

### 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 pharmaceuticals	EMA/CVMP/315/98	March 2000	EMA	
Sterilisation of the medicinal products	EMA/CVMP/CVMP/OWB/BWP/850/2015	September 2015	EMA	primary
Decision trees for selection of analytical methods	EMA/CVMP/1065/99	September 2000	EMA	for guidance on development pharmaceuticals

#### 2. Manufacture of medicinal product

Name	Number	Effective from	Source	Note
Manufacture of the finished product	EMA/CVMP/1126/95	June 1996	EMA	G
Start of shelf-life of the finished product	EMA/CVMP/453/01	December 2001	EMA	Annex 1 for guidance on the manufacture of the finished product
Process validation for finished products	EMA/CVMP/CVMP/OWB/BWP/850/2015	September 2015	EMA	in regulatory submissions

Limitations to the use of ionizing radiation in the manufacture of medicinal products	EMA	EMA/CVMP/271/02	March 2001		
Guideline	EMA	EMA/CVMP/271/02	March 2001		
Use of ionizing radiation in the manufacture of medicinal products	EMA	EMA/CVMP/271/02	March 2001	Eudralex	Guideline

3. Active substance

Name	Number	Effective from	Source	Note
Active substance master file procedure	EMA/CVMP/134/02	October 2012	EMA	Guideline
Chemistry of active substances	EMA/CVMP/70736/02	October 2018	EMA	Guideline
Summary of requirements for active substances in the part of the dossier	EMA/CVMP/1039/02	February 2005	EMA	Guideline
Template for the qualified person declaration on GMP manufacturing practice compliance	EMA/19629/2014	June 2014	EMA	Guideline
Chemical structure and impurity data for the evaluation of new active substances	EMA/CVMP/1629/07	October 2007	EMA	Reference
Use of cocrystals of active substances	EMA/CVMP/26400/2015	June 2015	EMA	Reference

4. Impurities

Name	Number	Effective from	Source	Note
Implementation of risk assessment for impurities in veterinary medicinal products	EMA/CVMP/QWP/6010/2017	October 2018	EMA	Guideline
Assessment and control of impurities in veterinary medicinal products	EMA/CVMP/QWP/377245/2016	June 2016	EMA	Guideline
Control of impurities of pharmaceuticals in accordance with the European Pharmacopoeia	EMA/CVMP/059/04	March 2004	EMA	Guideline
Setting specifications for related compounds	EMA/CVMP/QWP/15925/06	June 2013	EMA	Guideline
VICH GL10 Impurities in New Active Substances	EMA/VICH/397/00	September 2008	VICH	Guideline
VICH GL11 Impurities in New Active Substances	EMA/VICH/398/00	September 2008	VICH	Guideline
VICH GL18 Residual solvents in primary packaging of active substances and excipients	EMA/VICH/502/00	July 2012	VICH	Guideline
Annexes to VICH GL 18	EMA/CVMP/511/03	March 2013	EMA	Annex
Application of VICH GL 18 to veterinary medicinal products containing existing substances	EMA/CVMP/420/01	May 2001	EMA	Guideline

5. Excipients

Name	Number	Effective from	Source	Note
Excipients in the dossier for marketing authorisation for veterinary medicinal products	EMA/CVMP/004/98	June 1999	EMA	Guideline

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Inclusion of antioxidants and antioxidants in preservation in medicinal products	EMA/CVMP/QWP/015/95 January 1998	EMA	Guideline
Quality of water for pharmaceuticals	EMA/CVMP/QWP/158/01 June 2002	EMA	Guideline
Water for injection prepared by reverse osmosis	EMA/CVMP/QWP/287/08 March 2008	EMA	Reference

### 6. Packaging

Name	Number	Effective from	Source	Note
Plastic primary packaging for medicinal products	EMA/CVMP/205/04	December 2005	EMA	Guideline

### 7. Specifications, analytical procedures and analytical validation

Name	Number	Effective from	Source	Note
Parametric release	EMA/CVMP/QWP/339588/2005	January 2007	EMA	Guideline
Specifications and control tests on the finished product	3AQS1A	1992	Eudralex	Guideline
VICH GL1 Validation of analytical procedures: definitions and terminology	EMA/VICH/QP/590/98	October 1999	VICH	Guideline
VICH GL2 Validation of analytical procedures: methodology	EMA/VICH/QP/591/98	October 1999	VICH	Guideline
VICH GL39 Test procedures and acceptance criteria for veterinary drug substances and new formulations	EMA/CVMP/VICH/810/06	November 2006	VICH	Guideline
VICH GL40 Test procedures and acceptance criteria for veterinary biological products	EMA/CVMP/VICH/811/06	November 2006	VICH	Guideline
Dissolution specification for medicinal products	EMA/CVMP/QWP/339588/2005	January 2007	VICH	Reference

### 8. TSE

Name	Number	Effective from	Source	Note
Minimising the risk of transmitting animal spongiform encephalopathy to humans via human and animal derived products	<a href="#">EMA/142011</a>	2011	EMA	Guideline

### 9. Stability

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Name	Number	Effective from	Source	Note
Declaration of storage conditions for medicinal products of pharmaceutical veterinary medicinal products	EMA/CVMP/112/00	October 2003	EMA	Annex
In-use stability testing of medicinal products	EMA/CVMP/62/01	September 2002	EMA	Guidance
Maximum shelf-life for sterile ophthalmics after opening or following reconstitution	EMA/CVMP/198/99	February 2001	EMA	Guidance
Stability testing for applications for variation of product	EMA/CVMP/106/03	February 2004	EMA	Guidance
Stability testing of existing medicinal products and new products	EMA/CVMP/846/99	September 2001	EMA	Guidance
VICH GL3 Stability testing of drug substances and medicinal products	CVMP/VICH/399/99	January 2000	VICH	Guidance
VICH GL4 Stability testing of dosage forms	CVMP/VICH/600/99	May 2000	VICH	Guidance
VICH GL5 Stability testing of veterinary drug substances and medicinal products	CVMP/VICH/110/00	May 2000	VICH	Guidance
VICH GL8 Stability testing of mixtures	CVMP/VICH/186/99	December 2000	VICH	Guidance
VICH GL45 Bracketing and matrixing	EMA/CVMP/158/01	April 2001	VICH	Guidance
VICH GL51 Quality: stability	EMA/CVMP/158/01	April 2001	VICH	Guidance

### 10. Herbal medicinal products

Name	Number	Effective from	Source	Note
Declaration of herbal substances	EMA/CVMP/106/03	February 2004	EMA	Annex
Quality of combination herbal medicinal products	EMA/CVMP/106/03	February 2004	EMA	Guidance
Quality of herbal medicinal products	EMA/CVMP/106/03	February 2004	EMA	Guidance
Specifications: test procedures	EMA/CVMP/106/03	February 2004	EMA	Guidance

### 11. Specific veterinary dosage forms

Name	Number	Effective from	Source	Note
Additional quality requirements for medicinal products intended for incorporation into animal feeding-stuffs (medicinal products)	EMA/CVMP/106/03	February 2004	EMA	Annex
Quality aspects of pharmaceuticals for administration in drinking water	EMA/CVMP/106/03	February 2004	EMA	Guidance
Quality aspects of single-dose veterinary products	EMA/CVMP/106/03	February 2004	EMA	Guidance
Quality of modified release veterinary products	EMA/CVMP/106/03	February 2004	EMA	Guidance
Maximum in-use shelf-life of veterinary products	EMA/CVMP/106/03	February 2004	EMA	Guidance
Premixes for medicated feed	EMA/CVMP/106/03	February 2004	EMA	Guidance

**12. Minor uses / minor species (MUMS)**

Name	Number	Effective from	Source	Note
Quality data requirements for CVMP medicinal products intended for minor uses or minor species	EMA/CVMP/QWP/1287/2004	1 January 2007	EMA	CVMP
CVMP guidelines on data requirements for medicinal products intended for minor uses or minor species	EMA/CVMP/1367/2005	1 January 2007	EMA	CVMP