French National Agency for Medicines and Health Products Safety

Certificate No: 2017/BPD/052

CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR

Issued following an inspection in accordance with Art. 111(1) of Directive 2001/83/EC

The competent authority of France confirms the following:

The wholesale distributor (WDA): LABORATOIRES URGO - CHENOVE

Site address: 42 rue de Longvic, CHENOVE, 21300, France

Has been inspected under the national inspection programme in connection with authorisation number MM 17/088 in accordance with Art. 77 (1) of Directive 2001/83/ EC.

Scope of certificate:

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 2016-12-08, 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):

Signatory: Mrs Virginie Waysbaum, head of pharmaceutical product inspection and counterfeiting fight department --- The ANSM does not issue paper copies of good distribution practice certificates.

2017-04-27

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

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Details of the authorisation can be found in the Union Database.

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