# Objective

The objective of Dataset generation for M&S QC is to ensure 1) traceability of results to data, 2) compliance with Analysis Plan or study protocol, and 3) reproducibility.

This checklist template contains suggested review questions for activities of dataset generations. Sections and items of the Dataset Generation QC Checklist that are not applicable for the analysis will be indicated by a N/A checkbox. The QC Findings and Resolutions table will be used to describe any QC findings.

|  |  |
| --- | --- |
| **Protocol Number(s)** |  |
| **Project (Title)** |  |
| Data Analyst (or PM) |  |
| **QC Reviewer** |  |
| **Date** |  |

Fill in the below table for each model, as reported in the deliverable being review:

* Dataset file name:

# General Evaluation ☐ **N/A**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Item No.** | **Items Reviewed** | **QC Findings** | | |
| 2.1 | Was the administration time for IP dosing and the actual sampling time properly recorded? And accordingly, were the planned time, actual time, and TAD correctly reflected in the dataset? | YES | NO | N/A |
| 2.2 | Were there any missing data or outliers? | YES | NO | N/A |
| 2.3 | Did you have a policy for handling missing values and outliers? |  |  |  |
| 2.4 | Was the dosing information including ADDL, II, etc, correctly recorded? | YES | NO | N/A |
| 2.5 | For intravenous administrations, were the infusion-related details properly recorded? | YES | NO | N/A |
| 2.6 | Was the CMT correctly specified in accordance with the dosing information and DV? | YES | NO | N/A |
| 2.7 | Were the covariate details (such as gender, age, race, weight, height, BMI, foods, etc.) correctly entered according to the ID? | YES | NO | N/A |
| 2.8 | Was the dataset created with R? | YES | NO | N/A |
| 2.9 | Did script run from top to bottom without error and did the output agree with reported output? |  |  |  |
| 2.10 | Were there any coding errors in R script? |  |  |  |
| 2.11 | Do the values entered in the final dataset match those in the raw data? |  |  |  |

# QC Findings and resolution ☐ **N/A**

|  |  |  |  |
| --- | --- | --- | --- |
| **Item No.** | **QC Finding** | **Resolution** | **PMx**  **(검토자)** |
|  |  |  |  |
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# Quality Control Approval

The undersigned agree that the QC process has been followed and all QC findings have been resolved.

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| --- | --- |
| QC Reviewer Approval  *(Signature and date)* |  |
| Pharmacometrician Approval  *(Signature and date)* |  |