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| Sponsors – AODC 2017 | **Summary of quality and bioequivalence review - verification of the sameness form** |  |
|  | TMDA/DMC/MRE/F/045  Rev #: 00  Effective date: 30 June 2025 |

The applicant should fill out this template and serve as an assessment report. The summary of information contains critical information accepted by the reference recognized agency/regulatory authority (TMDA, WHO and NRAs with WHO - Maturity Level 3, 4 & WLAs) to ensure the sameness of data between the accepted product dossier and the new submission.

**Note:**

Do not copy and paste between the columns for RRA and TMDA submission. This must all be completed as per the exact information in the original documents.

1. A duly filled-in and completed copy of the abridged review template in *Microsoft Word format* as part of module 1 should be provided.
2. **API INFORMATION SUMMARY**

|  |  |
| --- | --- |
| API name(s) |  |
| CEP/ CPQ Number (*if applicable*) |  |
| APIMF number and version (*if applicable*) |  |
| Name and address of API manufacturing site(s) |  |
| GMP status and/or manufacturing license of the API manufacturing site(s), along with the name of the issuing competent regulatory authority from country of origin and where applicable other NRAs/legal existing Organisations |  |
| Polymorphic form (s) |  |
| Sterility, i.e., is the API sterile or nonsterile. |  |
| Quality standard claimed, e.g., BP, Ph. Eur, USP, In-House, etc. |  |
| FPP Manufacturer's API Specifications Number and version |  |
| API manufacturer's API Specification Number and version |  |
| Container Closure System |  |
| Retest period and/or Shelf life |  |
| Storage statement |  |

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| **2.3. S DRUG SUBSTANCE (or ACTIVE PHARMACEUTICAL INGREDIENT (API))** | | | |
| Confirm that the information on the API submitted to the Authority is the same concerning that reviewed and approved by WLA concerning the source of the API i.e. API manufacturing site(s) including the bock and/or unit number, the specifications for the API from the FPP manufacturer, the container closure system and the stability. | | | |
|  | | | |
| **Dossier aspects to verify** | **Reference (**TMDA, WHO and NRAs with WHO - Maturity Level 3/WL4 & WLAs) | **TMDA submission** | **TMDA comments** |
| **3.2. S.1.1** Name of the API |  |  |  |
| **3.2. S.1.3** General properties that may affect the performance of the finished product (for  example, polymorphism, solubility in physiological media) |  |  |  |
| **3.2.S.2.1** Name and address(es) (including specific blocks/units) of the manufacturer(s) of the API(s)/drug substance |  |  |  |
| **3.2.S.4.1** Control of the API (including the specification reference number, version and date – the copy of the current specification approved by reference recognized regulatory authorities should be included as an attachment to this report) |  |  |  |
| **3.2.S.4.2** Analytical procedures (including the analytical procedure reference number, version and date – the copy of the analytical procedure may be included as an attachment to this report) |  |  |  |
| **3.2.S.6** Container closure system (Description of container closure system, including specifications and COA) |  |  |  |
| **3.2. S.7** Stability summary and conclusions (including storage statement and re‑test period) |  |  |  |

1. **COMPARISON OF FINISHED PRODUCT INFORMATION**

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| Confirm that the information on the product/FPP submitted to the Authority is the same concerning that reviewed and approved by WLAs concerning the source of the FPP i.e. FPP manufacturing site(s) including the bock and/or unit number, composition of the FPP, the FPP specifications, the container closure system and the stability. | | | |
|  | | | |
| **Dossier aspects to verify** | **Reference (**TMDA, WHO and NRAs with WHO - Maturity Level 3/WL4 & WLAs) | **TMDA submission** | **TMDA comments** |
| **3.2. P.1** Description and composition of the FPP (Description of the finished pharmaceutical products as provided in FPP Specification and SmPC) |  |  |  |
| **3.2. P.3.1** Name(s) and complete address (including specific blocks/units) of the manufacturer(s) of the finished pharmaceutical product(s) [FPP(s)] or biological drug products(s) (DP(s)), including the final product release if different from the manufacturer |  |  |  |
| **3.2.P.3.2.** Description: Commercial batch size and batch formula |  |  |  |
| **3.2.P.3.3.** Description of manufacturing process |  |  |  |
| **3.2. P.5.1** Control of FPP/DP (state the specification reference number, version and date – a copy of the specification should be included as an attachment to the report) |  |  |  |
| **3.2. P.5.2** Analytical procedures (including the analytical procedure reference number, version and date–a copy of the analytical procedure should be included as an attachment to the report) |  |  |  |
| **3.2. P.7** Container closure system (including pack sizes, container size or volume specifications and certificate of analysis) |  |  |  |
| **3.2. P.8** Stability summary and conclusions (including the storage statement and shelf-life |  |  |  |

