MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

DEPARTAMENTO DE
MEDICAMENTOS
VETERINARIOS

LUTEOSYL 0.075 mg/ml solution for injection for cattle and pigs
PRELLIM 0.075 mg/ml solution for injection for cattle and pigs (UK)

Company:

LABORATORIOS SYVA, S.A.U

VARIATION ASSESSMENT REPORT

Variation procedure application N° ES/V/0143/001/IB/003

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VARIATION ASSESSMENT REPORT

PRODUCT DETAILS

Name of product	LUTEOSYL 0.075 mg/ml solution for injection for cattle and pigs
Active ingredient(s)	d-Cloprostenol (as d-cloprostenol sodium)
Target Species	Cattle and Pigs
Route of administration	Solution for injection (Intramuscular Use)

APPLICATION DETAILS

Type of Application	Type IB
Name and Address of Applicant	LABORATORIOS SYVA, S.A.U. Avda. Párroco Pablo Díez, 49-57 24010 LEÓN (SPAIN)
Phone and Fax Numbers	Telephone: +34 987 800 800 Telefax:: +34 987 805 852
Email address	Mª TERESA L. VARELA RODRÍGUEZ E-mail: teresa.varela@syva.es
Reference Number for Application	ES/V/0143/001/IB/003
Reference Number in RMS	1752 ESP
Date of the first marketing authorisation in RMS	20-June- 2007

REFERENCE MEMBER STATE DETAILS

Assessment Report prepared by	ES
Date of preparation	05/12/2014
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NATURE OF VARIATION

B.II.d.2.d) Change in the test procedure for the finished product. Other changes to a test procedure (including replacement or addition) (Type IB variation).

Current situation	Proposed changes
Reference method Chromatographic conditions: Column: Chiral AGP (150 mm x 4.0 mm, 5 mcm) Flow: 1.2 ml/min UV Detection: 220 nm Injection volume: 20 mcl Column temperature: - Mobile phase: Acetonitrile 70 ml Ammonium acetate solution 20 mM 930 ml.	**Test method** Chromatographic conditions: Column: Lux Cellulose-1 (100 mm x 4.6 mm, 5 mcm) Flow: 1.0 ml/min UV Detection: 205 nm Injection volume: 100 mcl Column temperature: 25 ºC Mobile phase: Water 400 ml Methanol 600 ml TFA 1 ml

SUMMARY OF THE DOSSIER

The analysis of enantiomeric purity in the veterinary medicinal product LUTEOSYL has been modified and, the proposed analytical method (Test method) improves the currently approved one (Reference method. A cross-validation has been carried out and the results obtained prove that the Test method increases the sensibility (lower DL and QL), and improves accuracy and precision. Subsequently of this change a type IB variation is submitted:

- **B.II.d.2.d)** Change in the test procedure for the finished product. Other changes to a test procedure (including replacement or addition).

For this purpose the applicant has submitted the following documents to support the modification of the analytical method:

- Revised Standard Operating procedure for Luteosyl for the enantiomeric purity analytical method. The revised SOP includes a description of the analytical method and revised specifications.
- Validation of the assay method for enantiomeric purity in the veterinary medicinal product LUTEOSYL 0.075mg/ml solution for injection.

- A copy of currently authorised specifications for the finished product, at release and at shelf life (appearance, pH, sterility, Chlorocresol and d- Chlorocresol identification, volume control, and packaging), have also been submitted.

RMS comments

The above variation is considered acceptable on the basis that the application has been submitted simultaneously to all Concerned Member States, the relevant fees have been paid as required by national competent authorities and correct supporting information and documents have also been presented according to the conditions specified for the proposed changes as listed in the Commission Guideline. Failure to comply with this provision may subsequently deem the variations invalid. Consequently, the Spanish Agency (AEMPS) can accept the variation detailed in the application.