

## **GUIDE ON HOW TO UPLOAD THE ANALYTICAL METHOD VALIDATION REPORT IN QUEST3+ SYSTEM UNDER SECTION E12 & SECTION E13**

### **Section E12 (Analytical Test Procedures)**

- All the documents submitted must be labelled accordingly.
- All the tests specified under section P5.1 (finished product specification) shall be included under Section E12.
- The document must be compressed into a maximum size of 5MB in order to upload as a single attachment. If the single document size exceeds 5MB, you may split the document into multiple attachments and label each attachment accordingly as per the examples below:

Example 1 :

Attachment 1 : General Test Procedure

Attachment 2 : Raw Data Report including chromatograms

Example 2 :

Attachment 1 : General Test Procedure (Assay, Dissolution, Related Substance)

Attachment 2 : General Test Procedure (Microbial Contamination Test)

Attachment 3 : Raw Data Report including chromatogram

\* Raw data report and chromatograms for routine test procedures are optional

### **Section E13 (Analytical Method Validation)**

- The documents must be separated according to the test validation (e.g.: assay, dissolution, related substances, Microbial Contamination Test) and each test validation must be labelled under Description.
- The document must be compressed into a maximum size of 5MB in order to upload as a single attachment for each test validation report.
- If the single file size exceeds 5MB, you may split the document into multiple attachments and label each attachment accordingly as per the examples below:

Example 1 :

#### **For assay, dissolution, related substances, residual solvent**

Test Category : Please select "Others"  
Method : Please select either "Non Compendial" or "Compendial"  
Description : Please define accordingly (e.g.: "Assay Rosuvastatin")

Attachment :

1. Document 1 : Method & Tabulated Result
2. Document 2 : Raw Data Chromatogram Part 1
3. Document 3 : Raw Data Chromatogram Part 2
4. Document 4 : N/A
5. Document 5 : N/A
6. Document 6 : N/A
7. Document 7 : N/A
8. Document 8 : N/A

\* Chromatograms/spectrums are optional for product registered with DCA reference country.

Example 2 :

#### **For Microbial Contamination Test, BET, Sterility**

Test Category : Please select "Others"  
Method : Please select either "Non Compendial" or "Compendial"  
Description : Please define accordingly (e.g.: "Microbial Contamination Test")

Attachment :

1. Document 1 : Method Validation
2. Document 2 : Result / Raw Data Validation
3. Document 3 : N/A
4. Document 4 : N/A
5. Document 5 : N/A
6. Document 6 : N/A
7. Document 8 : N/A
8. Additional Document : N/A

\* If the file size is smaller than 5MB (compressed file), please attach under Document 1 only

- Please note that starting from 1 JULY 2022, the generic product registration application will be REJECTED during screening stage if the attachments uploaded in QUEST 3+ system under section E12 & E13 are not labelled accordingly.