IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

AMOXICILLIN GLOBAL VET HEALTH 500 mg/g, powder for use in drinking water for chickens, turkeys, ducks and pigs

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

PRODUCT SUMMARY

EU Procedure number	IE/V/0350/001/DC
Name, strength and pharmaceutical form	AMOXICILLIN GLOBAL VET HEALTH 500 mg/g, powder for use in drinking water for chickens, turkeys, ducks and pigs
Active substance	Amoxicillin
Applicant	GLOBAL VET HEALTH SL C/Capçanes, nº12-baixos. Polígon Agro-Reus. REUS 43206 SPAIN
Legal basis of application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of procedure	21st October 2015
Target species	Chickens, turkeys, ducks and pigs
Indication for use	Treatment of infections in chickens, turkeys and ducks caused by bacteria susceptible to amoxicillin. Pigs: For the treatment of salmonellosis and pasteurellosis
ATCvet code	QJ01CA04

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Concerned Member States	BG, CY, EL, ES, FR, IT, MT, PL, RO, UK

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

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 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 benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and Quantitative Particulars

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The product contains amoxicillin 436 mg/g (as amoxicillin trihydrate 500 mg/g) and the excipient citric acid, anhydrous.

The veterinary medicinal product is packed in thermo-sealed polyethylene / aluminium / polypropylene bags of 100 g, 200 g, 500 g and 1 kg.

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 at a licensed manufacturing site.

Process validation data for the manufacturing process has been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is amoxicillin trihydrate, an established active 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 has been provided.

Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

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

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 has been provided. Batch analytical data from the proposed production site has been provided demonstrating compliance with the specification.

F. Stability

Stability data on the active substance has 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 has 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

Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

This application was for AMOXICILLIN GLOBAL VET HEALTH 500 mg/g, powder for use in drinking water for chickens, turkeys, ducks and pigs, containing amoxicillin trihydrate as active substance. The application was submitted using the decentralised application procedure in the RMS and seven CMSs. The application was for a generic product and was submitted in accordance with Article 13.1 of Directive 2001/82/EC, as amended.

The reference product cited by the applicant was Amoxinsol 50% w/w powder for oral solution (Vetoquinol UK Limited), first authorised in the RMS on 11th July 1995.

The candidate product is intended for dilution in drinking water prior to administration to all of the proposed target species.Having reconstituted the product in water, the product will be an aqueous oral solution at the time of administration to the target species. It was therefore accepted that the candidate product met the criteria necessary to claim bioequivalence with the reference product.

Further, the candidate formulation will be administered to the same target species using the same posology and route of administration already approved for the reference product.

Given the essential similarity with the reference product, an exemption from the requirement to demonstrate *in-vivo* bioequivalence was accepted.

III.A Safety Testing Pharmacological Studies

As this was a generic application submitted in accordance with Article 13.1 of Directive 2001/82/EC, as amended and bioequivalence with the reference product was accepted, the applicant was not required to provide the results of pharmacological studies.

Toxicological Studies

As this was a generic application submitted in accordance with Article 13.1 of Directive 2001/82/EC, as amended and bioequivalence with the reference product was accepted, the applicant was not required to provide the results of toxicological studies.

User Safety

No user safety assessment was required given that the candidate formulation is the same as the reference product in terms of the active substance (amoxicillin trihydrate) and the sole excipient (anhydrous citric acid) and is to be indicated for use in the same target species using the same posology and routes of administration. It was therefore accepted that the user of the product will not be exposed to a greater amount of the candidate formulation when compared to the reference product when handling, using, storing and disposing of the product.

The proposed user safety warnings are identical to those approved for the reference product and are in line with those included in the SPCs of other similar products recently authorised via European procedures.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

Phase I

The applicant provided a Phase I environmental risk assessment. Based on the results of the Phase I assessment, it was concluded that a Phase II assessment was required.

Phase II

Based on the results of the Phase II assessment, it was concluded that the candidate formulation will not present an unacceptable risk for the environment when handled, administered, stored and disposed of in accordance with the recommendations included in the proposed SPC.

Conclusion

The product is not expected to pose an unacceptable risk for the environment when stored, handled, administered and disposed of in accordance with the recommendations included in the SPC.

III.B Residues Documentation Residue Studies

No residue study data was provided. Given that bioequivalence between candidate and reference product formulations was accepted, residue depletion data was not required and that the depletion of residues in the target species, when administered the candidate formulation, will be the same as that when administered the reference product.

It was concluded that the candidate formulation will not present an unacceptable risk for the consumer of products derived from animals administered the product.

MRLs

Amoxicillin is listed in Table I of the Annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active substance	Marker residue	Animal species	MRL	Target tissue	Other relevant provisions
Amoxicillin	Amoxicillin	All food-producing species	50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg 4 µg/kg	Muscle Fat Liver Kidney Milk	For porcine and poultry species the fat MRL relates to 'skin and fat in natural proportions'. Not for use in animals from which eggs are produced for human consumption.

Withdrawal Periods

The candidate formulation was accepted as being bioequivalent to that of the reference product. Both products are to be administered using the same posology and route of administration in the same target species as an aqueous solution following mixing with water. It was concluded that no difference in depletion of residues in the target animal is to be expected.

Consequently, it was accepted that the withdrawal periods for meat and offal approved for the reference product, are also applicable to this generic product and are considered adequate to ensure consumer safety.

IV. CLINICAL ASSESSMENT

As this was a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, efficacy studies were not required. The

efficacy claims for this product are equivalent to those of the reference product.

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

No target animal tolerance studies were conducted. Given that this was a generic application and the candidate formulation will be administered to the same target species using the same posology and route of administration already approved for the reference product, it was concluded that no difference in tolerance in the target species is to be expected between candidate and reference product formulations. The omission of target animal tolerance data was therefore accepted.

Resistance

As the candidate formulation was accepted as being bioequivalent to that of the reference product and will be administered to the same target species using the same posology and route of administration, it was accepted that no difference is to be expected between candidate and reference products in terms of risk for resistance development.

Suitable warnings and precautions are included in the product literature to ensure effective use of the product.

IV.B Clinical Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, clinical studies and field trials were not required. The efficacy claims for this product are equivalent to those of the reference product.

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 for the

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

VI. 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 HPRA website.

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.

Quality Changes

Summary of change (Application number)	**Approval date**
Addition of a 100 g and 500 g pack size (IE/V/0350/II/003/G)	08/11/2018