LACOMEV

SEMINAIRE DE FORMATION POUR LES POINTS FOCAUX NATIONAUX OIE POUR LES PRODUITS VETERINAIRES

JOHANNESBOURG, **Afrique du Sud,**

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Partie II des dossiers d'AMM des Médicaments Vétérinaires

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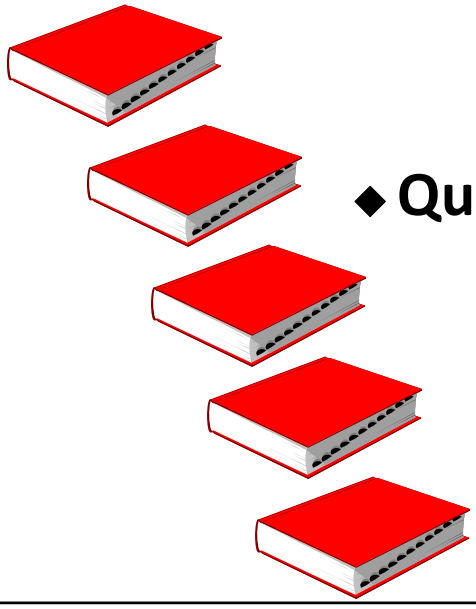
Marketing autorisation dossier



- Quality part

Regulatory Requirements

- Guidelines
  - ➔ VICH : harmonized regulatory requirements European Union, USA and Japan

    GLs 1, 2, 3, 4, 5, 8, 10, 11, 17, 18, 39, 40, 45
  - ➔ EMA : harmonized regulatory requirements European Union
- Pharmacopoeia :
  - ➔ European Pharmacopoeia
    - ➔Pharmacopoeia of a Member State: French Pharmacopoeia, British Pharmacopoeia…
      - ➔ USP

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Part II Framework

- A – Qualitative and Quantitative Particulars of the Constituents
- B – Description of the Manufacturing Method
- C – Control of Starting Materials
- D – Specific Measures Concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies (TSE)
- E – Control Tests carried out at Intermediate stage of the Manufacturing process
- F – Tests on the Finished Product
- G – Stability Test
- H – Other information

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A - Composition

- **A.1 – Formulation**

✓ Description of the pharmaceutical form

✓ Qualitative and Quantitative Composition

Quantity of active substance expressed per unit of volume, per unit of weight or per unit dose (e.g. tablet) active substance in the form of a salt or hydrate: quantitative composition expressed in terms of the mass or biological activity of the active ex : x mg levamisole (as levamisole sulphate)

- **A.2 – Container**

Brief description of the immediate packaging and administration devices supplied with the medicinal product

- **A.3 - Clinical trial formula(e)**
- **A.4 - Development pharmaceutics**

Justification of the formulation choice, manufacturing process, packaging material

B- Method of Preparation

- **B.1 - Manufacturing formula** Quantity of an active substance calculated from the actual assay value of the active substance batch

- **B.2 - Manufacturing process**

✓Detailed description of the manufacturing process and of inprocess controls

- **B.3 – Validation**

critical pharmaceutical process step

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C- Control of Starting Materials

- **C.1 – Control of active substance(s)**
  - specifications and routine tests
  - scientific data

- **C.2 – Control of excipient(s)**
  - specifications and routine tests
  - scientific data

- **C.3 – Control of packaging material**
  - specifications and routine tests
  - scientific data

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C.1 - Control of active substance(s)

C.1.2 - Scientific Data

	Applicant Part	Restricted Part
Specifications	+	
Nomenclature	+	
Description	+	
Manufacture brief outline (flow chart) detailed description	+ 	 +
QC during manufacture		+
Validation		+
Development chemistry evidence of structure potential isomerism physico-chemical characterisation analytical validation	+	
Impurities	+	
Batch analysis	+	
Stability	+	

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D- Specific Measures Concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies (TSE)

Demonstration that material of TSE-relevant animal species are in compliance with the *Note for Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products* and its updates as well as the corresponding EP monograph.

➔ European Pharmacopoeia Certificate of Suitability

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E – Control Tests carried out at Intermediate stage of the Manufacturing process

- **Intermediate product:**
  - ➔ **composition, specifications**
  - ➔ **analytical method description and validation**
  - ➔ **stability studies, shelf-life and storage conditions**
  - ➔ **batch analysis**

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F – Tests on the Finished Product

- **F.1 – Specifications and routine tests**
  - -product specifications
    - General characteristics (depending of the pharmaceutical form)
  - - description of control methods analytical
  - -validation of methods
  - - Identification and assay of active ingredient(s)
    - At release: 95 -105 % without further justification
  - - Identification and assay of excipient(s)
  - - batch analyses
- **F.2 – Scientific Data**

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G- Stability

- **G.1 Active substance(s)**
  - **Retest period and storage conditions**
  - **Stability data**
- **G.2 Finished product**
  - **Shelf-life, in-use shelf-life where appropiate (ex multi-dose product) and storage conditions**
  - **Shelf-life specifications**
  - **Stability data**

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G- Stability

ZONES CLIMATIQUES (OMS)

Zones climatiques	Conditions de températures et d'hygrométrie	
	TEMPERATURES (°C)	HYGROMETRIES (HR)
Zone I (climat tempéré)	21°C	45% HR
Zone II (climat méditerranéen et subtropical avec possibilité de forte humidité)	25°C	60% HR
Zone III (climat chaud et sec)	30°C	35% HR
Zone IV (climat chaud et humide)	30°C	65% HR

G- Stability

- **Storage Conditions : ex: Europe**
  - ➔ **long term testing: 25°C / 60 % RH**
  - ➔ **accelerated testing: 40°C / 75 % RH**
  - ➔ **intermediate testing: 30°C / 60 % RH**
- **Testing frequency :**
  - ➔ **long term testing : 0-3-6-9-12-18-24 months then annually**
  - ➔ **accelerated testing : 0-3-6-(9-12) months**

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THANKS YOU FOR YOUR ATTENTION