**Form C1.**

**CONFIDENTIAL BUSINESS INFORMATION SUBMISSION/RECEIPT FORM**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | **Provided (**applicant to tick/mark as appropriate**)** | | **Official Remarks** |
|  |  | **Yes** | **No** |  |
|  | Method of manufacture (e.g. synthesis pathway)[[1]](#footnote-1) |  | |  |
|  | 1. Description of production process/chemical pathways involved |  |  |  |
|  | 1. Discussion of formation of impurities |  |  |  |
|  | 1. Description of raw materials |  |  |  |
|  | 5 batch analysis; including method validation, representative chromatograms, spectra, etc. (as applicable).[[2]](#footnote-2) |  | |  |
|  | 1. Specifications of the technical grade (active ingredient)-Qualitative and quantitative analyses |  |  |  |
|  | 1. Method of analysis for impurities. |  |  |  |
|  | Source & Specifications (Composition) of the formulation[[3]](#footnote-3) |  |  |  |
|  | Any other information |  |  |  |

|  |  |
| --- | --- |
| Date Submitted (Applicant) |  |
| Date received (Official) |  |
| Trade name of the Product |  |
| Active ingredient(s) |  |
| Registrant |  |
| Manufacturer (s) of active ingredient |  |
| Formulator(s) |  |
| Exporter |  |
| Local agent |  |
| Submitted by (**Full Name, Date and** **signature) \*** |  |
| Received by: **Officer’s name, Date and** **signature** |  |
| Handed over to the **Head of department. Signature:** |  |

***\* Confidential business information received as it is subject to technical evaluation.***

1. should be provided, for each manufacturing plant; Fill separate Form for each site [↑](#footnote-ref-1)
2. Where an active ingredient is produced in different plants this information must be provided for each of the plants separately. Fill separate Form for each site [↑](#footnote-ref-2)
3. Should be provided, for each Formulation site. Fill separate Form for each site [↑](#footnote-ref-3)