**RESIDUES OVERALL SUMMARY (ROS)**

**General Instructions**

Residues Overall Summary (ROS) should be completed for pharmaceutical products intended for food producing species.

All sections and fields in the Summary sheet that would be applicable should be completed. Each summary information and the accompanying tables are intended to be for a single study, using one product which is administered to one food producing species. If there is more than one study, summaries of each study should be submitted.

It is understood that certain sections and fields may not apply and should be indicated as such by reporting “not applicable” in the appropriate area with an accompanying explanatory note.

The use of tables to summarize the information is encouraged, where possible. The tables included in this template may need to be expanded or duplicated (e.g., for multiple studies or species), as necessary.

These tables are included as illustrative examples of how to summarize information. Other approaches to summarize the information can be used if they fulfil the same purpose.

Please state the exact location of the full study report or any appended documents in the relevant sections of the form.

**Acceptable Daily Intake**

Please indicate the ADI established for each pharmacological substance

|  |  |  |
| --- | --- | --- |
| **Pharmacologically active substance(s)** | **ADI (µg/kg)** | **Source of information** |
|  |  | (e.g. Codex, EU, FDA) |
|  |  |  |

**Maximum residue limit(s) (MRL(s)):**

Please complete the MRL status of all the pharmacologically active substance(s) in the table below.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Pharmacologically active substance(s)** | **Species** | **Target tissue**  | **Marker residue**  | **MRLs (µg/kg)** | **Source of information** |
|  |  | Muscle |  |  | (e.g. Codex, EU, FDA) |
| Fat |  |  |
| Liver |  |  |
| Kidney |  |  |
| Milk/Eggs |  |  |
|  |  | Muscle |  |  |  |
| Fat |  |  |
| Liver |  |  |
| Kidney |  |  |
| Milk/Eggs |  |  |

**Proposed Withdrawal Period:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Species** | **Dose (mg/kg)** | **Tissue** | **Withdrawal Period (Hours/days)** |
|  |  | Meat |  |
|  | Milk/Eggs |  |
|  |  | Meat |  |
|  | Milk/Eggs |  |

**Summary of Residue Depletion Study:**

|  |  |  |
| --- | --- | --- |
| Name of Product: |  | Active Ingredient(s): |
| StudyIdentification: | Title: | GLP (Yes/No): |
|  | Study Ref No: | Date of study: |
|  | Site of residue study |  |
| Test System: | Species:  | Breed: |
|  | Age: | Sex:  |
| Test substance: | Name:  | Batch No\*: |
|  | Dose(s) given\*\*:  | Route & method of Admin: |
|  | Site of injection (if applicable): | Max injection volume (if applicable): |
| ExperimentalDesign: | Time points: | No. Animals/time point:  |
|  | Samples Collected:  | Water Temperature (fish only): |
|  | Statistical Analysis performed and Confidence intervals (I think we accept 95:95) |  |
| AnalyticalMethod\*\*\*: | Type of method: |
|  | LOD for each tissue: |
|  | LOQ for each tissue: |

\*

Please enclose certificate of analysis.

\*\* If given in feed, please quote figures for concentration in feed and amount per kilogram bodyweight.

\*\*\* Please include flow chart outlining the method and tables of validation data and required sensitivity relative to the MRL for the target residue

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| ***Assessor observations/comments:*** |

**Results For Residues In Mammalian Or Avian Tissues (Please quote results in μg/kg)**

|  |  |  |
| --- | --- | --- |
|  |  | **Time Points (days / hours) (Delete as appropriate)** |
| **Tissue** |  |  |  |  |  |  |  |  |  |
| **Liver** | Animal 1 |  |  |  |  |  |  |  |  |
|  | Animal 2 |  |  |  |  |  |  |  |  |
|  | Animal 3 |  |  |  |  |  |  |  |  |
|  | Animal 4 |  |  |  |  |  |  |  |  |
|  | Include additional animal no. if used |  |  |  |  |  |  |  |  |
|  | Mean ± S.D |  |  |  |  |  |  |  |  |
| **Kidney** | Animal 1 |  |  |  |  |  |  |  |  |
|  | Animal 2 |  |  |  |  |  |  |  |  |
|  | Animal 3 |  |  |  |  |  |  |  |  |
|  | Animal 4 |  |  |  |  |  |  |  |  |
|  | Include additional animal no. if used |  |  |  |  |  |  |  |  |
|  | Mean ± S.D |  |  |  |  |  |  |  |  |
| **Muscle** | Animal 1 |  |  |  |  |  |  |  |  |
|  | Animal 2 |  |  |  |  |  |  |  |  |
|  | Animal 3 |  |  |  |  |  |  |  |  |
|  | Animal 4 |  |  |  |  |  |  |  |  |
|  | Include additional animal no. if used |  |  |  |  |  |  |  |  |
|  | Mean ± S.D |  |  |  |  |  |  |  |  |
| **Fat / skin** | Animal 1 |  |  |  |  |  |  |  |  |
| **(Delete as** | Animal 2 |  |  |  |  |  |  |  |  |
| **appropriate)** | Animal 3 |  |  |  |  |  |  |  |  |
|  | Animal 4 |  |  |  |  |  |  |  |  |
|  | Include additional animal no. if used |  |  |  |  |  |  |  |  |
|  | Mean ± S.D |  |  |  |  |  |  |  |  |
| **Injection****Site (if applicable)** | Animal 1 |  |  |  |  |  |  |  |  |
| Animal 2 |  |  |  |  |  |  |  |  |
| Animal 3 |  |  |  |  |  |  |  |  |
| Animal 4 |  |  |  |  |  |  |  |  |
|  | Include additional animal no. if used |  |  |  |  |  |  |  |  |
|  | Mean ± S.D |  |  |  |  |  |  |  |  |

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| ***Assessor observations/comments:*** |

**Results For Residues In Mammalian Milk/Chicken Eggs (Please quote results in μg/kg)**

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| **Milk/ Eggs** | **Animal No.** | **Time Points (days / hours) (Delete as appropriate)** |
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|  | **Mean ± SD** |  |  |  |  |  |  |  |  |  |  |  |  |

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| ***Assessor observations/comments:*** |

**Analytical Method Validation:**

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| **Analytical method summary description** |  |
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| **Tissue** | **Assay No.** | **Concentration** | **Accuracy** **(%)** | **Precision** **(% CV)** | **Calibration conc. range** | **Limit of quantification (LOQ)** | **Storage length** | **Storage stability (% recovery)** |
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| ***Assessor observations/comments:*** |