**NATIONAL MEDICINES REGULATORY AUTHORITY, SRI LANKA**

**120, Norris Canal Road, Colombo 10, Sri Lanka.**

**Telephone: +94 011 2698896/7 Fax: +94 011 2689704 email: info@nmra.gov.lk**

**Application form for submission/notification of variation**

|  |
| --- |
| **For office use only** |
| Confirmed variation type | Payment required: Yes/No |
| Payment receipt No.: |
| Listed documents have been attached | Yes/NORemarks: |
| Checking pharmacist | …………………………………………………. Signature | Date: |
| Pharmacist for detailed review |  | Assigned by:………………………………………………………. Head of MRD |

**To be filled by the applicant:**

**Remark:** *Please complete each section of this application form electronically as a signed Word document or a text-selectable PFD document. Please ensure that the printed application form accompany with the submission.*

**SECTION 1: APPLICANT DETAILS AND CURRENT REGISTRATION**

|  |  |  |  |
| --- | --- | --- | --- |
| Dossier No. |  | Registration number |  |
| Registration Type | Full/PR for one year/PR for two years | Valid till  |  |
| Name of the applicant company (MAH) |  | Date of submission |  |
| Address of the MAH |  | Email: |  |
| Tel: |  |
| Fax: |  |
| Name of the product |  | Brand name (if applicable) |  |
| Name of the manufacturer |  |
| Address of the manufacturer |  |

**SECTION 2: VARATION DETAILS AND CHECKLIST**

Variation type: Major Minor for Minor for

(tick all applicable options) prior approval notification

Grouping of variations: Single Grouped 

|  |  |
| --- | --- |
| Proposed change(s) | 1.  |
|  |
|  |
|  |
|  |
| List of supporting documents attached | 1. Description of the change(s)
 | Yes/No |
| 1. Summary of changes
 | Yes/No |
| 1. Justification(s)
 | Yes/No |
| 1. Other NRA approvals (if applicable)
 | Yes/No |
| 1. Copy of existing certificate of registration
 | Yes/No |
| 1. Stability data
 | Yes/No |
| 1. PM specification, MoA & CoAs, Artwork and PIL
 | Yes/No |
| 1. Revised API specification, Method of Analysis and CoAs
 | Yes/No |
|  | 1. CEP of API
 | Yes/No |
| Reference authority if proposed change(s) has been approved  | - | Date(s) of approval | - |
| Additional comments/remarks |  |

**SECTION 3: DECLARATION BY THE RESPONSIBLE PHARMACIST**

*(Please check all declarations that are applicable)*

I declare that:

There are no changes being made other than those applied for in this submission, except for possible editorial changes. Any other changes will be applied separately.



The information contained herein and in supporting documents is true and accurate

Name: 

Designation

Signature: Date: 

NB: 1. Details/supporting documents/specimens (e.g. amended labels) should be attached

 2. NMRA reserves the right to re-route the variation type, split unrelated changes or request

 for additional information during course of screening/evaluation