

# NMRA Monthly fee for Medical Device - Effective from 01/08/2025 to 31/08/2025

Dollar rates are converted at the selling rate on last working day of the preceding month (31.07.2025) which was published by the Central Bank of Sri Lanka.

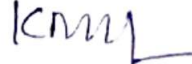
| Daily Exchange Rates | 2025/07/31        |                    |
|----------------------|-------------------|--------------------|
| Currency             | Buying Rate (Rs.) | Selling Rate (Rs.) |
| Dollar (USD)         | 298.3293          | 305.8759           |

## (I) Processing fee

| Type                                                        |                    | Fee (USD) | Amount (Rs.) | VAT (Rs.) @ 18% | Stamp Duty (Rs.) | SSCL (Rs.) 2.5% | Total (Rs.) |
|-------------------------------------------------------------|--------------------|-----------|--------------|-----------------|------------------|-----------------|-------------|
| New Application                                             | Foreign            | 1000      | 305,875.90   | 56,434.10       | -                | 7,646.90        | 369,956.90  |
|                                                             | Local - Category A | 750       | 229,406.93   | 42,325.58       | -                | 5,735.17        | 277,467.68  |
|                                                             | Local - Category B | 250       | 76,468.98    | 14,108.53       | -                | 1,911.72        | 92,489.23   |
| Application for Registration renewal after five years       | Foreign            | 750       | 229,406.93   | 42,325.58       | -                | 5,735.17        | 277,467.68  |
|                                                             | Local - Category A | 500       | 152,937.95   | 28,217.05       | -                | 3,823.45        | 184,978.45  |
|                                                             | Local - Category B | 200       | 61,175.18    | 11,286.82       | -                | 1,529.38        | 73,991.38   |
| Application for Manufacturing Plant (MP) approval - Foreign |                    | 1500      | 458,813.85   | 84,651.16       | -                | 11,470.35       | 554,935.36  |

## (II) Fees for additional data evaluation

| Type of evaluation                                      |                    | Fee (USD) | Amount (Rs.) | VAT (Rs.) @ 18% | Stamp Duty (Rs.) | SSCL (Rs.) 2.5% | Total (Rs.) |
|---------------------------------------------------------|--------------------|-----------|--------------|-----------------|------------------|-----------------|-------------|
| Additional data evaluation                              | Foreign            | 500       | 152,937.95   | 28,217.05       | -                | 3,823.45        | 184,978.45  |
|                                                         | Local - Category A | 200       | 61,175.18    | 11,286.82       | -                | 1,529.38        | 73,991.38   |
|                                                         | Local - Category B | 100       | 30,587.59    | 5,643.41        | -                | 764.69          | 36,995.69   |
| Additional data for Manufacturing Plant (MP) Evaluation |                    | 300       | 91,762.77    | 16,930.23       | -                | 2,294.07        | 110,987.07  |
| Variations that require review                          |                    | 200       | 61,175.18    | 11,286.82       | -                | 1,529.38        | 73,991.38   |

   
 Chairman Accountant  
 National Medicines Regulatory Authority

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### (III) Processing fees for Clinical Trial

| Type of Evaluation                      | Fee (USD) | Amount (Rs.)   | VAT (Rs.) @ 18% | Stamp Duty (Rs.) | SSCL (Rs.) 2.5% | Total (Rs.) |
|-----------------------------------------|-----------|----------------|-----------------|------------------|-----------------|-------------|
| Industry Sponsored                      | 1000      | 305,875.90     | 56,434.10       | -                | 7,646.90        | 369,956.90  |
| Local Investigator Sponsored            |           | Free of Charge |                 |                  |                 |             |
| Academic with International Sponsorship | 250       | 76,468.98      | 14,108.53       | -                | 1,911.72        | 92,489.23   |
| Amendments that require review          | 250       | 76,468.98      | 14,108.53       | -                | 1,911.72        | 92,489.23   |

