Appendix 1:
Declaration of Sameness and Compliance for the New Route

I/We, the undersigned, hereby declare and confirm that:

1. The product submitted to NPRA under the new route has obtained marketing authorisation approval from the chosen reference agency.
2. The approval issued by the chosen reference agency and referenced in this application is valid and was granted not more than three (3) months prior to submission to NPRA.
3. The product submitted to NPRA is identical to the chosen reference agency-approved product in terms of:
    a. active ingredient(s);
    b. strength(s);
    c. dosage form;
    d. route of administration;
    e. indication(s) and posology;
        i. For generic and biosimilar, the proposed indications and posology are in line with the Malaysian reference product.
        ii. The proposed indication for the product does not require a more stringent assessment based on Malaysia's local disease patterns and/or medical practices
        iii. The proposed indication for the medicine is based on broadly similar population demographics, disease profiles, and public health outcome expectations in Malaysia and those of the chosen reference agency.
    f. formulation composition and
    g. container closure system
4. All manufacturing, packaging, testing, and batch release sites for both drug product and the drug substance are identical to those approved by the chosen reference agency. The inclusion of any secondary repacker(s) has been duly justified and is supported by a valid GMP certificate recognized by NPRA.
5. The dossier submitted to NPRA is identical to the dossier approved by the chosen reference agency, and no data have been added, modified, substituted, or omitted.
6. The dossier does not include any post-approval changes and aligns with the initial approval by the chosen reference agency.
7. The Risk Management Plan implemented in Malaysia is identical to the chosen reference agency-approved RMP, with no modification.

8. I/We acknowledge and accept that any undisclosed discrepancy, misrepresentation, or false declaration may result in rejection of the application, suspension or cancellation of registration, and/or regulatory action.

Declared by:

Name:

Designation:

Company:

Signature:

Date: