## 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 the guideline on development pha | EMEA/CVMP/055/99 | 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 (An addendum to the guideline on the manufacture of the | EMEA/CVMP/453/01 | December 2001 | EMA | Adm |
| Process validation for finished products – information and data to be provided in regulatory submission | EMA/CHMP/CVMP/QWP/70278/2012 | August 2014 | EMA | Gui |

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|---|---|---|---|---|
| Limitations to the use of ethylene oxide in the manufacture of medicinal products | EMEA/CVMP/271/01 | March 2001 | EMA | Guideline |
| Use of ionizing radiation in the manufacture of medicinal products | EMEA/CVMP/QWP/407/96 | 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/707369/2017 | 2018 | EMA | Gui |
| Summary of requirements for active substances in the quality part of the dossier | EMEA/CVMP/1039/02 | February 2005 | EMA | Gui |
| Template for the qualified person's declaration concerning good manufacturing practice compliance | EMA/196322/2014 | June 2014 | EMA | Gui |
| Chemical structure and properties criteria to be considered in the evaluation of new active substances | EMA/CVMP/QWP/362/2016 | October 2017 | EMA | Ref |
| Use of cocrystals of active substances in medicinal products | CHMP/CVMP/QWP/208408/2015 | July 2016 | EMA | Ref |

## 4. Impurities

| Name | Number | Effective from | Source | Note |
|---|---|---|---|---|
| Implementation of risk assessment requirements for elemental impurities in veterinary medicines | EMA/CVMP/QWP/621010/2017 | January 2018 | EMA | Gu |
| HAssessment and control of DNA reactive (mutagenic) impurities in veterinary medicinal products | EMA/CVMP/SWP/377815/2016 | March 2018 | EMA | Dra |
| Control of impurities of pharmacopoeial substances - compliance with the European Pharmacopoeia | EMEA/CVMP/159/94 | March 2004 | EMA | Po |
| Setting specifications for related impurities in antibiotics | CHMP/CVMP/QWP/199250/2010 | 2013 | EMA | Gui |
| VICH GL10 Impurities in new veterinary drug substances | CVMP/VICH/837/99 - Revision 1 | February 2008 | VICH | Gui |
| VICH GL11 Impurities in new veterinary medicinal products | CVMP/VICH/838/99 - Revision 1 | 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 | EMEA/CVMP/423/01 | May 2001 | 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/004/98 | June 1999 | EMA | G |

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|---|---|---|---|---|
| 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/QWP/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 controls in the finished product | 3AQ1A | 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 med | EMEA/CVMP/VICH/810/99 | November 2006 | VICH | Gui |
| VICH GL40 Test procedures and acceptance criteria for new biotechnological/biological veterinary med | EMEA/CVMP/VICH/811/99 | November 2006 | VICH | Gui |
| Dissolution specification for generic oral immediate release products | EMEA/CHMP/CVMP/QWP/[illegible] | [illegible] | VICH | Ref |

## 8. TSE

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

## 9. Stability

| Name | Number | Effective from | Source | Note |
|---|---|---|---|---|
| Declaration of storage conditions of medicinal products | EMEA/CVMP/422/99 | October 2003 | EMA | Ad |
| In-use stability testing of veterinary medicinal products (excluding immunological | EMEA/CVMP/424/01 | Sept/Oct 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 | EMEA/CVMP/CVWP/641671/2011 | October 2014 | EMA | Gui |
| Stability testing of existing active substances and related finished products | EMEA/CVMP/346/99 | 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 of 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 products | CVMP/VICH/901/99 | May 2000 | VICH | Gui |
| VICH GL8 Stability testing of medicated premixes | CVMP/VICH/836/99 | December 2000 | VICH | Gui |
| VICH GL45 Bracketing and matrixing designs for stability testing of new veterinary drug substances and | EMEA/CVMP/VICH/5384/2007 | September 2007 | VICH | Gui |
| VICH GL51 Quality: statistical evaluation of stability data | EMEA/CVMP/VICH/3538/2011 | February 2014 | VICH | Gui |

## 10. Herbal medicinal products

| Name | Number | Effective from | Source | Note |
|---|---|---|---|---|
| Declaration of herbal substances and herbal preparations | EMEA/HMPC/CHMP/CVMP/QWP/375589/05 | Effective 2010 | EMA | Gui |
| Quality of combination herbal medicinal products | EMEA/HMPC/CHMP/CVMP/QWP/375589/2008 | 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 | Step 5 in 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 (mo | EMEA/CVMP/080/95 | July 1997 | EMA | Gu |
| Quality aspects of pharmaceuticals administered via drinking water | EMEA/CVMP/540/03 | January 2005 | EMA | Gui |
| Quality aspects of single dose veterinary spot-on products | EMEA/CVMP/CVWP/544481/2007 | March 2010 | EMA | Gui |
| Quality of modified release veterinary medicinal products | 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 | EMEA/CVMP/199/97 | August 1998 | EMA | Pos |

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

| Name | Number | Effective from | Source | Note |
|---|---|---|---|---|
| Quality data requirements for veterinary medicinal products intended for minor use or minor species | EMA/CVMP/QWP/128171/2004 | 1 January 2007 | EMA | G |
| CVMP guidelines on data requirements to overcome | EMEA/CVMP/133672/2005 | 1 January 2007 | EMA | CVM |