**Summary sheet**

|  |  |
| --- | --- |
|  | **Scope of Variation** |
| **Biological- (Imported or local) (reference or non-reference)** | **Type of Product** |
|  | **Applicant Name** |
|  | **License Holder /Marketing Authorization holder** |
|  | **Manufacturer of Active substance:** |
|  | **Manufacturer of Finished Product:** |
|  | **Manufacturer of Diluent** |
|  | **1ry Packager** |
|  | **2ry Packager** |
|  | **Batch Releaser** |
| **Active substance:**  **Finished product:**  **Diluent:** | **Stability Performed by** |
|  | **Trade Name** |
| **Finished product:**  **Diluent:** | **Active Ingredient** |
|  | **Dosage Form** |
|  | **Physical Characters of Active substance:** |
| **-If Powder then mention: 1- before reconstitution and 2-After reconstitution**  **-If powder & solvent then mention: 1-powder alone 2-solvent alone 3-After reconstitution** | **Physical Characters of Finished Product:** |
|  | **Shelf Life of Active substance:** |
|  | **Shelf Life of Finished Product:** |
|  | **Storage Conditions of Active substance:** |
|  | **Storage Conditions of Finished Product:** |
|  | **Precautions +Incompatibilities (if available)** |
|  | **Pack of Active substance:** |
|  | **Pack of Finished Product +Diluent:** |
|  | **Contact E-mail** |

**Summary of Stability Study:**

**The stability study data should be filled in the following table (Separate table for DS/ DP/ Diluent):**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Type of study (long or accelerated or stress)/In-use/Photostability** | **Batch no.** | **Man. site** | **Manufacturing date** | **Duration of study (available submitted data)** | **Storage conditions** | **Batch scale**  **(pilot or production)** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |