



**Veterinary  
Medicines  
Directorate**

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

**NATIONAL PROCEDURE**

**PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY  
MEDICINAL PRODUCT**

**Cyclofin 300 mg/ml + 20 mg/ml Solution for Injection for Cattle**

**Date Created: November 2023**

## MODULE 1

### PRODUCT SUMMARY

Name, strength and pharmaceutical form	Cyclofin 300 mg/ml + 20 mg/ml Solution for Injection for Cattle, Solution for injection
Applicant	Dechra Limited Snaygill Industrial Estate Keighley Road Skipton North Yorkshire BD23 2RW
Active substance	Flunixin Oxytetracycline
ATC Vetcode	QJ01AA56
Target species	Cattle
Indication for use	For the treatment of bovine respiratory disease caused by <i>Mannheimia (Pasteurella) haemolytica</i> where an anti-inflammatory and anti-pyretic effect is required.

## **MODULE 2**

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

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

## MODULE 3

### PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of conclusion of the procedure	9/9/2023

#### I. SCIENTIFIC OVERVIEW

The product is produced and controlled using validated methods and tests which ensure the consistency of the product released on the market. It has been shown that the product can be safely used in the target species, any reactions observed are indicated in the SPC.<sup>1</sup> The product is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC. The efficacy<sup>2</sup> of the product was demonstrated according to the claims made in the SPC. The overall benefit/risk analysis is in favour of granting a marketing authorisation.

The quality / safety / efficacy aspects of this product are identical to Hexasol LA. The initial application for Hexasol LA was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.

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

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

The product contains oxytetracycline and flunixin and the excipients sodium formaldehyde sulfoxylate, magnesium oxide, glycerol formal, polyethylene glycol 200, monoethanolamine and water for injections.

The container/closure system consists of Type II glass vials with Type 1 rubber stoppers and aluminium caps. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the absence of preservative are justified.

<sup>1</sup> SPC – Summary of product Characteristics.

<sup>2</sup> Efficacy – The production of a desired or intended result.

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

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

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site. The manufacturing method consists of: addition and dissolution.

Process validation data on the product have been presented in accordance with the relevant European guidelines.

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

The active substances are oxytetracycline and flunixin and are both established active substances described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

The excipients comply with the Ph. Eur. and/or USPNF.

#### ***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. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product. Satisfactory validation data for the analytical methods have been provided. Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification. Control tests on the finished product are those for: colour, impurity, pH, density and identification.

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

Stability data on the active substances have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

## ***G. Other Information***

Shelf life of the veterinary medicinal product as packaged for sale: 2 years  
Shelf life after first opening the immediate packaging: 28 days.

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

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

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

Not required due to the legal basis of the application.

#### ***Toxicological Studies***

Not required due to the legal basis of the application.

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

A user risk assessment was provided in compliance with the relevant guideline.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. Therefore the following applicant's user recommendations are appropriate:

Avoid eye contact and direct contact with skin.

To avoid possible sensitisation reactions, avoid contact with skin. Gloves should be worn during application.

Wash hands after use.

In the case of accidental contact with eyes, rinse immediately with plenty of water and seek medical advice.

The product may cause reactions in sensitive individuals. If you have known hypersensitivity for non-steroidal anti-inflammatory products, do not handle the product. Reactions may be serious.

Avoid accidental self-injection.

### ***Environmental Safety***

The Environmental Risk Assessment (ERA) was carried out in accordance with VICH and CVMP guidelines.

#### **Phase I:**

The initial predicted environmental concentration (PEC) in soil is less than 100 µg/kg. A Phase II ERA was not required.

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

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

No residue depletion studies were conducted because of the legal basis of the application.

#### ***Withdrawal Periods***

Based on the data provided, a withdrawal period of 35 days for meat in cattle. Not for use in cattle producing milk for human consumption.

## **IV. CLINICAL DOCUMENTATION**

### ***IV.I. Pre-Clinical Studies***

#### ***Pharmacology***

Not required due to the legal basis of the application and because bioequivalence was established.

#### ***Tolerance in the Target Species***

Tolerance studies were not required.

### ***IV.II. Clinical Documentation***

Not required due to the legal basis of the application.

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

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

## **MODULE 4**

### **POST- AUTHORISATION ASSESSMENTS**

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

The post-authorisation assessment (PAA) contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy 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))