MINISTRY OF NATIONAL DEFENSE ARMY MILITARY HEALTH SERVICE MEDICAL SUPPLY ORGANIZATION	TECHNICAL SPECIFICATIONS FOR MEDICATIONS أدوية	Specification №: AHC25CON-MEDI-001-I

A- All the items mentioned in the following list must comply with the following clauses and conditions:

1. Comply with the standards and regulations of one of the EMA, FDA, Japanese pharmacopoeia, and WHO recommendations.
2. Be registered by the Pharmaceutical Service Department of the Lebanese Ministry of Public Health (MOPH). (**Official Registration**)
3. Be delivered in their original packaging, as registered.
4. Accept any "Hospital Packaging" in the form of sachets, presented in accordance with applicable laws and decrees.
5. Be valid for a minimum period of **eighteen full months** from the date of delivery. Otherwise, the supplier must agree to exchange any unused quantity upon its expiration date, piece for piece or value for value.
   In any case, the supplier must formally commit to exchanging any unused quantity, piece for piece or value for value, within **three months** from the date of notification by the Military Healthcare Service.
6. Be governed by the law of the Pharmacy Profession Practice, as well as the applicable Lebanese decrees and laws.
7. The items mentioned in a group with the same sequential number are considered "Therapeutically Similar" and the selection of one of these items will be based on the lowest "Treatment Cost".
8. The quantity mentioned for each group of similar items refers to the unit of the first item listed in that group. However, this quantity is recalculated proportionally to the units of the other similar items mentioned in the same group.
9. The quantity mentioned for each group may be modified (increased or decreased) as needed.
10. Intravenous infusions must be delivered in appropriate boxes, containing no more than 20 liters of infusions per box.
    However, individual labeling of both the content and the container for product identification, usage instructions, composition, and expiration date is essential.
11. Any medication locally manufactured under the license of a research laboratory from one of the reference countries in production, drug control, and clinical trials will be accepted.
12. Any medication considered a "Copy", whose Intellectual Property Rights (Patent) is simultaneously valid in the United States and Europe, will be eliminated.

13. Any medication with a quality issue (Efficacy, Stability, Sterility, Clinical Evaluation, Therapeutic Effects, and/or Side Effects…) will be eliminated.
    The WHO, FDA, EMA, the Lebanese Ministry of Public Health, and the Military Healthcare are reference authorities.
14. All required documents for the evaluation of medications must be submitted with the technical offer.

B- The medications will be divided into three groups A, B, and C:

1. **Group A:**
   The medications must formally satisfy the previously mentioned 14 conditions and one of the following two conditions:
   (a) **Manufactured**, **Approved**, and **Used** in **one** reference country.[1]
   (b) **Approved** and **Used** in at least **two** reference countries.

2. **Group B:**
   The medications must formally satisfy the previously mentioned 14 conditions and one of the following two conditions:
   (a) **Approved** and **Used** in **one** reference country.
   (b) Products that are locally manufactured, approved, and used in the Lebanese Market will be accepted, provided they satisfy the conditions of Group C mentioned below, and the pharmaceutical factory has at least **five years** of experience in the Lebanese market.

3. **Group C:**
   Medications approved by the **FDA** or **EMA** and medications approved and used in **one** reference country will be accepted.
   Otherwise, all the following conditions must be applied:
   (a) The first 14 conditions mentioned above (In Section A)
   (b) A valid GMP Certificate
   A GMP certificate is valid for **three years** from the most recent date of inspection.
   (c) Presentation of documents concerning the quality of the medications (Bioequivalence, Bioavailability...).[2]
   Analyses must be carried out according to the Standards and Regulations of the WHO, FDA, or EMA and issued by independent specialized centers with a valid GLP certificate authorized by the Ministry of Health of the country of origin.

[1] Reference Countries – Cf. Appendix
[2] Tests Required – Cf. Appendix

(d) One of the following conditions must be applied:

i. Have a positive evaluation study by the Military Healthcare.
   Primary approval of the Study/Evaluation is necessary.
ii. Already used by the Army – Military Healthcare without any doubt or quality issues.
iii. Locally manufactured, approved, and used in the Lebanese market for more than **two years** from the date of the **official** registration.
iv. Having a local market share according to the IMS specific to the molecule itself exceeding 20%, **twelve months** before the date of adjudication.
   For hospital-use forms (Injectable Forms), they must be accepted in at least **two** of the reference hospitals.[3]

(e) The Stability Test must comply with the Standards and Regulations of the ICH (International Conference on Harmonization).

[3] Reference Hospitals – Cf. Appendix

APPENDIX

1- The countries classified as Reference in drug production, control, and clinical trials are: Austria, Australia, Belgium, Canada, Denmark, France, Finland, Germany, Italy, Ireland, Japan, Netherlands, Switzerland, Spain, Sweden, UK, and USA.

2- Tests required:

Form	Tests Required
Solid forms (Systemic Effect)	Bioequivalence or Bioavailability and Dissolution Test. Biowaiver if applicable
Ampoules, Serums, and Eye Drops	Sterility, Pyrogenicity, and Impurity tests of the active ingredient
Syrups and Elixirs	Microbiological tests
Suspensions	Microbiological tests, Bioequivalence, and dose uniformity
Creams, Ointments, Nasal and Ear Drops (Local Effect)	Microbiological tests
Nasal and Oral Sprays (Systemic Effect)	Microbiological tests and Bioequivalence

3- Reference Hospitals: AUBMC, HDF, Rizk and Saint Georges - Achrafieh.