The information requested in the Sample Submission Form is necessary for the proper conduct of the studies, therefore complete the entire document. You will find below definitions/explanations about the requested information. Drop down menus are built in to ease the data entry process electronically. Just click and select the option within the form that applies. Use the tab key to navigate through the form. These forms are very detailed but NAMSA is confident that the sample submission process will provide greater efficiencies to streamline your medical device development efforts. After completing the form, print, sign, date, and include it with your shipment.

Please send the test articles to the following address:
NAMSA
Sample réception
115 Chemin de l'Islon
38670 Chasse-sur-Rhône - FRANCE

Please send **a Sample Submission Form per test article**. If for the same study, you have to send **two different batches, please fill in two separate forms**. If one product is sent several times, please attach a copy of the form to each shipment or complete several forms if there are different batches.

The Sample Submission Form can be sent by e-mail before the arrival of the test articles, so preliminaries can begin like the protocol drafting. In this case, please still attach a copy of the form with the shipment in order to facilitate its identification and treatment.

If you have any questions or need help with the new Sample Submission Forms, please feel free to contact your usual contact at NAMSA or a Technical Advisor at +33 478 079 234. We will be happy to assist you.

1 - How to select the right Sample Submission Form

GLP Sample Submission Form - Select this form when submitting a test article for studies that require compliance to Good Laboratory Practice regulations (tests that are being submitted to regulatory agencies).

GLP Sample Submission Form with Control article - Select this form when submitting test and control articles for studies that require compliance to Good Laboratory Practice regulations (tests that are being submitted to regulatory agencies).

NAMSA will specify in the proposal when a sponsor-submitted control article is necessary.

Sample Submission Form - Select this form for projects that include non-GLP biocompatibility or chemical characterization testing (projects that are not being submitted to a regulatory agency).

Sample Submission Form: Microbiology studies - Select this form for microbiology studies.

Animal Explant Submission Form - Select this form when submitting an animal specimen for histological study.

Human Explant Submission Form - Select this form when submitting a human specimen for histological study.

2 - How to complete the Sample submission forms

How to complete the GLP Sample Submission Form 2
How to complete the Sample Submission Form 7
How to complete the Sample Submission Form: Microbiology studies 11

How to complete the GLP Sample Submission Form

<table>
<tr><th colspan="3">Sponsor Information</th></tr>
<tr><td colspan="2">Ship To</td><td>Bill To</td></tr>
<tr><td colspan="2">Clarify the information on the Sponsor in this field.
The protocol will be sent to the contact mentioned in this section. The address mentioned in this section will appear in the final report.</td><td>If the bill should not be send to the same address of study monitor, you can provide a different billing address in this field.</td></tr>
<tr><td>Mobile Phone</td><td>Please provide the mobile phone number of the Sponsor. This is a mandatory for protocol approval. If you don’t have a professional number, you could indicate in the drop down menu if this number is a personal number and if you accept or not that it will be used as phone contact as well or only for protocol approval.</td><td>Details of the order

Please indicate your purchase order reference (which will then appear on the invoice) and the corresponding proposal number.</td></tr>
<tr><th colspan="3">Test Article Characterization</th></tr>
<tr><td colspan="3">The Sponsor should assure the article has been characterized as required by Good Laboratory Practice regulations. Characterization is the responsibility of the Sponsor and is subject to GLP authorities’ audit.
The information you provide to NAMSA should be detailed enough to meet the requirements of GLP regulations. This information is necessary in order to allow test(s) to be performed according to the GLP.
The information given by the Sponsor needs to provide the NAMSA Study Director details regarding the characterization of the article which will ensure that testing is conducted properly. If full characterization is not available before the beginning of the study, testing could begin in agreement with the Study Director, but missing information should be provided during the course of the study. A thorough description of the article is required in the GLP final report. Absence of characterization information will result in a GLP deviation or in a non-GLP study.</td></tr>
<tr><td>*Name</td><td colspan="2">Please indicate the product name as it appears on the packaging (consider the special characters). To ensure the accuracy of the information indicated in the report, no translation will be performed by NAMSA.</td></tr>
<tr><td>*Reference</td><td colspan="2">Please indicate the product reference as it appears on the packaging (consider the special characters). The reference is the commercial reference of the product, which is indicated on the packaging. This is the code that identifies the product (registration number, benchmark).</td></tr>
<tr><td>*Batch/Lot ID</td><td colspan="2">Please indicate the product batch as it appears on the packaging (consider the special characters). The batch/lot number corresponds to a specific quantity of product manufactured in one process or one series of processes as it may be considered homogeneous.</td></tr>
<tr><td>Type</td><td colspan="2">Please indicate the category of the submitted test article (medical device, pharmaceutical...) using the drop down menu.
As part of a GLP study, the category "Other" is not acceptable. Information must be accurate in order to apply the appropriate GLP regulation.</td></tr>
<tr><td>*Physical Description</td><td colspan="2">Characterization data include the description of the device but illustrations or photos is the best way to show the entire configuration of the test article.
Therefore, please provide illustrations or photos of the test article. Note: This image may be included in the report to help in device description.
If it is not available, please provide a detailed description of the test article.
Examples:
Blue catheter of 50 cm length with two luer lock connectors (one purple, one green) packaged in a sterile pouch.
The test article is composed of two vials packaged in an opaque pouch: One plastic vial with 30 g of white powder, one opaque glass vial with 10 mL of clear liquid solution.</td></tr>
<tr><td>*Intended Clinical Use</td><td colspan="2">Please provide the IFU of the device. If the IFU is not available, please provide a detailed description of the device's intended purpose, the indications for use, its functions and any other pertinent relevant information.</td></tr>
<tr><td>*Sterility</td><td colspan="2">Please indicate if the submitted test article is sterile, not sterile or has to be sterilized at NAMSA. Be aware that it is not whether the product has been sterilized, but if it is being sent in sterile conditions. Some tests, in particular in vivo trials, are required to be performed on sterile test articles. NAMSA offers steam sterilization only, with a choice of which cycle to apply: 121°C for 20 min or 134°C for 18 min. Please refer to the proposal for the corresponding fees.
Sterilization process
In the case the test article is sterile, please specify the sterilization process (gamma irradiation, ethylene oxide…).</td></tr>
<tr><td>Certificate of analysis (dated and signed)</td><td colspan="2">For studies on liquid, gel, powder, paste, cream and/or if the test article is a Pharmaceutical or Biologic, please join a certificate of analysis for each batch tested. The document must indicate the test article identification and has to be approved.
In the absence of a certificate of analysis, could you please send us information in alternative formats to confirm the identity and properties of the test item?</td></tr>
</table>

