|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Company Specifications | | | | | |
| Company Name |  | | | postal code |  |
| CEO Name |  | Company Phone |  | National ID |  |
| Contacts Names |  | Contact Person's Mobile |  | Economic Code |  |
| Full Address |  | | | | |
| \* Email address to send electronic results and invoice | | |  | | |
| Requested Proforma Invoice: Including Value Added ☐ (10%) excluding VAT ☐ | | | | | |
| Announcing the results to the company's email: | | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| Completion of the following section (Latin) is required\* | | | |
|  | | | Applicant \* |
|  | | | Address\* |
|  | | | E mail\* |
|  | Customer name \* |  | Phone Number\* |
|  | Batch Number\* |  | Product Name \* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Product Detail | | | | | |
| Product Name |  | | | Total Number : | |
| Batch Number/Lot |  | | | Production Date: | Expiration Date: |
| Storage conditions | Ambient Temperature | Refrigerators (2-8) | Freezers (-20) | Other: | |
| Product Hazard Class | Hazard Class A (I) Hazard Class B (IIa & I\*) Hazard Class C (IIb) Hazard Class D (III) | | | | |
| Product Application |  | | | | |
| Sterilization Method | The product is non-sterile  ethylene oxide  gamma-ray  autoclave  and others: | | | | |

