

GMP AUDIT CERTIFICATE

Rephine hereby certifies that a Good Manufacturing Practices (GMP) audit was completed at the company's facilities located at

Audit Date
September 29th, 2023

LAVOLLÉE SAS
9, rue Louis Rouquier, F-92300
Levallois-Paris, France

Regulatory frame

EU Directive **2001/83/EC** (and amendments 2004/27/EC and 2011/62/EU), 21 CFR 210 & 211 and UK Human Medicines Regulations 2012 (SI 2012/1916).

Reference to

EU Directive (EU) 2017/1572, and the correspondent guidance **EUGMP Part II (ICH Q7)**.

The products in the audit scope encompassed **APIs**.

The audit was carried out following the rules and methodology set forth in Rephine's Quality System based on **ISO 9001 & ISO 17020**

Certificate Number
AUD-3024

Validity for
3 years

The results of this audit are described in a full report, filed by Rephine. The report is available to the interested parties, and bound by the terms and conditions of confidentiality, agreed with the audited company.

José C. Vergara
Technical Director

November 2023