MINISTERIO
DE SANIDAD, CONSUMO
Y BIENESTAR SOCIAL

agencia española de
medicamentos y
productos sanitarios

DEPARTAMENTO DE
MEDICAMENTOS
VETERINARIOS

Agencia Española de Medicamentos y Productos Sanitarios

C/Campezo 1, Edificio 8
28022 – Madrid
España
(Reference Member State)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

SPASMIPUR 20 MG/ML SOLUTION FOR INJECTION

CORREO ELECTRÓNICO

mresvet@aemps.es

C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 91 822 54 01
FAX: 91 822 5443

MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0298/001/DC
Name, strength and pharmaceutical form	SPASMIPUR 20 MG/ML SOLUTION FOR INJECTION
Applicant	RICHTER PHARMA AG
Active substance(s)	Hyoscine butylbromide
ATC Vet code	QA03BB01
Target species	Horses, cattle, sheep and pigs
Indication for use	Treatment of acute spasms of the gastrointestinal tract (colic) and of the urinary tract. As an aid in procedures for which reduced peristaltic activity of the gastrointestinal tract or reduced contractions in the urinary tract are required.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies website (http://www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	D210:06/02/19
Date product first authorised in the Reference Member State (MRP only)	-
Concerned Member States for original procedure	AT, BE, BG, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IS, IT, LT, LV, NL, NO, PL, PT, RO, SE, SI, SK, UK

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; the slight reactions observed are indicated in the SPC.
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 of the product was demonstrated according to the claims made in the SPC.
The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains 20 mg/ml of hyoscine butylbromide as active substance and benzyl alcohol and water for injection as excipients.

The container/closure system is a clear 50 ml glass vial, closed with a rubber-bromobutyl septum and an aluminium capsule (multiple dose container).

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

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

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

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

C. Control of Starting Materials

The active substance is hyoscine butylbromide, an established substance 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.

Scientific data and certificates of suitability issued by the EDQM have been provided and compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

D. Control on intermediate products

Not applicable

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.

F. Stability

Stability data on the active substance 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 during 30 months when stored under the approved conditions.

The claim of a 28 days stability after broaching is based on the demonstration of stability for a batch broached and stored.

G. Other Information

Not applicable

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

Since this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of pharmacological or toxicological tests are not required.

The main aspects of this product are identical to the reference product.

Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety of the product to users and the environment.

However, a potential risk for the consumers resulting from the zero days withdrawal period of the reference product was identified. Therefore, new withdrawal periods have been proposed. The reference product has been modified accordingly.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that the veterinary medicinal product is an irritant and may cause hypersensitivity.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the veterinary medicinal product will be used to treat a small number of animals in a flock or herd.

III.B Residues documentation

This application has been submitted in accordance with Article 13(1) of Directive 2001/82/EC, as amended. No residue depletion studies were conducted on the basis that bioequivalence with the reference product has been demonstrated.

Regarding the depletion of residues in the injection site, it is agreed that the depletion profile is expected to be the same since the composition is quantitative and qualitatively identical. This exception is described in section 4.4 of the guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/00-Rev.2).

MRLs

Butylscopolaminium bromide (hyoscine butilbromide) is an active substance listed in Table I of Council Regulation 37/2010

MRLs are listed below:

Pharmacologically Active Substance	Marker residue	Animal species	MRL	Target tissues
Butylscopolaminium bromide	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE

Withdrawal Periods

Based on the available information obtained from the Summary Report the following withdrawal periods are proposed:

Meat and offal:
Horse: 3 days
Cattle: 2 days
Sheep: 18 days
Pig: 9 days

Milk:
Horse, Cattle and Sheep: 12 hours

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product. This is in accordance with the guideline EMA/CVMP/016/00-Rev. 02

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 risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

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 veterinary Heads of Agencies website (www.hma.eu).

This section 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.

None