|  |  |
| --- | --- |
| Customer's Specific Request | |
|  | |
| Signature and Seal of the Company  Date: | **Company Logo** |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| \* If your product contains non-polarized substances, be sure to inform the laboratory about this  Biocompatibility Tests (according to 10993) | | | | | | | | | | | | | |
| Biocompatibility | **Row** | **Test Name** | **Test Standard** | | **Test Duration** | **Number of Samples** | | **Limit** | **Help** | | | **Select** | |
| 1 | Cytotoxicity | ISO 10993-5 | | 5 to 9 days | 3 pcs | | It doesn't need to be. | - | | |  | |
| 2 | Cell Adhesion | - | | - | 3 pcs | | It doesn't need to be. | - | | |  | |
| 3 | Sensitization | ISO 10993-10 | | 1 Month | 4 gr \_ 10ml | | It doesn't need to be. | - | | |  | |
| 4 | Irritation | ISO 10993-10 | | 7 days | 4 gr \_ 10ml | |  | Table 2 | | |  | |
| 5 | Subchronic systemic toxicity | ISO 10993-11 | | 3 months | 50 gr \_ 300ml | |  | Table 3 | | |  | |
| 6 | Chronic systemic toxicity | ISO 10993-11 | | 6 months | 100 gr \_ 10ml | |  |  | |
| 7 | Subacute systemic toxicity | ISO 10993-11 | | 1 Month | 15 gr \_ 400ml | |  |  | |
| 8 | Acute systemic toxicity | ISO 10993-11 | | 10 days | 4 gr \_ 10ml | |  |  | |
| 9 | Genotoxicity | ISO 10993-3 | | 7 days | 3 pcs | | It doesn't need to be. | \_ | | |  | |
| 10 | Implantation Test | ISO 10993-6 | | Variable | 9 Pieces | |  | Table 1 | | |  | |
| 11 | In vivo Pyrogenicity | USP & BP | | 7 days | 10 gr \_100ml | | It doesn't need to be. | \_ | | |  | |
| 12 | Hemocompatibility | ISO 10993-4 | | 6 days | 3 pcs | | It doesn't need to be. | \_ | | |  | |
| 13 | Ethylene oxide gas residue | ISO 10993-7 | | 3 to 10 days | 3 pcs | |  | Table 5 | | |  | |
| 14 | Carcinogenicity | ISO 10993-3 | | 20 months | 1200ml – 240gr | |  |  | | |  | |
| Microbial and Molecular Tests | | | | | | | | | | | | | |
| Microbial | 15 | Bioburden (Determination of Microbial Load of Equipment) | | | | ISO 11737 | | 5 to 7 days | 10 g/ml | | As declared by custome | Table 4 |  |
| 16 | Microbial Enumeration Tests (Pharmaceutical) | | | | Usp | | 5 to 7 days | 25 g/ml | | As declared by customer | Table 4 |  |
| Sterility | 17 | Sterility Test for Drugs | | | | USP <71> | | 16 days | 10 Pieces | | It doesn't need to be. | **-** |  |
| 18 | Sterility Test for Medical Devices | | | | ISO 11737-2 | | 16 days | 10 Pieces | | It doesn't need to be. | - |  |
| Pyrogenicity (LAL) | 19 | Endotoxin Test | | | | INSO 10572  USP <85> | | 3 days | 3 pcs | | Customer Announcement | Table 6 |  |
| Mycoplasma | 20 | Mycoplasma test (PCR) | | | | USP <63>  USP <1223> | | 8 days | 2 g/ml | | It doesn't need to be. | \_ |  |
| 21 | Mycoplasma test (by culture method) | | | | USP <63> | | 23 days | 2 g/ml | | It doesn't need to be. | - |  |
| Disinfectants | 22 | Antibacterial Properties of Chemical Disinfectants (General Use) | | | | INSO 2842  DIN EN BS 1276 | | One Month | | | | At least 200 ml |  |
| 23 | Antibacterial Properties of Disinfectants in Medicine | | | | INSO 10504  ISO 13727 | | At least 200 ml |  |