### (IV) Fees for Certificates of Registration

| Types of Registration Certificates                                  | Fee (USD) | Amount (Rs.) | VAT (Rs.) @ 18% | Stamp Duty (Rs.) | SSCL (Rs.) 2.5% | Total (Rs.) |
|---------------------------------------------------------------------|-----------|--------------|-----------------|------------------|-----------------|-------------|
| Certificate of Registration for five years                          | 400       | 122,350.36   | 22,573.64       | 2,000.00         | 3,058.76        | 149,982.76  |
|                                                                     | 200       | 61,175.18    | 11,286.82       | 2,000.00         | 1,529.38        | 75,991.38   |
|                                                                     | 100       | 30,587.59    | 5,643.41        | 2,000.00         | 764.69          | 38,995.69   |
| Provisional Registration (may be issued for a maximum of two years) | 200       | 61,175.18    | 11,286.82       | 2,000.00         | 1,529.38        | 75,991.38   |
|                                                                     | 100       | 30,587.59    | 5,643.41        | 2,000.00         | 764.69          | 38,995.69   |
|                                                                     | 50        | 15,293.80    | 2,821.71        | 1,529.38         | 382.34          | 20,027.24   |
| Duplicate Copy of Registration Certificate                          | 250       | 76,468.98    | 14,108.53       | 2,000.00         | 1,911.72        | 94,489.23   |
| Amendment of Registration Certificate                               | 100       | 30,587.59    | 5,643.41        | 2,000.00         | 764.69          | 38,995.69   |

### (V) Fees for License

| Types of licenses     | Fee (USD) | Amount (Rs.) | VAT (Rs.) @ 18% | Stamp Duty (Rs.) | SSCL (Rs.) 2.5% | Total (Rs.) |
|-----------------------|-----------|--------------|-----------------|------------------|-----------------|-------------|
| Sample Import license | 100       | 30,587.59    | 5,643.41        | 2,000.00         | 764.69          | 38,995.69   |
| Import License        | 100       | 30,587.59    | 5,643.41        | 2,000.00         | 764.69          | 38,995.69   |
| Manufacturing License | 100       | 30,587.59    | 5,643.41        | 2,000.00         | 764.69          | 38,995.69   |
|                       | 50        | 15,293.80    | 2,821.71        | 1,529.38         | 382.34          | 20,027.24   |
| Amendment of License  | 100       | 30,587.59    | 5,643.41        | 2,000.00         | 764.69          | 38,995.69   |

*[Signature]*

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Accountant

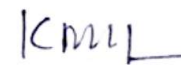


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## (VI) Fees for Other Approvals

| Type of Approval                                    |                                         | Fee (USD) | Amount (Rs.)   | VAT (Rs.) @ 18% | Stamp Duty (Rs.) | SSCL (Rs.) 2.5% | Total (Rs.) |
|-----------------------------------------------------|-----------------------------------------|-----------|----------------|-----------------|------------------|-----------------|-------------|
| Formulation Approval for local manufacturer         |                                         |           | Free of charge |                 |                  |                 |             |
| Approval for Packaging / Repackaging                |                                         | 50        | 15,293.80      | 2,821.71        | -                | 382.34          | 18,497.86   |
| Submission/ Approval fee for waiver of registration | Invoice value USD 2000 or below         | 50        | 15,293.80      | 2,821.71        | -                | 382.34          | 18,497.86   |
|                                                     | Invoice value USD 2,000- USD 10,000     | 100       | 30,587.59      | 5,643.41        | -                | 764.69          | 36,995.69   |
|                                                     | Invoice value USD 10,000- USD 15,000    | 200       | 61,175.18      | 11,286.82       | -                | 1,529.38        | 73,991.38   |
|                                                     | Invoice value USD 15,000- USD 20,000    | 500       | 152,937.95     | 28,217.05       | -                | 3,823.45        | 184,978.45  |
|                                                     | Invoice value USD 20,000 or above       | 750       | 229,406.93     | 42,325.58       | -                | 5,735.17        | 277,467.68  |
| Any clarification letter                            |                                         | 10        | 3,058.76       | 564.34          | -                | 76.47           | 3,699.57    |
| WHO GMP certificate                                 |                                         | 100       | 30,587.59      | 5,643.41        | 2,000.00         | 764.69          | 38,995.69   |
| Free Sale Certificate                               |                                         | 50        | 15,293.80      | 2,821.71        | 1,529.38         | 382.34          | 20,027.24   |
| Agency Transfer per each party                      | Manufacturer                            | 1000      | 305,875.90     | 56,434.10       | -                | 7,646.90        | 369,956.90  |
|                                                     | Each new marketing authorization holder | 1000      | 305,875.90     | 56,434.10       | -                | 7,646.90        | 369,956.90  |