<table>
<tr><td>*Date of Manufacture</td><td colspan="4">Please indicate the Manufacturing date for the submitted test article</td></tr>
<tr><td>*Stability</td><td colspan="4">Stability is the property of an article to remain in the same state without degrading or loosing its effectiveness. Shelf life is a common stability before opening packaging test.
Please indicate the Expiration date which is the designated date a test article is expected to remain within established shelf life specifications if stored under defined conditions and after which it should not be used. Be aware that we expect a specific date and not a duration.</td></tr>
<tr><td>*Stability after opening packaging</td><td colspan="4">It refers to the amount of time a product will remain stable and safe after it has first been opened. In case of stability changing upon packaging opening, please indicate for how long is the test article stable upon opening?
Examples:
o 1 hour
o 1 month in refrigerator (+2°C to +8°C)</td></tr>
<tr><td rowspan="8">*Composition</td><td>*Raw materials
(Name, CAS Number, Trade Name, % w/w)</td><td>Contact to Patient?
(direct, indirect or no contact)</td><td>Contact surface area ?
(if applicable)</td><td>Part name ?
(if applicable)</td></tr>
<tr><td>Please list the materials of which the device is made:</td><td>Please indicate whether the material is patient-contacting (direct or indirect) or non-patient contacting</td><td>Please indicate the surface area of the material which are in contact with the patient</td><td>Please indicate the corresponding device component/region where it is present</td></tr>
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- Masterbatch HT – MAB XXX Green (2-3 %)</td><td>No</td><td>Not applicable</td><td>Pusher Handle</td></tr>
<tr><td>- Polyvinyl Chloride (PVC) green,
- Dioctyl Terephtalate (DEHT)
- Green colorant (CAS No. XXXX XX-X, 1-2 %)</td><td>Yes, Direct Contact (Tissue)</td><td>X cm²</td><td>Pusher Tube</td></tr>
<tr><td>o Example 2:</td><td></td><td></td><td></td></tr>
<tr><td>- Hyaluronic Acid (CAS No. XXXX XX-X, 12% v/v), - Hydroxylapatite (CAS No. XXXX XX-X, 1 % v/v),
- Almond oil (CAS No. XXXX XX-X, 1% v/v)
- Poly-L-lactic Acid (Chemical formula: CaHXxx2x, CAS No. XXXX XX-X, 1 % v/v)
- qsp purified water (CAS No. XXXX XX-X)</td><td>Yes, Direct Contact</td><td>Not applicable</td><td>Not applicable</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td>*Has active ingredient?</td><td>Please indicate if your test article contains an active ingredient</td><td colspan="3">Active ingredient: An active ingredient is any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals. Please indicate the name of this ingredient
Examples :
o Stent with an anticoagulant: name of the anticoagulant
o Gel with a local anesthetic: name of the anesthetic
Strength is the concentration or amount of active ingredients in the tested article. If there is no active ingredient, this will not apply.
Example :
o If the strength of anesthetic in the test article is for example 0,1%. Please indicate in the field: 0.1%
Purity is typically described as the percentage of a specific material, chemical component or active pharmaceutical ingredient with respect to impurities. Impurities can arise during the manufacture, storage and handling of the specified material. If there is no active ingredient, this will not apply.
Example :
o If the purity of anesthetic used in the test article is for example 97%. Please indicate in the field: 97%</td></tr>
</table>

