


SUBMISSION FORM - BIOCOMPATIBILITY ANALYSIS

to be sent prior to you shipment to Medistri SA at lab@medistri.swiss for biocompatibility analysis

| CUSTOMER REFERENCES | | | |
|---|---|---|---|
| Company's name | | Your Reference (Delivery note or order) | |
| Contact person (your reference) | | Phone | |
| E-mail address for sending of certificates | | E-mail address for sending of invoices | |
| Address (street, n°) | | PLZ / postcode, City, Country | |
| Information regarding the tests to perform | | | |
| Type | Code | Choice | Sample |
| Cytotoxicity | 1006205 | <input type="checkbox"/> XTT on extract | 6 cm ² or 0.2 g |
| | 1006201 | <input type="checkbox"/> Direct contact | 6 cm ² or 0.2 g |
| | 1006202 | <input type="checkbox"/> Indirect contact agar diffusion test | 6 cm ² or 0.2 g |
| Toxicology | 100606 | <input type="checkbox"/> GC-MS Fingerprint | Approx. 60 cm ² or 5 g |
| | 100607 | <input type="checkbox"/> ICP Fingerprint | Approx. 60 cm ² or 5 g |
| Sensitization | 1006210 | <input type="checkbox"/> Buehler test | 420 cm ² or 7 g |
| | 1006209 | <input type="checkbox"/> Sensitization LLNA: local lymph node assay | 3 x 35 cm ² or 4 g |
| | 1006208 | <input type="checkbox"/> Maximization sensitization test | 3 x 90 cm ² or 6 x 3 g |
| Irritation | 1006211 | <input type="checkbox"/> Intracutaneous irritation | 2 x 30 cm ² or 2 x 1 g |
| | 1006212 | <input type="checkbox"/> Dermal irritation | 120 cm ² or 5 g |
| | 1006226 | <input type="checkbox"/> Oral irritation | 120 cm ² or 5 g |
| | 1006227 | <input type="checkbox"/> Ocular irritation | 120 cm ² or 5 g |
| | 1006228 | <input type="checkbox"/> Vaginal irritation | 200 cm ² or 25 g |
| | 1006229 | <input type="checkbox"/> Intranasal irritation | 2 x 40 cm ² or 2 x 80 cm ² |
| Acute systemic toxicity | 1006214 | <input type="checkbox"/> Acute systemic toxicity | 2 x 72 cm ² ou 2 x 3 g |
| Subacute systemic toxicity | 1006215 | <input type="checkbox"/> Subacute systemic toxicity | 14 x 400 cm ² ou 200 g |
| Genotoxicity | 1006216 | <input type="checkbox"/> Ames test (S. typhimurium reverse mutation test) | 4 x 30 cm ² ou 4 x 1 g |
| | 1006218 | <input type="checkbox"/> Chromosome aberration test (Human Lymphocyte) | 2 x 1'200 cm ² ou 2 x 40 g |
| | 1006217 | <input type="checkbox"/> Chromosome aberration test (V79 hamster cells) | 2 x 1'200 cm ² ou 2 x 40 g |
| | 1006221 | <input type="checkbox"/> Micronucleus test in vitro (Human lymphocyte) | 2 x 1'200 cm ² + 600 cm ² or 60 g |
| | 1006220 | <input type="checkbox"/> Micronucleus test in vitro (V79 Chinese hamster) | 2 x 1'200 cm ² + 600 cm ² or 60 g |
| | 1006219 | <input type="checkbox"/> Mouse Lymphoma test | 2 x 1'200 cm ² + 600 cm ² or 60 g |
| | 1006222 | <input type="checkbox"/> Micronucleus test in vivo (5 males and 5 females) | 1 x 750 cm ² and 1 x 2'250 cm ² or 1 x 25 g and 1x 75 g or 2 x 240 cm ² |
| Hemocompatibility | 1006224 | <input type="checkbox"/> Hemolysis test | 6 x 60 cm ² or 6 x 2 g |
| | 1006225 | <input type="checkbox"/> Dynamic test | 5 samples |
| Implantation | 1006223 | <input type="checkbox"/> Implantation test | |
| Extract for in vivo assays | | <input type="checkbox"/> Intravenous (IV) | <input type="checkbox"/> Intraperitoneal (IP) |
| ORDER DETAILS | | | |
| <input type="checkbox"/> express <small>Orders are processed upon receipt (working days), in priority and according to the minimum deadlines TAT (see price list). An additional 25% will be charged. Certificates are only released on working days.</small> | | <input type="checkbox"/> standard <small>Orders are processed during business days, according to our analysis schedule. Certificates are only released on working days.</small> | |
| Products | <input type="checkbox"/> IT / individual tests <input type="checkbox"/> PT / pooltest <small>(precise the quantity of products)</small> | Samples storage conditions | <input type="checkbox"/> room temperature (15 to 25° C) <input type="checkbox"/> refrigerated (2 to 8° C) <input type="checkbox"/> frozen (min. -20° C) |
| Tests to be performed according to GLP (extra charge) | <input type="checkbox"/> yes <input type="checkbox"/> no | Sterilisation conditions of samples | <input type="checkbox"/> non-sterile <input type="checkbox"/> sterile <input type="checkbox"/> sterilisation to be performed by Medistri SA <small>(<input type="checkbox"/> Eto <input type="checkbox"/> steam <input type="checkbox"/> other :)</small> |
| Samples disposition after analysis | <input type="checkbox"/> discard <input type="checkbox"/> return <input type="checkbox"/> keep the samples during : _____ (nb days) | Have you received an offer from Medistri ? <small>(if yes, please mention the offer reference n° ; if no, according to our price list)</small> | <input type="checkbox"/> yes <input type="checkbox"/> no <div style="text-align: right;">offer ref. n° #</div> |
| Language of the final report | <input type="checkbox"/> english <input type="checkbox"/> french | Certificate of analysis * | <input type="checkbox"/> one report for each sample <input type="checkbox"/> one report per kind of analysis |

