Revision 1.2

Non-clinical studies GLP compliance[[1]](#footnote-1) (Annex to the cover letter)

| **Study title/** **code**  | **Test facility(ies) /Test site(s) where the study was conducted (name and complete address)\***  | **Start date of study** | **Date of completion of the Final Report**  | **For studies conducted in EU, OECD, or fully MAD adherent countries: indicate (Y/N/NA) whether a successful inspection by its national GLP compliance monitoring authority took place within 3 years before or after the final study report date\*\***  | **For studies conducted in non-MAD adherent countries: indicate (Y/N/NA) whether the test facility and all test sites have been inspected and acknowledged as being OECD GLP compliant by an EU GLP compliance monitoring authority within 3 years before or after the final study report date\*\***  |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

1. Please see question 3.4.1 of the “[Pre-authorisation guidance”](https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/pre-authorisation-guidance) for further information.

\* Include a row for each test facility/test site.

\*\*Deviations should be clarified in annex to the table; NA: Not Applicable. [↑](#footnote-ref-1)