

الجداول المذكورة في الدليل الارشادي لمتطلبات تسجيل الأدوية البشرية

Tables mentioned in the GCC Data Requirements for Human Drugs Submission

|  |  |
| --- | --- |
| All fields are mandatory | جميع الحقول إلزامية |

|  |  |
| --- | --- |
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**As per the GCC Data Requirements for Human Drugs Submission, the following tables should be submitted. These tables are to be filled out and inserted in the relevant sections of the registration dossier.**

# **Module 1 Regional Administrative Information**

**Certificate of analysis – Drug Substance/Finished Product**

**The information on drug substance batch analyses is recommended to be presented as follows:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Batch number** | **Batch size** | **Batch type** | **Site(s) of:** | | **Date(s) of:** | |
| **Manufacturing** | **Analysis** | **Manufacturing** | **Analysis** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

**The information on finished product batch analyses is recommended to be presented as follows:**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Batch number** | **Batch size** | **Batch type** | **Site(s) of:** | | **Date(s) of:** | | **API manufacturer** |
| **Manufacturing** | **Analysis** | **Manufacturing** | **Analysis** |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

# **Module 3 Quality**

**3.2.S Drug Substance**

**3.2. S.2.5 Process Validation and/or Evaluation**

**The information on process validation and/or evaluation studies for STERILE drug substance is recommended to be presented as follows:**

|  |  |
| --- | --- |
| **Number of batches** |  |
| **Batch number** |  |
| **Batch type** |  |
| **Batch size** |  |
| **Are the submitted batches consecutive?** | Yes  No |
| **Is the process validation protocol submitted?** | Yes  No |
| **Are the process validation results submitted?** | Yes  No |

**3.2.S.3.2 Impurities**

**The information on impurities is recommended to be presented as follows:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Drug-related Impurity**  **(chemical name)** | **Structure** | **Origin** | **Acceptance**  **Criteria** | **Reference** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**3.2.S.4.2 Analytical Procedures**

**The information on analytical procedures is recommended to be presented as follows:**

|  |  |
| --- | --- |
| **Tested parameter** | *e.g. assay, related substances, … (one separate table for each tested parameter).* |
| **Reference** | *e.g. USP, BP, in-house method, …* |

|  |  |
| --- | --- |
| **Chromatographic Conditions:** | |
| * + Column |  |
| * + Flow rate |  |
| * + Wavelength |  |
| * + Injection volume |  |
| * + Temperature |  |
| * + Run time |  |
| * + Retention time |  |
| **Solutions preparation:** |  |
| * + Mobile phase |  |
| * + Buffer |  |
| * + Gradient programs *(if applicable)* |  |
| * + Stock standard solution |  |
| * + Standard solution |  |
| * + Test solution |  |
| * + System suitability solution |  |
| **Acceptance criteria for system suitability test:** | |
| * + % RSD |  |
| * + Tailing factor |  |
| * + No. of theoretical plates (N) |  |
| * + Resolution |  |

**GC for Residual Solvents:**

|  |  |
| --- | --- |
| **Chromatographic Conditions:** | |
| * + Column |  |
| * + Column flow |  |
| * + Carrier |  |
| * + Air flow |  |
| * + H2 flow |  |
| * + Split |  |
| * + Detector temperature |  |
| * + Load |  |
| * + Injector temperature |  |
| * + Makeup flow |  |
| **Solutions preparation:** |  |
| * + Stock solution(s) |  |
| * + Standard preparation |  |
| * + Sample Preparation |  |
| * + System suitability |  |
| **Acceptance criteria for system suitability test:** | |
| * + % RSD |  |
| * + Tailing factor |  |
| * + Resolution |  |

