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Declaration of the product registrant for MIV-2 Do-and-Tell

I hereby declare that:

- All changes submitted are categorised as MIV-2 Do-and-Tell, and no other changes have been included in this application.
- The change(s) will not adversely affect the quality, efficacy and safety of the therapeutic product concerned.
- All information provided by me in this MIV-2 Do-and-Tell is true and accurate.

Name	Signature	Date

D1	**Change in Packaging Material Not in Contact with Drug Product**
C	1. For change of packaging material not in contact with drug product, such as colour of flip-off caps, colour code rings on ampoules, change of needle shield. 2. The change does not concern a part of the packaging material which affects the delivery, use, safety or stability of the drug product.
D	1. Amendment of the relevant section(s) of the dossier (presented in the CTD format), including revised product labelling as appropriate.

D2	**Addition or Replacement of Site Responsible for Quality Control (QC) Testing of Drug Product**
C	1. The manufacturer and primary packager of the drug product remains unchanged. 2. Method transfer from the approved to the proposed site or test laboratory has been successfully completed.
D	1. Declaration from the drug product manufacturer / product owner on the following: a) The change does not affect the release and shelf life specifications of the drug product. b) The tests used by the proposed QC testing site are equivalent to the registered methods. c) List of tests used by the proposed QC testing site with indication if the method suitability / transfer / validation has been completed for each test.

D3	**Change of Product Owner or Change in Name and/or Address (for example: postal code, street name) of Product Owner**
C	1. The product registrant remains unchanged. 2. The manufacturing site remains unchanged.
D	**For change of product owner:** 1. Revised drafts of the package insert and labelling incorporating the proposed variation (where applicable). 2. A declaration on the transfer of ownership between the old product owner and new owner from the new product owner. 3. An official letter from the new product owner declaring the change and authorising the local registrant to be responsible for the product registration. 4. If the new product owner is not the manufacturer of the drug product, an official letter by the new product owner authorising the manufacturer to manufacture the drug product on its behalf. **For change of name and/or address of product owner:** 5. Revised drafts of the package insert and labelling incorporating the proposed variation (where applicable). 6. An official letter from the product owner declaring the change and authorising the local registrant to be responsible for the product registration.

D4	**Change in Ownership of Manufacturer**
C	1. The drug substance / drug product manufacturing site remains unchanged. 2. No other changes except for the change in ownership of the drug substance / drug product manufacturer.
D	1. Revised drafts of the package insert and labelling incorporating the proposed variation (where applicable). 2. A letter of justification on the transfer of ownership, such as a valid GMP certificate. 3. An official letter stating the transfer of ownership from the old manufacturer to the new manufacturer (where applicable). 4. In case of a contract manufacturer, an official letter from the product owner declaring the change and authorising the new manufacturer to manufacture the drug substance(s) or drug product(s) on its behalf.

D5	**Change of Name or Address (for example: postal code, street name) of Manufacturer of Drug Product**
C	1. Applicable to all sites involved in the drug product manufacturing process, e.g., intermediate, bulk production, primary packaging, secondary packaging, quality control sites.

	2. The manufacturing site remains unchanged. 3. No other changes except for the change of the name and/or address of a manufacturer of the drug product. 4. For a change in ownership of manufacturer, refer to MIV-2 D4.
D	1. Revised drafts of the package insert and labelling incorporating the proposed variation (where applicable). 2. A valid GMP certificate, a CPP which covers the GMP certification or an official document from a relevant authority confirming the new name and/or address. 3. An official letter from product owner authorising the manufacturer with the new name/address to manufacture the drug product.

D6	**Change of Name or Address (for example: postal code, street name) of Company or Manufacturer Responsible for Batch Release**
C	1. The manufacturer of the drug product remains unchanged. 2. The batch release site remains unchanged. 3. For a change in ownership of manufacturer, refer to MIV-2 D4.
D	1. Revised drafts of the package insert and labelling incorporating the proposed variation (where applicable). 2. A valid GMP certificate, a CPP which covers the GMP certification or an official document from a relevant authority confirming the new name and/or address (where applicable). 3. An official letter from the product owner authorising the company/manufacturer with the new name/address that is responsible for batch release. 4. A declaration from the product registrant that the change does not involve a change of batch release site.

