

*Agency for medicinal products and medical devices of the Republic of  
Slovenia*

Certificate No: 402-6/2021-4

**CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR**

**Issued following an inspection in accordance with Art. 111 of Directive 2001/83/EC**

The competent authority of Slovenia confirms the following:

The wholesale distributor: Galex, proizvodnja in promet s farmacevtskimi in drugimi proizvodi d.o.o.

Site address: Tišinska ulica 29g, Murska Sobota, 9000, Slovenia

Has been inspected under the national inspection programme in connection with authorisation number  
801-1/2019-3 in accordance with Art. 77 (1) of Directive 2001/83/EC

From the knowledge gained during inspection of this wholesale distributor, the latest of which was  
conducted on 2021-03-11, it is considered that it complies with the Good Distribution Practice  
requirements laid down in Article 84 of Directive 2001/83/EC.

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 the Union database. 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):**

The certificate is valid for wholesale distribution only to other holders of wholesale distribution  
authorisation for a restricted scope of customers, which covers the wholesale distribution of medicinal  
products that may be placed on the market in accordance with Medicinal Products Act (ZZdr-2), in line  
with the remark on the corresponding WDA.

2021-04-01

Name and signature of the authorised person of the  
Competent Authority of Slovenia



Mr Jaka Zavasnik

Agency for medicinal products and medical devices of the