(https://apvma.gov.au/node/1059)

Proposed changes to the existing guidance:

- Added text is highlighted in yellow
- Deleted text is marked in grey with a strikeout

~~Additional~~ International data guidelines for veterinary chemistry and manufacture (Part 2)

These pages contain information about the range of chemistry and manufacture (Part 2) data that the APVMA recommends submitting as part of your application.

We have adopted (with some conditions) guidelines that outline the procedures recommended for generating relevant chemistry and manufacture data for your application. Applicants should refer to these guidelines, in conjunction with the general guidelines for chemistry and manufacture of active constituents and products, when generating chemistry and manufacture data.

Chemistry and manufacture guidelines for veterinary chemical products

Chemistry and manufacture guidelines for veterinary chemical products include the following:

VICH guidelines

- GL1:Validation of analytical procedures: definition and terminology (link is external)
- GL2: Validation of analytical procedures: methodology (link is external)
- GL3(R): Stability: stability testing of new veterinary drug substances (revision) (link is external)
- GL4: Stability testing for new dosage forms (link is external)
- GL5 (Stability 3): Stability testing: photostability testing of new veterinary drug substances and medicinal products (link is external)
- GL8: Stability testing for medicated premixes (link is external)
- GL10(R): Impurities in new veterinary drug substances (revision) (link is external)
- GL11(R): Impurities in new veterinary medicinal products (revision) (link is external)
- GL17: Stability testing of new biotechnological/biological veterinary medicinal products (link is external)
- GL18: Impurities: residual solvents in new veterinary medicinal products, active substances and excipients (link is external)
- GL39: Test procedures and acceptance criteria for new veterinary drug substances and new medicinal products: chemical substances (link is external)
- GL40: Test procedures and acceptance criteria for new biotechnological/biological veterinary medicinal products (link is external)
- GL45: Quality: bracketing and matrixing designs for stability testing of new veterinary drug substances and medicinal products (link is external)
- GL51: Statistical evaluation of stability data (link is external)

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Other guidelines

The FDA, EMA and Heath Canada websites may also provide useful guidance in generating chemistry and manufacture data.

- U.S Food and Drug Administration (FDA) guidelines (link is external)
- European Medicines Agency (EMA) guidelines (link is external); eg In-use stability guideline EMEA/CVMP/424/01 (link is external)
- Health Canada guidelines (link is external)

Related guidelines

- Approval of Active Constituents for which information is not readily available