| 24 | Antibacterial property of hand sanitizer | | | | INSO 8512  BS EN 1500 | | At least 300 ml |  |
| 25 | Antibacterial properties of hygienic hand wash | | | | INSO 19708  DIN EN 1499 | | At least 300 ml |  |
| 26 | Antibacterial Properties of Textile Goods | | | | INSO 11070  ISO 20743 | | 6 pcs (5\*5 cm) |  |
| 27 | Antibacterial Properties of Plastic Surfaces | | | | INSO 10900  ISO 22196 | | 6 pcs (5\*5 cm) | **☐** |
| 28 | Antibacterial property of porous surfaces | | | | ASTM 11798 | | At least 20 ml | **☐** |
| 29 | Antibacterial Properties of Disinfectant Devices (UVGI) | | | | INSO 22808  ASTM E3135 | | - | **☐** |
| 30 | Antibacterial / Antifungal Properties of Surface Disinfectants (Test on Pore Surfaces) | | | | INSO 11798  DIN EN 13697 | | At least 200 ml | **☐** |
| 31 | Antifungal properties of chemical disinfectants (public use) | | | | INSO 6986  DIM EN 1650 | | At least 200 ml | **☐** |
| 32 | Antifungal properties of disinfectants in medicine | | | | INSO 19851  ISO 13624 | | At least 200 ml | **☐** |
| 33 | Antifungal properties of hand sanitizer | | | | INSO 16119  ASTM E2613 | | At least 200 ml | **☐** |
| Preservatives | 34 | Preservative Efficacy Test | | | | USP <51> | | 40 days | 150 ml | | It doesn't need to be. | \_ |  |
| Indicators | 35 | Chemical Indicators | | | | ISO-11140-1 | | 3 days | 10 Pieces | | It doesn't need to be. | \_ |  |
| 36 | Biological Indicators | | | | ISO 11138,  USP <55> | | 5 to 7 days | 10 Pieces | | It doesn't need to be. | \_ |  |
| Media Qualification | 37 | Growth Promotion Test (GP) of general and specific culture media | | | | INSO 9899 ISO | | 3 to 5 days | 3 pcs | | Customer Announcement | \_ |  |
| Clean room monitoring and all types of hoods | | | | | | | | | | | | | |
| Clean Room | 38 | Particle count, Differential pressure, Airflow velocity, Light, Humidity, Temp. | | ISO 14644 | | By coordination | By coordination | | | **DQ** | |  |  |
| **Iq** | |  |  |
| **OQ** | |  |  |
| **PQ** | |  |  |
| 39 | Microbial Monitoring | | ISO 14698 | | By coordination | By coordination | | | **Microbial** | |  |  |
| Monitoring of all types of hoods | 40 | Differential pressure, UV, Airflow velocity, Particle count, Light, Microbial monitoring, Sound level | | BS EN 12469 | | In harmony | In harmony | | | **Biological**  **Chemical** | |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Ethylene oxide chamber leg | | | | | |
| Ethylene Oxide Chamber Monitoring | 41 | Temperature, Humidity, Pressure, EO Gas Residual | ISO 11135  ISO 11137-1  ISO 11137-2 | In harmony |  |
| Determination of the amount of ethylene oxide gas residue |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Water Monitoring & Water Making Machine | | | | | | | |
| Water Monitoring & Water Making Machine | 42 | Water Validation  Microbial Load Count (Kant)  Measurement of specialized water parameters  (TDS, EC, pH, Cl, TOC, etc.) | USP, BP, ISO | 7 days | 200 mg | In harmony |  |
| Chain Carry Check Test (Cold-Hot) | | | | | | | |

