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

## Anxt-F Oral Solution

**Date Created: February 2018**

# MODULE 1

## PRODUCT SUMMARY

| | |
|---|---|
| Name, strength and pharmaceutical form | Anxt-F Oral Solution |
| Applicant | Complements of Scotland Limited<br>(Trading as Freeman's Homeopathic Pharmacy)<br>20 Main Street<br>Busby<br>Glasgow<br>G76 8DU<br>Scotland |
| Homeopathic material(s) and potency(ies) | Aconite (Aconitum Napellus) HAB 2005 10x, 200c<br>Avena Sativa HAB 2005 7x, 2c<br>Belladonna (Atropa Belladonna) HAB 2005 30c<br>Borax (Natrium Tetraboracicum) HAB 2005 6c, 30c<br>Calcium Phosphoricum HAB 2005 30c, 200c<br>Gelsemium (Gelsemium Sempervirens) HAB 2005 6c, 30c, 200c<br>Lycopodium (Lycopodium Clavatum) HAB 2005 6c, 30c<br>Natrium Carbonicum HAB 2005 30c, 200c<br>Natrium Chloratum (Natrium Muriaticum) HAB 2005 30c<br>Passiflora Incarnate HAB 2005 7x, 2c<br>Phosphorus HAB 2005 6c, 30c, 200c, 1M (1 in 100 dilution)<br>Rhododendron HAB 2005 6c<br>Scutellaria Lateriflora HAB 2005 7x, 2c<br>Silicea (Acidum Silicicum) HAB 2005 30c, 200c<br>Staphisagria HAB 6c, 30c |

| | | | |
|---|---|---|---|
| | (Delphinium Staphisagria) | 2005 | |
| | Stramonium (Datura Stramonium) | HAB 2005 | 30c |
| | Valeriana (Valeriana Officinalis) | HAB 2005 | 7x, 2c |
| Target species | All non-food animals | | |

# MODULE 2

## PUBLIC ASSESSMENT REPORT

| | |
|---|---|
| Legal basis of original application | Homeopathic |
| Date of conclusion of the procedure | 13th October 2009 |

## I. SCIENTIFIC OVERVIEW

This was an application for a homeopathic remedy, Anxt-F, which is produced from seventeen homeopathic formulations. 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 (an oral solution), contains the following:

| Stock Name | Specification | Dilution and Scale |
|---|---|---|
| Aconite (Aconitum Napellus) | HAB 2005 | 10x, 200 c |
| Avena Sativa | HAB 2005 | 7x, 2 c |
| Belladonna (Atropa Belladonna) | HAB 2005 | 30 c |

| Stock Name | Specification | Dilution and Scale |
|---|---|---|
| Borax (Natrium Tetraboracicum) | HAB 2005 | 6 c, 30 c |
| Calcium Phosphoricum | HAB 2005 | 30 c, 200 c |
| Gelsemium | | |

| | | |
|---|---|---|
| (Gelsemium Sempervirens | HAB2005 | 6 c, 30 c, 200 c |
| Lycopodium | | |
| (Lycopodium Clavatum) | HAB 2005 | 6 c, 30 c |
| Natrium Carbonicum | HAB 2005 | 6 c, 200 c |
| Passiflora Incarnate | HAB 2005 | 7x, 2 c |
| Phosphorus | HAB 2005 | 6 c, 30 c, 200 c, 1M (1 in 100 dilution) |
| Rhodedendron | HAB 2005 | 6 c |
| Scutellaria Lateriflora | HAB 2005 | 7x, 2 c |
| Silicea (Acidum Silicicum) | HAB 2005 | 30 c, 200 c |
| Staphisagria | HAB 2005 | 6 c, 30 c |
| (Delphinium Staphisagria) | HAB 2005 | |
| Stramonium | HAB 2005 | 30 c |
| (Datura Stramonium) | HAB 2005 | |
| Valeriana | HAB 2005 | 7x, 2 c |
| (Valeriana Officinalis | HAB 2005 | |

| **Other Substances** | | |
|---|---|---|
| **Diluents** | **Grade** | **Modifier** |
| Purified Water | Ph. Eur | qs to 15.0 ml |

| **Pharm base** | | |
|---|---|---|
| **Ingredients (oral solution)** | **Grade** | **% v/v** |
| Ethanol 96% | Ph. Eur | 20.0 |

The container/closure system consists of a white, opaque low density polyethylene dropper bottles with tamper evident caps. The particulars of the container 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 potentisation and dispensing of the product.

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

The homeopathic materials are manufactured in accordance with the European Pharmacopoeial (Ph. Eur) monograph 'Methods of preparation of homoeopathic stocks and potentisation'. 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 (PHARMACO-TOXICOLOGICAL)

### *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)