Chief Pharmaceutical Inspectorate

Certificate No: ISF.405.30.2026.IP.1.1 WTC/0608_01_01/51

CERTIFICATE OF GDP COMPLIANCE OF A DISTRIBUTOR OF ACTIVE SUBSTANCES FOR USE AS STARTING MATERIALS

Issued following an inspection in accordance with Art. 111(1) of Directive 2001/83/EC and Art. 123 of Regulation (EU) 2019/6

The competent authority of Poland confirms the following:

The active substance distributor (API): Ntc Andar Sp. z o.o.

Site address: Ul. Prymasa Augusta Hlonda 2a/90, Warsaw, Mazowieckie, 02-972

OMS Identifiers: (ORG-100036482 / LOC-100057682)

has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC and Art. 123 of Regulation (EU) 2019/6 and in connection with registration no* 159/WTC0608/API/20

Scope of certificate: Human Active Substances, Veterinary Active Substances

From the knowledge gained during inspection of this active substance distributor, the latest of which was conducted on 2026-02-18, it is considered that it complies with the principles of Good Distribution Practice for active substances referred to in Article 47 of Directive 2001/83/EC and in Article 95 (8) of Regulation (EU) 2019/6.

This certificate reflects the status of the site 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.

The authenticity of this certificate may be verified in the Union database. If it does not appear please contact the issuing authority.

2026-04-14

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

EudraGMDP

Confidential

Chief Pharmaceutical Inspectorate
Confidential

Confidential

EudraGMDP