



**Veterinary  
Medicines  
Directorate**

**United Kingdom  
Veterinary Medicines Directorate  
Woodham Lane  
New Haw  
Addlestone  
Surrey KT15 3LS**

**NATIONAL PROCEDURE**

**PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY  
Homeopathic Remedy**

**AconiteTablets 2c-MM**

**Date Created: February 2018**

## **MODULE 1**

### **PRODUCT SUMMARY**

Name, strength and pharmaceutical form	Aconite Tablets 2c-MM
Applicant	Complements of Scotland Limited (Trading as Freeman's Homeopathic Pharmacy) 20 Main Street Busby Glasgow G76 8DU Scotland
Homeopathic material(s) and potency(ies)	Aconite 2 c to MM
Target species	All non-food animals

## MODULE 2

### PUBLIC ASSESSMENT REPORT

Legal basis of original application	Homeopathic
Date of conclusion of the procedure	20 <sup>th</sup> March 2007

#### I. SCIENTIFIC OVERVIEW

This was an application for a homeopathic remedy, Aconite Tablets 2c-MM. The product is authorised for use in any non-food animal. There are no formal indications.

Part 9 of Schedule 1 (Marketing Authorisations of the Veterinary Regulations 2013, paragraph 65 (1)), states that the procedure for registering a homeopathic product is the same procedure as that for granting a marketing authorisation for a non-homeopathic veterinary medicine, as shown in Part 3. However, no proof of efficacy is required.

The overall benefit:risk analysis was in favour of accepting the registration, and the application was approved.

#### II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

##### *II.A. Composition*

The product (a tablet), contains the following:

<u>Stock Name</u>	<u>Specification</u>	<u>Dilution</u>	<u>Scale of Potency</u>
Aconite	HAB 2005	(2 to MM)	c
<u>Other Substances</u>			
<u>Diluents</u>		<u>Modifier</u>	
Ethanol	BP	qs	
Lactose	Ph. Eur		

**Pharm base**  
**Ingredients (tablet)**

Lactose  
Sucrose  
Acacia  
Hydrogenated castor oil  
Hydrogenated vegetable oil

The container/closure system consists of a 10 ml amber, glass, wide-necked bottle with tamper-evident high-density polyethylene cap, containing 100 tablets. The particulars of the containers and controls performed were provided and conformed to the regulation. The choice of the formulation and the absence of preservative were justified.

The product is established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

***II.B. Description of the Manufacturing Method***

Suitable descriptions were provided of the methods used for potentiation and dispensing of the product.

***II.C. Control of Starting Materials***

The homeopathic material is aconite, which is manufactured in accordance with the European Pharmacopoeial (Ph. Eur) monograph 'Methods of preparation of homoeopathic stocks and potentiation'. The homeopathic material specifications were considered adequate to control the quality of the material.

Compliance with appropriate quality standards was demonstrated for all the excipients used to manufacture the product. Appropriate certificates of analysis were provided.

The packaging used was supported by satisfactory specifications and technical drawings, accompanied by suitable declarations of conformity with Ph. Eur and food contact use requirements.

***II.C.4. Substances of Biological Origin***

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

#### ***II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process***

Not applicable.

#### ***II.E. Control Tests on the Finished Product***

The finished product specification controls the relevant parameters for the pharmaceutical form. Acceptable data from the proposed production sites have been provided.

#### ***II.F. Stability***

Stability data on the homeopathic material and final product have been provided in accordance with applicable European guidelines, demonstrating their stability when stored under the approved conditions.

### **III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACOTOXICOLOGICAL)**

#### ***III.A Safety Documentation***

##### ***Pharmacological Studies***

No pharmacological data are required for applications for homeopathic remedies.

##### ***User Safety***

No user safety data are required when the product is used as intended.

##### ***Environmental Safety***

No Environmental Risk Assessment is required for homeopathic remedies.

##### ***III.B.2 Residues documentation***

The applicant has provided proof that all substances included in the homeopathic remedy are suitable for use in food-producing animals under Regulation 37/2010.

##### ***Residue Studies***

No residues data are required for applications for homeopathic remedies.

#### **IV. CLINICAL DOCUMENTATION**

No proof of either efficacy or target species safety are required for applications for homeopathic remedies.

#### **V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT**

The data submitted in the dossier demonstrate that when the product is used in accordance with the labelling, the benefit/risk profile of the product is favourable.

## **MODULE 4**

### **POST-AUTHORISATION ASSESSMENTS**

The package leaflet may be updated to include new information on the quality and safety of the veterinary medicinal product.

The post-authorisation assessment (PAA) contains information on significant changes which have been made after the original procedure which are important for the quality and safety of the product.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

([www.gov.uk/check-animal-medicine-licensed](http://www.gov.uk/check-animal-medicine-licensed))