** เอกสารนี้ ใช้เพื่อตรวจสอบรายการหัวข้อเอกสารเท่านั้น ไม่ต้องแนบมากับคำขอ

รายการหัวข้อสำหรับข้อมูลด้านคุณภาพและการผลิตยาแบบ New Chemical Entity (NCE) หรือ Chemistry Manufacturing and Controls (CMC)

รายการหัวข้อ		หัวข้อที่ต้องมีขั้นต่ำ สำหรับการวิจัยระยะที่		
		1, BE	2	3, 4
DRUG SUBSTANCE (NAME, MANUFACTURER)		✓	✓	✓
S.1 General Information (name manufacturer)		✓	✓	✓
S.1.1 Nomenclature (name, manufacturer)		✓	✓	✓
-	Recommended International Non-proprietary name (INN)	✓	✓	✓
-	Compendial name, if relevant	-	✓	✓
-	Chemical name(s)	-	✓	✓
-	Company or laboratory code	✓	✓	✓
-	Other non-proprietary name(s) (e.g., national name, USAN, BAN)	-	✓	✓
-	Chemical Abstracts Service (CAS) registry number	-	✓	✓
S.1.2 Structure (name, manufacturer)		✓	✓	✓
-	Structural formula, including relative and absolute stereochemistry	✓	✓	✓
-	Molecular formula	✓	✓	✓
-	Molecular mass	✓	✓	✓
S.1.3 General Properties (name, manufacturer)		✓	✓	✓
-	Physical description (e.g., appearance, colour, physical state)	✓	✓	✓
-	Physical form (e.g., preferred polymorphic form, solvate, hydrate)	-	-	✓
-	Solubilities (eg. solubility profile, tabular format, reporting in (mg/mL)	✓	✓	✓
-	pH and pKa values	✓	✓	✓
-	Other relevant information	✓	✓	✓
S.2 Manufacture (name, manufacturer)		✓	✓	✓
S.2.1 Manufacturer(s) (name, manufacturer)		✓	✓	✓
-	Name, address, and responsibility of each manufacturer, including contractors, and each proposed production site or facility involved in the manufacturing of the batches to be used in this clinical trial	✓	✓	✓
S.2.2 Description of Manufacturing Process and Process Controls (name, manufacturer)		✓	✓	✓
-	Flow diagram of the synthetic process(es)	✓	✓	✓
-	Narrative description of the manufacturing process(es)	-	✓	✓
S.2.3 Control of Materials (name, manufacturer)		✓	✓	✓
-	For drug substances or drug substance manufactured with reagents obtained from sources that are at risk of transmitting Bovine Spongiform Encephalopathy	✓	✓	✓

<table>
<tr><th colspan="2" rowspan="2">รายการหัวข้อ</th><th colspan="3">หัวข้อที่ต้องมีขั้นต่ำ
สำหรับการวิจัยระยะที่</th></tr>
<tr><th>1, BE</th><th>2</th><th>3, 4</th></tr>
<tr><td></td><td>(BSE)/Transmissible Spongiform Encephalopathy (TSE) agents (e.g., ruminant origin), provide an attestation (with supporting documentation, if applicable) confirming that the material is free of BSE/TSE agents</td><td></td><td></td><td></td></tr>
<tr><td>-</td><td>Information on starting materials</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.2.4 Controls of Critical Steps and Intermediates (name, manufacturer)</td><td>-</td><td>-</td><td>✓</td></tr>
<tr><td>-</td><td>Summary of the controls performed at critical steps of the manufacturing process and on intermediates</td><td>-</td><td>-</td><td>✓</td></tr>
<tr><td colspan="2">S.3 Characterisation (name, manufacturer)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.3.1 Elucidation of Structure and other Characteristics (name, manufacturer)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>List of studies performed (e.g., IR, UV, NMR, MS, elemental analysis) and summary of the interpretation of evidence of structure</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Discussion on the potential for isomerism and identification of stereochemistry (e.g., geometric isomerism, number of chiral centres and configurations)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Summary of studies performed to identify potential polymorphic forms (including solvates), if available</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Summary of studies performed to identify the particle size distribution of the drug substance, if available</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Other characteristics</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.3.2 Impurities (name, manufacturer)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Identification of potential and actual impurities arising from the synthesis, manufacture and/or degradation</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td></td><td>List of drug-related impurities (e.g., starting materials, by-products, intermediates, chiral impurities, degradation products, metabolites), including chemical name and origin
<table><tr><td>Drug-related Impurity (chemical name or descriptor)</td><td>Structure</td><td>Origin</td></tr><tr><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td></tr></table></td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td></td><td>List of process-related impurities (e.g., residual solvents, reagents, catalysts), including compound name and step used in synthesis</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Actual levels of impurities (e.g., drug-related and process-related) found in batches to be used in this clinical trial
<table><tr><td>Impurity</td><td></td><td>Results</td></tr></table></td><td>✓</td><td>✓</td><td>✓</td></tr>
</table>