D7	**Change of Name or Address (for example: postal code, street name) of Manufacturer of Drug Substance**
C	1. Applicable to all sites involved in the drug substance manufacturing process, e.g., intermediate, drug substance, milling/micronisation, quality control sites. 2. The manufacturing site remains unchanged. 3. No other changes except for the change of the name and/or address of a manufacturer of the drug substance. 4. For a change in ownership of manufacturer, refer to MIV-2 D4.
D	1. Updated information of the manufacturer of the drug substance. 2. A valid GMP certificate, a CPP which covers the GMP certification or an official document from a relevant authority confirming the new name and/or address.

D8	**Withdrawal/Deletion of Alternative Manufacturer(s) for Drug Substance, Drug Substance Intermediate and/or Drug Product and/or Packager and/or batch releaser and/or QC Testing Laboratory of Drug Product**
C	1. An alternative manufacturer is registered.
D	2. Reason for withdrawal/deletion.

D9	**Obsolete**

D10	**Deletion of Pack Size for Drug Product**
C	1. The remaining pack sizes are adequate to accommodate the dosing regimen as per the approved product labelling.
D	1. Revised drafts of the package insert and labelling incorporating the proposed variation (where applicable). 2. Reason for the deletion.

D11	**Change of Batch Numbering System**
C	1. The manufacturing site remains unchanged.
D	1. Description of the revised batch numbering system. 2. An official letter stating the commencement date of the change.

D12	**Update of Product Labelling** For Administrative changes as listed below: • Rearrangement / re-formatting of text without any change in information in PI/PIL • Changes to non-English text (e.g., Chinese) in PI/PIL as long as the information is consistent with the approved English text • Addition / deletion / change of artwork (e.g., pantone colour), images and logos. • Amendment of typographical errors. • Change of product registrant information to align with submission via Transfer@PRISM
C	1. Applicable only to changes listed above. 2. The change does not have any impact on the product's safety, efficacy and quality.
D	1. Approved product labelling.

	2. Proposed product labelling: a pristine and annotated version highlighting the changes made. 3. Relevant document/reference or justification to support the changes (where applicable).

D13 Change of Batch Size of Drug Substance	
C	1. This is only applicable for change of batch size of non-sterile drug substance up to 10-fold compared to the approved batch size. Refer to MIV-2 C4 for change of batch size of non-sterile drug substance by more than 10-fold. 2. The change does not affect the reproducibility of the process. Any changes to the manufacturing process is only those necessitated by scale-up or downscaling, e.g., use of different-sized equipment. 3. Specifications of the drug substance remain unchanged. 4. The change should not be the result of unexpected events arising during manufacture or because of stability concerns.
D	1. A letter of declaration from the product registrant that the specifications of the drug substance have not changed, and the reproducibility of the process has not been affected and that the change is not the result of unexpected events arising during manufacture or because of stability concerns. 2. Amended relevant CTD Section S (where applicable). 3. Certificate of analysis or batch analysis data (in a comparative tabulated format) for at least two batches of the drug substance for all tests in the approved specification from the approved and proposed batch sizes.

D14 Change of In-process Tests or Limits Applied during Manufacture of Drug Substance	
C	1. Tightening of in-process limits. The test procedure remains the same, or changes in the test procedures are minor. 2. Addition of in-process tests and limits. The new test method that does not concern a novel non-standard technique or a standard technique used in a novel way. 3. Deletion of a non-significant in-process test. The specification parameter does not concern a critical parameter, e.g., assay, impurities, or any critical physical characteristics. 4. For widening of in-process test limits or deletion of a significant in-process test, refer to MIV-1 B3 or B4. 5. The change is not a consequence of any commitment from previous assessments to review the specification limits. 6. The change does not result from unexpected events arising during manufacture, e.g., new unqualified impurity or change in total impurity limits.

