***To be supplied by the sponsor for use by the Authority Inspector at the port of entry to authorize the importation of the trial product.***

|  |  |  |  |
| --- | --- | --- | --- |
| **Importation and Release of Investigational Products** | | | |
| **Checklist of required documentation** | | | |
| Are the following documents attached and correct, as indicated? | | **YES** | **NO** |
| 1 | A copy of NDA letter of approval of trial |  |  |
| 3 | CoA reflect at least the following information: |  |  |
|  | Product name or code |  |  |
|  | Name of company / Sponsor |  |  |
|  | Batch number |  |  |
|  | Expiry date |  |  |
|  | Date of issue |  |  |
|  | Signature, qualification and title of responsible person |  |  |
|  | Results of physical and analytical tests |  |  |
| 4 | A copy of valid Certificate of Manufacture issued by the competent Regulatory Authority in the country of origin |  |  |
| 5 | Application device included (if applicable) |  |  |
| 6 | The label clearly indicate Labeling: *outer packaging, immediate container* |  |  |
| 6.1 | The product is trial material, e.g. “For use in trial only” |  |  |
| 6.2 | Product name or unique code (if blinded) |  |  |
| 6.3 | The Storage temperature is stated |  |  |
| 6.4 | The Storage conditions indicated (e.g. protection from light) |  |  |
| 6.5 | The Batch number is stated |  |  |
| 6.6 | The Date of manufacture is stated |  |  |
| 6.7 | The Expiry date is stated |  |  |
| 6.8 | Details of Sponsor`s contacts is included |  |  |
| 7.0 | The physical condition of the consignment is acceptable |  |  |