**TECHNICAL SPECIFICATIONS**

 **Characteristics of the supplies**

## Name of the Supplies

All supplies must be presented and labelled:

* + - under their **International Non-proprietary Name (INN) in the case of** essential generic medicines.
    - under the name by which they are identified in this invitation to tender (see table of Technical Specifications of Supplies), for medico-pharmaceutical consumables, medical equipment, laboratory reagents and equipment and dental products.

## Reference Pharmacopoeias

The pharmaceutical products delivered will comply with one of the following internationally recognised pharmacopoeias in their latest versions:

#### British Pharmacopoeia (BP)

* ***United States Pharmacopoeia (USP)***

#### European Pharmacopoeia (PhEur)

* ***International Pharmacopoeia (IP)***

#### Chinese Pharmacopoeia

If a pharmaceutical product delivered does not comply with one of these reference pharmacopoeias, the following steps will be taken:

* in his offer, the candidate is required to indicate this and to specify the reference Pharmacopoeia to which he is referring (e.g.: In-house specifications, Indian Pharmacopoeia, etc. )
* The Licensee shall provide the corresponding control protocol or analytical method (*Process*) and the necessary standard substances.

## Reference standards

Some particular supplies are described in the context of international standards systems. The systems used as references in the Contract are CE, ISO and AFNOR standards.

The specific areas of application of certain standards are detailed in Article 3 of the Technical Specifications.

## Origin of Supplies

### Preliminary definitions

For the purposes of this clause, "origin of supplies" means the place where the supplies are extracted, grown or produced.

Supplies are "produced" when, through manufacture, processing or substantial and essential assembly of components, a product is obtained which is recognised as being suitable for marketing and whose basic characteristics, purpose or utility are substantially different from those of its components.

The origin of the supplies is distinct from the nationality of the holder or the manufacturer.

### Application clauses

The Contractor is obliged to deliver under the Contract supplies corresponding to those described in its pre-qualification file, both in terms of quality and origin (manufacturer and country of origin), to the exclusion of any alternative.

The impossibility of complying with this clause must be duly reported and justified to the Beneficiary as soon as possible.

 **Packaging**

## Specifications and protection of packaging

The Supplies and their packaging must have the technical characteristics necessary for their use in the climatic conditions prevailing in Madagascar (climate zone IV a).

All packages shall be delivered hermetically sealed and shall have a locking device to identify any tampering.

The supplier is required to refer to the WHO technical recommendations. (WHO Technical Report Series 902, Annex 9).

**IMPORTANT NOTE: It is strongly recommended that the legal information on primary packaging (blisters, strips, ampoules, infusion bottles, etc.) be engraved. If not, they can be printed with indelible ink, and therefore not erasable.**

|  |  |
| --- | --- |
| ***Type of printing used for legal notices*** | ***Accepted/Rejected*** |
| ***Engraved text*** | ***Accepted*** |
| ***Erasable ink printing*** | ***Rejected*** |
| ***Printing with indelible ink*** | ***Accepted*** |

## Presentation of dry oral forms (tablets and capsules)

Tablets and capsules should be presented in unitary packaging. Preference will be given in the price analysis to unitary packaging (blister packs or strips). Bulk packaging is not accepted. (See Supply List).

|  |  |
| --- | --- |
| Type of presentation of oral forms | Accepted/Rejected |
| Tablets or capsules in a bottle | Refused |

|  |  |
| --- | --- |
| Tablets or capsules in blister packs | Accepted |
| Tablets or Capsules in strips | Accepted |

### Presentation in unitary packaging:

Unitary packaging will be done according to one of the following options:

* under transparent film ;
* under opaque film ;
* in blister packs ;
* in plates with individual cells or *strips*, each cell containing all the information required to identify the product and the batch.

### It is strongly recommended that the legal information on the primary packaging (blister packs, strips) be engraved. If not, they can be printed with indelible ink, which cannot be erased.

The option chosen by the applicant and the materials used for the manufacture of the films or plates must guarantee good conservation of the products in the climatic conditions of Madagascar: resistance according to the chemical nature of the medicines, to air, humidity, light and heat.

* In order to be able to judge the relevance of its proposals, the applicant shall provide all the technical documentation relating to it, as well as the required references (pharmacopoeias, etc.).

### Presentation of injectable forms

Unless otherwise specified for a particular product, injectable solutions shall be packaged either in double-ended ampoules or in bottled ampoules. Solutions of a volume equal to or greater than 5 ml must be presented in bottled ampoules. Both forms of ampoules accepted must be self-closing.

Powders for reconstitution of solutions or suspensions for injection will be packaged in individual glass vials with aluminium/plastic caps and Flipp-Off closures.



*Fipp-Off capsule*

Water for Injection will be packaged in semi-rigid plastic bottles with an easy-to-open lid.

### Presentation of infusion solutions

Unless otherwise specified for a particular product, infusion solutions should be packaged using one of the following processes:

* or in *flexible bags*, made of material in conformity with the European Pharmacopoeia or in any other complex (formula to be indicated and Pharmacopoeias or reference standards to be specified), packaged according to a double packaging system;
* or in *rigid or semi-rigid plastic bottles*, in accordance with the European Pharmacopoeia.

The caps of the bottles must be made of a material that guarantees watertightness during use (EURO HEAD). NIPPLE HEAD" type vials will not be accepted unless the technical evaluation committee advises otherwise.

|  |  |
| --- | --- |
| Vial closure system for infusion solutions | Accepted/Rejected |
| DOUBLE PORT FOIL PLUG | Accepted |
|  | Accepted |

|  |  |
| --- | --- |
| NIPPLE HEAD TYPE PLUG | Rejected |

### Primary packaging :

The labelling of each box of bulk packaged medicines and each unit of packaging of medical devices shall be in accordance with WHO Good Practice Standard W210, and shall indicate in French or, failing that, in English:

* the name of the product under the International Non-proprietary Name,
* the dosage and the pharmaceutical form,
* the applicable pharmacopoeia standard
* the full name and address of the manufacturer,
* the batch number, date of manufacture and expiry date,
* any special storage conditions,
* the number of units contained in each packaging unit.

Tablets and capsules packaged in film or blister packs should be labelled with the international non - proprietary name, strength, batch number and expiry date either on each blister or on the blister. The box containing these films or blisters should be labelled in the same way as the bulk box.

Injectable ampoules should have these words written in indelible, non-erasable ink or engraved on each ampoule.

This information should be printed in indelible ink and therefore not erasable, or labelled on each other medicinal product and medico-surgical consumable presented in individual packaging.

***Any medicinal product offered in individual packaging must contain a legible leaflet in French, however the leaflet in English is accepted duly accompanied by its translation into French.***

### Secondary and tertiary packaging :

In addition to the compulsory information required by the pharmaceutical legislation of the country of origin of the product, the outer label of the assembly unit (carton) must mention in French:

* + - * the name of the product under the International Non-proprietary Name,
      * the dosage and the pharmaceutical form,
      * the full name and address of the manufacturer,
      * batch number, date of manufacture and expiry date,
      * special storage conditions,
      * the number of boxes contained in each packaging unit (carton).

### Product information leaflet

Each medicinal product supplied under the Market will be accompanied by a short leaflet summarising the main information available on the nature of the product, its conditions and precautions for use, and its storage conditions.

This leaflet will be attached to each primary packaging of the product and will be in a sales model version.

The notice must be written in French and in legible characters. A notice in English is accepted duly accompanied by its translation into French.

The text of the leaflet will present successively and at least the following information about the product:

\*Detailed unit composition: nature and dosage of active ingredient(s) and excipients;

\*The reference pharmacopoeia

\*presentation and form

\*Property of the product

\*The fate of the product in the body (pharmacokinetics);

\*therapeutic indications ;

\*instructions for use and dosage (adult and paediatric standards) \*\* ;

\*contraindications;

\*side effects and adverse reactions;

* the list of excipients
* the list of excipients with notable effects

\*Drug interactions (incompatibilities);

\*precautions for use and any warnings required; in pregnant and breastfeeding women.

\*conditions and precautions for storage and preservation.

* the full name and address of the manufacturer.

\*\* For drugs used in oncology, chemotherapy doses shall be expressed in milligrams per square meter of body surface area (mg/m2 )

 **Technical compliance of supplies**

The following standards apply to the technical specifications of certain categories of articles.

***All medical consumables regardless of type must contain a label indicating full legal informations : Expiration date, manufacturing site, batch number, name and address of the manufacturer.***

## Technical compliance of massive solutions for injection (isotonic saline, glucose, sodium bicarbonate solution, Ringer lactate solution, mannitol)

The vials must be of the EURO HEAD type. (see 2.2.3 Presentation of infusion solutions)

## Technical compliance of injectable ampoules

All injectable ampoules must be self-closing or, failing that, fitted with a file.

