

Medicines and Healthcare products Regulatory Agency

Certificate No: UK API 25 Insp GDP 25/4061-0033

CERTIFICATE OF GDP COMPLIANCE OF A DISTRIBUTOR OF ACTIVE SUBSTANCES FOR USE AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE

Issued following an inspection in accordance with Regulation 331 (4) (b) of the Human Medicines Regulations 2012

The wholesale distributor : ORGANON PHARMA (UK) LIMITED

Site address : ORGANON PHARMA (UK) LIMITED, SHOTTON LANE, CRAMLINGTON, NE23 3JU, UNITED KINGDOM

Has been inspected under the national inspection programme in accordance with The Human Medicines Regulations 2012 (SI 2012/1916)

From the knowledge gained during inspection of this active substance distributor, the latest of which was conducted on 03/01/2025, it is considered that it complies with the principles of good distribution practice for active substances referred to in Regulation B17 and C17 of The Human Medicines Regulations 2012 (SI 2012/1916).

This certificate reflects the status of the premises at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than five years have elapsed since the date of that inspection. However this period of validity may be reduced using regulatory risk management principles, by an entry in the Restrictions or Clarifying Remarks field.

This certificate is valid only when presented with all pages.

The authenticity of this certificate may be verified in MHRA-GMDP. If it does not appear please contact the issuing authority.

Any restrictions or clarifying remarks related to the scope of this certificate(For All Users):

This certificate is issued based on a desk-based assessment of GMP compliance information provided by the manufacturer. This certificate should be used in combination with the relevant authorisation/registration. A risk-based site inspection programme remains in force.

03/01/2025	Name and signature of the authorised person of the Competent Authority of United Kingdom
	Confidential
	Medicines and Healthcare products Regulatory Agency
	Confidential