

ANNEX 1 : PHARMACEUTICAL PRODUCT QUESTIONNAIRE

Please Note: Adjudication criteria are mentioned under each question, (where applicable), *in Italics*.

I Product identification

Product Number of this tender:.....

Active Pharmaceutical Ingredient(s) (use INN where it exists):

.....

Generic name of the product:

.....

Dosage form : Tablets Capsules Injection Oral solution Other:
Strength per dosage unit:

.....

Route of administration : Oral Intramuscular
 Intravenous Subcutaneous
 Other:

Description of primary packaging:.....

Description of secondary packaging:

Pack size: 50 100 1000 1000ml Other

List the standard batch size:

I.1 Attach the formula per unit if not attached to the CPP (section IV.2)

Absence of the unit formula may lead to disqualification of the product for the LICB

II. Manufacturer of the product

Name, address and activities of the manufacturer (or contract manufacturer and any additional primary packers):

Name	Physical address	Telephone number, Facsimile number and e-mail contact details	Activity (e.g. packaging)

II.1 The site(s) listed above is licensed by the relevant Regulatory Authority to perform the activity?

Yes No

Answer "No" may lead to disqualification of the product for the LICB.

II.2 Is the manufacturing site pre-qualified by WHO for GMP compliance under the TB Prequalification Project?

Yes No

Please attach a copy WHO notification of GMP Compliance under the TB prequalification Project

II.3 Is the manufacturing site certified for GMP compliance by a stringent Regulatory Authority party to the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use?

Yes No

Please attach a copy of the notification of GMP Compliance by the stringent Regulatory Authority

Answer "No" to both sections II.2 and II.3 may lead to disqualification of the product for the LICB

III. Supplier identification

(to be filled in if not identical to that indicated in question II)

Name.....

Address:
.....
.....

Telephone number:.....

Facsimile number:.....

E-mail:.....

III. 1 Please submit a "Letter of Authority" issued by the manufacturer uniquely for the intended LICB.

Absence of the letter may lead to disqualification of the product for the LICB.

Link with the product:

- Marketing license holder
- Distributor
- Manufacturer
- Other (Please indicate)

IV. Regulatory situation (licensing status) in the country of manufacture

Product registered and currently marketed
license n°.....
Please attach a copy

Product registered for export only
license n°.....
Please attach a copy

IV.1 Product has to be either registered for use in the country of manufacture or has to be registered for export to qualify.

IV.2 Please attach a Certificate of Pharmaceutical Product (CPP) according to the WHO Certification Scheme to qualify (WHO Technical Report Series No. 863. Earlier version is not acceptable).

V. Regulatory situation (licensing status) in other countries

List other countries (and licensing numbers) where the product is registered (*per product*) and is currently marketed:

.....

V.2 Dossier submitted to WHO Prequalification Project?

Yes No

If "Yes", please state application number

VI. Finished product specifications

- BP Edition (year)
 USP Edition (number and year)
 International Pharmacopoeia. Edition (Volume and year)
 Other

Limits for the content (assay; in percentage of label claim) for each API in the product:

95-105% 90-110 % Other (specify)

Each API (use INN):

.....

VI.1 Please attach a copy of the finished product specifications, if different from BP, USP or International Pharmacopoeia monograph specifications. If specifications additional to the BP, USP or International Pharmacopoeia monograph has been set (for instance additional related substances) these should be submitted.

Absence of copy may lead to disqualification of the product for the LICB

VI.2 Attach a copy of a valid certificate of analysis (CoA) for a production batch.

Absence of copy of CoA may lead to disqualification of the product for the LICB

VI.3 Are you willing to provide necessary information (analytical methods) for the tests to be replicated by another control laboratory?

Yes No

"No" may lead to disqualification of the product for the LICB

VII. Stability

VII.1 Stability testing data available:

Yes No

Answer “No” may lead to disqualification of the product for the LICB

If yes, type and conditions of testing:

VII.2 Real time testing, with test results at every 3 months in the first year, every 6th month in the second year, and then annually. Testing conditions:

- 25±2°C/ 60±5 % RH
- 30±2°C/ 65±5 % RH
- 30±2°C/ 75±5 % RH
- Other (please specify)
- Not done

Answer “Not done” may lead to disqualification of the product for the LICB

VII.3 Accelerated testing. Testing conditions:

- 40±2°C/ 75 ±5 % RH/ 6 months
- Other (please specify)
- Not done

Answer “Not done” may lead to disqualification of the product for the LICB

VII.4 Were the stability studies conducted on the product packaged in the same packaging as specified under point I (page 1),

Yes No

Answer “No” may lead to disqualification of the product for the LICB

VII.5 Were the stability studies conducted on the product manufactured using the same unit formula as specified under point I or point IV.2?

