National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name : APT TESTING AND RESEARCH PVT. LTD., S.NO. 36/1/1/MAIN 199, SINHAGAD ROAD, VADAGAON KHURD, PUNE, MAHARASHTRA, INDIA

Accreditation Standard ISO/IEC 17025:2017

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Validity 16/06/2022 to 15/06/2024 **Last Amended on** 16/09/2022

S.No	Discipline / Group	Materials or Products tested	Component, parameter or characteristic tested / Specific Test Performed / Tests or type of tests performed	Test Method Specification against which tests are performed and / or the techniques / equipment used
Permanent Facility				
1	BIOLOGICAL-TOXICOLOGY	Surface Medical devices Intact skin (Electrodes, External prostheses , fixation tape , compression, Bandages , monitors of various type) surface (Dressing or Healing devices, Occlusive patches for Ulcers, burns & granulation tissue) External communicating medical device : Blood path , indirect , (Solution, Administration sets, Extension sets , Transfer sets , Blood administration sets) Mucosal Membrane (Contact / Intraocular lenses , Urinary catheters, intravaginal and intra intestinal devices, endotracheal tube , bronchoscopes ,some dental prostheses, orthodontic devices , Copper - T , Tubal rings , condoms) Implant Medical Devices and Materials : Blood (Pace makers , electrodes , Artificial Arteriovenous fistulae , Heart valves , Vascular grafts , internal drug delivery catheters , Ventricular assist devices , Stents)	Qualitative In Vitro Cytotoxicity Elution Test	ISO 10993 - 5
2	BIOLOGICAL-TOXICOLOGY	Dressing or Healing devices, Occlusive patches for Ulcers, burns & granulation tissue External communicating medical device : Blood path ,indirect , (Solution, Administration sets, Extension sets , Transfer sets , Blood administration sets) Mucosal Membrane (Contact / Intraocular lenses , Urinary catheters, intravaginal and intra intestinal devices, endotracheal tube , bronchoscopes ,some dental prostheses, orthodontic devices , Copper - T , Tubal rings , condoms) Implant Medical Devices and Materials : Blood (Pace makers , electrodes , Artificial Arteriovenous fistulae , Heart valves ,Vascular grafts , internal drug delivery catheters , Ventricular assist devices , Stents)	Tests for genotoxicity, carcinogenicity and reproductive toxicity : In Vitro Chromosomal aberration test Qualitative	ISO 10993 - 3
3	BIOLOGICAL-TOXICOLOGY	Dressing or Healing devices, Occlusive patches for Ulcers, burns & granulation tissue External communicating medical device : Blood path ,indirect , (Solution, Administration sets, Extension sets , Transfer sets , Blood administration sets) Mucosal Membrane (Contact / Intraocular lenses , Urinary catheters, intravaginal and intra intestinal devices, endotracheal tube , bronchoscopes ,some dental prostheses, orthodontic devices , Copper - T , Tubal rings , condoms) Implant Medical Devices and Materials : Blood (Pace makers , electrodes , Artificial Arteriovenous fistulae , Heart valves ,Vascular grafts , internal drug delivery catheters , Ventricular assist devices , Stents) Ventricular assist devices, Stents) Cardiovascular devices and prostheses	Haemocompatibility Test	ISO 10993-4

