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TO WHOM IT MAY CONCERN

Declaration for GMP extension

The manufacturer **GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS**, site address **NORTH LONSDALE ROAD, ULVERSTON, LA12 9DR, UNITED KINGDOM**, has been inspected under the national inspection program by Medicines and Healthcare products Regulatory Agency (MHRA).

From the latest conducted inspection of this manufacturer on 22 May 2017, it was considered in compliance to the Good Manufacturing Practice requirements. Following the inspection, the GMP Certificate No. **UK API 4 Insp GMP 4/15697-0019** has been issued reflecting the status of the manufacturing site at the time of inspection.

Due to the restrictions caused by the spread of the COVID-19 pandemic, the validity of GMP certificate No. **UK API 4 Insp GMP 4/15697-0019** of the manufacturing site **GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS** is automatically extended until **the end of 2022**, as indicated in official MHRA website. (The GMP database on MHRA website can be accessed via the following link: <https://cms.mhra.gov.uk/mhra/gmp/>)

The above information can be confirmed by contacting the inspectorate at gmpinspectorate@mhra.gsi.gov.uk

No further document will be released by the MHRA.

The Certificate No. **UK API 4 Insp GMP 4/15697-0019** can be reviewed on the MHRA website:

https://cms.mhra.gov.uk/mhra/gmp?f%5B0%5D=certificate_number_gmp%3AUK%20API%204%20Insp%20GMP%204/15697-0019

Signed by:


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Date: 14 DEC 2021

Name and Position:

Neale Salton

Quality Director

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