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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 bacterial 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	ISO 11737-1 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	  
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	  

Code	Description	Technique / Method	Sample Size	TAT	Matrix
100318	Research of germs : Package 7 species Enterobacteria,Escherichiacoli,Pseudomonas aeruginosa,Staphylococcusaureus,Salmonella, Clostridium, yeast and moulds	ISO 11737-1 EP, USP	to be defined	5 - 10 days	  
100319	Research of germs : Package 5 species Enterobacteria,Escherichiacoli,Pseudomonasaeru- ginosa,Staphylococcusaureus,yeastandmoulds	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	approx40days	 
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, 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	 
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 controlled temperature	ASTM F1980 ISO 11607-1	to be defined	to be defined	  
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	  
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 nondamaged	5 - 10 days	  
100804	Temperature and humidity profiling	N/A	N/A	N/A	  








































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Code	Description	Technique / Method	Sample Size	TAT	Matrix
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	Ageing 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 validation 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 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	
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 analysis on extract-laser diffraction, Resolution: 1µm to 120µm	EP, USP, ISO 9276-1, AAMI TIR 42	1 product 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	









































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Code	Description	Technique / Method	Sample Size	TAT	Matrix
1001115	Analysedepolymèresparspectroscopieinfrarouge (FT-IR)incl.comparaisonduresultatavecbasededonnees pour identifier le type de materiel	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	Cytotoxicitybyindirectcontact:agardiffusion Qualitative	ISO10993-5	3 cm ²	14 days	  
100606	GC/MSFingerprintwith2solvents,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	ExtractableMetallicIons(ICP-Fingerprint)	ISO 10993-12, ASTM G 136-03	60 cm ² or 5 g	2-4 weeks	  
1006071	ExtractableMetallicIons(ICP-Fingerprint),1 solvent, 1 extraction	ISO 10993-12, ASTM G 136-03	30 cm ²	10 - 15 weeks	  
1006234	LC Fingerprint LC Fingerprint with 2 solvents (NVOC)	ISO 10993-12, 10993-18 ASTM G 136-03	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 Directcontactandextractiononhumanblood	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 forpreparation	6 weeks	
1006211	Irritation : intracutaneous reactivity on rabbits 2 extracts	ISO10993-10	2x30cm ² or 2x5g	Approx4weeks	
1006227	Irritation : ocular 2 extracts	ISO 10993-10	120cm ² or 5 g	Approx4weeks	




























































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Code	Description	Technique / Method	Sample Size	TAT	Matrix
1006226	Irritation : acute oral	ISO 10993-10	2x30cm ² or5g	6 - 8 weeks	 
1006228	Irritation : Vaginal 2 extracts	ISO 10993-10	200cm ² or25g	approx12weeks	 
1006229	Irritation : In Vitro Test	OECD 439 ISO 10993-10	3 g, 3 ml or 18 cm ²	6 - 7 weeks	  
1006209	SensibilizationLLNA:locallymphnodeassay 2 extracts	ISO 10993-10 OECD429, ISO 10993-12	3x35cm ² or 3x4g	8 weeks	 
1006210	Sensibilization by Buehler Test Testwithoutextract,appropriateforbandages, compresses...	ISO 10993-10	420cm ² or70ml	10 weeks	
1006208	SensibilizationaccordingtoMagnussonand Kligman on guinea pigs (GPMT) 2 extracts	ISO 10993-10, G ISO 10993-12	6x15 cm ² or 6x5 g	Approx7weeks	 
1006214	Acute systemic toxicity on mice 4 extracts, 72h observation period.	ISO 10993-11 ASTM F750 USP	Approx 5g	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,1mlor6cm 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	Micronucleustestinvitro(mammaliancells) Human lymphocyte cells	ISO10993-3 ISO10993-13 OECD487	2x1200cm ² and 600cm ² or60g	14 weeks	 
1006220	Micronucleustestinvitro(mammaliancells) V79 Chinese hamster cells	ISO10993-3 ISO10993-13 OECD487	2x1200cm ² and 600cm ² or60g	14 weeks	 
1006222	Micronucleus test in vivo Test on 10 animals (5 males, 5 females) Polar extraction	ISO10993-3 OECD474	2x240cm ²	17 weeks	 










































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Code	Description	Technique / Method	Sample Size	TAT	Matrix
1006216	Genotoxicity:SalmonellatyphimuriumReverse Mutation Test (ames-test)	ISO10993-3	4x30 cm ² ou 4x1g	4 weeks	 
1006219	Mouse Lymphoma Test	ISO10993-3 OECD476	1x750cm 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	Approx8weeks	  
10062141	USP VI - Acute systemic toxicity	USP 88	4x90 cm ²	Approx5weeks	  
10062231	USP VI - Intramuscular implantation Intramuscular implantation	USP 88	8x(10mmx1mm)	Approx5weeks	  
Environmental Monitoring, Air & Surfaces					
100413	Personal protection set for analysis (sterile head-cover, gloves, overshoes, disinfectant)				  
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	  
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	  
















































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Code	Description	Technique / Method	Sample Size	TAT	Matrix
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 titrations sodium sulphite/HCl	N/A	20ml	5 - 10 days	
100701	Residue test EtO/ ECH Ethylene Oxide, Ethylene Chlorohydrin, 3 extractions 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	 
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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