

**SCREENING CHECKLIST FOR PRODUCT REGISTRATION APPLICATION**

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| SECTION | | DOCUMENTS |  | Submitted? | |
|  | |  | Yes | No | Location  (Page numbers) |
| 1. | | ADMINISTRATIVE INFORMATION |  |  | |
|  | 1.1 | Comprehensive Table of Contents  **~Include a complete list of all documents provided in**  **the product dossier by module**  **~The location of each document should be located by**  **the module number** |  |  |  |
|  | 1.2 | Completed, signed and dated FORM 8A form |  |  |  |
|  | 1.3 | Introduction |  |  | |
|  |  | ~ Quality Information Summary |  |  |  |
|  |  | ~Justification for the lack of certain documents and  deviation(s) from guidelines |  |  |  |
|  | 1.4 | Labelling |  |  | |
|  | 1.4.1 | Copies of Outer carton Labels |  |  |  |
|  | 1.4.2 | Copies of Inner/Blister Labels |  |  |  |
|  | 1.4.3 | Copies of Package Insert (PI) |  |  |  |
|  | 1.4.4 | Copies of Patient Information Leaflet (PIL) |  |  |  |

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|  | 1.5 | SmPC for Innovator Product |  |  |  |
|  | 1.6 | GMP certification/proof of GMP compliance for each FPP manufacturer {inclusive of secondary packer(s)} from a competent authority |  |  |  |
|  |  | GMP certification/proof of GMP compliance for each active pharmaceutical ingredient (API) manufacturer |  |  |  |
| 2. | | COMMON TECHNICAL DOCUMENT SUMMARIES |  | | |
|  | **2.1** | **Overall CTD Table of Contents of Modules 2, 3, 4 and 5** |  | | |
|  | **2.2** | **Introduction** |  | | |
|  | 2.3 | Quality Overall Summary (QOS) |  |  |  |
|  | 2.4 | Non-clinical Overview |  |  |  |
|  | 2.5 | Clinical Overview |  |  |  |
|  | 2.6 | Non-clinical Summary |  |  |  |
|  | **2.6.1** | **Introduction** |  | | |
|  | **2.6.2** | **Pharmacology Written Summary** |  | | |
|  | **2.6.3** | **Pharmacology Tabulated Summary** |  | | |
|  | **2.6.4** | **Pharmacokinetics Written Summary** |  | | |
|  | **2.6.5** | **Pharmacokinetics Tabulated Summary** |  | | |
|  | **2.6.6** | **Toxicology Written Summary** |  | | |
|  | **2.6.7** | **Toxicology Tabulated Summary** |  | | |

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|  | 2.7 | Clinical Summary |  |  |  |
|  | **2.7.1** | **Summary of Biopharmaceutics and Associated Analytical Methods** |  | | |
|  | **2.7.2** | **Summary of Clinical Pharmacology Studies** |  | | |
|  | **2.7.3** | **Summary of Clinical Efficacy** |  | | |
|  | **2.7.4** | **Summary of Clinical Safety** |  | | |
|  | **2.7.5** | **Synopses of Individual Studies** |  | | |
| 3. | | QUALITY |  | | |
|  | 3.1 | Module 3 Table of Contents |  |  |  |
|  | **3.2** | **Body of Data** |  | | |
| 3.2.S | | ACTIVE PHARMACEUTICAL INGREDIENTS |  | | |
|  | | **~If CEP (Certificate of Suitability) is submitted,**  **waiver of documents for this section can be granted except for S4.1, S4.2 & S4.4.**  **~Please note that information not included in the**  **CEP**  **would have to be supported by substantial data**  **(e.g.**  **S6 & S7 is required if no retest period and/or packaging is stated in the CoA).** |  | | |
|  | | Certificate of suitability (CEP) |  |  |  |
| 3.2.S.2.1 | | Manufacturer(s) name and address |  |  |  |
| 3.2.S.2.2 | | Description of Manufacturing Process and Process  Controls |  |  |  |

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| 3.2.S.2.3 | | Control of Materials |  |  | \* |
| 3.2.S.2.4 | | Controls of Critical Steps and Intermediates |  |  | \* |
| 3.2.S.2.5 | | Process Validation and/or Evaluation  **~ Must be submitted for sterile APIs and NCEs** |  |  | \* |
| 3.2.S.2.6 | | Manufacturing Process Development |  |  | \* |
| **\*: For applications with DMF, sections S2.3, S2.4, S2.5 and**  **S2.6**  **are included in the closed part of DMF** | | |  | | |
| 3.2.S.3 | | CHARACTERISATION |  | | |
| **3.2.S.3.1** | | **Elucidation of Structure and other Characteristics** |  | | |
| **3.2.S.3.2** | | **Impurities** |  | | |
| 3.2.S.4 | | CONTROL OF API |  | | |
| 3.2.S.4.1 | | Specifications of API |  |  |  |
| 3.2.S.4.2 | | Analytical Procedures |  |  |  |
| 3.2.S.4.3 | | Validation of Analytical Procedures  **\*:** **Can be waived for methods that reference compendial methods** |  |  | \* |
| 3.2.S.4.4 | | Batch Analyses for three batches |  |  |  |
| 3.2.S.4.5 | | Justification of Specification  **\*: Justification is not required if compendial requirements are met** |  |  | \* |
| 3.2.S.5 | | REFERENCE STANDARDS |  | | |
| 3.2.S.6 | | CONTAINER CLOSURE SYSTEM |  | | |
|  |  | Specifications |  |  |  |

