Elanco France SAS
26, rue de la Chapelle
68330 HUNINGUE
France

BATCH CERTIFICATE

Product Name:	**Credelio Plus 225 / 8.44 mg - 1x3 Tablets**		
Dosage Form:	Tablet	Concentration of Lotilaner / Milbemycin oxime:	225 / 8.44 mg/tablet
Material Number:	CA5482003GN	Released Quantity:	6 144 folding boxes
Manufacturing Date:	05/2024	Expiry Date:	04/2027
Importing Country:	Austria Croatia Germany Slovenia	Marketing Authorization Number:	EU/2/21/271/010 EU/2/21/271/010 EU/2/21/271/010 EU/2/21/271/010

Sites involved in the Manufacture:		**Manufacturing Authorization Number:**
Manufacturing & Testing:	ELANCO France S.A.S. 26, rue de la Chapelle BP 224 68330 Huningue, France	V 827/87
Packaging:	Allpack Group AG Pfeffingerstr. 45, 4153 Reinach, Switzerland	511510-102708850

Tests:

- See Certificate of Analysis Elanco France SAS (Annex) — Batch: E170810
- See Certificate of Compliance Allpack (Annex) — Batch: AL170810C

Comments:

Lot meets Elanco Quality Requirements.

Bulk Shelf Life is not country specific and may be different from finished packs.

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country or product specification file for Investigational Medicinal Products. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Date and Signature:

A. FIALA

Pharmacist, Deputy, Qualified Person

allpack
Passion for Pharma Packaging

Certificate of Compliance

Order No. Allpack Group AG:	77390 (80905)
Order No. Elanco Animal Health:	4500172544
Product (short description & country):	CREDELIO PLUS TAB 225/8.44MG X3BLCD GN
Product No.:	CA5482003GN
Quantity delivered:	6`144 Folding Boxes
Batch No. finished product:	AL170810C
Expiry date:	04/2027
Batch No. (bulk):	E170810
Batch No. (blisters):	AL170810C
Bulk manufacturing date:	17.05.2024
Primary packaging date:	20.09.2024
Secondary packaging date:	20.09.2024
Bulk consumed:	19`326 tablets
MBR version used for batch record	Inlineverpackung Linie 5 Credelio Plus Display V01
Manufacturing Authorization No:	511510-102708850 (Swissmedic)
GMP Certificate No.:	GMP-CH-1004644 (Pfeff.)
Packaging Site:	Pfeffingerstr. 45, CH-4153 Reinach BL

I hereby confirm that the manufacturing stages have been carried out in full compliance with the cGMP requirements of the local Regulatory Authority.

The product specified above is packaged, labelled, assembled and stored in compliance with cGMP and according to the packaging specifications and instructions.

The batch records for the above mentioned product have been reviewed and it has been found to be in compliance with the production documents. The detailed documentation of each work step is checked and released.

Deviations, if any, have been investigated, explained and documented according to the relevant SOP.

Production

☒ No deviation(s) has/have been detected / registered.
☐ Deviation(s) has / have been detected / registered, and has / have been reviewed, investigated and approved in accordance with the relevant deviation procedure. The following deviation(s) has / have been registered: n.a.

Note:

Credelio bulk batch E170810 has been shipped under quarantine. Please refer to Elanco BSN-2024-002-BP.

Date: 24.09.24 Signature: i.V

Hüseyin Alpsoy / Head of Production

Quality Assurance and Responsible Person (FvP)

A copy of the Deviation Report(s) is attached: ☐ Yes ☒ N/A

Approval:

The order has been approved by Quality Assurance and Responsible Person (FvP).

Date: 24.09.24 Signature:

Michael Paulisch / Head of QA & FvP