

































# 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.

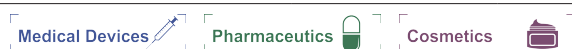
In terms of consulting, Medistri SA proposes the documentary constitution of literature search report, toxicological assessment, biological safety assessment, among others ...

Code	Description	Technique / Method	Sample Size	TAT	Matrix
<b>Microbiology</b>					
100303	<b>Bioburden</b> Total Aerobic bacteria microbial count (TAMC), yeast and moulds (TYMC)	ISO 11737-1 EP, USP	1pc, 1ml or 1g	5 - 10 days	  
100304	<b>Bioburden</b> Anaerobic Bacteria	ISO 11737-1 EP, USP	1pc, 1ml or 1g	5 - 10 days	  
100313	<b>Bioburden,</b> Total Aerobic bacteria (TAMC)	ISO 11737-1 EP, USP	1pc, 1ml or 1g	5 - 10 days	  
100301	<b>Bioburden product testing : Validation</b>	ISO 11737-1 EP, USP	5 pcs	5 - 15 days	  
100312	<b>Enumeration on biological indicator</b>	N/A	to be defined	5 - 10 days	 
100308	<b>Bacterial endospore staining</b>	ISO 11737-1 MSDA	1 pure culture	5 - 10 days	  
100309	<b>Gram coloration</b>	ISO11737-1 MSDA	1 pure culture	5 - 10 days	  
100320	<b>PCR identification of germs</b> : bacterial germ (16S) or fongies (ITS), Purification included 95-98% of germ determination	ISO 11737-1	1 pure culture	1 - 3 weeks	  
100321	<b>Biochemical identification of germs (Vitek)</b> with microbiological evaluation. 80-85% of germ determination.	ISO 11737-1 EP, USP	1 pure culture	5 - 10 days	  
100326	<b>Research of Campylobacter</b> qualitative method	MSDA	to be defined	5 - 10 days	  
100328	<b>Research of Germs</b> 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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Code	Description	Technique / Method	Sample Size	TAT	Matrix
100310	<b>Research of specified germ, individual :</b> - Enterobacteria - Escherichia Coli - Pseudomonas aeruginosa - Staphylococcus aureus - Salmonella - Clostridium - Yeast and moulds	ISO 11737-1 EP, USP	to be defined	5 - 10 days	  
100318	<b>Research of germs : Package 7 species</b> Enterobacteria, Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella, Clostridium, yeast and moulds	ISO 11737-1 EP, USP	to be defined	5 - 10 days	  
100319	<b>Research of germs : Package 5 species</b> Enterobacteria, Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, yeast and moulds	ISO 11737-1 EP, USP	to be defined	5 - 10 days	  
100327	<b>Research of Legionella</b> , qualitative method	MSDA	1000ml	30 days	  
100505	<b>Endotoxin Test</b> Quantitative colorimetric kinetic method Pyrogen	EP, USP, AAMI	1 product	2 - 5 days	 
100501	<b>LAL - Endotoxin testing validation</b> Quantitative colorimetric kinetic method, pyrogen.	EP, USP, AAMI	3 lots	3 - 10 days	 
100331	<b>Antimicrobial Effectiveness Testing</b>	PE, USP	to be defined according to category	approx 40 days	 
<b>Sterility</b>					
100103	<b>Product sterility test : aerobic &amp; anaerobic, on 2 culture media</b> Cleanroom environment	EP, USP, ISO 11737-2	2 products	14 - 20 days	  
100108	<b>Product sterility test : Validation</b> Bacteriostasis, fungistasis	EP, USP, ISO 11737-2	6 products	5 - 10 days	  
100901	<b>Biological Indicators population Control</b> , including report	ISO 11138-1 ISO 11138-2	4 BI's	10 days	
100201	<b>Biological Indicator sterility testing on strips, thread or discs</b>	ISO 11138 ISO 14161 ISO 11135-1 EP, USP	1 product	7 - 10 days	 
100202	<b>Biological Indicator sterility testing (suspension)</b>	ISO 11138 ISO 1416 ISO 11135-1 EP, USP	1 product	7 - 10 days	 
100330	<b>Evaluation of bioburden resistance</b> 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><b>Steam Validation Review</b> : annual quick review Generally done 1 year after basis validation, including :</p> <ul style="list-style-type: none"> <li>- Customer confirmation on no changes on products, manufacturing process, bioburden</li> <li>- Customer confirmation about routine service was acceptable</li> <li>- Medistri yearly review on deviations, Medistri equipment review record</li> <li>- Medistri confirmation on process calibration and maintenance</li> <li>- Final assessment report</li> </ul>				
<b>Biocompatibility</b>					
100607	<b>Extractable Metallic Ions (ICP-Fingerprint)</b>	ISO 10993-12, ASTM G 136-03	60 cm <sup>2</sup> or 5 g	2-4 weeks	  
