

**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**  |   |