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| --- | --- | --- | --- | --- | --- | --- |
| Chain of Custody Validation | 43 | Coldchain Validation | USP, BP, ISO | Depends on the storage temperature | Desired Temperature : ................. |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Determine the lifespan of the product and packaging | | | | | | | |
| Category | **Row** | **Test Name** | **Test Standard** | **Test Duration** | **Number of Samples** | **Description** | Select |
| Stability (Shelf-Life) Accelerated | 44 | Accelerated Aging (Packaging) | ASTM F1980 ISO 11607 | Based  Lifetime | Depends on the number of months | **Number of Months Required ..........................**  Sterility  Packaging |  |
| 45 | Specific Sustainability of Each Product (Accelerated Aging) | According to the product | Based  Lifetime | Depends on the number of months | **Number of Months Required**  **………………..**  Requested Tests  .............................. |  |
| Stability (Shelf-Life)  real time | 46 | Packaging Stability | ASTM F1980 ISO 11607 | Based  Lifetime | Depends on the number of months | **Number of Months Required ..........................**  Sterility  Packaging |  |
| 47 | Specific Sustainability of Each Product | According to the product | Based  Lifetime | Depends on the number of months | Number of Months Required  .............................  Requested Tests  .............................. |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Tests for determining the Medical Grade of Raw Materials | | | | | | | |
| Medical Grade | 48 | Medical Grade Determination Test | ISO3451-5 & ISIRI1239  Ph.Eur.3.1.1  ASTM D2124/ E1131/D3749 | One Month | 5 to 10 | Sample Material: ......................................................... |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| General Physical Exams | | | | | | |
| General Physical Tests | 49 | Packaging Test ((Tensile - Leakage - Buble- Burst) | USP, BP, ISO | Variable | 3 pcs |  |
| 50 | Tensile Strength / Compressive Strength | USP, BP, ISO | Variable | 3 pcs |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Chemistry Tests** | **Row** | **Test Name** | **Test** | **Sample quantity** |
| 51 | pH test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 10g or 100ml |
| 52 | EC/TDS Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 10g or 100ml |
| 53 | Viscosity Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 20g or 150ml |
| 54 | Density Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 2g |
| 55 | Moisture Percentage Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 10g |
| 56 | Ash Percentage Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 10g |
| 57 | Acid Insoluble Ash Percentage Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 5g |
| 58 | Fat Percentage Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 20 grams. |
| 59 | Fiber Percentage Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 10g |
| 60 | Protein Percentage Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 5g |
| 61 | TVN Exam | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 5g |
| 62 | Zein Number Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 5g |
| 63 | Acid Number Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 20 grams. |
| 64 | Peroxide Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 20 grams. |
| 65 | Carbohydrate Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 20 grams. |
| 66 | Salt Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 10g |
| 67 | Reducing Sugars Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 20 grams. |
| 68 | Total Glucose Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... |
| 69 | Sucrose Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... |
| 70 | Acidity and alkalinity test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 10g |
| 71 | Oxidation and Reduction Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 10g |
| 72 | Silver nitrate purity percentage test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 5g |
| 73 | Formalin Purity Percentage Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 5g |
| 74 | Sodium Bicarbonate Purity Percentage Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 10g |
| 75 | Spectroscopy Test (UV-Vis Absorption) | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 5g |
| 76 | Phthalate Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 5g |
| 77 | Formaldehyde Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 10g or 250ml |
| 78 | Polyphenol Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 10g |
| 79 | Vitamin B1 Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 5g |
| 80 | Vitamin B2 Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 5g |
| 81 | Vitamin B3 Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 5g |
| 82 | Vitamin B5 Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 5g |
| 83 | Vitamin B6 Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 5g |
| 84 | Vitamin B7 Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 5g |
| 85 | Vitamin B9 Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 5g |
| 86 | Vitamin B12 Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 5g |
| 87 | Vitamin A Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 20 grams. |
| 88 | Vitamin C Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 5g |
| 89 | Vitamin D3 Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 30g |
| 90 | Caffeine Test | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 5g |
| 91 | Heavy Metals TestRequested Metals: ............................... | According to the submitted analysis sheet  Announcing the acceptable limit: ...................... | 5g |