Shipping conditions	To preserve the integrity of the test item, care should be taken to avoid it being exposed to environmental conditions which may be detrimental. Prior to sending the test article there should be a mechanism to establish the conditions the test item is expected to be subject to during transportation. Special care should be taken if the test item is temperature, light and/or humidity sensitive. Appropriate monitoring measures, such as the use of data loggers, max/min thermometers may be required commensurate to risk. Please indicate the conditions of sending in order to be able to check them at the test article receipt.
***Storage Conditions at NAMSA**	Please indicate the storage conditions when receiving the submitted article. In case some special conditions are required, please contact us before sending the test article to verify if NAMSA can guarantee these conditions.
Quantity of test article(s) submitted	According to the GLP, the quantity of test article received shall be recorded. In addition, this information is important for NAMSA to determine if the quantity received is sufficient to perform the tests. If you need help to calculate the test article quantities, please feel free to contact your usual contact at NAMSA or a Technical Advisor. Please specify the quantity of test article sent and the quantity per vial or package.
Test Article Preparation All the questions mentioned below, are listed to understand the test article preparation in order to try to mimic as possible the clinical use and/or to facilitate the preparation of the test article.	
If the test device is a gel, liquid, cream or powder, please indicate:	**Homogeneity** is consistency of the chemical and physical compositions of a material, and uniformity in response to a biological endpoint. Is only applicable to liquids, gels and powders, which require sampling before testing (e.g. sampling of a defined quantity in the submitted vial). Homogeneity is not applicable when no sampling is needed (testing of the totality of the vial). If the test article is not homogeneous, please indicate the instruction to assure homogeneity. Examples: ○ Shake 10 seconds before use. ○ Mix the powders with the liquids during 30 seconds.
	Chemical properties of the test article including pH and osmolality are some factors to consider when designing some studies. Please indicate this information, it could be important for tests design.
	If in clinical use, specific needles is recommended, we advise to use them in the tests, as possible. Please indicate if you will send needles with the test article.
Need a cleaning and/or disinfection before use?	It is recommended that the test article which are clean, sterile and disinfected, will be processed by the method recommended by the manufacturer and handled aseptically, if appropriate to the test procedure. If this is applicable to your test article, please indicate the procedure to be applied. Example: ○ Clean the tip and the shaft with sterile gauze soaked with sterile water at room temperature (+15°C to +25°C) during 30 seconds +/- 5 seconds. Rinse the distal tip and shaft with sterile water.
Need a specific preparation or handling before use?	The test article preparation shall be appropriate to the nature and use of the final product and to the purpose of the test. If this is applicable to your test article, please describe the procedure to be applied. Examples: ○ Flush the catheter with saline. Insert the guidewire into the catheter. Remove the guidewire which is not in contact with the patient. ○ Keep the test article at room temperature 15-25°C, 30 minutes before use.
Part(s) of the test article need to be excluded?	Non-patient contacting portions of the medical device should, if possible, be excluded either physically from test article. The photo or scheme requested for the physical description could be used for a precise description of the part that has to be tested. If this is applicable to your test article, please describe the preparation.
Can be Cut	Please indicate if your test article can be cut. For several tests, it could be necessary to cut the device for technical reasons. Examples: ○ Selection of representative portions ○ Extraction: Materials may be cut into small pieces before the extraction to enhance submersion in the extract media
Is an Absorbent ?	The absorption capacity of the test article is a factor to consider for some studies. Example: ○ For the extraction, it may be necessary to determine the volume of extraction vehicle absorbed by the test article. Then, during extraction, this additional volume will be added to the calculated extraction volume. Please indicate if your product is an absorbent. If yes, please describe the absorption capacity Example: ○ 1 mL of water/cm²

<table>
<tr><td>Is there any surface coating?</td><td colspan="3">The presence of a coating can be a factor to consider for design changes.
Example:
○ In case of a coating delamination, design (of the test or of the test article) has to be changed to avoid medical device failures that could result in adverse biological responses.</td></tr>
<tr><td>Other Special Instructions</td><td colspan="3">Please describe any other information/instruction that could be relevant for the proper conduct of the studies. Be aware that without instructions, the whole test article will be tested. This means that everything that is in the blister after opening packaging will be tested.</td></tr>
<tr><td>Is the test article tested in its final product form and condition (packaging)?</td><td colspan="3">Except if your test article is a device in early stage of development, testing shall be performed on the final medical device, or representative samples from the final device or materials processed in the same manner as the final medical device.
Please indicate if the test article is a final finish product.</td></tr>
<tr><td colspan="4">Test article Extraction</td></tr>
<tr><td>Includes multiple components with different thicknesses (> and < 0.5 mm)?</td><td colspan="3">If the medical device includes multiple tissue contacting components with different thicknesses, the extraction ratio should be justified. One way to do this is to base the ratio on the thinnest material layer of that component.
Please indicate this information, if it is applicable for your test article.</td></tr>
<tr><td rowspan="2">*Extracts to be Prepared by