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4	BIOLOGICAL-TOXICOLOGY	Dressing or Healing devices, Occlusive patches for Ulcers, burns & granulation tissue External communicating medical device : Blood path ,indirect , (Solution, Administration sets, Extension sets , Transfer sets , Blood administration sets) Mucosal Membrane (Contact / Intraocular lenses , Urinary catheters, intravaginal and intra intestinal devices, endotracheal tube , bronchoscopes ,some dental prostheses, orthodontic devices , Copper - T , Tubal rings , condoms) Implant Medical Devices and Materials : Blood (Pace makers , electrodes , Artificial Arteriovenous fistulae , Heart valves ,Vascular grafts , internal drug delivery catheters , Ventricular assist devices , Stents	Tests for genotoxicity, carcinogenicity and reproductive toxicity :AMES	ISO 10993-3
5	BIOLOGICAL-TOXICOLOGY	Dressing or Healing devices, Occlusive patches for Ulcers, burns & granulation tissue) External communicating medical device : Blood path , indirect , (Solution, Administration sets, Extension sets , Transfer sets , Blood administration sets) Mucosal Membrane (Contact / Intraocular lenses , Urinary catheters, intravaginal and intra intestinal devices, endotracheal tube , bronchoscopes ,some dental prostheses, orthodontic devices , Copper - T , Tubal rings , condoms) Implant Medical Devices and Materials : Blood (Pace makers , electrodes , Artificial Arteriovenous fistulae , Heart valves , Vascular grafts , internal drug delivery catheters , Ventricular assist devices , Stents)	Material mediated Pyrogenecity (Rabbit)	USP: 44 Chapter 88
6	BIOLOGICAL-TOXICOLOGY	Dressing or Healing devices, Occlusive patches for Ulcers, burns & granulation tissue, External communicating medical device : Blood path , indirect , (Solution, Administration sets, Extension sets , Transfer sets , Blood administration sets) Mucosal Membrane (Contact / Intraocular lenses , Urinary catheters, intravaginal and intra intestinal devices, endotracheal tube , bronchoscopes ,some dental prostheses, orthodontic devices , Copper - T , Tubal rings , condoms) Implant Medical Devices and Materials : Blood (Pace makers , electrodes , Artificial Arteriovenous fistulae , Heart valves , Vascular grafts , internal drug delivery catheters , Ventricular assist devices , Stents)	Material mediated Pyrogenecity (Rabbits)	ISO 10993 - 11
7	BIOLOGICAL-TOXICOLOGY	Dressing or Healing devices, Occlusive patches for Ulcers, burns & granulation tissue, External communicating medical device : Blood path , indirect Mucosal Membrane (intra intestinal devices, endotracheal tube , bronchoscopes, some dental prostheses, orthodontic devices) Implant Medical Devices and Materials : Blood (internal drug delivery catheters)	Oral Mucosa Irritation Test (Hamster)	ISO 10993 23

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8	BIOLOGICAL-TOXICOLOGY	Intact skin (Compression, Bandages) surface (Dressing or Healing devices, Occlusive patches for Ulcers) External communicating medical device : Mucosal Membrane (Contact / Intraocular lenses)	Occular Irritation Test (Rabbits)	ISO 10993 Part 23
9	BIOLOGICAL-TOXICOLOGY	Intact skin (Electrodes, External prostheses , fixation tape , compression, Bandages , monitors of various type) surface (Dressing or Healing devices, Occlusive patches for Ulcers, burns & granulation tissue) External communicating medical device : Blood path , indirect , (Solution, Administration sets, Extension sets , Transfer sets , Blood administration sets) Mucosal Membrane (Contact / Intraocular lenses , Urinary catheters, intravaginal and intra intestinal devices, endotracheal tube , bronchoscopes ,some dental prostheses, orthodontic devices , Copper - T , Tubal rings , condoms) Implant Medical Devices and Materials : Blood (Pace makers , electrodes, Artificial Arteriovenous fistulae , Heart valves , Vascular grafts , internal drug delivery catheters, Ventricular assist devices, Stents)	Animal Irritation test or Animal Intracutaneous/ Intradermal Reactivity Test (Rabbit)	ISO 10993 23
10	BIOLOGICAL-TOXICOLOGY	Intact skin (Electrodes, External prostheses, fixation tape , compression, Bandages , monitors of various type) surface (Dressing or Healing devices, Occlusive patches for Ulcers, burns & granulation tissue) External communicating medical device : Blood path , indirect , (Solution, Administration sets, Extension sets , Transfer sets, Blood administration sets) Mucosal Membrane (Contact / Intraocular lenses, Urinary catheters, intravaginal and intra intestinal devices, endotracheal tube, bronchoscopes, some dental prostheses, orthodontic devices , Copper - T , Tubal rings , condoms) Implant Medical Devices and Materials : Blood (Pace makers , electrodes , Artificial Arteriovenous fistulae ,Heart valves , Vascular grafts , internal drug delivery catheters , Ventricular assist devices , Stents)	Skin Sensitisation Test (Guinea Pigs)	ISO 10993 - 10
11	BIOLOGICAL-TOXICOLOGY	Intact skin (Electrodes, External prostheses, fixation tape, compression, Bandages, monitors of various type) surface (Dressing or Healing devices, Occlusive patches for Ulcers, burns & granulation tissue) External communicating medical device : Blood path , indirect , (Solution, Administration sets, Extension sets , Transfer sets , Blood administration sets) Mucosal Membrane (Contact / Intraocular lenses, Urinary catheters, intravaginal and intra intestinal devices, endotracheal tube, bronchoscopes, some dental prostheses, orthodontic devices, Copper - T, Tubal rings , condoms) Implant Medical Devices and Materials : Blood (Pace makers , electrodes , Artificial Arteriovenous fistulae , Heart valves , Vascular grafts , internal drug delivery catheters , Ventricular assist devices, Stents)	Acute Systemic Toxictity (intravenous, intramuscular, intraperitoneal, intradermal, oral) (Rodent-Rat or mice)	ISO 10993-11