## Technical compliance of hydrophilic non-woven compresses

Sterile non-woven hydrophilic compresses should be made of purified cellulose, 10 cm x 10 cm and 20 cm x 10 cm in folded format, with a weight of 40g/m2 , and 4 layers. Their absorption capacity should be 10g/l. The breaking strength should average 35 N/5cm and 14 N/5cm across. They must not fray. They must have a bacterial contamination of less than 100 cfu/g.

They will be packaged in packs of 10 in tamper-evident packaging, bearing the regulatory markings.

## Compliance of Vitamin B complex tablets and injectables

Tablets :

* + - Composition per coated tablet: Thiamine or vitamin B1 - 15mg

Riboflavin or vitamin B2 -15mg Nicotinamide or Vitamin PP- 50mg Pyridoxine or vitamin B6-10mg

Calcium Panthotenate or Vitamin B5- 25mg

Solution for injection :

* + - Composition per 2ml ampoule: Thiamine or vitamin B1 - 10mg

Riboflavin or vitamin B2 -5.47mg Nicotinamide or Vitamin PP- 40mg Pyridoxine or vitamin B6-4mg

Calcium panthotenate or vitamin B5- 6mg

## Technical compliance of probes

* + - Nasogastric tubes should be clear thermosensitive PVC with ORX line, open distal end, 4 side ports, centimetric marking 5-75 cm, 100-125 cm long.
    - Gastric lavage tubes (Faucher tube) should be made of heat-sensitive PVC, open distal end, 4 side ports, marking every 5 cm from 15 to 75 cm, length 150 cm
    - Oxygen probes should be PVC, 40 cm long, end port, 8 side ports, universal tip, green in colour.
    - Bronchial suction catheters (De Lee type) should be PVC, open end, straight and blunt, one side port, 27 cm long for CH 8, 47 cm minimum length for CH 14, CH 16.
    - Foley bladder catheters should be 40 cm long, straight cylindrical, silicon latex, 2 or 3 way with a 30 ml balloon.

All probes must be

* + - * single-use ;
      * sterile and non-pyrogenic;
      * Packaged in an individual sterility protector in the form of a peelable bag bearing the regulatory information and all the indications for use.

## Technical compliance of synthetic wadding

The synthetic orthopaedic wadding, which can be sterilised in an autoclave, is made of 100% polyester water-repellent synthetic fibres. The required dimensions are 7.5 cm x 2.7 m.

The packaging will be individual, and a grouping can be made by 12 in tamper-evident packaging.

## Technical compliance of plasters

Plasters with a size of 10 cm x 5 m and 18 cm x 5 m perforated must meet the following requirements:

* roll of zinc oxide woven plaster, flesh-coloured or white, consisting of a hand-breakable cellulose acetate backing
* coated on one side only with a zinc oxide adhesive mass of normal skin tolerance, with high and prolonged adhesion and easy handling for the user. **Unsatisfactory adhesion will not be accepted**.
* perforated, hydrophobic, with serrated edge,
* with embossed polyethylene protector,
* and packaged in individual protective packaging with all the relevant information.

## Technical compliance of epicranial needles (micro infusers)

* Epicranial needles (micro infusers) must meet the following standards: NFS 90 011, 90 013, 90 015, ISO 594-2, CE
* They will have the following components:
* a triple-bevelled needle;
* a needle protector;
* two standard coloured fins (green for the 21G micro infusers and blue for the 23G micro infusers);

 a transparent soft PVC tube, 30cm long;

 a PE luer-lock end cap, 6% taper, with obturator.

 Each epicranial needle should be packaged in an individual peel-off blister pack, with all the indications for use, and grouped in boxes of 100.

 Sterilisation with ethylene oxide.

## Technical compliance of catheter needles

Catheters must comply with AFNOR NF S 90-040 standards. Catheters must have :

 a siliconised, triple-bevelled needle with an orientation pin for easier and less traumatic

penetration;

 a cannula at least 40 mm long for catheters below Gauge 20

 flexible wings for secure and comfortable attachment

 a transparent reflux chamber with hydrophobic membrane plug and universal plug.

 An injection site Catheters must be :

 single-use ;

 sterile and non-pyrogenic;

 packaged in an individual sterility package in the form of a peelable blister bearing the regulatory information and all the indications for use.