1. **COMPARISON OF THE COMPOSITION OF FINISHED PHARMACEUTICAL PRODUCT**
2. **Reference** (TMDA, WHO and NRAs with WHO - Maturity Level 3/WL4 & WLAs)

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| **Component and quality standard** | **Function** | **Quant. per unit (mg)** | **%** |
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| Total |  |  |  |
| ***TMDA Comments*** |  | | |

Note: where applicable, for example, for layered tablets, the % composition should be computed based on the layer subtotal

1. **TMDA submission**

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| **Component and quality standard** | **Function** | **Quant. per unit (mg)** | **%** |
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|  |  |  |  |
| Total |  |  |  |
| ***TMDA Comments*** |  | | |

Note: where applicable, for example, for layered tablets, the % composition should be computed based on the layer subtotal

1. **COMPARISON OF COMMERCIAL BATCH SIZE AND BATCH FORMULA**
2. **Reference** (TMDA, WHO and NRAs with WHO - Maturity Level 3/WL4 & WLAs)

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| --- | --- |
| **Proposed commercial batch size(s) (e.g. number of dosage units)** |  |
| **Component and quality standard (and grade, if applicable)** | **Quantity per batch (kg/batch)** |
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| Total |  |
| ***TMDA Comments*** |  |

1. **TMDA Submission**

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| **Proposed commercial batch size(s) (e.g. number of dosage units)** |  |
| **Component and quality standard (and grade, if applicable)** | **Quantity per batch (kg/batch)** |
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| Total |  |
| ***TMDA Comments*** |  |

1. **COMPARISON OF SAFETY AND EFFICACY**
2. **Bioequivalence Information**

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| **Bioequivalence/comparative pharmacokinetics** | | | |
| **Dossier aspects to verify** | **Reference** (TMDA, WHO and NRAs with WHO - Maturity Level 3/WL4 & WLAs) | **TMDA submission** | **TMDA comments** |
| **Study Number** |  |  |  |
| **Study title** |  |  |  |
| **Name and address of the clinical facility (or the contract**  **research organisation)** |  |  |  |
| **Name and address of bioanalytical laboratories** |  |  |  |
| **Number of participants** |  |  |  |
| **Test product** (name, manufacturer, batch number, manufacturing and expiry date, batch size, location of multipoint dissolution data in physiological media and release media, if  different) |  |  |  |
| **Reference product** (name,  manufacturer, source, batch  number, expiry date) |  |  |  |
| **Results** (geometric ratio and the 90% confidence intervals for the PK parameters) |  |  |  |
| **Assessor’s overall comments on bioequivalence/ comparative**  **pharmacokinetics** |  | | |

1. **BCS-based biowaiver**

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| **BCS-based biowaiver Information** | | | |
| **Dossier aspects to verify** | **Reference** (TMDA, WHO and NRAs with WHO - Maturity Level 3/WL4 & WLAs) | **TMDA submission** | **TMDA comments** |
| **Name and address of the laboratory or contract research organisation(s) where the BCS-based**  **Biowaiver, solubility, and dissolution studies were conducted.** |  |  |  |
| **API in the proposed product about the comparator (confirm that the proposed product contains the same active substance, including salt, ester, ether, or isomer, if applicable)** |  |  |  |
| **Test product** (name, manufacturer, batch number, manufacturing and expiry dates,  batch size, location of multipoint dissolution data in physiological media and release media, if  different) |  |  |  |
| **Reference product** (name,  manufacturer, source, batch  number, expiry date) |  |  |  |
| **Dissolution method (media, agitation speed, apparatus, volume)** |  |  |  |
| **Assessor’s comments on BCS-based biowaiver** |  | | |
| **Assessor’s overall comments on BCS biowaiver** |  | | |

1. **Additional Strength biowaiver**

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| **Additional strength biowaiver information** | | | |
| **Dossier aspects to verify** | **Reference** (TMDA, WHO and NRAs with WHO - Maturity Level 3/WL4 & WLAs) | **TMDA submission** | **TMDA comments** |
| **Name and address of laboratory or contract research organisation(s) where the biowaiver solubility and dissolution studies were conducted** |  |  |  |
| **Reference strength selected for the BE study** |  |  |  |
| **Biowaiver batch** (manufacturer, batch number, manufacturing and expiry dates,  batch size, location of multipoint dissolution data in physiological media and release media, if  different) |  |  |  |
| **Biobatch** (manufacturer, batch number, manufacturing and expiry dates,  batch size) |  |  |  |
| **Dissolution method (media, agitation speed, apparatus, volume)** |  |  |  |
| **Assessor’s overall comments on additional strength biowaiver** |  | | |