100606	<p><b>GC/MS Fingerprint with 2 solvents, Identification of extracted substances</b> Brief toxicological evaluation (one substance)</p>	ISO10993-12	2x5g or 2x60 cm <sup>2</sup>	2 - 4 weeks	  
1006201	<p><b>Cytotoxicity by direct contact</b> Qualitative</p>	ISO10993-5	3 cm <sup>2</sup>	14 days	  
1006202	<p><b>Cytotoxicity by indirect contact : agar diffusion</b> Qualitative</p>	ISO10993-5	3 cm <sup>2</sup>	14 days	  
1006205	<p><b>XTT cytotoxicity test on extract</b> Qualitative and quantitative analysis</p>	ISO10993-5 ISO10993	6cm <sup>2</sup> or 0.2g	14 days	  
1006217	<p><b>Chromosome Aberration Test</b> V79 Chinese hamster cells</p>	ISO10993-3 OECD473	2x1200 cm <sup>2</sup> or 2x40g	21 weeks	 
1006218	<p><b>Chromosome Aberration Test</b> Human lymphocyte</p>	ISO10993-3 OECD473	2x1200 cm <sup>2</sup> or 2x40g	21 weeks	 
1006221	<p><b>Micronucleus test in vitro (mammalian cells)</b> Human lymphocyte cells</p>	ISO10993-3 ISO10993-13 OECD487	2x1200cm <sup>2</sup> and 600cm <sup>2</sup> or 60g	14 weeks	 
1006220	<p><b>Micronucleus test in vitro (mammalian cells)</b> V79 Chinese hamster cells</p>	ISO10993-3 ISO10993-13 OECD487	2x1200cm <sup>2</sup> and 600cm <sup>2</sup> or 60g	14 weeks	 
1006222	<p><b>Micronucleus test in vivo</b> Test on 10 animals (5 males, 5 females) Polar extraction</p>	ISO10993-3 OECD474	2x240cm <sup>2</sup>	17 weeks	 
1006216	<p><b>Genotoxicity: Salmonella typhimurium Reverse Mutation Test (ames-test)</b> 5 strains of Salmonella typhimurium Polar and non-polar extractions</p>	ISO10993-3	4x30 cm <sup>2</sup> ou 4x1g	4 weeks	 
1006219	<b>Mouse Lymphoma Test</b>	ISO10993-3 OECD476	1x750 cm <sup>2</sup> and 1x2250 cm <sup>2</sup> or 1x25g and 1x75g	17 weeks	 
1006225	<p><b>Dynamic Hemocompatibility with Human Blood</b> Dynamic blood contact</p>	ISO10993-4	5 products	10 weeks	
1006224	<p><b>Hemolysis test</b> Direct contact and extraction on human blood</p>	ISO10993-4 ASTM F756	6x60cm <sup>2</sup> or 6x2g	4 weeks	
1006223	<p><b>Implantation test</b> 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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Code	Description	Technique / Method	Sample Size	TAT	Matrix
1006212	<b>Dermal Irritation (alternative test for use by contact with skin)</b> Extraction and single application on rabbits, 4 hours contact time minimum with intact skin, 72h observation period.	ISO10993-10	120cm <sup>2</sup> or 5g for preparation	6 weeks	
1006211	<b>Irritation : intracutaneous reactivity on rabbits</b> 2 extracts	ISO10993-10	2x30cm <sup>2</sup> or 2x5g	3 weeks	
1006227	<b>Irritation : ocular</b> 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 <sup>2</sup> or 5 g	11 weeks	
1006226	<b>Irritation : acute oral</b>	ISO 10993-10	120cm <sup>2</sup> or 5 g	9 weeks	
1006228	<b>Irritation : Vaginal</b> 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 <sup>2</sup> or 25g	approx 12 weeks	
1006229	<b>Irritation : In Vitro Test</b>	OECD 439 ISO 10993-10	3 g, 3 ml or 18 cm <sup>2</sup>	6 - 7 weeks	
1006209	<b>Sensibilization LLNA: local lymph node assay</b> 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 <sup>2</sup> or 3x4g	8 weeks	
1006210	<b>Sensibilization by Buehler Test</b> Test without extract, appropriate for bandages, compresses...	ISO 10993-10	420cm <sup>2</sup> or 70m	10 weeks	
1006208	<b>Sensibilization according to Magnusson and Kligman on guinea pigs</b> Qualitative analysis	ISO 10993-10 ISO 10993-12	3x90 cm <sup>2</sup> or 6x3 g	8 weeks	
1006214	<b>Acute systemic toxicity on mice</b> 4 extracts, 72h observation period.	ISO 10993-11 ASTM F750 USP	x5g, 2x60 cm <sup>2</sup> , (thickness >0.05mm) or 2x120cm <sup>2</sup> (thickness < 0.5mm)	4 weeks	
1006215	<b>Subacute subchronic systemic toxicity</b> 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	<b>In Vitro eye irritation test (epiocular)</b>	OECD 492	1g, 1ml or 6cm <sup>2</sup>	6 - 7 weeks	
1006231	<b>In Vitro skin corrosion</b>	OECD 431	3g, 3ml or 18cm <sup>2</sup>	6 - 7 weeks	
1006232	<b>Direct Peptide Reactivity Assay(DPRA) Sensitization potential</b>	OECD 442C	5g, 5ml or 30cm <sup>2</sup>	6 - 7 weeks	
1006233	<b>Skin Sensitization - KeratinoSens™</b>	OECD 442D	30g, 30ml or 180cm <sup>2</sup>	6 - 7 weeks	
<b>Environmental Monitoring, Air &amp; Surfaces</b>					
100413	<b>Personnal protection set for analysis</b> (sterile head-cover, gloves, overshoes, disinfectant)				