## Technical compliance of infusers

The infusers must comply with the following standards: AFNOR: NF S 90 202 or ISO 8536-4 or European Pharmacopoeia (EC). No leakage in the device is tolerated.

The infuser shall include the following components:

* a perforator with a built-in air intake with a hydrophobic membrane that can be closed by a valve, ensuring bacteriological filtration of the air;
* a transparent semi-rigid chamber with a dropper calibrated at 20 drops/ml, with a volume of 8 ml, with an optional particle filter with a porosity of 15 microns
* a flow regulator with roller clamp;
* a transparent PVC pipe with an internal diameter of 3 mm and a minimum length of 170 cm;
* a device for extemporaneous injections (Y-site or 3-way tap) located at least 20 cm from the end-piece. Injection sites located less than 20 cm from the end-cap are not accepted.
* Please note: the new HIV transmission precautions regulations prohibit rubber injection sites interspersed in the PVC line.
* a male luer lock terminal;
* a 20 G vein needle with

## Technical compliance of transfusion devices

Transfusers must comply with AFNOR standards: NF S 90 202 or ISO 8536-4 or European Pharmacopoeia (EC). No leakage in the device is tolerated.

The transfuser shall have the following components:

a perforator with a built-in air intake with a hydrophobic membrane that can be closed by a valve, ensuring bacteriological filtration of the air;

a transparent semi-rigid chamber with a dropper calibrated at 20 drops/ml, with a volume of 8 ml, with a 10 cm filter2 with 200 micron mesh;

a flow regulator with roller clamp;

a transparent PVC pipe with an internal diameter of 3 mm and a minimum length of 170 cm An injection site or device for extemporaneous injections (Y-site or 3-way tap) located at least

20 cm from the end-piece. Injection sites located less than 20 cm from the end-piece are not

accepted.

Please note: the new HIV transmission precautions regulations prohibit rubber injection sites interspersed in the PVC line.

a male "luer lock" terminal;

an accompanied 21G vein needle.

## Compliance of urine collection bags

It must comply with ISO or NFS 90-631 standards.

The urine collection bag shall have the following characteristics: made of transparent PVC with a white bottom, graduated in 100 ml, with a nominal volume of 2 litres, with a non-return valve and a push-pull drain cock. It is equipped with 2 reinforced suspension holes, a translucent tube 90 cm long, with an internal diameter of 5 mm, a notched connection with a cap, conical, standardised, adaptable to all bladder catheters and penile bags.

## Technical compliance of X-ray films

X-ray films should be manufactured to ISO 9002 or EN 46002 standards. They should be spaced or tropicalised (with certificate).

## Compliance of surgical gloves

Sterile surgical gloves should meet AFNOR standards: NF S 90 000, EN 455, or ISO.

Sterile single-use surgical gloves must meet the following requirements: made of natural latex, internally powdered with FDA-approved corn starch, anatomically shaped with indication of right and left hand in the double wrapper, with a cuff with a rolled edge reinforced wrist, hypoallergenic.

Size 7 surgical gloves should have the following dimensions: length at least 270 mm, width at palm 89 mm +/- 5 mm.

Size 7 ½ surgical gloves should have the following dimensions: length 270mm minimum, width at palm 95mm +/- 5mm.

Particular attention should be paid to flexibility, elongation at break, tensile strength, thinness and ease of donning. The double packaging must be easily peelable (sagittal opening), to avoid aseptic errors as much as possible. Scissor-cut packaging is not accepted.

Single-use sterile surgical gloves will be packaged in pairs, in double-wrapped sagittal opening bags, and grouped in a box of 50 pairs.

## Technical compliance of non-sterile examination gloves

Non-sterile examination gloves must comply with AFNOR NFS 90 001 or ISO

###  Compliance of non-sterile latex examination gloves size medium (7/8)

Non-sterile latex gloves must have the following characteristics: natural latex, with an inner coating of bio-resorbable corn starch. They must be ambidextrous in shape, with a rolled edge reinforcement at the wrist, and hypoallergenic.

The required dimensions are as follows: medium size (7/8), minimum length 230 mm, palm width 95 mm +/- 10 mm, minimum thickness 0.08 mm.

###  Compliance of non-sterile latex examination gloves size small (6/7)

Non-sterile size 6/7 latex examination gloves must have the following characteristics: natural latex, with an inner coating of bio-resorbable corn starch. They must be ambidextrous in shape, with a rolled edge wrist reinforcement, and hypoallergenic.