Yes No

Answer “No” may lead to disqualification of the product for the LICB

VII.6 Attach stability report(s)

Absence of stability report(s) may lead to disqualification of the product for the LICB

VIII. Label and insert information

VIII.1 Shelf-life: 5 years 4 years 3 years 2 years Not determined

Answer “Not determined” may lead to disqualification of the product for the LICB

VIII.2 Attach label and insert information

Absence of label and insert information may lead to disqualification of the product for the LICB

IX. Samples

IX.1 Free non-returnable samples, with insert information, to be submitted with the Pharmaceutical Product Questionnaire

Answer “No” may lead to disqualification of the product for the LICB

X. Therapeutic equivalence

X.1 Evidence establishing the safety and efficacy of the proposed product should be submitted, in compliance with WHO Guidelines and Good Clinical Practices. (See WHO Technical Report series, No. 937, Annex 7: Multi-source (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability)

Therapeutic equivalence is demonstrated:

By in vivo bio-equivalence studies

- Reference product:
 Number of volunteers:
 Country of study:
 Performed (year):
 Organization (that performed study) and Study Number:

Or by another method claimed by the supplier/manufacturer

(Please describe briefly):

Or by comparative in vitro dissolution testing (see WHO Technical Report series No.937, Annex 7 for dissolution testing requirements and determination of dissolution profile similarity and Annex 8 for APIs that may be acceptable for biowaiver dissolution studies according to the BCS)

- Reference product:
 not demonstrated not relevant unknown

X.II Attach copy of the study report (*in vivo* or *in vitro*), unless not relevant

Absence of in vivo bioequivalence and/or in vitro study reports, as appropriate, may lead to disqualification of the product for the LICB

XI. Active Pharmaceutical Ingredients(s) (APIs)

(In case more than one API is used, answer this question for each API.)
(In case more than one manufacturer for a particular API is used, answer this question for each manufacturer of that particular API)

Manufacturer (name, physical address + country):
.....

XI.1 GMP certified by:

- Yes** (attach a copy of the GMP certificate if any) **No** **Unknown**

Answer "No or Unknown" may lead to disqualification of the product for the LICB

XI. 2 Specifications and standard test methods exist for each API and excipient

- Yes** **No**

Answer "No" may lead to disqualification of the product for the LICB

XI.3 Has a valid Certificate of suitability to the European Pharmacopoeia (CEP) been issued?

- Yes** **No**

Certificate N°:

A copy of the CEP is in our possession (including annex if any)

If it is, attach a copy of the CEP and annex

XI.4 Has a Drug Master File (DMF) has been submitted to (specify country(ies)):

Yes No

XI.5 A copy of the closed or open part of the DMF is in our possession

Yes No

Answer "No" to all of XI.3, XI.4 and XI.5 may lead to disqualification of the product for the LICB

XI.6 Quality standard for API(s):

BP USP PhEur International Pharmacopoeia

Other (e.g. "in-house")

Please attach a copy of the API specifications, if different from BP, USP, PhEur or International Pharmacopoeia monograph specifications. If specifications additional to the BP, USP or International Pharmacopoeia monograph has been set (for instance additional related substances, residual solvents or particle size) these should be submitted.

Absence of copy(ies) may lead to disqualification of the product for the LICB

No Pharmacopoeia monograph exists*

***If there is no monograph in a recognized Pharmacopoeia, then the following information should be provided for each relevant API:**

XII. Information of non-compendial APIs:

- The chemical structure, INN and systematic name, molecular formula and relative molecular mass.
- If relevant, the isomeric nature of the API, including stereochemical configuration (e.g. pure enantiomer, racemate, cis- and trans-isomers).
- The solubility of the active ingredient in water (indicate temperature);
- The solubility of the active ingredient in other solvents such as ether, dichloromethane, ethanol, acetone, and buffers at different pH values (if the active ingredient is acidic and/or basic),
- Other relevant physicochemical characteristics of the active ingredient such as partition coefficient (usually octanol/water) and the existence of polymorphs;
- Copies of infrared, nuclear magnetic resonance (proton and C-13), ultraviolet and mass spectra with assignment and/or discussion to indicate structure correctness;
- Information on the chemical stability of the API, and on physicochemical stability if relevant (e.g. formation of a hydrate, change of polymorphic form).

XIII. Commitment

I, the undersigned, _____,
 _____(position in the company, e.g. General Manager, Authorised Person, Responsible Pharmacist), acting as responsible person for the company _____(name of the company), certify that the information provided (above) is correct and true (if the product is marketed in the country of origin, tick the

adequate following box) and I certify that the product offered is identical in all aspects of manufacturing and quality to that marketed in (country of origin), including formulation, method and site of manufacture, sources of active and excipient starting materials, quality control of the product and starting material, packaging, shelf-life and product information.

and I certify that the product offered is identical to that marketed in (name of country),
except:

.....
(e.g. formulation, method and site of manufacture, sources of active and excipient starting materials, quality control of the finished product and starting material, packaging, shelf-life, indications, product information)

Date:.....

Signature.....