<table>
<tr><th colspan="4">รายการหัวข้อ</th><th>หัวข้อที่ต้องมีขั้นต่ำ
สำหรับการวิจัยระยะที่
1, BE</th><th>2</th><th>3, 4</th></tr>
<tr><td></td><td colspan="3"><table>
<tr><td rowspan="2">(drug-related and process-related)</td><td rowspan="2">Acceptance Criteria</td><td colspan="3">(include batch number and use)
(e.g., clinical)</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
</table></td><td></td><td></td><td></td></tr>
<tr><td colspan="4">S.4 Control of the Drug Substance (name, manufacturer)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="4">S.4.1 Specification (name, manufacturer)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td colspan="3">Specification for the drug substance<table>
<tr><th>Test</th><th>Acceptance Criteria</th><th>Analytical Procedure
(Type and Source)</th></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
</table></td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="4">S.4.2 Analytical Procedures (name, manufacturer)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td colspan="3">Summary of the analytical procedures (e.g., suitability, key method parameters, conditions)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="4">S.4.3 Validation of Analytical Procedures (name, manufacturer)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td colspan="3">Tabulated summary of the validation information (e.g., system suitability testing, validation parameters and results)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="4">S.4.4 Batch Analyses (name, manufacturer)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td colspan="3">Description of the batches to be used in this clinical trial<table>
<tr><th>Batch Number</th><th>Batch Size</th><th>Date of Manufacture and
Site of Production</th><th>Use (e.g., clinical)</th></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
</table></td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td colspan="3">Summary of results for the batches to be used in this clinical trial (should include tests, types of analytical procedures (e.g., HPLC, GC), and actual results)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="4">S.4.5 Justification of Specification (name, manufacturer)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td colspan="3">Justification of the drug substance specification (e.g., manufacturing experience, stability, historical batch analysis results, safety considerations)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="4">S.6 Container Closure System (name, manufacturer)</td><td>✓</td><td>✓</td><td>✓</td></tr>
</table>

<table>
<tr><th colspan="2" rowspan="2">รายการหัวข้อ</th><th colspan="3">หัวข้อที่ต้องมีขั้นต่ำ
สำหรับการวิจัยระยะที่</th></tr>
<tr><th>1, BE</th><th>2</th><th>3, 4</th></tr>
<tr><td>-</td><td>Description of the container closure system(s) for the storage and shipment of the drug substance</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.7 Stability (name, manufacturer)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.7.1 Stability Summary and Conclusions (name, manufacturer)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Summary of stability studies to support this clinical trial (e.g., studies conducted, protocols used, results obtained)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Proposed storage conditions for the drug substance</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.7.2 Stability Protocol and Stability Commitment (name, manufacturer)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>If full long term stability data is not available at the time of filing, provide a summary of the stability protocol and a commitment for the continued monitoring of the drug substance stability according to the protocol</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.7.3 Stability Data (name, manufacturer)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>The actual stability results (i.e., raw data) may be found in</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Summary of analytical procedures and validation information for those procedures not previously summarized in 2.3.S.4 (e.g., analytical procedures used only for stability studies)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">DRUG PRODUCT (NAME, DOSAGE FORM)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.1 Description and Composition of the Drug Product (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Description of the dosage form</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Composition of the dosage form</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td></td><td>Composition, i.e., list of all components of the dosage form, and their amounts on a per unit basis (including overages, if any)
<table>
<tr><th rowspan="3">Component and Quality Standard (and Grade, if applicable)</th><th rowspan="3">Function</th><th colspan="4">Strength (label claim)</th></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>Quantity per unit</td><td>%</td><td>Quantity per unit</td><td>%</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Total</td><td></td><td></td><td></td><td></td><td></td></tr>
</table></td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td></td><td>Composition of all components that are mixtures (e.g., colorants, coatings, capsule shells, imprinting inks)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Description of accompanying reconstitution diluent(s), if applicable</td><td>✓</td><td>✓</td><td>✓</td></tr>
</table>

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<tr><th colspan="2" rowspan="2">รายการหัวข้อ</th><th colspan="3">หัวข้อที่ต้องมีขั้นต่ำ
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<tr><th>1, BE</th><th>2</th><th>3, 4</th></tr>
<tr><td>-</td><td>Type of container closure system used for accompanying reconstitution diluent(s), if applicable</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Qualitative list of the components of the placebo samples to be used in this clinical trial, if different from the components listed in 2.3.P.1(b)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.2 Pharmaceutical Development (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Discussion on the development of the dosage form, the formulation, manufacturing process, etc</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>For sterile, reconstituted products, summary of compatibility studies with diluents/containers</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.3 Manufacture (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.3.1 Manufacturer(s) (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Name, address, and responsibility of each manufacturer, including contractors, and each proposed production site or facility involved in the manufacturing of the batches to be used in this clinical trial</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Attestation that the dosage form was manufactured under Good Manufacturing Practices (GMP) conditions</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.3.2 Batch Formula (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>List of all components of the dosage form to be used in the manufacturing process, and their amounts on a per batch basis (including overages, if any)
<table>
<tr><td>Strength (label claim)</td><td></td></tr>
<tr><td>Batch Size(s) (number of dosage units)</td><td></td></tr>
<tr><td>Component and Quality Standard
(and Grade, if applicable)</td><td>Quantity per batch</td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td>Total</td><td></td></tr>
</table></td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.3.3 Description of Manufacturing Process and Process Controls (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Flow diagram of the manufacturing process</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Detailed narrative description of the manufacturing process, including equipment type and working capacity, process parameters</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>For sterile products, details and conditions of sterilization and lyophilization</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.4 Control of Excipients (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.4.1 Specifications (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
</table>

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<tr><th>1, BE</th><th>2</th><th>3, 4</th></tr>
<tr><td colspan="2">P.4.5 Excipients of Human or Animal Origin (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>List of excipients that are of human or animal origin (including country of origin)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Summary of the information (e.g., sources, specifications, description of the testing performed, viral safety data) regarding adventitious agents for excipients of human or animal origin</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>For excipients obtained from sources that are at risk of transmitting Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE) agents (e.g., ruminant origin), provide an attestation (with supporting documentation, if applicable) confirming that the material is free of BSE/TSE agents</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.4.6 Novel Excipients (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Summary of the details on the manufacture, characterization, and controls, with cross references to supporting safety data (nonclinical and/or clinical) on novel excipients</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.5 Control of Drug Product (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.5.1 Specification(s) (name, dosage form)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Specification(s) for the drug product<table><tr><th>Test</th><th>Acceptance Criteria</th><th>Analytical Procedure
(Type and Source)</th></tr><tr><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td></tr></table></td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.5.2 Analytical Procedures (name, dosage form)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Summary of the analytical procedures (e.g., key method parameters, conditions, suitability)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.5.3 Validation of Analytical Procedures (name, dosage form)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Tabulated summary of the validation information (e.g., system suitability testing, validation parameters and results)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.5.4 Batch Analyses (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Description of the batches to be used in this clinical trial (or representative batches)<table><tr><th>Strength and
Batch Number</th><th>Batch
Size</th><th>Date of Manufacture and
Site of Production</th><th>Input Drug
Substance Batch</th><th>Use (e.g.,
clinical)</th></tr><tr><td></td><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr></table></td><td>✓</td><td>✓</td><td>✓</td></tr>
</table>

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<tr><th>1, BE</th><th>2</th><th>3, 4</th></tr>
<tr><td>-</td><td>Summary of results for the batches to be used in this clinical trial or representative batches (should include tests, types of analytical procedures (type and source), and actual results)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.5.5 Characterisation of Impurities (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Information on the characterization of impurities, not previously provided in S.3.2 (e.g., summary of actual and potential degradation products)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.5.6 Justification of Specification(s) (name, dosage form)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Justification of the drug product specification (e.g., manufacturing experience, stability, historical batch analysis results, safety considerations)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.7 Container Closure System (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Description of the container closure systems, including unit count or fill size, container</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Materials of construction of each primary packaging component</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>For sterile products, details of washing, sterilization and depyrogenation procedures for container closures</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.8 Stability (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.8.1 Stability Summary and Conclusions (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Summary of stability studies to support this clinical trial (e.g., studies conducted, protocols used, results obtained)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td></td><td>Description of stability study details
<table>
<tr><th>Storage Conditions (°C, % RH, light)</th><th>Strength and Batch Number</th><th>Batch Size and Date of Manufacture</th><th>Container Closure System</th><th>Completed (and Proposed) Test Intervals</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
</table></td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td></td><td>Summary and discussion of stability study results</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Proposed storage conditions and shelf life (and in-use storage conditions and in-use period, if applicable)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.8.2 Post-approval Stability Protocol and Stability Commitment (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>If full long term stability data is not available at the time of filing, provide a summary of the stability protocol and a commitment that the stability of the clinical trial samples or representative batches will be monitored throughout the duration of the clinical trial or proposed shelf life</td><td>✓</td><td>✓</td><td>✓</td></tr>
</table>

รายการหัวข้อ		หัวข้อที่ต้องมีขั้นต่ำ สำหรับการวิจัยระยะที่		
		1, BE	2	3, 4
P.8.3 Stability Data (name, dosage form)		✓	✓	✓
-	The actual stability results (i.e., raw data) may be found in	✓	✓	✓
-	Summary of analytical procedures and validation information for those procedures not previously summarized in 2.3.P.5 (e.g., analytical procedures used only for stability studies)	-	✓	✓

ATTACHMENTS

Attachment Number	Subject