As per ISO 10993 standard part 12, the sponsor has to provide the exact surface area and thickness of the test article, as this information is needed for determination and application of the extraction ratio. This information is under the Sponsor’s responsibility. However, when necessary for the proper conduct of the trial, the Study Director might have to adapt the required conditions, while remaining in accordance to ISO 10993 standard part 12.</td><td rowspan="2">Surface ratio
Select a surface ratio when surface area can be determine.
Then, based on the thickness of the material, please select the appropriate ratio.

Weight ratio
Select a weight ratio when the surface area cannot be provided.
Then, please select the appropriate weight ratio applicable for your device.

Filling Ratio
This ratio is applicable if only the internal parts of the test article are in contact with the patient.
Examples:
○ Dialysis filter
○ Blood bag</td><td>*Test Article Surface Area

(Total contact surface area)</td><td>How to calculate the surface area of the submitted test article?
The entire surface area that will be in contact with the patient has to be considered. This area includes the combined area of all tissue contacting surfaces of the test article and ignores the contribution of indeterminate surface irregularities.
So, include the external surface in direct contact but also possibly the inner surface with indirect contact.
Non-patient contacting portions of the medical device should be excluded in the surface area calculation.
If only a portion of the submitted article has to be tested, specify the surface area of this part only.</td></tr>
<tr><td>*Test Article Weight</td><td>For tests that require extraction and when the surface area cannot be provided, please specify the weight of one test article. If only a portion of the submitted article has to be tested, specify the weight of this part.</td></tr>
<tr><td>*Extraction Conditions</td><td>Cytotoxicity:
Extraction at 37 ± 1°C for 24 ± 2 h is acceptable for cytotoxicity testing of limited-contact medical devices. For medical devices which are in limited contact with intact skin or mucosa and which are not implanted, extraction times of less than 24 h, but not less than 4 h, are acceptable for cytotoxicity testing (see ISO 10993-5). For medical devices which are in prolonged (>24 h to 30 d) or long-term
(>30 d) contact, extraction duration of 72 h is recommended for cytotoxicity testing because extraction for 24 h may not be sufficient to obtain an extract that represents the chemicals released beyond 24 h of device use</td><td colspan="2">Other Tests:
As per ISO 10993 standard part 12, the extraction conditions used should be appropriate to the nature and use of the final product.
Extraction should not cause significant degradation of the material, unless the material is intended to dissolve or be resorbed during use. The extraction temperature is dependent upon the physico-chemical characteristics of the medical device material(s).
Extraction conditions of time and temperature to simulate exaggerated exposure wherever possible. The period of extraction should be sufficient to maximize the amount of material extracted. In practice, use of these standard conditions of time and temperature for extraction are recommended in lieu of other non-validated or non-standard conditions.
Therefore, NAMSA recommend to use the highest temperature that will not degrade the test article or at least a temperature of 50°C in case of doubt regarding the test article degradation.</td></tr>
</table>

Other Information	
Countries/Regions that test data will be submitted to	Some countries required specific design of tests. Please indicate the regions for the submission in order to check if the testing is appropriate.
***Disposal**	Please specify what has to be done with the submitted article once the study is over. - Discard unused article, after the end of the study (the used test articles are systematically discarded after use). - Return unused article (the used test articles are systematically discarded after use). - Return used and unused article. Please refer to the Cost Estimate and Proposal for payment conditions.
For test article to be returned	If you select the return of the test article, please indicate the carrier information that you want us to use (Name, account…)
Safety Data	A detailed composition list and current MSDS must accompany any pharmaceutical, cosmetic, biologic or medical device presented as a liquid, powder, paste, gel… If a solid medical device has any safety concern, please provide safety data or instructions to prevent any safety issue. A certificate of testing or reprocessing must be submitted for any human-tissue-derived article or clinically used medical device. Please indicate the precautions for use. Join the instructions for use if necessary.
Nature of the test article's contact	
Surface device	As per ISO 10993 standard part 1, medical devices shall be categorized according to the nature and duration of body contact. The categorization of medical devices facilitates selection of appropriate data sets. Please select the appropriate category of your device.
External communicating device	
Implant device	
Population	Population, contact duration and clinical exposure of the test article are some factors to consider when designing some studies Example: ○ For toxicity studies when a device is intended for use in only one sex, testing should be done on that sex.
Contact duration	
Clinical exposure per patient	
Dose Based Threshold (DBT) (For chemical analysis only)	As per ISO 10993 standard part 18, please indicate the DBT in µg/day

How to complete the Sample Submission Form

Sponsor Information	
Ship To	**Bill To**
Clarify the information on the Sponsor in this field. The report will be sent to the contact mentioned in this section. The address mentioned in this section will appear in the final report.	If the bill should not be send to the same address of study monitor, you can provide a different billing address in this field. **Details of the order** Please indicate your purchase order reference (which will then appear on the invoice) and the corresponding proposal number.