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Code	Description	Technique / Method	Sample Size	TAT	Matrix
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	  
<b>Water Analysis / for injection / purified</b>					
100602	Aerobic bacterial count on TSA	EP, USP	100ml	5 - 10 days	  
1002114	Conductivity	EP, USP	100ml	5 days	  
100603	<b>Hardness</b> Colorimetric, limit assay <1.5; 1.5 - 2.5; >2.5mmol/l CaCO3	EP, USP	100 ml	5 days	  
100601	<b>Endotoxin</b> Endotoxin test on water, quantitative colorimetric kinetic method	EP, USP, AAMI st 72	100ml	5 days	  
1002104	<b>Mesophilic aerobic germs R2A</b> Oligotroph aerobic germs R2	EP, USP, ISO 11737-1	100ml	5 days	  
1002105	<b>Legionella sp</b> Research of Legionella sp	ISO 11731 ISO 15883-1	100ml	10 - 15 days	  
1002118	<b>Mycobacteria</b> Research of Mycobacterium or Mycoplasma, qualitative	ISO 15883-1	100ml	10 - 60 days	  
1002115	pH	EP, USP	100ml	5 days	  
1001105	<b>Total Organic Carbons (TOC) on water</b>	EN 1484, ASTM G 136-03	100ml	5 - 10 days	  
100604	<b>Sterility testing</b> Sterility test pharma water	EP, USP	to be defined	15 - 20 days	  
100605	<b>Titration</b> Acid base complexometry, redox	EP, USP	to be defined	5 - 10 days	  
1002119	<b>Heavy Metals, limit essay (LOQ : 0.1 mg/l)</b>	EP, USP	100ml	10 days	  
1002120	<b>Nitrate, limit essay (LOQ : 0.1 mg/l)</b>	EP, USP	100ml	10 days	  