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| --- | --- | --- | --- | --- | --- | --- |
|  | | Specialized Medical Equipment Tests | | | | |
| Exam Name | **Standard** | | **Select** | **Test Name** | **Standard** | **Select** |
| Medicated Paraffin Gauze | INSO 11032  USP 30-NF 25 | |  | **Rubber Surgical Gloves** | INSO 1644  ISO 10282 |  |
| Hydrophilic cotton | INSO 258  SANS 228 | |  | **Household Gloves** | INSO 3671  ISO 20057 |  |
| Medical Gauze Dressing | INSO 3061  AS 2835-1 | |  | **Rubber condoms for clinical trials** | ISIRI 9551  ISO 16037 |  |
| Gypsum band | ISIRI 11806  IS 4738 | |  | **Female Condoms** | INSO 18439  ISO 25841 |  |
| Flat and non-sticky banding | ISIRI 5557  BS 7505 | |  | **Men's latex condoms** | ISO 4047  INSO 14768 |  |
| Bandage Bandage | INSO 583  EN 14079 | |  | **Urine sac** | ISIRI 4928  ISO 8669 |  |
| Wound Adhesive | TS 3957 | |  | **Blood bag** | INSO 12139-1  ISO 3826-1 |  |
| Initial wound dressings | INSO 21495  BS 13726 | |  | **Hot Water Bag** | INSO 20490  BS 1970 |  |
| Orthopedic Molding Band | INSO 18149  ASTM F1536 | |  | **PET Bottle** | ISO 12418  INSO 11610 |  |
| Dental Amalgam | INSO 21005  ISO 24234 | |  | **Surgical Coverings & Gannes** | EN 13795  INSO 14350 |  |
| Dentures | INSO 11791  ISO 22112 | |  | **All kinds of disposable medical utensils (... & safety box)** | ISIRI 8502  AS 4031 |  |
| Dental sealer | INSO 18029  ISO 6876 | |  | **Surgical Thread Needles** | INSO 14351  JIS T 3102 |  |
| Dental floss with handle | INSO 14019  ISO 28158 | |  | **Stainless Steel Needle Tube** | INSO 3981  ISO 9626 |  |
| Hand toothbrush | ISO 20126  INSO 2063 | |  | **Needles under the skin** | INSO 3979  ISO 7864 |  |
| Medical Mask | INSO 6138  EN 14683 | |  | **Dental needles** | INSO 5554  ISO 7885 |  |
| Lipstick | INSO 14622  BIS 9875 | |  | **Subcutaneous syringe** | INSO 770-1  ISO 7886-1 |  |
| Perfume | ISIRI 1022  IS 8482 | |  | **Insulin Syringe** | INSO 3591  ISO 8537 |  |
| Paper & Cardboard | ISO 3781  ISO 1924-2,3 | |  | **Self-destruct syringe** | INSO 770-3  ISO 7886-3 |  |
| Surgical knife with detachable blade | ISIRI 5187  ISO 7740 | |  | **Suction catheter** | ISO 8836 |  |
| Blood Lancet | ISIRI 8501  DIN 58916 | |  | **Needle catheters for peripheral vessels** | INSO 7325-5,1  ISO 10555-5,1 |  |
| Ureteral stent | ASTM F1828 | |  | **Central Vein Catheters** | INSO 7325-3,1  ISO 10555-3,1 |  |
| Surgical sutures | SANS 494  INSO 7327 | |  | **Angiography catheters** | INSO 7325-2,1  ISO 10555-2,1 |  |
| Fluid Transmission Pipe | INSO 8357-9  ISO 8536-9 | |  | **Ballooned catheters** | INSO 7325-4,1  ISO 10555-4,1 |  |
| Aluminum tubes | INSO 2149  BS 15421 | |  | **Set-Serum** | ISO 8536-4  INSO 8357-4 |  |
| Polyvinyl/Latex Examination Gloves | INSO 9552-1,2  ISO 11193-1,2 | |  | **Water Analysis** | INSO 1728  ISO 3696  ASTM D1193 |  |
| Don't get used to it. | ISO 1135-4  INSO 4638-4 | |  | **Chemical Indicator Validation** | INSO 8436-1  ISO 11140-1  ISO 15882 |  |
| Microset | INSO 8357-5  ISO 8536-5 | |  | **Biological Indicator Validation** | INSO 5610  ISO 11138 |  |
| Elongation Tube | ISIRI 7326-4  ISO 8536-4 | |  | **Gamma Ray Chamber Validation** | ISO 11137-1 |  |
| Catheter | ISIRI 4641  EN 1695-1 | |  | **Verification of ethylene oxide chamber gas** | INSO 7216-7  ISO 10993-7 |  |
| Angioket | ISO 10555-1  INSO 7325-1 | |  | **Symbols in medical devices (markup)** | INSO 8629  ISO 15223 |  |