Test Article Characterization	
The information given by the Sponsor needs to provide the NAMSA Study Director details regarding the characterization of the article which will ensure that testing is conducted properly. If full characterization is not available before the beginning of the study, testing could begin in agreement with the Study Director, but missing information should be provided during the course of the study.	
***Name**	Please indicate the product name **as it appears on the packaging** (consider the special characters). **To ensure the accuracy of the information indicated in the report, no translation will be performed by NAMSA.**
*Reference	Please indicate the product reference **as it appears on the packaging** (consider the special characters). The reference is the commercial reference of the product, which is indicated on the packaging. This is the code that identifies the product (registration number, benchmark).
***Batch/Lot ID**	Please indicate the product batch **as it appears on the packaging** (consider the special characters). The batch/lot number corresponds to a specific quantity of product manufactured in one process or one series of processes as it may be considered homogeneous.
Type	Please indicate the product name **as it appears on the packaging** (consider the special characters). **To ensure the accuracy of the information indicated in the report, no translation will be performed by NAMSA.**
***Physical Description**	Characterization data include the description of the device but illustrations or photos is the best way to show the entire configuration of the test article. Therefore, please provide illustrations or photos of the test article. Note: This image may be included in the report to help in device description. If it is not available, please provide a **detailed** description of the test article. Examples: o Blue catheter of 50 cm length with two luer lock connectors (one purple, one green) packaged in a sterile pouch. o The test article is composed of two vials packaged in an opaque pouch: One plastic vial with 30 g of white powder, one opaque glass vial with 10 mL of clear liquid solution.
Intended Clinical Use	Please provide the IFU of the device. If the IFU is not available, please provide a **detailed** description of the device's intended purpose, the indications for use, its functions and any other pertinent relevant information.
***Sterility**	Please indicate if the submitted test article is sterile, not sterile or has to be sterilized at NAMSA. Be aware that it is not whether the product has been sterilized, but if it is being sent in sterile conditions. Some tests, in particular *in vivo* trials, are required to be performed on sterile test articles. NAMSA offers steam sterilization only, with a choice of which cycle to apply: 121°C for 20 min or 134°C for 18 min. Please refer to the proposal for the corresponding fees. **Sterilization process** In the case the test article is sterile, please specify the sterilization process (gamma irradiation, ethylene oxide…) using the drop down menu.
***Stability**	Stability is the property of an article to remain in the same state without degrading or loosing its effectiveness. Shelf life is a common stability before opening packaging test. **Please indicate the Expiration date** which is the designated date a test article is expected to remain within established shelf life specifications if stored under defined conditions and after which it should not be used. **Be aware that we expect a specific date and not a duration.**
Stability after opening packaging	It refers to the amount of time a product will remain stable and safe after it has first been opened. In case of stability changing upon packaging opening, please indicate for how long is the test article stable upon opening? Examples: o 1 hour o 1 month in refrigerator (+2°C to +8°C)

