Address -: National Medicines Regulatory Authority Date -………/……../………

**F/ACC/04**

No 120, Norris Cannel Rd,

Colombo 10

…………………………………………..

………………………………………….

………………………………………….

**Processing of Additional Documents - Medicines**

**File Number**: - …………………….

1. Request letter Yes No
2. Copy of previous evaluation Yes No
3. Copy of previous registration (if available) Yes No
4. Attached documents Yes No Documents Page Number
5. ………………………… …………………..
6. ………………………… …………………..
7. ………………………… …………………..
8. ………………………… …………………..
9. ………………………… …………………..
10. ………………………… …………………..
11. Number of total pages : ………………………
12. Checked by : ……………………… (Pharmacist /P -Code)
13. Declaration by local agent

I hereby certify that I have submitted additional documents for file number ……………. and there are a total of ……pages with label /without label/sample which I have numbered and checked by the NMRA pharmacist.

………………………… …..…………………… ……………….

Name and Designation of local agent Signature of the local agent Date

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **(II) Fees for additional data evaluation** | | |  |  |
|  |  |  |  |  |
|  | **Type of evaluation** | | **Fee (USD)** | **Total Amount in (Rs)**  **(VAT 8% + Stamp Duty)** |
|  | Additional data evaluation | Foreign | 500 |  |
|  | Local - Category A | 200 |  |
|  | Local - Category B | 100 |  |
|  | Additional data for MP Evaluation | | 500 |  |
|  | Variations that require review | | 200 |  |

* The money should be paid to the account of National Medicines regulatory Authority- BOC A/C No.78088835, Regent Street Branch
* Please submit the cash receipt (Form Gen 172) (Act. No 5 of 2015) to NMRA, No 120, Norris Cannel Rd, Colombo 10 for further action.
* This payment is required in accordance with the General Gazette Extra Ordinary No 2023/30-Wednesday, June 14, 2017 as processing fee.

(**Please note that: Dollar rate conversion rate is at the selling rate that prevailed on last day of the preceding month as published by the central bank)**

**(Please kindly fill your file number on your bank deposit slip for our reference [compulsorily advised]**

Thank You

For Chairman/ CEO

National Medicines Regulatory Authority