|  |
| --- |
| Other Specialty Tests/Client Requirements |
| Description: |

**Admission Guide**

* **Please specify the place and type of exam based on the use of your product in the exams specified in the admission form. If needed, contact the counseling unit.**

**Biocompatibility (Animal) Tests**

|  |  |  |
| --- | --- | --- |
| Implantation Test / Implantation Test | | |
|  | Implantation in **the subcutaneous area** | Administration site |
|  | Implantation in the muscle area |
|  | Implantation in **the bone area** |
|  | Implantation in the area **of brain tissue** |

**Table No. (1)**

Description:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Irritation Test / Irritation Test | | | | | | |
| Skin | Intracutaneous | Chronic Skin (Frequent Exposure) | Penile | Vaginal | Acute Ophthalmic | Chronic Ophthalmic |

**Table No. (2)**

|  |  |  |  |
| --- | --- | --- | --- |
| / Systemic toxicity test | | | |
| Intraperitoneal injection (in the abdominal cavity)  ☐ | Intramuscular Injection  ☐ | Subcutaneous injection  ☐ | **Administration site** |
| Gavage (feeding the substance directly to the animal) | Intravenous (intravenous) injection  ☐ |

**Table No. (3)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| / Bioburden Test Acceptance Limit | | | |  |
| Route of administration | **TAMC**\*  (CFU/g/ml) | **TYMC** \*  (CFU/g/ml) | **Specified micro-organisms** |  |
| Non-aqueous preparations for oral use | 103 | 102 | Absence of Escherichia coli (1 g or 1 ml) |  |
| Aqueous preparations for oral use | 102 | 101 | Absence of Escherichia coli (1 g or 1 ml) |  |
| Rectal use | 103 | 102 | - |  |
| Oromucosal use  Gingival use  Cutaneous use  Nasal use  Auricular use | 102 | 101 | Absence of Staphylococcus aureus (1 g or 1 ml)  Absence of Pseudomonas aeruginosa (1 g or 1 ml) |  |
| Vaginal use | 102 | 101 | Absence of Pseudomonas aeruginosa (1 g or 1 ml)  Absence of Staphylococcus aureus (1 g or 1 ml)  Absence of Candida albicans (1 g or 1 ml) |  |
| Transdermal patches (limits for one patch including adhesive layer and backing) | 102 | 101 | Absence of Staphylococcus aureus (1 patch)  Absence of Pseudomonas aeruginosa (1 patch) |  |
| Inhalation use (special requirements apply to liquid preparations for nebulisation) | 102 | 101 | Absence of Staphylococcus aureus (1 g or 1 ml)  Absence of Pseudomonas aeruginosa (1 g or 1 ml)  Absence of bile-tolerant gram-negative bacteria (1 g or 1 ml) |  |
| Special Ph. Eur. provision for oral dosage forms containing raw materials of natural (animal, vegetal or mineral) origin for which antimicrobial pretreatment is not feasible and for which the competent authority accepts TAMC of the raw material exceeding 103 CFU per gram or per milliliter. | 104 | 102 | Not more than 102 CFU of bile-tolerant  gram-negative bacteria (1 g or 1 ml)  Absence of Salmonella (10 g or 10 ml)  Absence of Escherichia coli (1 g or 1 ml)  Absence of Staphylococcus aureus (1 g or 1 ml) |  |
| Special Ph. Eur. provision for herbal medicinal products consisting solely of one or more herbal drugs (whole, reduced or powdered):  — herbal medicinal products to which boiling  — herbal medicinal products to which boiling | 107 | 105 | Not more than 102 CFU of Escherichia coli (1 g or 1 ml)  Not more than 103 CFU of bile-tolerant  gram-negative bacteria (1 g or 1 ml) |  |
| Special Ph. Eur. provision for herbal medicinal products consisting solely of one or more herbal drugs (whole, reduced or powdered):  — herbal medicinal products to which boiling  — herbal medicinal products to which boiling water is not added before use | 105 | 104 | Absence of Escherichia coli (1 g or 1 ml)  Absence of Salmonella (10 g or 10 ml) |  |

**Table No. (4)**

|  |  |  |
| --- | --- | --- |
| / Ethylene Oxide Test Acceptance Limit | | |
| Device Category | **Ethylene Oxide Limits** | **Product type** |
| Limited (<24 hour) | 4mg |  |
| Prolonged (>24 h <30 day) | 60mg / 30 d |  |
| Permanent (>30 d) | 2.5g / lifetime |  |
| Tolerable contact limit (TCL) | 10μg/cm2 or negligible irritation |  |
| Intraocular lens | 0.5 μg/lens/d, 1.25 μg/lens |  |
| Blood cell separator (apheresis) | 10mg |  |
| Blood oxygenators | 60mg |  |
| Cardiopulmonary bypass devices | 20mg |  |
| Blood purification devices | 4.6mg |  |
| Drapes contacting intact skin | 10μg/cm2 or negligible irritation |  |

**Table No. (5)**

**LAL Endotoxin Test Acceptance Limit -**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Endotoxin test / Limit for acceptance of febrile test (Endotoxin LAL) | | | | |
| 20 EU/Device | **2.15 EU/Device** | **0.5 EU/ml** | **0.25 EU/ml** | **Other : ...........................** |

**Table No. (6)**

|  |  |
| --- | --- |
| **Company Name :**  **Date:** | **Signature and Seal of the Company** |