D	1. A description of the analytical method and summary of validation data must be provided for all new analytical methods (where applicable). 2. Comparative tabulated format of the approved and proposed in-process controls and the relevant changes. 3. Certificate of analysis or batch analysis data (in a comparative tabulated format) for at least two production batches of the drug substance for all tests in the approved and proposed specification (where applicable). 4. (For deletion of non-significant in-process test) Justification/risk assessment, as appropriate, that the in-process tests are non-significant, or that the in-process tests are obsolete.

D15 Change of Specification of Drug Substance a) Specification limits are tightened. b) Deletion of non-significant parameter (e.g., obsolete parameter)	
C	1. For widening of specification limits and deletion of significant test parameter and limits of the drug substance, refer to MIV-1 B5. For addition or replacement of a specification parameter and limit, refer to MIV-1 C6. 2. Test procedures remain the same or changes in the test procedure are minor.
D	**Specification limits are tightened** 1. Technical justification for the change. 2. Comparative tabulated format of the approved and proposed specification of the drug substance with changes highlighted. 3. Certificate of analysis or batch analysis data (in a comparative tabulated format) for at least two pilot batches of the drug substance for all tests in the approved and proposed specification. **Deletion of non-significant parameter** In addition to documents (1) and (2), 4. Justification/risk assessment showing that the parameter is non-significant or that it is obsolete.

D16 Change of Specification of Drug Substance to comply with latest compendium	
C	1. Applicable to compendial specifications only. All the tests in the specification need to correspond to the pharmacopoeia standard after the change, except any additional supplementary tests. 2. Change is made to comply with an update of the relevant monograph of the compendium or from one recognised pharmacopoeia to another. 3. Pharmacopoeia recognised by HSA: United States Pharmacopeia, European Pharmacopoeia, British Pharmacopoeia and Japanese Pharmacopoeia.

	4. No significant changes in qualitative and quantitative impurities profile unless the specifications are tightened.
D	1. Tabulation of the approved and proposed release and/or shelf-life specifications of the drug substance with changes highlighted. 2. Certificate of analysis or batch analysis of at least two batches of drug substance for all tests in the proposed specification.

D17 Change of Test Procedure of Drug Substance	
C	1. Minor change to an approved test procedure. 2. Deletion of a test procedure, if an alternative test procedure is already included in the approved drug substance specification. 3. Appropriate validation studies have been performed and show that the updated test procedure is at least equivalent to the former procedure. 4. There have been no changes of the total impurity limits, and no new unqualified impurities are detected.
D	1. Description of the test procedure, and a summary of validation data (where applicable). 2. Specification of the drug substance. 3. Comparative analytical results between the approved and proposed test (where applicable).

D18 Revision of CEP	
C	1. For submission of a revision of CEP for an approved manufacturer only. 2. For minor change to the drug substance, includes change of manufacturing process, change of batch size, in-process controls, specification (tightening or addition of test parameters), test procedure, shelf life/re-test period, and/or storage condition, that are covered by a valid CEP. 3. Refer to MIV-1 B4 if this change is due to a major change of the manufacturing process of the drug substance. 4. Refer to MIV-1 B6 if this change is due to a widening of the specification limits or deletion of test parameters.
D	1. A copy of the valid CEP, including all annexes as issued by the EDQM, and a copy of the Letter of Access from the CEP holder to authorise the applicant to refer to the CEP in support of their application. 2. Specification of the drug substance (where applicable). 3. Results of batch analysis from the drug substance manufacturer* demonstrating compliance with the Ph. Eur. monograph and including additional test/limits listed on the CEP (where applicable).