<table>
<tr><td rowspan="8">*Composition</td><td>*Raw materials
(Name, CAS Number, Trade Name, % w/w)</td><td>Contact to Patient?
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(if applicable)</td><td>Part name ?
(if applicable)</td></tr>
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<tr><td>- Polyvinyl Chloride (PVC) green,
- Dioctyl Terephtalate (DEHT)
- Green colorant (CAS No. XXXX XX-X, 1-2 %)</td><td>Yes, Direct Contact (Tissue)</td><td>X cm^2</td><td>Pusher Tube</td></tr>
<tr><td>o Example 2:</td><td></td><td></td><td></td></tr>
<tr><td>- Hyaluronic Acid (CAS No. XXXX XX-X, 12% v/v), - Hydroxylapatite (CAS No. XXXX XX-X, 1 % v/v),
- Almond oil (CAS No. XXXX XX-X, 1% v/v)
- Poly-L-lactic Acid (Chemical formula: CaHXxx2x, CAS No. XXXX XX-X, 1 % v/v)
- qsp purified water (CAS No. XXXX XX-X)</td><td>Yes, Direct Contact</td><td>Not applicable</td><td>Not applicable</td></tr>
<tr><td>Shipping conditions</td><td colspan="4">To preserve the integrity of the test item, care should be taken to avoid it being exposed to environmental conditions which may be detrimental. Prior to sending the test article there should be a mechanism to establish the conditions the test item is expected to be subject to during transportation. Special care should be taken if the test item is temperature, light and/or humidity sensitive. Appropriate monitoring measures, such as the use of data loggers, max/min thermometers may be required commensurate to risk.
Please indicate the conditions of sending in order to be able to check them at the test article receipt</td></tr>
<tr><td>*Storage Conditions at NAMSA</td><td colspan="4">Please indicate the storage conditions when receiving the submitted article.
In case some special conditions are required, please contact us before sending the test article to verify if NAMSA can guarantee these conditions.</td></tr>
<tr><td>Quantity of test article (s) submitted</td><td colspan="4">The quantity of test article received shall be recorded. In addition, this information is important for NAMSA to determine if the quantity received is sufficient to perform the tests. If you need help to calculate the test articles quantities, please feel free to contact your usual contact at NAMSA or a Technical Advisor.
Please specify the quantity of test article sent and the quantity per vial or package.</td></tr>
<tr><td colspan="5">Test Article Preparation
All the questions mentioned below, are listed to understand the test article preparation in order to try to mimic as possible the clinical use and/or to facilitate the preparation of the test article.</td></tr>
<tr><td rowspan="3">If the test device is a gel, liquid, cream or powder, please indicate:</td><td colspan="4">Homogeneity is consistency of the chemical and physical compositions of a material, and uniformity in response to a biological endpoint.
Is only applicable to liquids, gels and powders, which require sampling before testing (e.g. sampling of a defined quantity in the submitted vial). Homogeneity is not applicable when no sampling is needed (testing of the totality of the vial).
If the test article is not homogeneous, please indicate the instruction to assure homogeneity.
Examples:
o Shake 10 seconds before use
o Mix the powders with the liquids during 30 seconds.</td></tr>
<tr><td colspan="4">Chemical properties of the test article including pH and osmolality are some factors to consider when designing some studies.
Please indicate this information, it could be important for tests design.</td></tr>
<tr><td colspan="4">If in clinical use, specific needles is recommended, we advise to use them in the tests, as possible.
Please indicate if you will send needles with the test article.</td></tr>
<tr><td>Need cleaning and/or disinfection before use?</td><td colspan="4">It is recommended that the test article which are clean, sterile and disinfected, will be processed by the method recommended by the manufacturer and handled aseptically, if appropriate to the test procedure.
If this is applicable to your test article, please indicate the procedure to be applied.
Example:
Clean the tip and the shaft with sterile gauze soaked with sterile water at room temperature (+15°C to +25°C) during 30 seconds +/-5 seconds. Rinse the distal tip and shaft with sterile water.</td></tr>
</table>

<table>
<tr><td>Need specific preparation or handling before use?</td><td colspan="3">The test article preparation shall be appropriate to the nature and use of the final product and to the purpose of the test.
If this is applicable to your test article, please describe the procedure to be applied.
Examples:
o Flush the catheter with saline. Insert the guidewire into the catheter. Remove the guidewire which is not in contact with the patient.
o Keep the test article at room temperature 15-25°C, 30 minutes before use.</td></tr>
<tr><td>Part (s) of the test article need to be excluded?</td><td colspan="3">Non-patient contacting portions of the medical device should, if possible, be excluded either physically from test article. The photo or scheme requested for the physical description could be used for a precise description of the part that has to be tested.
If this is applicable to your test article, please describe the preparation.</td></tr>
<tr><td>Can be Cut</td><td colspan="3">For several tests, it could be necessary to cut the device for technical reasons.
Examples:
o Selection of representative portions
o Extraction: Materials may be cut into small pieces before the extraction to enhance submersion in the extract media
Please indicate if your test article can be cut.</td></tr>
<tr><td>Is an Absorbent ?</td><td colspan="3">The absorption capacity of the test article is a factor to consider for some studies.
Example:
o For the extraction, it may be necessary to determine the volume of extraction vehicle absorbed by the test article. Then, during extraction, this additional volume will be added to the calculated extraction volume.
Please indicate if your product is an absorbent. If yes, please describe the absorption capacity
Example:
1 mL of water/cm²</td></tr>
<tr><td>Is there any surface coating?</td><td colspan="3">The presence of a coating can be a factor to consider for design changes.
Example:
o In case of a coating delamination, design (of the test or of the test article) has to be changed to avoid medical device failures that could result in adverse biological responses.</td></tr>
<tr><td>Other Special Instructions</td><td colspan="3">Please describe any other information/instruction that could be relevant for the proper conduct of the studies
Be aware that without instructions, the whole test article will be tested. This means that everything that is in the blister after opening packaging will be tested.</td></tr>
<tr><td>Is the test article tested in its final product form and condition (packaging)?</td><td colspan="3">Except if your test article is a device in early stage of development, testing shall be performed on the final medical device, or representative samples from the final device or materials processed in the same manner as the final medical device.
Please indicate if the test article is a final finish product.</td></tr>
<tr><td colspan="4">Test article Extraction</td></tr>
<tr><td>Includes multiple components with different thicknesses (> and < 0.5 mm)?</td><td colspan="3">If the medical device includes multiple tissue contacting components with different thicknesses, the extraction ratio should be justified. One way to do this is to base the ratio on the thinnest material layer of that component.
Please indicate this information, if it is applicable for your test article.</td></tr>
<tr><td rowspan="2">*Extracts to be Prepared by

