



CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

UK Manufacturer

Part 1

Issued following an inspection in accordance Schedule 2 of the Veterinary Medicines Regulations 2013 as it has effect in Northern Ireland and Great Britain.

The competent authority of: UNITED KINGDOM (*Veterinary*) confirms the following:

The manufacturer: **Hydrachem Ltd**

Site address: Gilmans Industrial Estate
Billingshurst
West Sussex
RH14 9EZ
United Kingdom

Has been inspected under the national inspection programme in connection with Manufacturing Authorisation no. **ManA20725** in accordance with Good Manufacturing Practice (GMP)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **21st March 2022**, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice as required by the Veterinary Medicines Regulations 2013.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended 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 and both Parts 1 and 2.

The authenticity of this certificate may be verified on EudraGMP or on GOV.UK. If it does not appear, please contact the issuing authority.

Signature: Confidential

Date: 15th June 2022

Name: Confidential

Veterinary Medicines Directorate
Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911
Search for VMD on GOV.UK



Part 2

Veterinary Medicinal Products

1. MANUFACTURING OPERATIONS	
1.1	Sterile Products: N/A
1.2	Non-sterile products: 1.2.1.13 Tablets
1.3	Biological medicinal products: N/A
1.4	Other products or manufacturing activity: N/A
1.5	Packaging only: 1.5.1.13 Tablets 1.5.2 Secondary packaging
1.6	Quality Control testing: 1.6.3 Chemical/ physical

2. IMPORTATION OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products N/A
2.2	Batch certification of imported medicinal products N/A

Any restrictions or clarifying remarks related to the scope of this certificate:

The scope of this certificate is limited to the manufacture of tablets containing NaDCC for dissolution in water.

Name and signature of the authorised person of
the Competent Authority of the UK:

Signature: Confidential

Date: 15th June 2022

Name: Confidential

Veterinary Medicines Directorate
tel: confidential
email:confidential