

Medistri.SA

a must in medical chain














In addition to the tests described in the list below, Medistri SA offers complete validations (examples: verification of cleaning processes with markers, search for residues and impurities, sterilization, stability studies, etc.), depending on the (EP, USP, ICH, ISO, ASTM, AAMI, ISTA ...) and target markets.

In terms of consulting, Medistri SA proposes the documentary constitution of literature search report, toxicological assessment, biological safety assessment, among others ...

| Code | Description | Technique / Method | Sample Size | TAT | Matrix |
|---------------------|---|------------------------|----------------|-------------|--------|
| Microbiology | | | | | |
| 100303 | Bioburden Total Aerobic bacteria microbial count (TAMC), yeast and moulds (TYMC) | ISO 11737-1 EP, USP | 1pc, 1ml or 1g | 5 - 10 days | |
| 100304 | Bioburden Anaerobic Bacteria | ISO 11737-1 EP, USP | 1pc, 1ml or 1g | 5 - 10 days | |
| 100313 | Bioburden, Total Aerobic bacteria (TAMC) | ISO 11737-1 EP, USP | 1pc, 1ml or 1g | 5 - 10 days | |
| 100301 | Bioburden product testing : Validation | ISO 11737-1 EP, USP | 5 pcs | 5 - 15 days | |
| 100312 | Enumeration on biological indicator | N/A | to be defined | 5 - 10 days | |
| 100308 | Bacterial endospore staining | ISO 11737-1 MSDA | 1 pure culture | 5 - 10 days | |
| 100309 | Gram coloration | ISO11737-1 MSDA | 1 pure culture | 5 - 10 days | |
| 100320 | PCR identification of germs : bacterial germ (16S) or fongies (ITS), Purification included 95-98% of germ determination | ISO 11737-1 | 1 pure culture | 1 - 3 weeks | |
| 100321 | Biochemical identification of germs (Vitek) with microbiological evaluation. 80-85% of germ determination. | ISO 11737-1 EP, USP | 1 pure culture | 5 - 10 days | |
| 100326 | Research of Campylobacter qualitative method | MSDA | to be defined | 5 - 10 days | |
| 100328 | Research of Germs For one germ in the following list : - Enterobacteria - Escherichia Coli - Salmonella - Pseudomonas aeruginosa - Staphylococcus aureus - Clostridium - Yeast, moulds | MSDA | to be defined | 5 - 10 days | |




































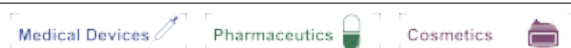
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|------------------|--|--|-------------------------------------|----------------|---|
| 100310 | Research of specified germ, individual : - Enterobacteria - Escherichia Coli - Pseudomonas aeruginosa - Staphylococcus aureus - Salmonella - Clostridium - Yeast and moulds | ISO 11737-1 EP, USP | to be defined | 5 - 10 days |  |
| 100318 | Research of germs : Package 7 species Enterobacteria, Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella, Clostridium, yeast and moulds | ISO 11737-1 EP, USP | to be defined | 5 - 10 days |  |
| 100319 | Research of germs : Package 5 species Enterobacteria, Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, yeast and moulds | ISO 11737-1 EP, USP | to be defined | 5 - 10 days |  |
| 100327 | Research of Legionella , qualitative method | MSDA | 1000ml | 30 days |  |
| 100505 | Endotoxin Test Quantitative colorimetric kinetic method Pyrogen | EP, USP, AAMI | 1 product | 2 - 5 days |  |
| 100501 | LAL - Endotoxin testing validation Quantitative colorimetric kinetic method, pyrogen. | EP, USP, AAMI | 3 lots | 3 - 10 days |  |
| 100331 | Antimicrobial Effectiveness Testing | PE, USP | to be defined according to category | approx 40 days |  |
| Sterility | | | | | |
| 100103 | Product sterility test : aerobic & anaerobic, on 2 culture media Cleanroom environment | EP, USP, ISO 11737-2 | 2 products | 14 - 20 days |  |
| 100108 | Product sterility test : Validation Bacteriostasis, fungistasis | EP, USP, ISO 11737-2 | 6 products | 5 - 10 days |  |
| 100901 | Biological Indicators population Control , including report | ISO 11138-1 ISO 11138-2 | 4 BI's | 10 days |  |
| 100201 | Biological Indicator sterility testing on strips, thread or discs | ISO 11138 ISO 14161 ISO 11135-1 EP, USP | 1 product | 7 - 10 days |  |
| 100202 | Biological Indicator sterility testing (suspension) | ISO 11138 ISO 1416 ISO 11135-1 EP, USP | 1 product | 7 - 10 days |  |
| 100330 | Evaluation of bioburden resistance Evaluation of the natural bioburden located in a worst-case location compared to the internal biological indicator (IPCD). Flat rate for 10 pieces inoculation including : - Formulation of a microbial population representative of the natural product bioburden. - Generation of customized BI's with inoculation in a worst case location with a defined population of cfu. | ISO 11737-1 | 10 products | to be defined |  |