**3.2.S.4.3 Validation of Analytical Procedures**

**The information on validation of analytical procedures is recommended to be presented as follows:**

|  |  |
| --- | --- |
| **Tested parameter** | *e.g. assay, related substances, … (one separate table for each tested parameter).* |

|  |  |  |
| --- | --- | --- |
| **Specificity** | | |
| * Brief summary on how it was performed: |  | |
| * Representative chromatogram(s) | *The chromatogram(s) can be found in page No…* | |
| **Linearity** | | |
| * No. of concentrations |  | |
| * Specified ranges |  | |
| * Parameters: | **Acceptance criteria** | **Results** |
| * *Correlation coefficient* |  |  |
| * *y-intercept* |  |  |
| * *Residual sum of squares* |  |  |
| **Accuracy** | | |
| * Brief summary on how it was performed: |  | |
| * Parameters: | **Acceptance criteria** | **Results** |
| * *% Recovery* |  |  |
| * *% RSD* |  |  |
| * *CI* |  |  |
| **Precision (repeatability and intermediate precision)** | | |
| * Brief summary on how it was performed: |  | |
| * Parameter: | **Acceptance criteria** | **Results** |
| * *% RSD* |  |  |
| **LOQ/LOD** | | |
| * Brief summary on how it was performed: |  | |
| * LOD |  | |
| * LOQ |  | |
| **Robustness** | | |
| * Brief summary on how it was performed: |  | |
| **Systems suitability** | | |
| * Parameters: | **Acceptance criteria** | **Results** |
| * *% RDS* |  |  |
| * *Tailing factor* |  |  |
| * *No. of theoretical plates* |  |  |
| * *Resolution* |  |  |

**Method transfer *(if applicable):***

|  |  |  |
| --- | --- | --- |
| **Protocol:** |  | |
| * **Tested Parameters:** | **Acceptance criteria** | **Results** |
|  |  |  |
|  |  |  |

**3.2.S.4.4 Batch Analyses**

**The information on drug substance batch analyses is recommended to be presented as follows:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Batch number** | **Batch size** | **Batch type** | **Site(s) of:** | | **Date(s) of:** | |
| **Manufacturing** | **Analysis** | **Manufacturing** | **Analysis** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

**3.2.S.5 Reference Standards or Materials**

**The information on reference standards/reference materials is recommended to be presented as follows:**

|  |  |
| --- | --- |
| **Type of reference standards** | Primary reference standard  Working or secondary reference standard  Manufacturer reference standard |
| **Information on potency** | *……… %* |
| **Information on calibration of working standard with primary reference standard** |  |

**3.2.S.7 Stability**

**3.2.S.7.1 Stability Summary and Conclusions**

**The information on stability studies is recommended to be presented as follows:**

|  |  |  |
| --- | --- | --- |
|  | **Accelerated stability studies** | **Long term stability studies** |
| **Storage conditions (°C, % RH)** |  |  |
| **Batch number** |  |  |
| **Batch type** |  |  |
| **Batch size** |  |  |
| **Completed (and proposed) testing intervals** |  |  |
| **Container closure system** |  |  |
| **Manufacturing site** |  |  |
| **Manufacturing date** |  |  |
| **Stability start date** |  |  |
| **Storage conditions and the proposed retest date or shelf-life** |  | |

**3.2.P Drug Product**

**3.2.P.3.5 Process Validation and/or Evaluation**

**The information on process validation and/or evaluation studies for STERILE product is recommended to be presented as follows:**

|  |  |
| --- | --- |
| **Number of batches** |  |
| **Batch number** |  |
| **Batch type** |  |
| **Batch size** |  |
| **Are the submitted batches consecutive?** | Yes  No |
| **Is the process validation protocol submitted?** | Yes  No |
| **Are the process validation results submitted?** | Yes  No |

**3.2.P.5.2 Analytical Procedures**

**The information on analytical procedures is recommended to be presented as follows:**

|  |  |
| --- | --- |
| **Tested parameter** | *e.g. assay, related substances, … (one separate table for each tested parameter).* |
| **Reference** | *e.g. USP, BP, in-house method, …* |

|  |  |
| --- | --- |
| **Chromatographic Conditions:** | |
| * + Column |  |
| * + Flow rate |  |
| * + Wavelength |  |
| * + Injection volume |  |
| * + Temperature |  |
| * + Run time |  |
| * + Retention time |  |
| **Solutions preparation:** | |
| * + Mobile phase |  |
| * + Buffer |  |
| * + Gradient programs *(if applicable)* |  |
| * + Stock standard solution |  |
| * + Standard solution |  |
| * + Test solution |  |
| * + System suitability solution |  |
| **Acceptance criteria for system suitability test:** | |
| * + % RSD |  |
| * + Tailing factor |  |
| * + No. of theoretical plates (N) |  |
| * + Resolution |  |

