

Check List for Prequalification

1. Manufacturer / Supplier Company Profile

- i. Name, address, site address & contact details of manufacturer/supplier
- ii. Manufacturing experience (no. of years), company history
- iii. GMP certificate
- iv. International standards of the plant – medical devices

2. Product Information

- i. Analytical report of finished product
- ii. Analytical report of active pharmaceutical ingredients
- iii. Stability data
- iv. Annual turnover for the product
- v. COPP certificate – pharmaceuticals/free sale certificate for medical devices
- vi. NMRA Certificate (certified copy)
- vii. Bio Equivalence data

3. Local Agent's Information

- i. Name, address & contact details

4. Letter of Authorization from the manufacturer/supplier to represent as the Local agent

5. Manufacturer Financial information for latest 03 years in English

- i. Auditor Authorized or signed statement of Cash flow
- ii. Auditor Authorized or signed statement of Financial Position or Balance sheets
- iii. Auditor Authorized or signed statement of Income & statement of Profit & Loss
- iv. Authorized or signed Independent Auditors' reports
- v. If submitting translated financial statements should certify by authorized translator on the translated copy.

- vi. If the Subsidiary company submitting Financial statement of parent company's or Mothers company should attach the proof documents or certified letter from parent company and claim that subsidiary does not prepare separate financial statements.
- vii. Other necessary documents.

General Remarks.

- GMP certificate & COPP **for the pharmaceutical items** should be certified as true copies by the Sri Lankan Embassy in the country of manufacture. (If the originals are not submitted)
- ISO & Free Sale certificates **for the surgical items** should be certified as true copies by the Sri Lankan Embassy in the country of manufacture. (If the originals are not submitted)
- ISO certificate web link of the accreditation body can be submitted instead of the authorization of the Sri Lankan ambassador.
- All pages of the documents submitted with the application should be numbered. A list of documents submitted with folio numbers to be included as the first page. (Index)
- The prequalified suppliers are removed from the PQ list once their NMRA registration is expired. The prequalification status would be reinstated once a certified copy of re-registration certificate is submitted. Certificate should be certified by an attorney at law/JP.
- Stability data should be submitted for different dosage forms of the same product.
- Copies of COPP and registration certificates of evidence countries should be submitted.
- Each SR number will be considered as a separate item and payment should be made for each SR number.
- One guideline should be filled for each SR number.