World Health Organization

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In reply please refer to: P5-447-3/SC/AB/1

Your reference:

Dr Rabab Tayyem
Director/CEO
ACDIMA Center for Bioequivalence and Pharmaceutical Studies
P.O. Box 925161
Amman, 11190
Jordanie

27 January 2017

Dear Dr Tayyem,

WHO Prequalification Team – Inspection Services
Closing of Inspection

I refer to the inspection that was performed by Ms Stephanie Croft and Dr Alexandru Sirbu, the details of which are outlined below:

CRO name:	ACDIMA Jordan
Facility:	Sweifieh, Salah Sohaimat Street, Building 18 P.O. Box: 925161 Amman 11190, Jordan
Date:	21 to 23 September 2016

Thank you for your letter dated 22 December 2016 and the corrective actions to the deficiencies listed in the inspection report. The actions taken, or proposed to be taken, to correct the deficiencies have been reviewed by the Prequalification Inspection Group.

In general, they are considered to be acceptable. Therefore, taking into account these responses, as well as the findings of the inspection, the Prequalification Inspection Group has recommended that the studies with the following details are therefore can be considered to be performed in compliance with WHO Good Clinical Practice (GCP) and/or Good Laboratory Practice Guidelines (GLP) published by the World Health Organization (WHO).

WHO Reference Number	Name of Product	Study Number	Part of the Study: • Clinical part • Bio-analytical part • Clinical and bio-analytical parts
HA665	Sofosbuvir 400mg tablets	BC-SOF-15/431	All of the above

Please note that acceptance of compliance with WHO GCP and/or GLP does not necessarily mean that the product for which the study has been performed has been prequalified by WHO. You will be notified of the outcome of the assessment of your prequalification application in due course.

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Please do not hesitate to send an email to **prequalinspection@who.int** should you require any further information regarding the closing of this inspection.

Yours sincerely,

Ms Josée Hansen
Acting Group Lead, Inspection Services
Prequalification Team
Regulation of Medicines and other Health Technologies