EMA and VICH Guidelines

Here you can find a list of quality guidelines for veterinary medicinal products as published by European Medicines Agency (EMA) and Veterinary International Co-operation on Harmonization (VICH). These guidelines together with requirements of the current version of European and Czech Pharmacopoeia should be taken into consideration for the preparation of the quality part of a registration dossier.

Apart from the following guidelines, EMA also publishes and continuously updates a list of questions and answers (Part 1 and Part 2) concerning interpretation and implementation of the guidelines.

1. Development pharmaceuticals

Name	Number	Effective from	Source	Note
Development pharmaceutics for veterinary medicinal products	EMEA/CVMP/315/98	March 2000	EMA	
Sterilisation of the medicinal product, active substance, excipient and primary container	EMA/CHMP/CVMP/QWP/BWP/850374/2015		EMA	
Decision trees for selection of sterilisation methods (Annex to note for guidance on development pha	EMEA/CVMP/065/99	September 2000	EMA	

2. Manufacture of medicinal product

Name	Number	Effective from	Source	Note
Manufacture of the finished dosage form	EMEA/CVMP/126/95	June 1996	EMA	G
Start of shelf-life of the finished dosage form (Annex to note for guidance on the manufacture of the	EMEA/CVMP/453/01	December 2001	EMA	A
Process validation for finished products – information and data to be provided in regulatory submissions	EMA/CHMP/CVMP/QWP/BWP/70278/2012	August 2012	EMA	Gi

Limitations to the use of ethylene oxide in the manufacture of medicinal products	EMEA/CVMP/27101	March 2001	EMA	Guideline
Use of ionizing radiation in the manufacture of medicinal products	3AQ4A	July 1992	Eudralex	Gui

3. Active substance

Name	Number	Effective from	Source	Note
Active substance master file procedure	EMEA/CVMP/134/02	October 2012	EMA	Gu
Chemistry of active substances: new active substances	EMA/CVMP/QWP/703668/2017	2018	EMA	Gui
Summary of requirements for active substances in the quality part of the dossier	EMEA/CVMP/1969/02	February 2005	EMA	Gui
Template for the qualified person's (QP) declaration concerning good manufacturing practice compliance	EMA/196229/2014	June 2014	EMA	Gui
Chemical structure and properties criteria to be considered for the evaluation of new active substances	EMA/CVMP/QWP/362269/2016	October 2017	EMA	Ref
Use of cocrystals of active substances in medicinal products	EMA/CVMP/QWP/284408/2015	July 2015	EMA	Ref

4. Impurities

Name	Number	Effective from	Source	Note
Implementation of risk assessment requirements for elemental impurities in veterinary medicin	EMA/CVMP/QWP/620110/2017	January 2018	EMA	Gu
Assessment and control of DNA reactive (mutagenic) impurities in veterinary medicinal products	EMA/CVMP/SWP/377845/2016		EMA	Dra
Control of impurities of pharmacopoeial substances and compliance with the European Pharmacopoeia	EMEA/CVMP/059/04	March 2004	EMA	Pos
Setting specifications for related impurities in antibiotics	CHMP/CVMP/QWP/199256/2012	2013	EMA	Gui
VICH GL10 Impurities in new veterinary drug substances	CVMP/VICH/837/99	February 2008	VICH	Gui
VICH GL11 Impurities in new veterinary medicinal products	CVMP/VICH/838/99	February 2008	VICH	Gui
VICH GL18 Residual solvents in new veterinary medicinal products, active substances and excipients	CVMP/VICH/502/99	July 2012	VICH	Gui
Annexes to VICH GL 18	EMEA/CVMP/511/03	March 2013	EMA	Ann
Application of VICH GL 18 on residual solvents to veterinary medicinal products containing existing ac	EMEA/CVMP/423/01	May 2004	EMA	Gui

5. Excipients

Name	Number	Effective from	Source	Note
Excipients in the dossier for application for marketing authorisation for veterinary medicinal products	EMEA/CVMP/104/98	June 1998	EMA	G

Inclusion of antioxidants and antimicrobial preservatives in medicinal products	CVMP/QWP/115/95	January 1998	EMA	Gui
Quality of water for pharmaceutical use	CPMP/QWP/158/01	June 2002	EMA	Gui
Water for injection prepared by reverse osmosis	CHMP/CVMP/28271/08	March 2008	EMA	Ref

6. Packaging

Name	Number	Effective from	Source	Note
Plastic primary packaging materials	EMEA/CVMP/205/04	December 2005	EMA	G

