalification)
Part 7 - Steps before Prequalification
Part 8 - Steps following Prequalification (from 01 March 2014, only changes to the published information are included)

** This summary of product characteristics/patient information leaflet focus on uses of the medicine covered by WHO Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities (term to be revised). The medicine may be authorised for additional or different uses by national medicines regulatory authorities.*

Samples of the artworks of the SPC/PIL/labelling have not been submitted. Therefore, control of compliance with WHOPAR guidelines (contents and format) has not been possible.