**Instructions:** Electronically complete a single form for each set or batch of samples submitted using Microsoft Word.

**Fields identified in bold** are mandatory to perform the studies in compliance with GLP requirements. The form must be completed in its entirety to expedite the study initiation. **Fields marked with** \* must be completed before your order can be processed and may appear on your final report.

Upon completion, please print, sign and date the form at the bottom. Please include this form with your sample and ship to the NAMSA address that appears below. If you have any questions, please reach your usual contact at NAMSA or a Technical Advisor at +33 478 079 234 for France.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Sponsor Information** | | | | | | | | |
| **Ship To** (this address may be reported in the final report) | | | | | **Bill To**  Same as Ship To Information | | | |
| **Company Name** |  | | | | Company Name | |  | |
| **Contact** |  | | | | Address | |  | |
| **Address** |  | | | | City, State, Zip | |  | |
| **City, State, Zip** |  | | | | Country | |  | |
| Country |  | | | | Phone (Accounts Payable) | |  | |
| Phone |  | | | | **Details of the order** | | | |
| E-mail |  | | | |
| Mobile Phone  Mandatory for electronic signature | Please select one | | | | Purchase Order Number | |  | |
|  | | | | Proposal Number | |  | |
| **Test Article Characterization**  The Sponsor assures the below test article has been characterized for identity, stability and composition as required by GLP Regulations.  Definitions are available on our website: [How to Address a Sample Submission Form](https://namsa.com/app/uploads/2020/05/Lyon-How-to-address-Sample-Submission-Forms.pdf) / [Guide de remplissage de la Fiche Information Produit](https://namsa.com/app/uploads/2020/05/Lyon-Guide-de-remplissage-de-la-Fiche-Information-Produit.pdf) | | | | | | | | |
| **\*Name** |  | | | | | | | |
| **\***Reference |  | | | | | | | |
| **\*Batch/Lot ID** |  | | | | | | | |
| **Type:** | Please select one | | If Other, please describe: | | | | | |
| **\*Physical Description**  Illustrations or photos of the device are **required** | Illustrations or photos attached  If not available, please provide a detailed description for characterization and identification of the test article (nature of material**,** shape of material, color, consistency, size, packaging, …): | | | | | | | |
| **\*Intended Clinical Use**  Information for Use is **required** | IFU attached  If IFU not available, please provide a detailed description : | | | | | | | |
| **\*Sterility** | Sterile – Please select process  Not Sterile  Aseptically Prepared  NAMSA to Sterilize (Steam – Additional fee will apply)  Please select Time/Temp If Other, please describe: | | | | | | | |
| **Certificate of analysis**  **(dated and signed)** | Mandatory for liquid, gel, powder, paste, cream and/or if the test article is a Pharmaceutical or Biologic | | | | | | | |
| Certificate is enclosed (this certificate will be enclosed in the final report)  Not available  Analytical Method: Performed under GxP:  YES  NO | | | | | | | |
| **\*Date of Manufacture** | Please enter or select date | | | | | | | |
| **\*Stability** | Stability testing is the responsibility of the sponsor and is subject to authorities audit  Expiration date (Shelf life): Please enter or select date | | | | | | | |
| **\*Stability after opening packaging** | Does the stability of the test article change upon opening?  No (Not applicable)  Yes  If yes, for how many hours, days, months is the test article stable upon opening: | | | | | | | |
| **\*Composition**  Please complete the 4 sections or provide a separate document with these information in a tabular format | **\* Raw materials**  (Name, CAS Number, Trade Name, % w/w) | | | Contact to Patient?  (direct, indirect or no contact) | | Contact surface area?  (if applicable) | | Part name?  (if applicable) |
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| Separate document attached | | | | | | | |
| **\*Has active ingredient?** | No | Yes | | **Active ingredient**  **Strength:**  **Purity:** | |  | | |

