**Appendix V - RECORD SHEET**

**Use of Non-Pharmaceutical Grade Articles/ New Chemical Entities**

(Including chemicals/small molecules, biologics, peptides, and others)

Please fill in all details for all test article categories below, especially those without MSDS. If some information is unavailable, use “NA”. Please consider the formulation (= final dilution in a vehicle for dosing) for categories such as pH, stability or osmolarity.

|  |  |
| --- | --- |
| **Name of the Test Article\*:** |  |
| **MSDS available:** | Please select |
| **Classification (antibody, cytotoxic, etc.):** |  |
| **Known toxic effects:** |  |
| **Grade/purity:** |  |
| **Pyrogenicity:** |  |
| **Dose level, site and route of administration:** |  |
| **Dosing volume, frequency and duration:** |  |
| **Formulation (provide vehicle information):** |  |
| **Stability of dosing formulation:** |  |
| **Sterility of dosing formulation (include method to sterilize):** |  |
| **pH of dosing formulation:** |  |
| **Osmolarity/ Osmolality of dosing formulation:** |  |

***Notes:***

*\* If more than one test article is used, please use one record form per article.*