

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. Cash flow statement
- ii. Balance sheet
- iii. Profit & loss account
- iv. Independent Auditors' reports

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.