







































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 recovery / inhibiting substancer | ISO 11737-1 EP, USP | to be defined | 5 - 15 days | |
| 100302 | Bioburden - Validation (inhibition/culture alone) | ISO 11737-1 EP, USP | to be defined | 5 - 15 days | |
| 100505 | Endotoxin Test Quantitative colorimetric kinetik method | EP, USP, AAMI | 1 product | 2 - 5 days | |
| 100501 | Endotoxin testing validation Quantitative colorimetric kinetik method | EP, USP, AAMI | 3 lots | 3 - 10 days | |
| 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 | |
| 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 | |
| 100326 | Research of Campylobacter qualitative method | MSDA | to be defined | 5 - 10 days | |

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| Code | Description | Technique / Method | Sample Size | TAT | Matrix |
|---|---|--|---|--------------------|---|
| 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 |    |
| 100312 | Enumeration on biological indicator | N/A | to be defined | 5 - 10 days |   |
| 100322 | Mass spectrometric identification bacteria, fungi | ISO 11737-1 | 1 pure culture | 5 - 10 days |   |
| 100331 | Antimicrobial Effectiveness Testing | PE, USP | to be defined according to category | Approx 40 weeks |   |
| Sterility | | | | | |
| 100103 | Product sterility test : aerobic & anaerobic, on 2 culture media Cleanroom environment | ISO 11737-2 | 2 products | 14 - 20 days |    |
| 100108 | Product sterility test : Validation Bacteriostasis, fungistasis | ISO 11737-2 | 6 products | 5 - 10 days |    |
| 100901 | Biological Indicators population Control, includ- ing 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 |   |
| Packaging tests, stability study | | | | | |
| On Porous, non porous, header bag, peel pouch, Blister. + real time aging test (shelf life) | | | | | |
| 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 con- trolled temperature | ASTM F1980 ISO 11607-1 | to be defined | to be defined |    |
| 100870 | Transport simulation test (conditioning, vibra- tion, drop, impact. tests to be defined) | ASTMD4169- 16, ASTM D7386-12 ISTA serie | to be defined | 1 - 2 months |    |















































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| Code | Description | Technique / Method | Sample Size | TAT | Matrix |
|---|--|---|---|--------------|--------|
| 100850 | Bubble emission test on packaging (for porous or non-porous packages). | 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 | N/A | N/A | N/A | |
| 100830 | Seal peel test | ISO 11607 ASTM F88 / F88M-15 | final packaging non damaged | 5 - 10 days | |
| 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 | |
| 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 | |
| Cleaning / Cleanliness - Validation of reusable and new manufactured devices (disinfection, sterilisation) manual / automatic Complete cleaning/disinfection validation studies on request (different markers), cleaning agent, disinfecting agent End of life study on request (multiple reprocessing cleaning and sterilization) Simulated aging on request | | | | | |
| 1001106 | Analysis of residual Total Organic Carbon (TOC) medical devices | NF EN 1484, ISO 10993-12 | 1 product, min 20cm ² | 10 - 15 days | |
| 1001108 | Validation, TOC, recovery TOC Residual from medical devices, Method vali- dation as per ICH Q2 R1. | ISO 10993-12 NF EN148 | 3 - 5 products, min 45cm ² / product | 10 - 15 days | |
| 1001111 | Total Hydrocarbons (THC) | ISO 10993-12 ISO 9377-2 | 1 product, min 12cm ² | 5 - 10 days | |
| 1001113 | THC residual from medical devices Total Hydrocarbon Residues on medical devices. Method validation s per ICH Q2 R1/ correction factor | ISO 10993-12 ISO 9377-2 | 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 | Validation recovery, residual Proteins, Method validation as per ICH Q2 R1; compliant with USP and EP. Chemical marker / correction factor | FDA, ISO 15883, AAMI TIR 30 | 3 - 5 products | 5 - 10 days | |






























