Maldives Food and Drug Authority
Republic of Maldives
Male'

Declaration of Sameness of Pharmaceutical Product

To be issued by the Manufacturer / Marketing Authorization Holder (MAH)/Importer

1. Product Information

- Product Name (Brand Name): _____
- International Nonproprietary Name (INN): _____
- Strength: _____
- Dosage Form: _____
- Pack Size: _____

2. Manufacturer and Batch Release Site

- Name of Manufacturer: _____
- Full Address of Manufacturing and batch release Site: _____

3. Reliance

3.1 Reference Regulatory Approval (Reliance Basis)

- Name of Reference NRA / Authority: _____
- Country of Approval: _____
- Marketing Authorization Number: _____
- Date of Approval: _____
- Official Website Link for Verification: _____

OR

3.2 . PICs approved/PICs certified approval (Reliance Basis)

- Full Address of Manufacturing site: _____

- Country of Approval: _____
- Date of Approval: _____
- Official Website Link for Verification: _____

4. Declaration of Sameness

I/We hereby declare that the product submitted to the Maldives Food and Drug Authority (MFDA) under the **Reliance Registration Pathway** is **identical in all respects** to the product approved by the above-mentioned pathway.

This includes full sameness in:

- Qualitative and quantitative composition (API and excipients)
- Manufacturing process, controls, and specifications
- Manufacturing site and batch release site
- Quality control methods and acceptance criteria
- Primary and secondary packaging materials
- Stability data, storage conditions, and shelf life
- Product information (SmPC, PIL, labeling, indications) *(except for administrative or country-specific labeling differences, where applicable)*

6. GMP Compliance Statement

We confirm that:

- The manufacturing site is compliant with **GMP standards** acceptable to MFDA
- Valid GMP certification is available and corresponds to the site stated above
- No changes to the manufacturing site or GMP status have occurred since approval

7. Commitment and Regulatory Undertaking

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We undertake that:

- The product supplied to Maldives shall be **identical to the approved reference product**
- No changes or variations shall be made without prior notification and approval from MFDA
- Any variation approved by the Reference NRA will be **promptly communicated** to MFDA
- The product will maintain the same **quality, safety, and efficacy profile** as approved by the Reference NRA

8. Batch-Level Assurance

We confirm that:

- Each batch supplied will comply with the approved specifications
- Batch Certificate of Analysis (CoA) will be made available upon request
- Full traceability of batches supplied to Maldives will be maintained

9. Authorized Signatory *(Manufacturer / Marketing Authorization Holder (MAH)/Importer)*

- Name: _____
- Designation: _____
- Company: _____
- Signature: _____
- Date: _____
- Official Stamp/Seal: _____

Please note that This declaration is mandatory for all Reliance applications

- ***Must be:***
  - ***On company letterhead***
  - ***Signed by authorized person***
  - ***Supported by verifiable NRA approval***