

Medicines and Healthcare products Regulatory Agency

Certificate No: UK WDA(H) 11515 Insp GDP 11515/9024085-0012

CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR

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

The wholesale distributor : OTSUKA PHARMACEUTICAL EUROPE LIMITED

Site address : OTSUKA PHARMACEUTICAL EUROPE LIMITED, GALLIONS, WEXHAM SPRINGS, FRAMEWOOD ROAD, WEXHAM, SLOUGH, SL3 6PJ, UNITED KINGDOM

Has been inspected under the national inspection programme in connection with authorisation number UK WDA(H) 11515 Insp GDP 11515/9024085-0012 in accordance with regulation 18 of the Human Medicines Regulations 2012

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 22/11/2021, it is considered that it complies with the principles of good distribution practice requirements referred to in regulation C17 of the Human Medicines Regulations 2012

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 remote inspection of GDP compliance as part of a risk-based site inspection programme.

28/03/2022	Name and signature of the authorised person of the Competent Authority of United Kingdom
	Confidential
	Medicines and Healthcare products Regulatory Agency
	Confidential