Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number	UK WDA(H) 19611
2. Name of Authorisation Holder	NICHE GENERICS LIMITED
3. Legally registered address of Authorisation Holder	NICHE GENERICS LIMITED, UNIT 1, WATERLOO FARM COURTYARD, STOTFOLD ROAD, ARLESEY, SG15 6XP, UNITED KINGDOM
4. Address(es) of Site(s)	NICHE GENERICS LIMITED, UNIT 1, WATERLOO FARM COURTYARD, STOTFOLD ROAD, ARLESEY, SG15 6XP, UNITED KINGDOM
5. Scope of authorisation (complete for each site under 4)	ANNEX 1
6. Legal basis of authorisation	Regulation 18 of the Human Medicines Regulations 2012
7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation	Confidential
8. Date	23/11/2022
9. Annexes attached	Annex 1 Scope of wholesale distribution authorisation Annex 2 (Optional) Address(es) of contract wholesale distribution sites and their authorisation number Annex 3 (Optional) Name(s) of responsible person(s) Annex 4 (Optional) Date of Inspection on which authorisation was granted Annex 5 Additional provisions

ANNEX 1

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Name and address of the site:

NICHE GENERICS LIMITED, UNIT 1, WATERLOO FARM COURTYARD, STOTFOLD ROAD, ARLESEY, SG15 6XP, UNITED KINGDOM

1. MEDICINAL PRODUCTS

1.1 With “an authorisation” (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration)

1.3 Without “an authorisation” (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) and not intended for the UK market

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1 Procurement

MHRA-GMDP MHRA-GMDP MHRA

2.3 Supply

2.5 Other Activities

Reference details for Hitchin site (please note the Hitchin address is the registered address), while the Arlesey address is the office address.

Any restrictions or clarifying remarks (for all users)

4 Categories of Products Handled at this Site: 4.1 Prescription Only Medicines, 4.2 General Sales List, 4.4 Pharmacy

MHRA-GMDP MHRA-GMDP MHRA MHRA