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|---|---|---|-----------------------------------|---------------|---|
| 1001112 | Washing desinfector, cycle reserved automatic | ISO 15883 | to be defined | 1 - 5 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 |   |
| 100423 | Particle counting, Validation recovery 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-disinfector 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 | ISO 10993-18 | 1 product | 10 - 15 days |  |
| 1001114 | Analyse par XRF: identification d'alliage, dépistage de traces de métaux lourds | ISO 10993-18 | 1 product | 10 - 15 days |   |
| 1001115 | Analyse de polymères par spectroscopie infra-rouge (FT-IR) incl. comparaison du résultat avec base de données pour identifier le type de matériel | ISO 10993-18 | 1 product | 10 - 15 days |   |
| Biological evaluation - Biocompatibility and chemical characterization | | | | | |
| 1006205 | XTT cytotoxicity test on extract Qualitative and quantitative analysis | ISO10993-5 ISO10993 | 3 - 6cm ² or 0.2g | 5 - 10 days |    |
| 1006201 | Cytotoxicity by direct contact Qualitative | ISO10993-5 | 3 - 6cm ² or 0.2g | 5 - 10 days |    |
| 1006202 | Cytotoxicity by indirect contact : agar diffusion Qualitative | ISO10993-5 | 3 cm ² | 14 days |    |
| 100606 | GC/MS Fingerprint with 2 solvents, Identification of extracted substances | ISO10993-12, 18 | 2X(3-30cm ²) | 2 - 4 weeks |    |
| 1006061 | GC/MS fingerprint with 1 solvent, 1 extraction, Identification of extracted substances | ISO10993-12, 18 | 60 cm ² or 5 g | 5 - 10 weeks |    |
| 100607 | Extractable Metallic Ions (ICP-Fingerprint) | ISO 10993-12, ASTM G 136-03 | 60 cm ² or 5 g | 2-4 weeks |    |
| 1006071 | Extractable Metallic Ions (ICP-Fingerprint), 1 solvent, 1 extraction | ISO 10993-12, ASTM G 136-03 | 30 cm ² | 10 - 15 weeks |    |















































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| Code | Description | Technique / Method | Sample Size | TAT | Matrix |
|---------|--|---------------------------------------|--|-----------------|---|
| 1006234 | LC Fingerprint LC Fingerprint with 2 solvents (NVOC) | ISO 10993-12, 10993-18 ASTMG136-03 | 60 cm ² or 5 g | 2-4 weeks |    |
| 1006213 | Material mediated pyrogenicity | ISO 10993-11 | 240 cm ² | 5 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 | 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 | | | |  |
| 1006212 | Dermal Irritation (alternative test for use by contact with skin) 2 extracts | ISO10993-10 | 120cm ² or 5g for preparation | 6 weeks |  |
| 1006211 | Irritation : intracutaneous reactivity on rabbits 2 extracts | ISO10993-10 | 2x30cm ² or 2x5g | Approx 4 weeks |  |
| 1006227 | Irritation : ocular 2 extracts | ISO 10993-10 | 120cm ² or 5 g | Approx 4 weeks |  |
| 1006226 | Irritation : acute oral | ISO 10993-10 | 2x30cm ² or 5 g | 6 - 8 weeks |   |
| 1006228 | Irritation : Vaginal 2 extracts | 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 2 extracts | 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 70ml | 10 weeks |  |
| 1006208 | Sensibilization according to Magnusson and Kligman on guinea pigs (GPMT) 2 extracts | ISO 10993-10, G ISO 10993-12 | 6x15 cm ² or 6x5 g | Approx 7 weeks |   |
| 1006214 | Acute systemic toxicity on mouses 4 extracts, 72h observation period. | ISO 10993-11 ASTM F750 USP | Approx 5g | 4 weeks |    |




































































