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Veterinary Medicines and Product Data Management

# Framework for a correlation table (NTA:CTD) for ASMFs/Part 2 in CTD format for dossiers for veterinary medicinal products

The following table is only a framework for an acceptable correlation table.

As the NTA and CTD have completely different chapters/sections, and not similar ones, it is very difficult to give a definitive comparative list. Furthermore the dossier structure will vary depending on several factors such as the type of product, number and type of active substance(s), etc.

Also, the headings in the legislation (Annex 1 of Directive 2001/82/EC as amended) have still not been reflected in Volume 6B (Notice to Applicants) of The rules governing medicinal products in the European Union, therefore there are currently 2 different schemes, both of which are generally acceptable in the EU.

The table below shows the headings from the current legislation (as Volume 6B will be revised in accordance with that). Other types of correlation tables and other more detailed subheadings may also be acceptable.

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| NTA | NTA headings (from legislation) | EU CTD | CTD |
|---|---|---|---|
| --- | --- | MODULE 3 TABLE OF CONTENTS | 3.1 |
| **Part 2** | **PHARMACEUTICAL (PHYSICO-CHEMICAL, BIOLOGICAL OR MICROBIOLOGICAL INFORMATION (QUALITY))** | BODY OF DATA | 3.2 |
| **2.A** | **QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS** | | |
| 2.A.1 | Qualitative particulars | Description and composition of the drug product | 3.2.P.1 |
| 2.A.2 | Usual terminology | | |
| 2.A.3 | Quantitative particulars | | |
| 2.A.4 | Development pharmaceutics | Pharmaceutical Development | 3.2.P.2 |
| **2.B** | **DESCRIPTION OF THE MANUFACTURING METHOD** | Manufacture | 3.2.P.3 |
| | | Manufacturer(s) | 3.2.P.3.1 |
| | | Batch formula | 3.2.P.3.2 |
| | | Description of Manufacturing Process and Process Controls | 3.2.P.3.3 |
| | | Facilities and Equipment | 3.2.A.1 |
| | | Controls of critical steps and intermediates | 3.2.P.3.4 |
| | | Process validation and/or evaluation | 3.2.P.3.5 |
| **2.C** | **CONTROL OF STARTING MATERIALS** | | |
| 2.C.1 | General requirements | | |
| 2.C.1.1 | Active substances | DRUG SUBSTANCE | 3.2.S |
| 2.C.1.1.1 | Active substances listed in pharmacopoeias | | |
| 2.C.1.1.2 | Active substances not in a pharmacopoeia | | |
| | | General Information | 3.2.S.1 |
| | | Nomenclature | 3.2.S.1.1 |
| | | Structure Description: | 3.2.S.1.2 |
| | | General Properties | 3.2.S.1.3 |
| | | Manufacture | 3.2.S.2 |
| | | Manufacturer(s) | 3.2.S.2.1 |
| | | Description of manufacturing process and process controls | 3.2.S.2.2 |
| | | Control of materials | 3.2.S.2.3 |
| | | Controls of critical steps and intermediates | 3.2.S.2.4 |
| | | Process validation and/or evaluation | 3.2.S.2.5 |
| | | Manufacturing process development | 3.2.S.2.6 |
| | | Characterisation | 3.2.S.3 |
| | | Elucidation of structure and other characteristics | 3.2.S.3.1 |
| | | Impurities | 3.2.S.3.2 |
| | | Control of drug substance | 3.2.S.4 |
| | | Specification | 3.2.S.4.1 |
| | | Analytical Procedures | 3.2.S.4.2 |
| | | Validation of analytical procedures | 3.2.S.4.3 |
| | | Batch analyses | 3.2.S.4.4 |
| | | Justification of Specification | 3.2.S.4.5 |

| NTA | NTA headings (from legislation) | EU CTD | CTD |
|---|---|---|---|
| | | Reference Standards or Materials | 3.2.S.5 |
| 2.C.1.1.3 | Physico-chemical characteristics liable to affect bioavailability | | |
| 2.C.1.2 | Excipients | Control of excipients | 3.2.P.4 |
| 2.C.1.3 | Container-closure systems | | |
| 2.C.1.3.1 | Active substance | Container Closure System | 3.2.S.6 |
| 2.C.1.3.2 | Finished Product | Container Closure System | 3.2.P.7 |
| 2.C.1.4 | Substances of biological origin | Adventitious Agents Safety Evaluation | 3.2.A.2 |
| | | Excipients of human or animal origin | 3.2.P.4.5 |
| **2.D** | **CONTROL TESTS CARRIED OUT AT INTERMEDIATE STAGES OF THE MANUFACTURING PROCESS** | Controls of critical steps and intermediates | 3.2.P.3.4 |
| **2.E** | **TESTS ON THE FINISHED PRODUCT** | Control of drug product | 3.2.P.5 |
| 2.E.1 | General characteristics of the finished product | Specification(s) | 3.2.P.5.1 |
| | | Justification of specification(s) | 3.2.P.5.6 |
| | | Characterisation of Impurities | 3.2.P.5.5 |
| | | Analytical Procedures | 3.2.P.5.2 |
| | | Batch analyses | 3.2.P.5.4 |
| 2.E.2 | Identification and assay of active substance(s) | Validation of Analytical Procedures | 3.2.P.5.3 |
| | | Reference Standards or Materials | 3.2.P.6 |
| 2.E.3 | Identification and assay of excipient components | Validation of Analytical Procedures | 3.2.P.5.3 |
| | | Reference Standards or Materials | 3.2.P.6 |
| 2.E.4 | Safety tests | | |
| **2.F** | **STABILITY TESTS** | | |
| 2.F.1 | Active substances | Stability | 3.2.S.7 |
| 2.F.2 | Finished Product | Stability | 3.2.P.8 |
| **2.G** | **OTHER INFORMATION** | | |
| | *Post Approval Change Management Protocols (new)* | | |
| | | APPENDICES | 3.2.A |
| | | LITERATURE REFERENCES | 3.3 |