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| 1006007 | <p>Steam Validation Review : annual quick review Generally done 1 year after basis validation, including :</p> <ul style="list-style-type: none"> - Customer confirmation on no changes on products, manufacturing process, bioburden - Customer confirmation about routine service was acceptable - Medistri yearly review on deviations, Medistri equipment review record - Medistri confirmation on process calibration and maintenance - Final assessment report | | | |  |
| Biocompatibility | | | | | |
| 100607 | Extractable Metallic Ions (ICP-Fingerprint) | ISO 10993-12, ASTM G 136-03 | 60 cm ² or 5 g | 2-4 weeks |    |
| 100606 | GC/MS Fingerprint with 2 solvents, Identification of extracted substances Brief toxicological evaluation (one substance) | ISO10993-12 | 2x5g or 2x60 cm ² | 2 - 4 weeks |    |
| 1006201 | Cytotoxicity by direct contact Qualitative | ISO10993-5 | 3 cm ² | 14 days |    |
| 1006202 | Cytotoxicity by indirect contact : agar diffusion Qualitative | ISO10993-5 | 3 cm ² | 14 days |    |
| 1006205 | XTT cytotoxicity test on extract Qualitative and quantitative analysis | ISO10993-5 ISO10993 | 6cm ² or 0.2g | 14 days |    |
| 1006217 | Chromosome Aberration Test V79 Chinese hamster cells | ISO10993-3 OECD473 | 2x1200 cm ² or 2x40g | 21 weeks |   |
| 1006218 | Chromosome Aberration Test Human lymphocyte | ISO10993-3 OECD473 | 2x1200 cm ² or 2x40g | 21 weeks |   |
| 1006221 | Micronucleus test in vitro (mammalian cells) Human lymphocyte cells | ISO10993-3 ISO10993-13 OECD487 | 2x1200cm ² and 600cm ² or 60g | 14 weeks |   |
| 1006220 | Micronucleus test in vitro (mammalian cells) V79 Chinese hamster cells | ISO10993-3 ISO10993-13 OECD487 | 2x1200cm ² and 600cm ² or 60g | 14 weeks |   |
| 1006222 | Micronucleus test in vivo Test on 10 animals (5 males, 5 females) Polar extraction | ISO10993-3 OECD474 | 2x240cm ² | 17 weeks |   |
| 1006216 | Genotoxicity: Salmonella typhimurium Reverse Mutation Test (ames-test) 5 strains of Salmonella typhimurium Polar and non-polar extractions | ISO10993-3 | 4x30 cm ² ou 4x1g | 4 weeks |   |
| 1006219 | Mouse Lymphoma Test | ISO10993-3 OECD476 | 1x750 cm ² and 1x2250 cm ² or 1x25g and 1x75g | 17 weeks |   |
| 1006225 | Dynamic Hemocompatibility with Human Blood Dynamic blood contact | ISO10993-4 | 5 products | 10 weeks |  |
| 1006224 | Hemolysis test Direct contact and extraction on human blood | ISO10993-4 ASTM F756 | 6x60cm ² or 6x2g | 4 weeks |  |
| 1006223 | <p>Implantation test The exposure time for implantation studies depends on the clinical use of the device. For implantable device, an evaluation of systemic toxicity after subcutaneous implantation is recommended as a local tolerance after implantation. Relevant and consistent information about the device must be provided by the sponsor. Quoted on demand</p> | | | |  |