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| **Shipping conditions**  Sponsor’s responsibility :  The Sponsor needs to establish the conditions the test item is expected to be subject to during transportation (appropriate vehicle, container …).  Appropriate monitoring measures or special care is required if the test item is temperature, light and/or humidity sensitive. | Temperature sensitive | | | | No (uncontrolled conditions)  Yes (please complete below) | | | | | | | | | | | | | |
| Temperature: | | | | Please select one | | | | | | | | | | If Other, describe: | | | |
| Monitoring system: | | | | Please select one | | | | | | | | | | If Other, describe: | | | |
| Refrigerant : | | | | Please select one | | | | | | | | | | If Other, describe: | | | |
| Light sensitive | | | | | No | | Yes | | Describe special care: | | | | | | | | |
| Humidity sensitive | | | | | No | | Yes | | Describe special care: | | | | | | | | |
| Other: | | | | |  | |  | | Describe special care: | | | | | | | | |
| **\*Storage Conditions at NAMSA** | Please select temperature | | | | | | | | | | | | | | | | | |
| Protected from light | | | | | No | | Yes | | Describe special care: | | | | | | | | |
| Protected from Humidity | | | | | No | | Yes | | Describe special care: | | | | | | | | |
| Other: | | | | | | | | | Describe special care: | | | | | | | | |
| **\***Quantity of test article (s) submitted | If liquid or gel | | Number (vials, syringes…): | | | | | |  | | Quantity per container: | | | | | | | mL |
| If powder | | Number (vials, syringes…): | | | | | |  | | Quantity per container: | | | | | | | g |
| If solid | | Quantity (devices, packages…): | | | | | |  | | Quantity per package: | | | | | | |  |
| **Test Article Preparation** | | | | | | | | | | | | | | | | | | |
| If the test device is a gel, liquid, cream or powder, please indicate: | | | **\*Test article is a homogeneous gel, liquid, cream or powder** | | | | | | | | | | | | | | | |
| **\*Test article is a non-homogeneous gel, liquid, cream or powder** | | | | | | | | | | | | | | | |
| **Instruction before use to assure homogeneity:** | | | | | | | | | | | | |  | | |
| Osmolality: | | | |  | | | | | | | pH: | |  | | |
| Needles are provided | | | | | | | | | | | | | | | |
| Need cleaning and/or disinfection before use? | | | No | | | Yes, describe: | | | |  | | | | | | | | |
| Need specific preparation or handling before use? | | | No | | | Yes, describe: | | | |  | | | | | | | | |
| Part (s) of the test article need to be excluded? | | | No | | | Yes, list: | | | |  | | | | | | | | |
| Can be Cut | | | No | | | Yes (cutting can expose inner surfaces – cutting will destroy the test article) | | | | | | | | | | | | |
| Is an absorbent? | | | No | | | Yes, describe: | | | |  | | | | | | | | |
| Is there any surface coating? | | | No | | | Yes, describe: | | | |  | | | | | | | | |
| Other Special Instructions | | |  | | | | | | | | | | | | | | | |
| Is the test article tested in its final product form and condition (packaging)? | | | No  Yes | | | | | | | | | | | | | | | |
| **Test article Extraction** | | | | | | | | | | | | | | | | | | |
| Includes multiple components with different thicknesses (> and < 0.5 mm)? | | | | No  Yes (If yes, is advised to choose the ratio below based on the thinnest material layer of that component) | | | | | | | | | | | | | | |
| **\***Extracts to be Prepared by | | Please select ratio  When needed, NAMSA might adapt the ratio | | | | | | | | **\***Test Article Surface Area  (Total contact surface area) | | | | | | | cm2 | |
| **\***Test Article Weight | | | | | | | g | |
| **\***Extraction Conditions  (the highest temperature that will not degrade the test article is recommended) | | Cytotoxicity: Please select Time/Temp  If Other, please describe:  Other conditions to be justified. The extraction time may be less than 24h but no less than 4h | | | | | | | | Other Tests: Please select Time/Temp  If Other, please describe:  Other conditions to be justified | | | | | | | | |
| **Other Information** | | | | | | | | | | | | | | | | | | |
| Countries/Regions that test data will be submitted to | | USA  Europe | | | | | China  Japan | | | | | Other:  Not known | | | | | | |
| **\*Disposal** | | Please select one | | | | | | | | | | | | | | | | |
| For test article to be returned | | Please select carrier  Special handling instructions: | | | | | Other: | | | | | | Account #: | | | | | |
| **\***Safety Data | | Mandatory for liquid, gel, powder, paste, cream and/or if the test article is a Pharmaceutical or Biologic  Please select one | | | | | | | | | | | | | | | | |

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| **Nature of the test article's contact** | | | | | |
| Surface device | Please select one | | | | |
| External communicating device | Please select one | | | | |
| Implant device | Please select one | | | | |
| Population | Male | Female | | | |
| Adults | Children | Neonates | | |
| Minimum weight if specified: | | | | |
| Contact duration | Please select contact duration | | | | |
| If < 4h, Please specify contact duration: | | | |  |
| If > 30 days | | | Please select duration | |
| Clinical exposure *per* patient | Maximum number of test article that could be used in a patient\*\*: | | | | |
| Dose Based Threshold (DBT)  (For chemical analysis only) | µg/day | | | | |

\*\* If more than one, please describe the exposure scenario (for example: “two devices will be implanted at the same time”; “a new device will be implanted every three years”; “a patient may use the re-usable device daily, up to four treatments/day, 10 minutes/treatment”; etc.)

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| --- | --- |
| **Please print this form and sign. \*Signature must be handwritten.**  By this signature, the Sponsor assures the exactitude of the information listed above. | |
| **Sponsor Function:**  **\*Signature:** | Date: |

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| --- | --- |
| **Shipping Information** | |
| Please, include a signed copy of this form and ship to the facility as designated below. Thank you for your business. | |
| Germany Facility:   * Chemical Analysis * Chemical Characterization | France Facility:   * *In Vitro* Toxicology * *In Vivo* Toxicology * *In Vivo* Efficacy and Functional * Antimicrobial and Microbiology Specials * Microbiology (Bioburden, Sterility, LAL) * Histology |
| NAMSA Laboratory Services GmbH  Attention: Samples reception  Industrie Center Obernburg  63784 Obernburg  Germany | NAMSA  Attention: Samples reception  115 Chemin de l’Islon  38670 Chasse sur Rhône  France |

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| **Documentation Required** |
| Please, include these documents attached with this form. |
| * Information for Use (IFU) * Illustrations or photos of the test article   If applicable :   * Certificate of analysis * Safety Data |