	* *If the drug substance manufacturer is CEP-certified and the drug product manufacturer claims otherwise (USP, JP, In-house etc.), data covering S4.1 to S4.5 from the drug product manufacturer should be submitted.* 4. Additional data to address any relevant parameter(s) not addressed in the CEP, such as stability data (S7) if a re-test period is not stated on the CEP and physicochemical characteristics (e.g., particle size, polymorphism etc.), where applicable. 5. If this change is due to a drug substance specification change, a commitment letter to conduct relevant stability studies of the drug product in accordance with the *ASEAN Guideline on Stability Study of Drug Product* to support the approved shelf life. The product registrant shall report to the Health Sciences Authority of any out-of-specification result (with proposed action). Submission of the data in the form of a finalised report is not required but the data shall be provided to the Health Sciences Authority.

D19 Submission of CEP for an Approved Drug Substance Manufacturer	
C	1. Submission of CEP for an approved drug substance manufacturer that is currently supported by Drug Master File (DMF) / ICH Common Technical Document (CTD) / ASEAN CTD (ACTD) dossier. 2. If there are other changes to the drug substance, the relevant MIV checklists will apply.
D	1. Specify the registered DMF number to be replaced. 2. A copy of the valid CEP, including all annexes as issued by the EDQM and a copy of the Letter of Access from the CEP holder to authorise the applicant to refer to the CEP in support of their application. 3. A letter of declaration from the product registrant that there are no other changes except for the change from DMF / ICH CTD / ACTD to CEP.

D20 Change of In-process Controls Applied during Manufacture of Drug Product	
C	1. Tightening of in-process limits. The test procedure remains the same, or changes in the test procedures are minor. 2. Deletion of a non-significant in-process test. The specification parameter does not concern a critical parameter, e.g., assay, impurities, or any critical physical characteristics. 3. For widening of specification limits of IPC or deletion of test parameters and limits of IPC, refer to MIV-1 B24. For addition or replacement of new IPC, refer to MIV-2 C16. 4. Release and shelf-life specifications of the drug product remain unchanged. 5. The change is not a consequence of any commitment from previous assessments to review the specification limits. 6. The change does not result from unexpected events arising during manufacture, e.g., new unqualified impurity or change in total impurity limits.

D	1. A description of the analytical methodology and summary of validation data must be provided for all new analytical methods (where applicable). 2. Comparative tabulated format of currently approved and proposed in-process controls. 3. Proposed in-process specifications together with justification and relevant process validation data. 4. Certificate of analysis or comparative batch analysis data of the drug product of at least two production batches. 5. (For deletion of non-significant in-process test) Justification/risk assessment , as appropriate, that the in-process tests are non-significant, or that the in-process tests are obsolete.

D21 Minor Change in the Manufacturing Process for Drug Product	
C	1. The change, as per Level 1, Part VI Manufacturing, SUPAC Guideline. 2. No change in qualitative and quantitative impurity profile or in physico-chemical properties. 3. The manufacturing principle including the single manufacturing steps remain unchanged, e.g., processing intermediates and there are no changes to any manufacturing solvent used in the process. 4. The approved process has to be controlled by relevant in-process controls and no changes (widening or deletion of limits) are required to these controls. 5. The specifications of the finished product or intermediates are unchanged. 6. The proposed process must lead to an identical product regarding all aspects of quality, safety and efficacy. 7. Relevant stability studies in accordance with the relevant guidelines have been started with at least one pilot scale or production scale batch and at least three months stability data are at the disposal of the applicant. Assurance is given that these studies will be finalized and that the data will be provided immediately to the competent authorities if outside specifications or potentially outside specifications at the end of the approved shelf life (with proposed action).
D	1. Amendment of the relevant section(s) of the dossier, as appropriate, including a direct comparison of the approved process and the proposed process. 2. For semi-solid and liquid products in which the active substance is present in non-dissolved form: appropriate validation of the change including microscopic imaging of particles to check for visible changes in morphology; comparative size distribution data by an appropriate method. 3. For solid dosage forms: dissolution profile data of one representative production batch and comparative data of the last three batches from the previous process; data on the next two full production batches should be available on request or reported if outside specification (with proposed action). 4. Justification for not submitting a new bioequivalence study) according to the ASEAN Guidelines For The Conduct of Bioavailability and Bioequivalence Studies (where applicable).