| INFORMATIONS REGARDING THE SAMPLES | | | |
|---|---|--|---|
| Product name | | Product reference | |
| Manufacturing batch # | | Product surface area in cm ² | |
| Dimensions / weight | | Quantity of sample submitted | |
| Physical description and composition of the product | | Product special instruction for preparation and/or holding | |
| Product can be cut | <input type="checkbox"/> yes <input type="checkbox"/> no | Type | <input type="checkbox"/> medical device <input type="checkbox"/> pharmaceutical <input type="checkbox"/> cosmetic <input type="checkbox"/> other |
| Clinical use | | Dangerous product (MSDS included) | <input type="checkbox"/> yes <input type="checkbox"/> no |
| Stability period (Shelflife) | | | |

| SAFETY DECLARATION | |
|---|--|
| Is there any chemical, drugs, toxic substances or explosive products inside your products / box ? <input type="checkbox"/> YES <input type="checkbox"/> NO (if yes, please join the Safety Data Sheet , cross the concerned pictogrammes below and precise the UN code : _____) | |
|  | |
| If yes, please wait for Medistri's confirmation before sending your products / box ! Medistri has the right to refuse the delivery and / or the process of your products for security reasons. | |

| Information relative the extraction of the product (if applicable) | | |
|---|--|---|
| Extraction conditions | <input type="checkbox"/> 37°C/24 hours (for cytotoxicity) <input type="checkbox"/> 37°C/72 hours (generally) <input type="checkbox"/> N.A. <input type="checkbox"/> Other | The extraction conditions are based on an exaggeration of product use (ISO-10993-12). For insoluble materials select the highest temperature that would not degrade the material |
| Thickness and extraction ratio according to ISO 10993-12 (Only for solid product) | <input type="checkbox"/> < 0.5 mm ratio of 6 cm ² /mL <input type="checkbox"/> > 0.5 mm ratio of 3 cm ² /mL | Choose one of the following only if the surface area cannot be determined due to the shape of the product : <input type="checkbox"/> 0.2 g/mL for irregularly shaped objects <input type="checkbox"/> 0.2 g/mL for irregularly shaped porous objects |

| Characterization of the product (Pharma/AIMD, combination products only) | | | |
|--|--|---------------------------------|--|
| Stability (before and after opening the packaging) | <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> n.a. <input type="checkbox"/> if no specify : | Active compounds in the product | <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> n.a. <input type="checkbox"/> if no specify : |
| Composition | | Purity | <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> n.a. <input type="checkbox"/> if no specify : |

| FINALISATION AND SIGNATURE | | |
|---|------|-----------|
| By its signature, the customer confirms that all the informations on this submission form are correct and agrees with Medistri's general sales conditions (available on : www.medistri.com/en/general-terms-and-conditions) | Date | Signature |
| | | |

| TO BE FILLED BY MEDISTRI SA ONLY | | | |
|--------------------------------------|---|-----------------------------|--|
| Date de réception | | Nombre de paquets reçus | |
| Heure de réception | | Nombre d'échantillons reçus | Signature opérateur Medistri SA |
| Etat des échantillons à la réception | <input type="checkbox"/> Bon état <input type="checkbox"/> Dommage mineur <input type="checkbox"/> Dommage majeur | Actions et plus-values | <input type="checkbox"/> Plus-value administrative <input type="checkbox"/> Plus-value manipulation <input type="checkbox"/> Envoi des photos des dommages au client (préciser la date : _____) |

| | |
|------------------|--|
| N° de labo-batch | |
|------------------|--|

* In case of results supported by specific regulatory limits (chemical residues, biological response), the test is evaluated as "conform" if the result (including the measure uncertainty) is within the specified limits. The test is evaluated as "non-conform" for any other result (potentially non-conform or strictly non-conform).