**3.2.P.5.3 Validation of Analytical Procedures**

**The information on validation of analytical procedures is recommended to be presented as follows:**

|  |  |
| --- | --- |
| **Tested parameter** | *e.g. assay, related substances, … (one separate table for each tested parameter).* |

|  |  |  |
| --- | --- | --- |
| **Specificity** | | |
| * Brief summary on how it was performed: |  | |
| * Representative chromatogram(s) | *The chromatogram(s) can be found in page No…* | |
| **Linearity** | | |
| * No. of concentrations |  | |
| * Specified ranges |  | |
| * Parameters: | **Acceptance criteria** | **Results** |
| * *Correlation coefficient* |  |  |
| * *y-intercept* |  |  |
| * *Residual sum of squares* |  |  |
| **Accuracy** | | |
| * Brief summary on how it was performed: |  | |
| * Parameters: | **Acceptance criteria** | **Results** |
| * *% Recovery* |  |  |
| * *% RSD* |  |  |
| * *CI* |  |  |
| **Precision (repeatability and intermediate precision)** | | |
| * Brief summary on how it was performed: |  | |
| * Parameter: | **Acceptance criteria** | **Results** |
| * *% RSD* |  |  |
| **LOQ/LOD** | | |
| * Brief summary on how it was performed: |  | |
| * LOD |  | |
| * LOQ |  | |
| **Robustness** | | |
| * Brief summary on how it was performed: |  | |
| **Systems suitability** | | |
| * Parameters: | **Acceptance criteria** | **Results** |
| * *% RDS* |  |  |
| * *Tailing factor* |  |  |
| * *No. of theoretical plates* |  |  |
| * *Resolution* |  |  |

**Method transfer *(if applicable):***

|  |  |  |
| --- | --- | --- |
| Protocol: |  | |
| * Tested Parameters: | **Acceptance criteria** | **Results** |
|  |  |  |
|  |  |  |

**3.2.P.5.4 Batch Analyses**

**The information on finished product batch analyses is recommended to be presented as follows:**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Batch number** | **Batch size** | **Batch type** | **Site(s) of:** | | **Date(s) of:** | | **API manufacturer** |
| **Manufacturing** | **Analysis** | **Manufacturing** | **Analysis** |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

**3.2.P.6 Reference Standards or Materials**

**The information on reference standards/reference materials is recommended to be presented as follows:**

|  |  |
| --- | --- |
| **Type of reference standards** | Primary reference standard  Working or secondary reference standard  Manufacturer reference standard |
| **Information on potency** | *……… %* |
| **Information on calibration of working standard with primary reference standard** |  |

**3.2.P.8 Stability**

**3.2.P.8.1 Stability Summary and Conclusions**

**A summary of stability study information is recommended to be presented as follows:**

|  |  |  |
| --- | --- | --- |
|  | **Accelerated stability studies** | **Long term stability studies** |
| **Storage conditions (°C, % RH)** |  |  |
| **FPP batch number** |  |  |
| **Batch type** |  |  |
| **Batch size** |  |  |
| * ***Drug substance batch number(s)*** |  |  |
| * ***Drug substance manufacturer(s)*** |  |  |
| **Completed testing intervals** |  |  |
| **Proposed testing intervals** |  |  |
| **Container closure system** |  |  |
| **Manufacturing site** |  |  |
| **Manufacturing date** |  |  |
| **Stability starting date** |  |  |
| **Conclusions with respect to storage conditions and proposed shelf-life** |  | |
| **Conclusions with respect to in-use storage conditions and shelf-life, if applicable** |  | |

**The information on the in-use stability study is recommended to be presented as follows:**

|  |  |
| --- | --- |
| **Number of batches** |  |
| **Batch numbers** |  |
| **Batch type** |  |
| **Batch size** |  |
| **Manufacturing date** |  |
| **Starting date of the study** |  |
| **Tested parameters** |  |
| **Is the study protocol submitted?** | Yes  No |

**The information on the compatibility study is recommended to be presented as follows:**

|  |  |
| --- | --- |
| **Number of batches** |  |
| **Batch numbers** |  |
| **Batch type** |  |
| **Batch size** |  |
| **Manufacturing date** |  |
| **Starting date of the study** |  |
| **Tested parameters** |  |
| **Reconstitution diluent(s)** |  |
| **Is the study protocol submitted?** | Yes  No |