The required dimensions are as follows: size small (6/7), minimum length 230 mm, palm width 80 mm

+/- 10 mm, minimum thickness 0.08 mm.

The qualities of suppleness, resistance and finesse will be particularly observed.

## Technical compliance of scalpel blades

Scalpel blades should meet BS 2982 or ISO 7740 standards.

They must be made of stainless steel, gamma sterilised, and packaged in individual peelable, easy-to- open (sagittal opening) boxes of 100 slides. Carbon blades are not accepted.

## Technical compliance of wires and ligatures

Wire and ligatures shall meet ISO 9000 or 9001, or EN 46001 standards.

Loose wires should be packaged in a spool that allows for easy unwinding of the wires.

## Technical compliance of vitamin C 500mg tablets

In addition to the section on Reference Pharmacopoeia of pharmaceutical products and their packaging, the information described below is specifically applicable to the following product:

Vitamin C or ascorbic acid 500mg tablets should be of the 'chewable' or 'suckable' type. This should be clearly visible on the blister packs and on the boxes.

## Technical compliance of insulins

Insulins should be in injectable suspension, of biogenetic human origin, pure or mixed according to their indications, and presented :

* 10ml bottle containing 100 IU per ml of suspension.
* or in 3 ml cartridges containing 100 IU per ml of suspension, packed in boxes of 5 or 10 cartridges.

## Technical compliance of sterile protection kits

Protective kits must be made of non-woven material: caps, masks, headgear (15 g/m²), gowns (20 g/m²), overshoes (20 g/m²)

## Ban on advertising on packaging

Packaging of an advertising nature is not permitted. **(Words or images tending to self-medication or over-consumption)**

## International recommendations on the progressive use of calcium gluconate solutions packaged in plastic containers

In order to limit patient exposure to aluminium, it is recommended that calcium gluconate solutions be used in plastic containers.

## Reagent compliance

Manufacturers must follow the standards:

ISO 13485 for laboratory reagents and consumables

ISO 9000 series for products that do not fall into the ISO 13485 category.

## Compliance of arteriovenous lines with haemodialysis needles

* Universal line for Dialog, Gambro, Althin, Fresenius.
* Sterilisation method: Radiation (validated for beta and gamma).
* Colour coded patient clamp, 2l drainage bag, Spike.

## Compliance concerted solutions of acids for haemodialysis.

Packaging: 5L or 10L can Composition:

1000ml of purified water contains:

* + - Sodium Chloride 210.7 grams or 138mmmol/l ±5%.
    - Calcium Chloride 7.72grams or 1.50 mmmol/l ±5%.
    - Potassium Chloride 5.22 grams or 2.00 mmmol/l ±5%.
    - Magnesium chloride 7.12 grams or 1.00 mmmol/l ±5
    - Acetic acid 6.31 grams or 3.0 mmmol/l ±5%. The legal information on the can should be clear and complete.

## Compliance of dialysis machines or artificial kidneys

* High performance, low flow dialyser (F6= 1.3 m2 ; F7= 1.6 m2 ; F8= 1.8 m2) ,
* α Polysulfone, sterilization by oxygen-free gamma radiation.
* Ultrafiltration coefficient ml / h / mmHg QB = 300 ml / min 11-17;
* Clearance (dialysate flow rate = 500 ml / min, ultrafiltration rate (QF) = 0 ml / min) Urea: 192-310, creatinine: 180-290, phosphate: 150-220, vitamin B12: 90-130
* The packaging must contain all relevant information: surface, marking, nature of sterilisation, batch, sterilisation date and expiry date.

## Compliance of double flow catheters for haemodialysis

* Double lumen catheter 15-20 cm, incl.
* 18 G (1.3 mm) valve cannula,
* Marked guide wire with flexible J-tip in dispenser, 12 Fr dilator, scalpel, injection plug, connection cable for intra-auricular ECG probe, syringe: 5 ml,
* Priming volume: 12-14 ml
* Flow rate: 200 - 240 ml / min distal; 240-270 ml / min proximal
* DEHP-free

## Compliance of bicarbonate cartridges for haemodialysis

Compatible with original dialysis machines, bicarbonate powder or granule cartridge in sufficient quantity for one dialysis session, 650g. Bag packaging is not accepted.