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12	BIOLOGICAL-TOXICOLOGY	Intact skin (Fixation tape , compression, Bandages) surface (Dressing or Healing devices, Occlusive patches for Ulcers, burns & granulation tissue) External communicating medical device : Blood path , indirect Mucosal Membrane Urinary catheters, intravaginal, Copper - T , Tubal rings , condoms) Implant Medical Devices and Materials : Blood (Artificial Arteriovenous fistulae , internal drug delivery catheters)	Vaginal Irritation test (Rabbit)	ISO 10993 - 23
13	BIOLOGICAL-TOXICOLOGY	Intact skin (Fixation tape , compression, Bandages) surface (Dressing or Healing devices, Occlusive patches for Ulcers, burns & granulation tissue) External communicating medical device : Blood path , indirect Mucosal Membrane Urinary catheters, intravaginal, Copper - T , Tubal rings , condoms) Implant Medical Devices and Materials : Blood (Artificial Arteriovenous fistulae , internal drug delivery catheters)	Penile Irritation (Rabbits)	ISO 10993 23
14	BIOLOGICAL-TOXICOLOGY	Intact skin (Fixation tape , compression, Bandages) surface (Dressing or Healing devices, Occlusive patches for Ulcers, burns & granulation tissue) External communicating medical device :Implant Medical Devices and Materials : Blood (Artificial Arteriovenous fistulae , internal drug delivery catheters)	Rectal Irritation (Rabbit)	ISO 10993 23
15	BIOLOGICAL-TOXICOLOGY	Intact skin (Fixation tape , compression, Bandages) surface (Dressing or Healing devices) Mucosal Membrane (intra intestinal devices) Implant Medical Devices and Materials : Blood (internal drug delivery catheters ,)	Nasal Irritation Test (Rabbit)	ISO 10993-23
16	BIOLOGICAL-TOXICOLOGY	Packaging materials (Low-density polyethylene (LDPE), Linear Low-Density Polyethylene (LLDPE), Ultra Low-Density Polyethylene (ULDPE), Medium-density polyethylene (MDPE), High-density polyethylene (HDPE), Polypropylene, Polycarbonate (PC), Polyvinyl Chloride (PVC), Polyethylene Terephthalate (PET), Biaxially-oriented polyethylene terephthalate (BOPET), Polyvinylidene Chloride (PVDC), Polyamide/Nylon, aluminum foils)	In Vitro Cytotoxicity Test Direct Contact Test	USP: 44 Chapter 87
17	BIOLOGICAL-TOXICOLOGY	Packaging materials (Low-density polyethylene (LDPE), Linear Low-Density Polyethylene (LLDPE), Ultra Low-Density Polyethylene (ULDPE), Medium-density polyethylene (MDPE), High-density polyethylene (HDPE), Polypropylene, Polycarbonate (PC), Polyvinyl Chloride (PVC), Polyethylene Terephthalate (PET), Biaxially-oriented polyethylene terephthalate (BOPET), Polyvinylidene Chloride (PVDC), Polyamide/Nylon, aluminum foils)	Acute Systemic Toxicity (Rat, Rabbit, Mice, Guinea Pig)	USP: 44 Chapter 88