As per ISO 10993 standard part 12, the sponsor has to provide the exact surface area and thickness of the test article, as this information is needed for determination and application of the extraction ratio. This information is under the Sponsor's responsibility. However, when necessary for the proper conduct of the trial, the Study Director might have to adapt the required conditions, while remaining in accordance to ISO 10993 standard part 12.</td><td rowspan="2">Surface ratio
Select a surface ratio when surface area can be determine.
Then, based on the thickness of the material, please select the appropriate ratio.

Weight ratio
Select a weight ratio when the surface area cannot be provided.
Then, please select the appropriate weight ratio applicable for your device.
Filling Ratio
This ratio is applicable if only the internal parts of the test article are in contact with the patient.
Examples:
o Dialysis filter
o Blood bag</td><td>*Test Article Surface Area

(Total contact surface area)</td><td>How to calculate the surface area of the submitted test article?
The entire surface area that will be in contact with the patient has to be considered. This area includes the combined area of all tissue contacting surfaces of the test article and ignores the contribution of indeterminate surface irregularities.
So, include the external surface in direct contact but also possibly the inner surface with indirect contact.
Non-patient contacting portions of the medical device should be excluded in the surface area calculation.
If only a portion of the submitted article has to be tested, specify the surface area of this part only.</td></tr>
<tr><td>*Test Article Weight</td><td>For tests that require extraction and when the surface area cannot be provided, please specify the weight of one test article. If only a portion of the submitted article has to be tested, specify the weight of this part.</td></tr>
</table>

*Extraction Conditions	**Cytotoxicity:** Extraction at 37 ± 1°C for 24 ± 2 h is acceptable for cytotoxicity testing of limited-contact medical devices. For medical devices which are in limited contact with intact skin or mucosa and which are not implanted, extraction times of less than 24 h, but not less than 4 h, are acceptable for cytotoxicity testing (see ISO 10993-5). For medical devices which are in prolonged (>24 h to 30 d) or long-term (>30 d) contact, extraction duration of 72 h is recommended for cytotoxicity testing because extraction for 24 h may not be sufficient to obtain an extract that represents the chemicals released beyond 24 h of device use	Other Tests: As per ISO 10993 standard part 12, the extraction conditions used should be appropriate to the nature and use of the final product. Extraction should not cause significant degradation of the material, unless the material is intended to dissolve or be resorbed during use. The extraction temperature is dependent upon the physico-chemical characteristics of the medical device material(s). Extraction conditions of time and temperature to simulate exaggerated exposure wherever possible. The period of extraction should be sufficient to maximize the amount of material extracted. In practice, use of these standard conditions of time and temperature for extraction are recommended in lieu of other non-validated or non-standard conditions. Therefore, NAMSA recommend to use the highest temperature that will not degrade the test article or at least a temperature of 50°C in case of doubt regarding the test article degradation.
Other Information		
Countries/Regions that test data will be submitted to	Some countries required specific design of tests. Please indicate the regions for the submission in order to check if the testing is appropriate.	
***Disposal**	Please specify what has to be done with the submitted article once the study is over. - Discard unused article, after the end of the study (the used test articles are systematically discarded after use). - Return unused article (the used test articles are systematically discarded after use). - Return used and unused article. Please refer to the Cost Estimate and Proposal for payment conditions.	
For test article to be returned	If you select the return of the test article, please indicate the carrier information that you want us to used (Name, account…)	
Safety Data	A detailed composition list and current MSDS must accompany any pharmaceutical, cosmetic, biologic or medical device presented as a liquid, powder, paste, gel… If a solid medical device has any safety concern, please provide safety data or instructions to prevent any safety issue. A certificate of testing or reprocessing must be submitted for any human-tissue-derived article or clinically used medical device. Please indicate the precautions for use. Join the instructions for use if necessary.	
Nature of the test article's contact		
Surface device External communicating device Implant device	As per ISO 10993 standard part 1, medical devices shall be categorized according to the nature and duration of body contact. The categorization of medical devices facilitates selection of appropriate data sets. Please select the appropriate category of your device.	
Population Contact duration Clinical exposure per patient	Population, contact duration and clinical exposure of the test article are some factors to consider when designing some studies Example: ○ For toxicity studies when a device is intended for use in only one sex, testing should be done on that sex.	
Dose Based Threshold (DBT) (For chemical analysis only)	As per ISO 10993 standard part 18, please indicate the DBT in µg/day	

