

Compliance with Good Distribution Practice:

A certificate of Good Distribution Practice (GDP) is issued to a wholesale distributor by the national competent authority that carried out an inspection if the outcome of the inspection confirms that the wholesale distributor complies with Good Distribution Practice, as provided by European Union legislation.

API Registration:

The Community format for the API Registration Certificate was established in accordance with Art. 47 of Directive 2004/27/EC and Art. 51 of Directive 2004/28/EC, amending Directives 2001/83/EC and 2001/82/EC respectively.

The Community format for the API Registration Certificate is published in the Compilation of Community Procedures. API Registration Certificates are to be entered into EudraGMDP, as referred to in Art. 111(6) of Directive 2001/83/EC and Art. 80(6) of Directive 2001/82/EC.

Registration Holder	Oldenburger Fritom
Registration Number	109318 API
EudraGMDP Document Reference Number	46871
OMS Organisation Identifier	ORG-100046874
OMS Location Identifier	LOC-100077366
NCA Site Reference Number	1699365123360
EudraGMDP Site Reference Number	195043
Competent Authority	NL_FARMATEC
Site Name	Oldenburger Fritom
Site Address/Country	De Zwaaiikom 24 9641 KW Veendam The Netherlands

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Due to the restrictions caused by COVID-19, the period of validity of GMP and GDP certificates issued by EEA authorities is automatically extended until the end of 2024, except where clarifying remarks in the document state otherwise. Manufacturers, importers and distributors must continue to comply with GMP/GDP and all other legal obligations. On-site inspections are now being conducted and scheduling of these inspections may be independent of the extended validity period stated above. Competent authorities will continue to perform risk based supervision of sites by either on-site inspections or distant assessments and, based on the outcome, may continue to issue, withdraw or restrict GMP and GDP certificates, as appropriate.