	5. Copy of approved release and shelf life specifications. 6. Certificate of analysis and/or batch analysis data (in a comparative tabulated format) on a minimum of one batch manufactured to both the approved and the proposed process. Batch analysis data on the next two full production batches should be made available upon request and reported by the product registrant if outside specification (with proposed action). 7. A commitment letter to conduct relevant stability studies of the drug product in accordance with the *ASEAN Guideline on Stability Study of Drug Product* to support the approved shelf life. The product registrant shall report to the Health Sciences Authority of any out-of-specification result (with proposed action). Submission of the data in the form of a finalised report is not required but the data shall be provided to the Health Sciences Authority upon request.

D22 Change of Release and/or Shelf-life Specifications of Drug Product a) Specification limits are tightened. b) Deletion of non-significant parameter (e.g., obsolete parameter)	
C	1. The variation should not be submitted as a result of unexpected events that may lead to product defects. Variation is only to be submitted after concerns have been addressed and CAPAs concurred. Refer to the *Product Defect Reporting and Recall Procedures* on the HSA website for product defect reporting. 2. Test procedures remain unchanged, or changes in the test procedures are minor (MIV-2 C24 is also applicable if there is change in test methods). 3. For widening of specification limits and/or deletion of test parameter and limits of the drug product, refer to MIV-1 B9. For addition of new test parameters and limits, refer to MIV-2 C21. 4. For a change in specification due to update of the compendium for compendial drug product, refer to MIV-2 D23.
D	1. Technical justification for the change. 2. Comparative tabulated format of the approved and proposed release and shelf-life specifications of the drug product with changes highlighted. 3. Certificate of analysis or batch analysis data of the drug product on at least two batches (preferably production scale) for all tests in the proposed specification. **Deletion of non-significant parameter** In addition to documents (1) and (2), 4. Justification/risk assessment showing that the parameter is non-significant or that it is obsolete.

D23 Change of specification of Drug Product to Comply with Latest Compendium	
C	1. The variation should not be submitted as a result of unexpected events that may lead to product defects. Variation is only to be submitted after concerns have been

	addressed and CAPAs concurred. Refer to the *Product Defect Reporting and Recall Procedures* on the HSA website for product defect reporting 2. Applicable to the test parameters and limits described in the compendial only. 3. Change is made to comply with an update of the relevant monograph of the compendium or from one recognised pharmacopoeia to another. 4. Pharmacopoeia recognised by HSA: United States Pharmacopeia, European Pharmacopoeia, British Pharmacopoeia and Japanese Pharmacopoeia. 5. Any change should be within the range of currently approved limits. 6. The test procedure remains the same, or changes in the test procedures are minor. 7. The change does not concern any impurities (including genotoxic) or dissolution.
D	1. Updated release and/or shelf-life specifications. 2. Tabulation of the approved and proposed release and/or shelf-life specifications of the drug product with changes highlighted. 3. Certificate of analysis or batch analysis of at least two batches of drug product for all tests in the proposed specification.

D24 Minor change of Test Procedure for Excipient	
C	1. For minor change of a test procedure for excipient. For replacement or addition of a test procedure for excipients, refer to MIV-2 C19. 2. The method of analysis should remain the same (e.g., change in column height or temperature, but not a different type of column or method). 3. The specification of the excipient remains unchanged, and there is no change of the total impurities and no new impurities detected.
D	1. Description of the analytical methodology with a comparative tabulation of the changes. 2. Results of appropriate method validation to show proposed test procedure to be at least equivalent to the approved procedure, if applicable. 3. For quantitative test change, comparative analytical validation results showing that the approved and proposed tests are equivalent.