7. Specifications, analytical procedures and analytical validation

Name	Number	Effective from	Source	Note
Parametric release	EMA/CVMP/QWP/339588/2005	January 2007	EMA	Gu
Specifications and control tests on the finished product	3AQ11A	June 1992	Eudralex	Gui
VICH GL1 Validation of analytical procedures: definition and terminology	CVMP/VICH/590/98	October 1999	VICH	Gui
VICH GL2 Validation of analytical procedures: methodology	CVMP/VICH/591/98	October 1999	VICH	Gui
VICH GL39 Test procedures and acceptance criteria for new veterinary drug substances and new me	EMEA/CVMP/VICH/810/04	November 2006	VICH	Gui
VICH GL40 Test procedures and acceptance criteria for new biotechnological/biological veterinary me	EMEA/CVMP/VICH/811/04	November 2006	VICH	Gui
Dissolution specification for generic oral immediate release products	EMA/CHMP/CVMP/QWP/336031/2017	August 2017	VICH	Ref

8. TSE

Name	Number	Effective from	Source	Note
Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary	EMEA/410/01	July 2011	EMA	Guideline

9. Stability

Name	Number	Effective from	Source	Note
Declaration of storage conditions: in the product information of pharmaceutical veterinary medicin	EMEA/CVMP/422/99	October 2003	EMA	An
In-use stability testing of veterinary medicinal products (excluding immunological veterinary medicina	EMEA/CVMP/424/01	September 2002	EMA	Gui
Maximum shelf-life for sterile medicinal products after first opening or following reconstitution	EMEA/CVMP/198/99	February 2001	EMA	Gui
Stability testing for applications for variations to marketing authorisation	EMA/CHMP/CVMP/QWP/441071/2011	October 2014	EMA	Gui
Stability testing of existing active substances and related finished products	EMEA/CVMP/846/99	September 2001	EMA	Gui
VICH GL3 Stability testing of new veterinary drug substances and medicinal products	CVMP/VICH/899/99	January 2008	VICH	Gui
VICH GL4 Stability testing for new veterinary dosage forms	CVMP/VICH/900/99	May 2000	VICH	Gui
VICH GL5 Stability testing: photostability testing of new veterinary drug substances and medicinal pro	CVMP/VICH/901/00	May 2000	VICH	Gui
VICH GL8 Stability testing for medicated premixes	CVMP/VICH/838/99	December 2000	VICH	Gui
VICH GL45 Bracketing and matrixing designs for stability testing of new veterinary drug substances an	EMEA/CVMP/VICH/534667/2007	April 2010	VICH	Gui
VICH GL51 Quality: statistical evaluation of stability data	EMA/CVMP/VICH/858875/2011	February 2014	VICH	Gui

10. Herbal medicinal products

Name	Number	Effective from	Source	Note
Declaration of herbal substances and herbal preparations in herbal medicinal products/traditional her	EMEA/HMPC/CHMP/CVMP/287539/05	December 2010	EMA	Gu
Quality of combination herbal medicinal products/traditional herbal medicinal products	EMEA/HMPC/CHMP/CVMP/214869/2006	November 2008	EMA	Gui
Quality of herbal medicinal products/traditional herbal medicinal products	CPMP/QWP/2819/00	April 2012	EMA	Gui
Specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and	CPMP/QWP/2820/00	September 2011	EMA	Gui

11. Specific veterinary dosage forms

Name	Number	Effective from	Source	Note
Additional quality requirements for products intended for incorporation into animal feeding-stuffs (me	EMEA/CVMP/080/95	July 1997	EMA	Gu
Quality aspects of pharmaceutical veterinary medicines for administration via drinking water	EMEA/CVMP/540/03	January 2005	EMA	Gui
Quality aspects of single-dose veterinary spot-on products	EMEA/CVMP/QWP/544461/2007	February 2010	EMA	Gui
Quality of modified release dosage forms for veterinary use	EMEA/CVMP/680/02	February 2004	EMA	Gui
Maximum in-use shelf-life for medicated drinking water	EMEA/CVMP/1090/02	December 2002	EMA	Pos
Premixes for medicated feeding stuffs for veterinary use versus powders/granules for oral use or use	EMEA/CVMP/199/97	August 1998	EMA	Pos

12. Minor uses / minor species (MUMS)

Name	Number	Effective from	Source	Notes
Quality data requirements for veterinary medicinal products intended for minor use or minor species	EMA/CVMP/QWP/128710/2004	February 2007	EMA	G(
CVMP guidelines on data requirements for veterinary medicinal products intended for minor uses o	EMEA/CVMP/133672/2005	January 2007	EMA	CVM