***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.***

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| **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 |  |  |