D25 Change of specification of Excipient or Drug Substance Starting Material to Comply with Latest Compendium	
C	1. Applicable to compendial specifications only. All the tests in the specification need to correspond to the pharmacopoeia standard after the change, except any additional supplementary tests. 2. Change is made to comply with an update of the relevant monograph of the compendium or from one recognised pharmacopoeia to another. 3. Pharmacopoeia recognised by HSA: United States Pharmacopeia, European Pharmacopoeia, British Pharmacopoeia and Japanese Pharmacopoeia.

D	1. Revised specification of the excipient or drug substance starting material. 2. Comparative tabulated format of the approved and proposed specification of excipient or drug substance starting material with changes highlighted. 3. Certificate of analysis or batch analysis of the excipient or starting material for all tests in the new specification of at least two batches. 4. A declaration that the change has no impact on the manufacturing process and quality of the drug product or drug substance.

D26 Change in Source of Empty Hard Capsule	
C	1. From TSE-risk material to vegetable-sourced or synthetic capsule. For change of vegetable-sourced or synthetic to TSE-risk material capsule, please refer to MIV-2 C20. 2. Not applicable to a change from a hard capsule to a soft gel. 3. The formulation and manufacturing process of the drug product remain unchanged. 4. The specifications of excipients and specifications of the release and shelf-life of drug product remain unchanged.
D	1. A letter of declaration from the manufacturer or the product registrant of the material that it is purely of vegetable or synthetic origin. 2. Technical specifications and composition of the empty hard capsule of the proposed source. 3. Certificates of analysis of the empty hard capsule of the proposed source. 4. Comparative dissolution profile data of one batch representative of pilot/production batch of the drug product using the hard capsule between the two sources (where applicable) as per US FDA SUPAC IR or MR guidelines. 5. A commitment letter to conduct relevant stability studies of the drug product in accordance with the *ASEAN Guideline on Stability Study of Drug Product* to support the approved shelf life. The product registrant shall report to the Health Sciences Authority of any out-of-specification result (with proposed action). Submission of the data in the form of a finalised report is not required but the data shall be provided to the Health Sciences Authority upon request.

D27 Change or Addition of Pack Size for Drug Product	
C	1. For change or addition of pack size involving the following: • Number of blister strips in a pack, where the number of tablets/capsules per blister strip remains unchanged • Number of containers in a pack (e.g., vials, ampoules) where the content per container (e.g., fill volume/weight) remains unchanged Otherwise, refer to MIV-1 B16 or MIV-2 C28. 2. The type and specification of the primary packaging material remain unchanged.

	3. The product presentation(s) must be adequate for the dosing regimen and duration of use as per the approved product labelling.
D	1. Revised drafts of the package insert and labelling incorporating the proposed variation (where applicable). 2. A letter of declaration from the product registrant stating that there are no other changes except for the change of pack sizes for a drug product. 3. A commitment letter to conduct relevant stability studies of the drug product in accordance with the *ASEAN Guideline on Stability Study of Drug Product* to support the approved shelf life (where applicable).

D28	**Change in the Specification Parameters and/or Limits or Test Procedure of Primary Packaging Material**
C	1. The primary packaging material remain unchanged. 2. Tightening of specification limits. Any change should be within the range of approved limits. 3. Addition of a new specification parameter to the specification with its corresponding test method. Any new test method does not concern a novel non-standard technique or a standard technique used in a novel way. 4. Deletion of a non-significant specification parameter (e.g., deletion of obsolete parameter)
D	1. Comparative tabulated format of the approved and proposed specifications of the primary packaging material. 2. Revised CTD Sections S6 or P7 (where applicable). 3. Declaration of compliance to the appropriate international standards or pharmacopoeia.

D29	**Obsolete**

D30	**Update of Anatomical Therapeutic Chemical (ATC) code**
C	1. The revised ATC code is as per the code assigned by the World Health Organization Collaborating Centre for Drug Statistics Methodology (WHOCC) and is consistent with the current approved therapeutic use of the product in Singapore.
D	1. Revised drafts of the package insert and labelling incorporating the change of ATC code (where applicable).