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|  |  | Test Methods |  |  |  |
| 3.2.S.7 | | STABILITY |  | | |
| 3.2.S.7.1 | | Stability Summary and Conclusions |  | | |
| 3.2.S.7.2 | | Post-approval Stability Protocol and Stability  Commitment |  |  |  |
| 3.2.S.7.3 | | Stability Data  **~ At point of submission, at least 12 months of real time data and 6 months of accelerated data on at least 3 primary batches of the API should be provided** |  | | |
|  | | Forced Degradation studies |  |  |  |
|  | | Accelerated Stability Studies |  |  |  |
|  | | Real-Time Stability Studies |  |  |  |
|  | | **NOTE: S6 & S7 would have to be submitted if the retest period is not stated in the CEP** |  | | |
| 3.2.P | | FINISHED PHARMACEUTICAL PRODUCT (FPP) |  | | |
| 3.2.P.1 | | Description and Composition of the FPP |  |  |  |
| 3.2.P.2 | | Pharmaceutical Development |  |  |  |
| 3.2.P.3 | | Manufacture |  | | |
|  | 3.1 | Manufactuer(s) name(s) and physical address(es) |  |  |  |
|  | 3.2 | Batch Formula  **~For multiple batch sizes, batch formula for each batch sizes are to be provided** |  |  |  |
|  | 3.3 | Description of manufacturing process and process controls |  |  |  |

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|  | 3.4 | Control of critical steps and intermediates |  |  |  |
|  | 3.5 | Process validation  **~For three consecutive batches** |  |  |  |
| 3.2.P.4 | | Control of Excipients |  | | |
|  | 4.1 | Specifications |  |  |  |
|  | 4.2 | Analytical Procedures |  |  |  |
|  | 4.3 | Validation of Analytical Procedures |  |  |  |
|  | 4.4 | Justification of Specifications |  |  |  |
|  | 4.5 | Excipients of Human or Animal Origin  **\*: BSE / TSE free certification** |  |  | \* |
|  | 4.6 | Novel excipients  \*: **Provide information provided as per full API**  **Section** |  |  | \* |
| 3.2.P.5 | | Control of FPP |  | | |
|  | 5.1 | Specification(s) of Finished Pharmaceutical Product (FPP) |  |  |  |
|  | 5.2 | Analytical Procedures |  |  |  |
|  | 5.3 | Validation of Analytical Procedures |  |  |  |
|  | 5.4 | Batch Analyses for two batches |  |  |  |
|  | 5.5 | Characterisation of Impurities |  |  |  |
|  | 5.6 | Justification of Specification(s) |  |  |  |
| 3.2.P.6 | | Reference Standards |  | | |
| 3.2.P.7 | | Container- Closure System |  | | |
|  |  | Test Methods |  |  |  |

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|  |  | Specifications |  |  |  |
| 3.2.P.8 | | Stability |  | | |
|  | 8.1 | Stability Summary and Conclusions |  | | |
|  | 8.2 | Post-approval Stability Protocol and Stability  Commitment |  |  | \* |
|  | 8.3 | Stability Data  **~accelerated for 6 months for two batches**  **~real time for at least 6 months for two batches \*: (at time of approval at least 12 months real time stability data should have been provided)** |  | | |
|  |  | Photostability Data |  |  |  |
|  |  | Accelerated Stability Data |  |  |  |
|  |  | Real-time Stability Data |  |  |  |
| 3.2.R | | REGIONAL INFORMATION/ REQUIREMENTS |  | | |
| 3.2.R.1 | | Production documentation  **Executed production documents**  **Master production documents** |  |  | \* |
|  |  |  | | |
| 3.2.R.2 | | Analytical procedures and validation information |  |  | \* |
| 3.3 | | LITERATURE REFERENCES |  |  | \* |
| 4 | | NON-CLINICAL STUDY REPORTS |  | | |
|  | **4.1** | **Table of Contents** |  | | |
|  | 4.2 | Study Reports |  |  |  |
|  | 4.2.1 | Pharmacology |  |  |  |
|  | 4.2.2 | Pharmacokinetics |  |  |  |
|  | 4.2.3 | Toxicology |  |  |  |
|  | 4.3 | List of Literature References |  |  |  |
| 5 |  | CLINICAL STUDY REPORTS |  | | |
|  | **5.1** | **Module 5 Table of Contents** |  | | |
|  | 5.2 | Tabular Listing |  | | |
|  | 5.3 | Clinical Study Reports |  |  |  |
|  | 5.3.1 | Reports of Biopharmaceutical Studies |  |  |  |
|  | 5.3.2 | Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials |  |  |  |
|  | 5.3.3 | Reports of Pharmacokinetic (PK) Studies |  |  |  |
|  | 5.3.4 | Reports of Pharmacodynamic (PD) Studies |  |  |  |
|  | 5.3.5 | Reports of Efficacy and Safety Studies  **~ Study reports of ALL clinical trials, including the appendices & tables**  **~ Study reports of pivotal or relevant clinical trials** |  |  |  |
|  | 5.3.6 | Reports of Post-marketing Experience |  |  |  |
|  | 5.3.7 | Case Report Forms and Individual Patient Listings |  |  |  |
|  | **5.4** | **List of Key Literature References** |  | | |
|  | **5.5** | **Other Supporting Documents** |  | | |