How to complete the Sample Submission Form: Microbiology studies

<table>
<tr><th colspan="4">Sponsor Information</th></tr>
<tr><td colspan="2">Ship To</td><td colspan="2">Bill To</td></tr>
<tr><td colspan="2">Clarify the information on the Sponsor in this field.
The protocol will be sent to the contact mentioned in this section. The address mentioned in this section will appear in the final report.</td><td colspan="2">If the bill should not be send to the same address of study monitor, you can provide a different billing address in this field.</td></tr>
<tr><td colspan="2" rowspan="4">Mobile Phone

Please provide the mobile phone number of the Sponsor. This is a mandatory for protocol approval. If you don’t have a professional number, you could indicate in the drop down menu if this number is a personal number and if you accept or not that it will be used as phone contact as well or only for protocol approval.</td><td colspan="2">Details of the order</td></tr>
<tr><td colspan="2">Please indicate your purchase order reference (which will then appear on the invoice).</td></tr>
<tr><td>Test code</td><td>Please indicate the test code of the test ordered.</td></tr>
<tr><td>Quantity</td><td>Please indicate the quantity of test(s) ordered</td></tr>
<tr><td></td><td></td><td>Price per unit</td><td>Please indicate the price per unit of the test ordered</td></tr>
<tr><th colspan="4">Test Article Information</th></tr>
<tr><td>*Name</td><td colspan="3">Please indicate the product name as it appears on the packaging (consider the special characters). To ensure the accuracy of the information indicated in the report, no translation will be performed by NAMSA.</td></tr>
<tr><td>*Reference</td><td colspan="3">Please indicate the product reference as it appears on the packaging (consider the special characters). The reference is the commercial reference of the product, which is indicated on the packaging. This is the code that identifies the product (registration number, benchmark).</td></tr>
<tr><td>*Batch/Lot ID</td><td colspan="3">Please indicate the product batch as it appears on the packaging (consider the special characters). The batch/lot number corresponds to a specific quantity of product manufactured in one process or one series of processes as it may be considered homogeneous.</td></tr>
<tr><td>Type</td><td colspan="3">Please indicate the category of the submitted test article using the drop down menu. If the test article is not classified as Medical device, please contact NAMSA before to send us the test article.</td></tr>
<tr><td>*Sterility</td><td colspan="3">Please indicate if the submitted test article is sterile, not sterile or has to be sterilized at NAMSA. Be aware that it is not whether the product has been sterilized, but if it is being sent in sterile conditions. Some tests, in particular in vivo trials, are required to be performed on sterile test article. NAMSA offers steam sterilization only, with a choice of which cycle to apply: 121°C for 20 min or 134°C for 18 min. Please refer to the proposal for the corresponding fees.
Sterilization process
In the case the test article is sterile, please specify the sterilization process (gamma irradiation, ethylene oxide…).</td></tr>
<tr><td>Expiration date</td><td colspan="3">Please indicate the Expiration date after sterilization</td></tr>
<tr><td>Shipping conditions</td><td colspan="3">To preserve the integrity of the test item, care should be taken to avoid it being exposed to environmental conditions which may be detrimental. Prior to sending the test article there should be a mechanism to establish the conditions the test item is expected to be subject to during transportation. Special care should be taken if the test item is temperature, light and/or humidity sensitive. Appropriate monitoring measures, such as the use of data loggers, max/min thermometers may be required commensurate to risk.
Please indicate the conditions of sending in order to be able to check them at the test article receipt</td></tr>
<tr><td>*Storage Conditions at NAMSA</td><td colspan="3">Please indicate the storage conditions when receiving the submitted article.
In case some special conditions are required, please contact us before sending the test article to verify if NAMSA can guarantee these conditions.</td></tr>
<tr><td>*Quantity Submitted</td><td colspan="3">The quantity of test article received shall be recorded. In addition, this information is important for NAMSA to determine if the quantity received is sufficient to perform the tests. If you need help to calculate the test articles quantities, please feel free to contact your usual contact at NAMSA or a Technical Advisor.
Please specify the quantity of test article sent and the quantity per vial or package.</td></tr>
<tr><td>Special Instructions</td><td colspan="3">Please describe any other information/instruction that could be relevant for the proper conduct of the study. Describe the part that has to be tested in case the whole test article should not be used (e.g. remove plastic protection, cut the printed area…).
Be aware that without special instructions, the whole test article will be tested. This means that everything that is in the blister after opening packaging will be tested. Therefore, we suggest that you send a sketch with the precise description of the part that has to be tested.</td></tr>
<tr><td>Study Context</td><td colspan="3">Please indicate the study context of the test using the drop down menu.</td></tr>
<tr><td>Associated validation</td><td colspan="3">For routine test, please indicate if the test ordered is associated to previous validation(s) performed at NAMSA.</td></tr>
<tr><td>Report language</td><td colspan="3">Please indicate the report language using the drop down menu.</td></tr>
</table>

Other Information	
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