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18	BIOLOGICAL-TOXICOLOGY	Packaging materials (Low-density polyethylene (LDPE), Linear Low-Density Polyethylene (LLDPE), Ultra Low-Density Polyethylene (ULDPE), Medium-density polyethylene (MDPE), High-density polyethylene (HDPE), Polypropylene, Polycarbonate (PC), Polyvinyl Chloride (PVC), Polyethylene Terephthalate (PET), Biaxially-oriented polyethylene terephthalate (BOPET), Polyvinylidene Chloride (PVDC), Polyamide/Nylon, aluminum foils)	In Vitro Cytotoxicity Test Elution Test	USP: 44 Chapter 87
19	BIOLOGICAL-TOXICOLOGY	Surface Medical devices (Dressing or Healing devices, Occlusive patches for Ulcers, burns & granulation tissue) External communicating medical device : Blood path , indirect , (Solution, Administration sets, Extension sets , Transfer sets , Blood administration sets) Implant Medical Devices and Materials : Blood (Pace makers , electrodes , Artificial Arteriovenous fistulae , Heart valves , Vascular grafts , internal drug delivery catheters , Ventricular assist devices , Stents) Mucosal Membrane (Contact / Intraocular lenses , Urinary catheters, intravaginal and intra intestinal devices, endotracheal tube , bronchoscopes, some dental prostheses, orthodontic devices , Copper - T , Tubal rings)	Implantation (Bone, Muscle, Subcutaneous) (Rabbit and Rat)	ISO 10993- 6
20	BIOLOGICAL-TOXICOLOGY	Surface Medical devices Intact skin (Electrodes, External prostheses , fixation tape , compression, Bandages , monitors of various type) surface (Dressing or Healing devices, Occlusive patches for Ulcers, burns & granulation tissue) External communicating medical device : Blood path , indirect , (Solution, Administration sets, Extension sets , Transfer sets , Blood administration sets) Mucosal Membrane (Contact / Intraocular lenses , Urinary catheters, intravaginal and intra intestinal devices, endotracheal tube , bronchoscopes ,some dental prostheses, orthodontic devices , Copper - T , Tubal rings , condoms) Implant Medical Devices and Materials : Blood (Pace makers , electrodes , Artificial Arteriovenous fistulae , Heart valves , Vascular grafts , internal drug delivery catheters , Ventricular assist devices , Stents)	In Vitro Cytotoxicity Test Direct Contact Test	ISO 10993 - 5
21	BIOLOGICAL-TOXICOLOGY	Water Treatment Chemicals (Coagulants, antiscalants, disinfectants, sanitizer, antialgal, oxidizing agents) Epoxy and Coatings (Phenolic resins, amino resins, polyester resins, silicone resins, epoxy resins, and polyurethanes (polyesters, vinyl esters, epoxies, bismaleimides, cyanate esters, polyimides and phenolics), Adhesives and Sealants, mineral-based molecules such as phosphites, and minor elements such as silicon	Acute Inhalation (Rodent-Rat, Mice)	OECD 403

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22	BIOLOGICAL-TOXICOLOGY	Water Treatment Chemicals (Coagulants, antiscalants, disinfectants, sanitizer, antialgal, oxidizing agents) Epoxy and Coatings (Phenolic resins, amino resins, polyester resins, silicone resins, epoxy resins, and polyurethanes (polyesters, vinyl esters, epoxies, bismaleimides, cyanate esters, polyimides and phenolics), Adhesives and Sealants, Protein hydrolysates, Chitosan and other biopolymers, mineral-based molecules such as phosphites, and minor elements such as silicon)	Acute Oral Toxicity-Acute Toxic Class Method (Rodent-Rat, Mice)	OECD 423
23	BIOLOGICAL-TOXICOLOGY	Water Treatment Chemicals (Coagulants, antiscalants, disinfectants, sanitizer, antialgal, oxidizing agents) Packaging materials (Low-density polyethylene (LDPE), Linear Low- Density Polyethylene (LLDPE), Ultra Low-Density Polyethylene (ULDPE), Medium-density polyethylene (MDPE), High-density polyethylene (HDPE), Polypropylene, Polycarbonate (PC), Polyvinyl Chloride (PVC), Polyethylene Terephthalate (PET), Biaxially-oriented polyethylene terephthalate (BOPET), Polyvinylidene Chloride (PVDC), Polyamide/Nylon, aluminum foils) Epoxy and Coatings (Phenolic resins, amino resins, polyester resins, silicone resins, epoxy resins, and polyurethanes (polyesters, vinyl esters, epoxies, bismaleimides, cyanate esters, polyimides and phenolics), Adhesives and Sealants, Chitosan and other biopolymers, mineral-based molecules such as phosphites, and minor elements such as silicon)	Acute Eye Irritation/Corrosion (Rabbit)	OECD 405
24	BIOLOGICAL-TOXICOLOGY	Water Treatment Chemicals (Coagulants, antiscalants, disinfectants, sanitizer, antialgal, oxidizing agents) Packaging materials (Low-density polyethylene (LDPE), Linear Low- Density Polyethylene (LLDPE), Ultra Low-Density Polyethylene (ULDPE), Medium-density polyethylene (MDPE), High-density polyethylene (HDPE), Polypropylene, Polycarbonate (PC), Polyvinyl Chloride (PVC), Polyethylene Terephthalate (PET), Biaxially-oriented polyethylene terephthalate (BOPET), Polyvinylidene Chloride (PVDC), Polyamide/Nylon, aluminum foils) Epoxy and Coatings (Phenolic resins, amino resins, polyester resins, silicone resins, epoxy resins, and polyurethanes (polyesters, vinyl esters, epoxies, bismaleimides, cyanate esters, polyimides and phenolics), Adhesives and Sealants, Chitosan and other biopolymers, mineral-based molecules such as phosphites, and minor elements such as silicon)	Acute Dermal toxicity (Rodent-Rat)	OECD 402

