

[Letterhead of the Manufacturer]

Include company logo, full address, phone, email, and website

[Date]

Chief Executive Officer,
National Medicines Regulatory Authority
Sri Lanka

Declaration regarding local representation, manufacturing site status, readiness for inspection, and accuracy of submitted documents

Dear Sir/Madam,

We, **[Name of Manufacturer]**, located at **[Manufacturing Address]**, hereby submit the following declarations in support of our application for the site registration.

1. Local agent representation

We confirm that we have not appointed any other local agent or representative for this application other than **[Name & address of local agent]**. No other entity is authorized to act on our behalf in this matter.

2. Manufacturing Site Status

We declare that the manufacturing operations are carried out as follows:

- **Site Address:** [Manufacturing site address]
- **Site Status:** [Tick]
 - ☐ Own manufacturing site
 - ☐ Contract manufacturing site
 - ☐ Other: [Please specify]

3. Readiness for Inspection

We confirm that the above-mentioned manufacturing facility is fully prepared and available for inspection by the relevant regulatory authority upon request.

4. Accuracy of SMF and submitted documents

We hereby declare that the Site Master File (SMF) and all other documents submitted along with it are true, accurate, and complete to the best of our knowledge and belief.

We fully understand that providing false or misleading information may result in rejection or withdrawal of the registration or approval.

Should further information be required, please do not hesitate to contact us

Sincerely,

.....

Name of the Signatory:

Designation:

Company Seal: