Veterinary medicinal product

Presentation and format of the registration dossier

- Refer to Notice to Applicants while preparing registration dossier for veterinary medicinal product http://www.pharm.am/index.php/en/veterinary-drugs1/5102-veterinary-medicines-registration-guideline
- Reminder. Provide Part 1 as a hard copy (exceptions for part 1 are listed below), Parts 2-4 with an electronic carrier (storage device), each part - in a separate folder, submit the captions included in each part's content list as a reference. Submit electronic versions of documents in PDF format (with content search feature).

PART 1: SUMMARY OF THE DOSSIER

1.A: Administrative information

1.A.0 Cover Letter

1.A.1 Comprehensive Table of Contents

1.A.2 Application Form

1.A.3 Detailed description of the Pharmacovigilance System (electronic versions in PDF format)

1.A.4 Manufacturing Authorisations (including all appencies) for all manufacturing sites involved in the manufacturing process of the medicinal product and the active substances issued by the competent authority of country of origin (duly certified copy).

1.A.5 GMP certificates or other proof of GMP compliance or EudraGMP documents or inspection reports for all manufacturing sites involved in the manufacturing process of the medicinal product and the active substance issued by the competent authority of country of origin (duly certified copy).

1.A.6 Marketing Authorisation (Registration certificate) or Certificate of Pharmaceutical Product (CPP – WHO format) issued by the competent authority of the country of Applicant (Marketing authorization holder) (original or duly certified copy).

1.A.7 Worldwide registration status (if available): Copies of Marketing Authorisations or tabular listing of authorizations by specifying marketing authorization number, date of authorization, country, trade name and etc.

1.A.8 Letter(s) of access to Active Master File(s) or copy of Ph. Eur. Certificate(s) of suitability. Ph. Eur. Certificate(s) of suitability for TSE.

1.A.9 Copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications.

1.A.10 Assessment report of the reference competent authority (applicable only for the simplified national registration procedure). Documents appended to the report – specifications, original SmPC and Package Leaflet and their translated versions (if not in English language) should be included in appropriate sections of the registration dossier.

1.B: Summary of Product Characteristics, Labelling and Package leaflet

1.B.1. Summary of Product Characteristics, labelling and package leaflet (electronic versions in Microsoft Word format)

1.B.1.1. Translation of SmPC and Package Leaflet into Armenian language, if available (electronic versions in Microsoft Word format)

1.B.2. Mock-ups of the packagings and label (electronic versions in PDF format)

1.B.3. SmPCs and Package leaflets already approved in other countries (applicable only to the national standard registration procedure)

1.C: Detailed and critical summaries (including CV of the experts)

1.C.1. Detailed and critical summary report - Quality

1.C2. Detailed and critical summary report - Safety and Residues

1.C.3. Detailed and critical summary report - Efficacy

PART 2: QUALITY PART Option 1

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2.B.2.3. Manufacturing process of the finished product

2.B.2.3.1. Preparation

2.B.2.3.2. Process of manufacture

2.B.2.4. In-process control

2.B.2.5. Description of the manufacturing chain

2.B.3. Validation of the manufacturing process

2.C: Control of starting materials

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2.C.1.1.1. Active substance(s) listed in pharmacopoeias

2.C.1.1.2. Active substance(s) not in a pharmacopoeia

2.C.1.1.3. Physico-chemical characteristics liable to affect bioavailability

2.C.1.2. Excipients

2.C.1.2.1. Excipients described in a pharmacopoeia

2.C.1.2.2. Excipients not described in a pharmacopoeia

2.C.1.3. Container-closure system

2.C.1.3.1. Active substance

2.C.1.3.2. Finished product

2.C.1.4. Materials of biological origin

2.D: Control tests on intermediate products

2.E: Control tests on finished product

2.E.1. General characteristics of the finished product

2.E.1.1. Product specifications and tests for release at time of manufacture

2.E.1.1.1. Justification of specifications

2.E.1.2. Batch analysis

2.E.2. Identification and assay of active substance(s)

2.E.2.1. Test procedures

2.E.2.2. Validation

2.E.3. Identification and assay of excipient components

2.E.4. Safety tests

2.F: Stability

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2.F.2.1. Quality specification for the proposed shelf-life

2.F.2.2. Stability tests on the finished product

2.F.2.2.1. Study design

2.F.2.2.2. Characteristics studied

2.F.2.2.3. Evaluation test procedures

2.F.2.2.4. Batches tested and packaging

2.F.2.2.5. Results

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2.F.2.3. In-use stability tests

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PART 2: QUALITY PART Option 2[1]

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2.A.3. Clinical trial formula

2.A.4. Development

2.B Description of the manufacturing method

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2.B.2. Manufacturing process

2.B.3. Validation of the process

2.C Control of starting materials

2.C.1. Active substance

2.C.2. Excipients

2C.3. Container closure system

[1] According to Nta volume 6B

2.D Specific measures concerning the prevention of the transmission of animal spongiform encephalopathies

2.E Control tests on intermediate products

2.F Control tests of finished product

2.G Stability
2.G1. Active substance
2.G2. Finished product

2.H Genetically modified organisms

2.Q Other information

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3.2.S.1.2 Structure
3.2.S.1.3 General Properties
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3.2.S.2.4 Controls of Critical Steps and Intermediates
3.2.S.2.5 Process Validation and/or Evaluation
3.2.S.2.6 Manufacturing Process Development
3.2.S.3 Characterisation
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3.2.S.4 Control of Drug Substance
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3.2.S.4.2 Analytical Procedures
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[2] According to Common Technical Document (CTD) structure

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3.2.S.4.5 Justification of Specification

3.2.S.5 Reference Standards or Materials

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3.2.P.8.2 Post-approval Stability Protocol and Stability Commitment

3.2.P.8.3 Stability Data

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3.2.A.1 Facilities and Equipment

3.2.A.2 Adventitious Agents Safety Evaluation (name, dosage form, manufacturer)

3.2.A.3 Excipients

3.2.R Regional information

PART 3: SAFETY AND RESIDUES TESTS

PART 3 A: Safety Tests

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3.A.1.1. Details of the active substance

3.A.1.2. Details of the product

3.A.1.3. Chemical Abstract Service (CAS) number

A.1.4. therapeutic, pharmacological and chemical classification

A.1.5. synonyms and abbreviations,

A.1.6. structural formula,

A.1.7. molecular formula,

A.1.8. molecular weight,

A.1.9. degree of impurity,

A.1.10. qualitative and quantitative composition of impurities,

A.1.11 .description of physical properties

A.1.11.1. melting point,

A.1.11.2. boiling point,

A.1.11.3. vapour pressure,

A.1.11.4. solubility in water and organic solvents expressed in g/l, with indication of temperature,

A.1.11.5. density,

A.1.11.6. spectra of refraction, rotation, etc.,

A.1.11.7. pKa,

A.1.11.8. protein binding.

A.2. Pharmacology

A.2.1. Pharmacodynamics

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A.3. Toxicology

A.3.1. Single-dose toxicity

A.3.2. Repeat-dose toxicity

A.3.2.1. repeat-dose (90-day) oral toxicity testing

A.3.2.2. repeat-dose (chronic) toxicity testing

A.3.3. Tolerance in the target species

A.3.4. Reproductive toxicity including teratogenicity

A.3.4.1. Study of the effects on reproduction

A.3.4.2. Study of developmental toxicity

A.3.5. Genotoxicity

A.3.6. Carcinogenicity

A.3.7. Exceptions

A.4. Other Requirements

A.4.1. Special studies (e.g. immunotoxicity, neurotoxicity)

A.4.2. Microbiological properties of residues (if relevant)

A.4.2.1. Potential effects on the human gut flora

A.4.2.2. Potential effects on the microorganisms used for industrial food processing

A.4.3. Observations in humans

A4.4. Development of resistance

A5. User Safety (Determination of ADI or alternative limit)

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A.5.2. Exposure

A.5.3. Risk

A.6. Environmental Risk Assessment

A.6.1. Risk Environmental risk assessment of veterinary medicinal products not containing or consisting of genetically modified organisms

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PART 3.1 B: Performance of tests

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3.1.B.2. Metabolism and residue kinetics

3.1.B.2.1. Pharmacokinetics in food producing species (absorption, distribution, metabolism, excretion)

3.1.B.2.2. Depletion of residues

3.1.B.2.2.1. Identification of marker residue

3.1.B.2.2.2. Ratio of marker to total residues

3.1.B.3. Monitoring and exposure data, if relevant

3.1.B.4. Residue Analytical Method

3.1.B.4.1. Description of the method

3.1.B.4.2. Validation of the method

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3.2.B.1. Identification of the product

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4.1.A.2. Development of resistance (if applicable)

4.1.A.3. Pharmacokinetics (for each target species)

4.1.A.3.1 Bioavailability/bioequivalence study (if required)

4.1.B. Tolerance in the target animal species

PART 4.2: Clinical Documentation

4.2.1. General principles

4.2.2. Conduct of clinical trials

PART 4.3: Particulars and documents

4.3.1. Results of pre-clinical trials

4.3.2. Results of clinical trials

References