

State Institute For Drug Control

UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION

Human medicinal products

1. Authorisation Number : sukls115349/2023
2. Name of Authorisation Holder : Astrasana Pharma s.r.o.
(ORG-100049904 / LOC-100087103)
3. Legally registered address of Authorisation Holder : Ponavka 185/2, Zabrdovice, Brno-Stred, 602 00
4. Address(es) of Site(s) : Ponavka 185/2, Zabrdovice, Brno-Stred, 602 00, CZECHIA
5. Scope of authorisation (complete for each site under 4) : ANNEX 1
6. Legal basis of authorisation : Art. 77(1) of Directive 2001/83/EC
7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation : Confidential, Confidential
8. Signature :
9. Date : 2023-07-26
10. 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 (Optional) Additional provisions based on national requirements

ANNEX 1

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Name and address of the site: Astrasana Pharma s.r.o.
(ORG-100049904 / LOC-100087103)
, Ponavka 185/2, Zabrdovice, Brno-Stred, 602 00, CZECHIA

Human medicinal products

<p>1. MEDICINAL PRODUCTS</p> <p>1.1 with a Marketing Authorisation in EEA country(s) 1.2 without a Marketing Authorisation in the EEA and intended for EEA market* 1.3 without a Marketing Authorisation in the EEA and intended for exportation</p>
<p>2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS</p> <p>2.1 Procurement 2.2 Holding 2.3 Supply 2.4 Export</p>
<p>3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS</p> <p>3.1.2 Medicinal products derived from blood 3.1.3 Immunological medicinal products 3.3 Cold chain products(requiring low temperature handling)</p>

*Art 5 of Directive 2001/83/EC or Art 83 of Regulation EC/726/2004

**Without prejudice to further authorisations as may be required according to national legislation