**IMP-Approval Form**

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| 1. **Site Information (Section 1 and 2 has to be filled in by Manufacturer/IMP Supplier/Sponsor only)**
 |
| **Study No:** |  | **Site ID:** |  |
| **Sponsor/Manufacturer/****Supplier:** |  | **Principal Investigator:** |  |
| **Courier Service:** |  |
| **Date of shipment:**(DD-MM-YYYY)**:** |  | **Shipment No:** |  [ ]  **NA** |

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| 1. **Shipment Information (Section 1 and 2 has to be filled in by Manufacturer/IMP Supplier/Sponsor only)**
 |
| **IMP name:**  |  | **Typ**: | Please select type of IMP. |
| **Number of IMP:** |  | **Batch No:**  |
| **Expiry date** (DD-MM-YYYY)**:** |  |
| **Comments:** |

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| 1. **Receipt Information (to be filled by study center)**
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| **Date of IMP receipt** (DD-MM-YYYY): |  | **Time of receipt** (hh:mm)**:** |  |
| **IMP receipt correctly:**  | [ ]  YES [ ]  NO | [ ]  damaged (please comment)\* |
| **Number of IMP received:** | [ ]  according to shipment list | [ ] other quantity received (please comment) |
| **Only fill in, if shipment is temperature controlled:** |
| **IMP received in cooled condition**(e.g. by: alarm during transport, confirmation of courier, visible marks on a logger…)**:** | [ ]  YES | ☐ NO (please comment)\* |
| **Comments:** |

***\*If IMP is not received within the temperature condition or damaged DO NOT USE the IMP! Store per protocol conditions, quarantine and contact your responsible clinical monitor.***

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| 1. **Responsibilities**
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| **IMP received and stored appropriately by:** | **After signing fax/email this form to:** |
| **Position:** |  | **Name:** |  ***-> please prefill with contact details of Sponsor*** |
| **Name:** |  | **Fax:** |  |
| **Signature:** |  | **E-Mail:** |  |
| **Date:** |  | **Phone:** |  |

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| 1. **IMP-Approval by Sponsor/Manufacturer/Supplier**
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| **Form received and complete:** | [ ]  YES | [ ]  NO (please comment)\* | **Deviation reported:** | [ ]  YES (please comment)\* | [ ]  NO |
| **Comments\*:** | **If yes, Stability Statement or Deviation Report available:** | [ ]  YES [ ]  NO |
| **IMP Approval given:** | [ ]  YES [ ]  NO (IMP has to be quarantine) |  |
| **Name:** |  | **Date (DD-MM-YYYY):** |  |
| **Position:** |  | **Signature:** |  |