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| 1006212 | Dermal Irritation (alternative test for use by contact with skin) Extraction and single application on rabbits, 4 hours contact time minimum with intact skin, 72h observation period. | ISO10993-10 | 120cm ² or 5g for preparation | 6 weeks | |
| 1006211 | Irritation : intracutaneous reactivity on rabbits 2 extracts | ISO10993-10 | 2x30cm ² or 2x5g | 3 weeks | |
| 1006227 | Irritation : ocular Ocular irritation, 2 extracts per animal (polar and apolar) if direct application is not possible. 3 Rabbits. Single conjunctival (or repeated on request), 72h observation period (up to 14 days). | ISO 10993-10 | 120cm ² or 5 g | 11 weeks | |
| 1006226 | Irritation : acute oral | ISO 10993-10 | 120cm ² or 5 g | 9 weeks | |
| 1006228 | Irritation : Vaginal 2 eluates test on rabbits Intravaginal, daily for 5 days Histopathological observation (macroscopic), assessment of the application sites assessment of the vagina and surrounding tissues | ISO 10993-10 | 200 cm ² or 25g | approx 12 weeks | |
| 1006229 | Irritation : In Vitro Test | OECD 439 ISO 10993-10 | 3 g, 3 ml or 18 cm ² | 6 - 7 weeks | |
| 1006209 | Sensibilization LLNA: local lymph node assay Mice/SpF-CBA/Ca, isolation of lymphatic cells, extraction media: acetone/oliveoil mixture Quantitative method, determination in-vitro of 3HT dTR Note : for complexe medical devices FDA decides the acceptance of the LLNA | ISO 10993-10 OECD429, ISO 10993-12 | 3x35cm ² or 3x4g | 8 weeks | |
| 1006210 | Sensibilization by Buehler Test Test without extract, appropriate for bandages, compresses... | ISO 10993-10 | 420cm ² or 70m | 10 weeks | |
| 1006208 | Sensibilization according to Magnusson and Kligman on guinea pigs Qualitative analysis | ISO 10993-10 ISO 10993-12 | 3x90 cm ² or 6x3 g | 8 weeks | |
| 1006214 | Acute systemic toxicity on mouses 4 extracts, 72h observation period. | ISO 10993-11 ASTM F750 USP | x5g, 2x60 cm ² , (thickness >0.05mm) or 2x120cm ² (thickness < 0.5mm) | 4 weeks | |
| 1006215 | Subacute subchronic systemic toxicity ISO10993-11 The duration of studies depends on the clinical use of the device. A minimum of 14 consecutive applications for 14 days is required. Implantable device: a long-time evaluation of toxicity combined with test of implantation and toxicity is recommended. Relevant and consistent information about the device must be provided by the sponsor. | | | | |
| 1006230 | In Vitro eye irritation test (epiocular) | OECD 492 | 1g, 1ml or 6cm ² | 6 - 7 weeks | |
| 1006231 | In Vitro skin corrosion | OECD 431 | 3g, 3ml or 18cm ² | 6 - 7 weeks | |
| 1006232 | Direct Peptide Reactivity Assay(DPRA) Sensitization potential | OECD 442C | 5g, 5ml or 30cm ² | 6 - 7 weeks | |
| 1006233 | Skin Sensitization - KeratinoSens™ | OECD 442D | 30g, 30ml or 180cm ² | 6 - 7 weeks | |
| Environmental Monitoring, Air & Surfaces | | | | | |
| 100413 | Personnal protection set for analysis (sterile head-cover, gloves, overshoes, disinfectant) | | | | |



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| 100408 | Transport costs, per kilometer | | | | |
| 100401 | Plate analysis (Aerobic bacteria and moulds) | ISO 14001 14644-1 14698-1 14698-2 EU GMP | 1 plate | 5 - 10 days | |
| 100402 | Plate analysis (Anaerobic bacteria) | ISO 14001 14644-1 14698-1 14698-2 EU, GMP | 1 plate | 5 - 10 days | |
| 100403 | Air monitoring plate (TSA) | N/A | 1 plate | N/A | |
| 100404 | Surface or handprints monitoring plate (CT) | N/A | 1 plate | N/A | |
| Water Analysis / for injection / purified | | | | | |
| 100602 | Aerobic bacterial count on TSA | EP, USP | 100ml | 5 - 10 days | |
| 1002114 | Conductivity | EP, USP | 100ml | 5 days | |
| 100603 | Hardness Colorimetric, limit assay <1.5; 1.5 - 2.5; >2.5mmol/l CaCO3 | EP, USP | 100 ml | 5 days | |
| 100601 | Endotoxin Endotoxin test on water, quantitative colorimetric kinetic method | EP, USP, AAMI st 72 | 100ml | 5 days | |
| 1002104 | Mesophilic aerobic germs R2A Oligotroph aerobic germs R2 | EP, USP, ISO 11737-1 | 100ml | 5 days | |
| 1002105 | Legionella sp Research of Legionella sp | ISO 11731 ISO 15883-1 | 100ml | 10 - 15 days | |
| 1002118 | Mycobacteria Research of Mycobacterium or Mycoplasma, qualitative | ISO 15883-1 | 100ml | 10 - 60 days | |
| 1002115 | pH | EP, USP | 100ml | 5 days | |
| 1001105 | Total Organic Carbons (TOC) on water | EN 1484, ASTM G 136-03 | 100ml | 5 - 10 days | |
| 100604 | Sterility testing Sterility test pharma water | EP, USP | to be defined | 15 - 20 days | |
| 100605 | Titration Acid base complexometry, redox | EP, USP | to be defined | 5 - 10 days | |
| 1002119 | Heavy Metals, limit essay (LOQ : 0.1 mg/l) | EP, USP | 100ml | 10 days | |
| 1002120 | Nitrate, limit essay (LOQ : 0.1 mg/l) | EP, USP | 100ml | 10 days | |
| Packaging tests, stability study | | | | | |
| <i>On Porous, non porous, header bag, peel pouch, Blister. + real time aging test (shelf life)</i> | | | | | |