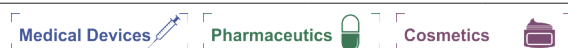
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| Code | Description | Technique / Method | Sample Size | TAT | Matrix |
|--|---|--------------------------------------|---|----------------|---|
| 1006215 | Subacute subchronic systemic toxicity ISO10993-11 The duration of studies depends on the clinical 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 |    |
| 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) | 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 |   |
| USP class VI Plastic material | | | | | |
| 10062112 | USP VI - Intradermal tolerance | USP 88 | 4x80 cm ² | Approx 8 weeks |    |
| 10062141 | USP VI - Acute systemic toxicity | USP 88 | 4x90 cm ² | Approx 5 weeks |    |
| 10062231 | USP VI - Intramuscular implantation Intramuscular implantation | USP 88 | 8x(10mmx1mm) | Approx 5 weeks |    |
| Environmental Monitoring, Air & Surfaces | | | | | |
| 100413 | Personal protection set for analysis (sterile head-cover, gloves, overshoes, disinfectant) | | | |    |
| 100408 | Transport costs, per kilometer | | | |    |









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| Code | Description | Technique / Method | Sample Size | TAT | Matrix |
|---|---|---|---------------|--------------|---|
| 100401 | Plate analysis (Aerobic bacteria and moulds) | ISO 14001 14644-1 14698-1 14698-2 EU GMP | 1 plate | 5 - 10 days |    |
| 100405 | Particle counting - non viable | ISO 14001 14644-1 14698-1 14698-2 EU GMP | 1 sample | 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 |    |
| 100407 | Air monitoring plate (SDA) | N/A | 1 plate | N/A |    |
| 100404 | Surface or handprints monitoring plate (CT) | N/A | 1 plate | N/A |    |
| Water quality tests (microbiology, chemistry) | | | | | |
| 100602 | Aerobic bacterial count on TSA | EP, USP | 100ml | 5 - 10 days |    |
| 1002104 | Oligotrophic germs on R2A | ISO 11737-1 EP, USP | 100ml | 5 days |    |
| 100601 | Endotoxin, LAL test | EP, USP, AAMI st 72 | 100ml | 5 days |    |
| 1002105 | Legionella sp Research of Legionella sp | ISO 11731 ISO 15883-1 | 100ml | 10 - 15 days |    |
| 1002118 | 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 | 14 - 18 days |    |
| 1002114 | Conductivity | EP, USP | 100ml | 5 days |    |
| 100603 | Hardness (total) | EP, USP | 100ml | 5 days |    |
| 100605 | Titration Acid base complexometry, redox | EP, USP | to be defined | 5 - 10 days |    |
| 1002116 | Elemental impurities (ICP) | EP, USP | 50ml | 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 |    |
| Chemical Tests | | | | | |
| 100703 | Glutaraldehyde Titration Potentiometric titration sodium sulphite / HCl | N/A | 20ml | 5 - 10 days |  |
| 100701 | Residue test EtO/ ECH Ethylene Oxide, Ethylene Chlorohydrin, 3 ex- tractions included | ISO 10993-7 & ISO 10993-12 EMA | 1 product | 5 - 10 days |   |
| 100704 | Residue test - EG | ISO 10993-7 ISO 10993-2 | to be defined | 5 - 10 days |   |














































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| Code | Description | Technique / Method | Sample Size | TAT | Matrix |
|--------|--|----------------------|-------------------------|----------------|---|
| 100702 | Residue test EtO/ECh or EG - Additional Extraction | N/A | N/A | N/A |  |
| 100705 | Products Containing Cannabidiol Nicotine dosage by Gas Chromatography | Swissmedic directive | 0.5 - 1.0g | Approx 2 weeks |  |
| 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 |  |



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| Code | Description | Technique / Method | Sample Size | TAT | Matrix |
|---|--|--------------------|-------------|-----|---|
| 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 | | | |    |
| 1005306 | OOS investigation | | | |    |
| 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 | Cold pack | | | |    |



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