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's Financial information for latest 03 years (in English)

i. Cash flow statement
ii. Balance sheet
iii. Profit & loss account
iv. Independent Auditor's reports

General Remarks.

- GMP / COPP / Free Sale / ISO Certificates should be certified as true copies by the Sri Lankan Embassy in the country of manufacture. (If originals are not submitted)
- 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.
- For surgical items catalogues to be submitted whenever possible.