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|--------|---|--|-----------------------------|---------------|--------|
| N/A | Special Project, Device Life Cycle (aging), multiple cleaning and sterilisation Test cleaning (manual, semi-automatic and automatic) and sterility testing (steam, EtO) cycle for reusable devices, according to user manual (IFU) ISO 11134, ISO 17665, ISO 17664 | | | | |
| 100803 | Accelerated Aging Tests on packaging with controlled temperature Price per day according to load volume (up to 400L, min CHF 15.75) and temperature (-20°C to 60°C). | ASTM F1980 ISO 11607-1 | to be defined | to be defined | |
| 100850 | Bubble emission test on packaging (for porous or non-porous packages), price for each package | ISO 11607 ASTM F2096-11 | final packaging non damaged | 5 - 10 days | |
| 100810 | Burst test | ISO 11607 ASTM F1140 / F1140-13 | final packaging non damaged | 5 - 10 days | |
| 100820 | Creep test | ISO 11607 ASTM F1140 / F1140-13 | final packaging non damaged | 5 - 10 days | |
| 100840 | Dye migration test | ISO 11607, ASTM F1929-15 or ASTM F3039-15 | final packaging non damaged | 5 - 10 days | |
| 100808 | Visual inspection of packaging | ISO 11607 ASTM F1886 | final packaging non damaged | 5 - 10 days | |
| 100804 | Temperature and humidity profiling per day (°C/%RH) during the routine test | N/A | N/A | N/A | |
| 100830 | Seal peel test | ISO 11607 ASTM F88 / F88M-15 | final packaging non damaged | 5 - 10 days | |
| 100870 | Transport simulation test (conditioning, vibration, drop, impact. tests to be defined) | ASTM D4169-16, ASTM D7386-12 ISTA serie | to be defined | 1 - 2 months | |
| 100809 | Peeling test | NF EN 868-5 Annex C | final packaging non damaged | 5 - 10 days | |
| 100801 | Determination of pH of aqueous extracts | ISO 11607, ISO 6588-1 | min 2x2cm ² | 5 - 10 days | |
| 100802 | Determination of pH - extra samples Price per extra sample performed at the same time | N/A | N/A | N/A | |
| 100880 | Stability study on packaging In controlled temperature and humidity environment, 25°C / 60% RH, 30°C / 65% RH, 40°C / 75% RH. Price according to load volume and conditions | ASTM F1980 ISO 11607-1 ICH Q1A R2 | to be defined | N/A | |
| 100881 | Aging test, ambient temperature Non-controlled environment. Price per day per pallet | ASTM F1980 ISO 11607-1 ICH-Q1 E | to be defined | N/A | |