### Packaging tests, stability study







































*On Porous, non porous, header bag, peel pouch, Blister. + real time aging test (shelf life)*






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Code	Description	Technique / Method	Sample Size	TAT	Matrix
N/A	<b>Special Project, Device Life Cycle (aging), multiple cleaning and sterilisation</b> 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	<b>Accelerated Aging Tests on packaging with controlled temperature</b> 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	<b>Bubble emission test</b> 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	<b>Burst test</b>	ISO 11607 ASTM F1140 / F1140-13	final packaging non damaged	5 - 10 days	
100820	<b>Creep test</b>	ISO 11607 ASTM F1140 / F1140-13	final packaging non damaged	5 - 10 days	
100840	<b>Dye migration test</b>	ISO 11607, ASTM F1929-15 or ASTM F3039-15	final packaging non damaged	5 - 10 days	
100808	<b>Visual inspection of packaging</b>	ISO 11607 ASTM F1886	final packaging non damaged	5 - 10 days	
100804	<b>Temperature and humidity profiling</b> per day (°C/%RH) during the routine test	N/A	N/A	N/A	
100830	<b>Seal peel test</b>	ISO 11607 ASTM F88 / F88M-15	final packaging non damaged	5 - 10 days	
100870	<b>Transport simulation test</b> (conditioning, vibration, drop, impact. tests to be defined)	ASTM D4169-16, ASTM D7386-12 ISTA serie	to be defined	1 - 2 months	
100809	<b>Peeling test</b>	NF EN 868-5 Annex C	final packaging non damaged	5 - 10 days	
100801	<b>Determination of pH of aqueous extracts</b>	ISO 11607, ISO 6588-1	min 2x2cm <sup>2</sup>	5 - 10 days	
100802	<b>Determination of pH - extra samples</b> Price per extra sample performed at the same time	N/A	N/A	N/A	
100880	<b>Stability study on packaging</b> 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	<b>Aging test, ambient temperature</b> Non-controlled environment. Price per day per pallet	ASTM F1980 ISO 11607-1 ICH-Q1 E	to be defined	N/A	
<b>Chemical Tests</b>					
100703	<b>Glutaraldehyde Titration</b> Potentiometric titration sodium sulphite / HCl	N/A	20ml	5 - 10 days	
100701	<b>Residue test EtO/ ECh</b> 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	<b>Residue test - Ethylene Glycol</b>	ISO 10993-7 ISO 10993-2	to be defined	5 - 10 days	

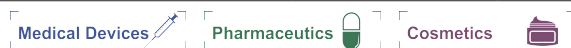
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Code	Description	Technique / Method	Sample Size	TAT	Matrix
100702	Residue test EtO/ECh or Ethylene - Additional Extraction	N/A	N/A	N/A	 
100705	Products Containing Cannabidiol Nicotine dosage by Gas Chromatography	Swissmedic directive	0.5 - 1.0g	10 - 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	
<b>Cleaning / Cleanliness - Validation of reusable and new manufactured devices (disinfection, sterilisation)</b>					
1001106	Analysis of residual Total Organic Carbon (TOC) medical devices	NF EN 1484, ISO 10993-12, ASTM G 136-03	1 product, min 20cm <sup>2</sup>	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 <sup>2</sup> / product	N/A	 
1001111	Total Hydrocarbons (THC)	ISO 10993-12 ISO 9377-2 ASTM G136-03	1 product, min 12cm <sup>2</sup>	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-Hexame (extraction C10 - C40).	ISO 10993-12 ASTM G 136-03 EN1484	3 - 5 products, min 12cm <sup>2</sup> / 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 desinfector, 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 <sup>2</sup>	5 - 10 days	 
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-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	ASTM F2847, ISO 10993-18	1 product	10 - 15 days	

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Code	Description	Technique / Method	Sample Size	TAT	Matrix
<b>Miscellaneous</b>					
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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