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25	BIOLOGICAL-TOXICOLOGY	Water Treatment Chemicals (Coagulants, antiscalants, disinfectants, sanitizer, antialgal, oxidizing agents) Packaging materials (Low-density polyethylene (LDPE), Linear Low- Density Polyethylene (LLDPE), Ultra Low-Density Polyethylene (ULDPE), Medium-density polyethylene (MDPE), High-density polyethylene (HDPE), Polypropylene, Polycarbonate (PC), Polyvinyl Chloride (PVC), Polyethylene Terephthalate (PET), Biaxially-oriented polyethylene terephthalate (BOPET), Polyvinylidene Chloride (PVDC), Polyamide/Nylon, aluminum foils) Epoxy and Coatings (Phenolic resins, amino resins, polyester resins, silicone resins, epoxy resins, and polyurethanes (polyesters, vinyl esters, epoxies, bismaleimides, cyanate esters, polyimides and phenolics), Adhesives and Sealants, Chitosan and other biopolymers, mineral-based molecules such as phosphites, and minor elements such as silicon)	Bacterial Reverse Mutation Test (AMES)	OECD 471
26	BIOLOGICAL-TOXICOLOGY	Water Treatment Chemicals (Coagulants, antiscalants, disinfectants, sanitizer, antialgal, oxidizing agents) Packaging materials (Low-density polyethylene (LDPE), Linear Low- Density Polyethylene (LLDPE), Ultra Low-Density Polyethylene (ULDPE), Medium-density polyethylene (MDPE), High-density polyethylene (HDPE), Polypropylene, Polycarbonate (PC), Polyvinyl Chloride (PVC), Polyethylene Terephthalate (PET), Biaxially-oriented polyethylene terephthalate (BOPET), Polyvinylidene Chloride (PVDC), Polyamide/Nylon, aluminum foils) Epoxy and Coatings (Phenolic resins, amino resins, polyester resins, silicone resins, epoxy resins, and polyurethanes (polyesters, vinyl esters, epoxies, bismaleimides, cyanate esters, polyimides and phenolics), Adhesives and Sealants, Chitosan and other biopolymers, mineral-based molecules such as phosphites, and minor elements such as silicon)	In Vitro chromosomal aberration test	OECD 473
27	BIOLOGICAL-TOXICOLOGY	Water Treatment Chemicals (Coagulants, antiscalants, disinfectants, sanitizer, antialgal, oxidizing agents) Packaging materials (Low-density polyethylene (LDPE), Linear Low- Density Polyethylene (LLDPE), Ultra Low-Density Polyethylene (ULDPE), Medium-density polyethylene (MDPE), High-density polyethylene (HDPE), Polypropylene, Polycarbonate (PC), Polyvinyl Chloride (PVC), Polyethylene Terephthalate (PET), Biaxially-oriented polyethylene terephthalate (BOPET), Polyvinylidene Chloride (PVDC), Polyamide/Nylon, aluminum foils) Epoxy and Coatings (Phenolic resins, amino resins, polyester resins, silicone resins, epoxy resins, and polyurethanes (polyesters, vinyl esters, epoxies, bismaleimides, cyanate esters, polyimides and phenolics), Adhesives and Sealants, Chitosan and other biopolymers, mineral-based molecules such as phosphites, and minor elements such as silicon)	Skin Sensitisation Guinea Pig Maximisation Test and Buehler Test (Guinea Pig)	OECD 406

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28	BIOLOGICAL-TOXICOLOGY	Water Treatment Chemicals (Coagulants, antiscalants, disinfectants, sanitizer, antialgal, oxidizing agents) Packaging materials (Low-density polyethylene (LDPE), Linear Low- Density Polyethylene (LLDPE), Ultra Low-Density Polyethylene (ULDPE), Medium-density polyethylene (MDPE), High-density polyethylene (HDPE), Polypropylene, Polycarbonate (PC), Polyvinyl Chloride (PVC), Polyethylene Terephthalate (PET), Biaxially-oriented polyethylene terephthalate (BOPET), Polyvinylidene Chloride (PVDC), Polyamide/Nylon, aluminum foils) Epoxy and Coatings (Phenolic resins, amino resins, polyester resins, silicone resins, epoxy resins, and polyurethanes (polyesters, vinyl esters, epoxies, bismaleimides, cyanate esters, polyimides and phenolics), Adhesives and Sealants, Chitosan and other biopolymers, mineral-based molecules such as phosphites, and minor elements such as silicon,)	Acute Dermal Irritation/ Corrosion (Rabbit)	OECD 404