Chemical Tests























































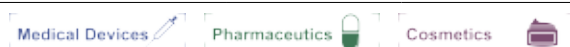
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|---|--|---|---|--------------|--------|
| 100703 | Glutaraldehyde Titration Potentiometric titration sodium sulphite / HCl | N/A | 20ml | 5 - 10 days | |
| 100701 | Residue test EtO/ ECh Ethylene Oxide, Ethylene Chlorohydrin (cold storage and manipulation of samples are not included), 3 extractions included | ISO 10993-7 & ISO 10993-12 EMEA | 1 product | 5 - 10 days | |
| 100704 | Residue test - Ethylene Glycol | ISO 10993-7 ISO 10993-2 | to be defined | 5 - 10 days | |
| 100702 | Residue test EtO/ECh or Ethylene - Additionnal Extraction | N/A | N/A | N/A | |
| 100705 | Products Containing Cannabidiol Nicotine dosage by Gas Chromatography | Swissmedic directive | 0.5 - 1.0g | 10 - 15 days | |
| 100706 | Products Containing Cannabidiol THC, CBD dosage by Gas Chromatography | Swissmedic directive | 0.5 - 1.0g | 10 - 15 days | |
| 100707 | Determination of Alcohol Residuals By Gas Chromatography | USP 621 | 2 ml - 2 g | 5 - 10 days | |
| 100609 | Cosmetic - pH Determination | EP, USP | min 1 g or 1ml | 5 - 10 days | |
| 100608 | Cosmetic - Appearance Visual or sensorial subjective analysis. Reference comparison based on 3 criteria ; odor, consistency, color. | N/A | 1 product + 1 reference | 5 - 10 days | |
| Cleaning / Cleanliness - Validation of reusable and new manufactured devices (disinfection, sterilisation) | | | | | |
| 1001106 | Analysis of residual Total Organic Carbon (TOC) medical devices | NF EN 1484, ISO 10993-12, ASTM G 136-03 | 1 product, min 20cm ² | 10 - 15 days | |
| 1001108 | Validation TOC TOC Residual from medical devices, Method validation as per ICH Q2 R1. Chemical marker acc to FDA. Extraction vehicle : water for TOC. | ISO 10993-12 ASTM G 136-03 NF EN148 | 3 - 5 products, min 20cm ² / product | N/A | |
| 1001111 | Total Hydrocarbons (THC) | ISO 10993-12 ISO 9377-2 ASTM G136-03 | 1 product, min 12cm ² | 5 - 10 days | |
| 1001113 | THC Validation Total Hydrocarbon Residues on medical devices. Method validation according to ICH Q2 R1, chemical markers according to FDA, extraction vehicle : N-Hexane (extraction C10 - C40). | ISO 10993-12 ASTM G 136-03 EN1484 | 3 - 5 products, min 12cm ² / product | 10 - 15 days | |
| 1001107 | Analysis of residual proteins of medical devices | EN ISO 15883 ISO 15883 AAMI TIR30 | 1 product | 5 - 10 days | |
| 1001109 | Residual Proteins, Validation Method validation as per ICH Q2 R1; compliant with USP and EP. Chemical marker | FDA, ISO 15883, AAMI TIR 30 | 3 - 5 products | 5 - 10 days | |
| 1001112 | Washing disinfectant, cycle reserved automatic | ISO 15883 | to be defined | 5 - 10 days | |
| 1001104 | Extractable Metallic Ions ICP - Fingerprint with toxicological evaluation | ISO 10993-2 ASTM G 136-03 | 5 metallic ions | 2 weeks | |
| 100421 | Particle in liquid analyse on extract - laser diffraction, Resolution: 1µm to 120µm | EP, USP, ISO 9276-1, AAMI TIR 42 | 1 products min 20 cm ² | 5 - 10 days | |



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|---|---|--|---------------|--------------|---|
| 100423 | Particle counting Validation , 2 particle size, determination of a correction factor for 1 product. | EP, USP, ICH Q2 R1 ISO 9276-1 AAMI TIR 42 | 3 products | 10 - 15 days |    |
| 300115 | Cleaning by piece | N/A | to be defined | 5 - 10 days |  |
| 1001101 | Detection of Mycoplasma by PCR Washer-disinfectant qualification | ISO 15883 | 10 - 100ml | 5 - 10 days |   |
| 1001102 | Detection of Mycoplasma by PCR - Extra Sample | N/A | N/A | N/A |   |
| 1001103 | Cleaning - XPS (X-ray) in situ analysis of the cleanliness of a standard surface | ASTM F2847, ISO 10993-18 | 1 product | 10 - 15 days |  |
| Miscellaneous | | | | | |
| 100800 | Cost of starting (chemical, biological or physical Specific preparation) | | | |    |
| 1006207 | Fee to run one analysis according to GLP: +20% with a minimum of 250 CHF | | | |    |
| 1005301 | Laboratory preparation for tests and on-site work | | | |    |
| 1005402 | Consulting Laboratory : price per hour of work for the following consulting - development of procedure | | | |  |
| 1001504 | Administrative Cost including sample treatment after test (elimination) | | | |    |
| 1005304 | Protocol for laboratory test validation | | | |    |
| 1005302 | Summary Test Report | | | |    |
| 1005305 | Validation Report | | | |    |
| 100408 | Transport costs, per kilometer | | | |    |
| 300119 | Special handling for residual test | | | |    |
| 200507 | Sample for lab testing extracted from pattets or boxes | | | |    |
| 300127 | Storage of sample for laboratory testing (2-8°C) | | | |    |
| 300128 | Storage of sample for laboratory testing (frozen min -20°C) | | | |    |
| In case of taking care by your staff, Medistri can provide to you specific packaging (sterile, pyrogenic, TOC free,...) | | | | | |
| 1001501 | Container for sample - sterile 500ml bottle | | | |    |
| 1005303 | Cold pack | | | |    |



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