  
 Chairman  
  
 Accountant  
 National Medicines Regulatory Authority

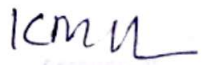
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## (VII) Fees for Analysis

|     | Analysis                                                          |                                                                                                          | Fee (USD) | Amount (Rs.) | VAT (Rs.) @ 18% | Stamp Duty (Rs.) | SSCL (Rs.) 2.5% | Total (Rs.) |
|-----|-------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|-----------|--------------|-----------------|------------------|-----------------|-------------|
| (a) | Biological test                                                   |                                                                                                          | 250       | 76,468.98    | 14,108.53       | -                | 1,911.72        | 92,489.23   |
| (b) | Microbiological Test                                              |                                                                                                          | 250       | 76,468.98    | 14,108.53       | -                | 1,911.72        | 92,489.23   |
| (c) | Assay Test (Chemical, Microbiological, Biological)                |                                                                                                          | 250       | 76,468.98    | 14,108.53       | -                | 1,911.72        | 92,489.23   |
| (d) | Limit Test (performed using Analytical Equipment - HPLC,AAS etc.) |                                                                                                          | 250       | 76,468.98    | 14,108.53       | -                | 1,911.72        | 92,489.23   |
| (e) | Three tests or less than three tests                              | i). If all three tests are in categories (a), (b), (c) & (d) specified above                             | 750       | 229,406.93   | 42,325.58       | -                | 5,735.17        | 277,467.68  |
|     |                                                                   | (ii). Otherwise                                                                                          | 500       | 152,937.95   | 28,217.05       | -                | 3,823.45        | 184,978.45  |
| (f) | Four tests or more than four tests                                | (i). If all four tests or more than four tests are in the categories (a), (b), (c) & (d) specified above | 1500      | 458,813.85   | 84,651.16       | -                | 11,470.35       | 554,935.36  |
|     |                                                                   | (ii). Otherwise                                                                                          | 1000      | 305,875.90   | 56,434.10       | -                | 7,646.90        | 369,956.90  |
| (g) | Single test                                                       | Test other than the categories (a), (b), (c), & (d) specified above                                      | 175       | 53,528.28    | 9,875.97        | -                | 1,338.21        | 64,742.46   |

  
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## (VIII) Fee for Good Manufacturing Practice Inspection (GMP) - Local

| Type                          |            | Fee (USD) | Amount (Rs.) | VAT (Rs.) @ 18% | Stamp Duty (Rs.) | SSCL (Rs.) 2.5% | Total (Rs.) |
|-------------------------------|------------|-----------|--------------|-----------------|------------------|-----------------|-------------|
| A Manufacturing site          | Category A | 300       | 91,762.77    | 16,930.23       | -                | 2,294.07        | 110,987.07  |
|                               | Category B | 100       | 30,587.59    | 5,643.41        | -                | 764.69          | 36,995.69   |
| A Packaging/ Repackaging site |            | 100       | 30,587.59    | 5,643.41        | -                | 764.69          | 36,995.69   |

## (IX) Fee for Good Manufacturing Practice Inspection (GMP) - Foreign

| Country         | Fee (USD) | Amount (Rs.) | VAT (Rs.) @ 18% | Stamp Duty (Rs.) | SSCL (Rs.) 2.5% | Total (Rs.)  |
|-----------------|-----------|--------------|-----------------|------------------|-----------------|--------------|
| SAARC Countries | 15000     | 4,588,138.50 | 846,511.55      | -                | 114,703.46      | 5,549,353.51 |
| Other Countries | 20000     | 6,117,518.00 | 1,128,682.07    | -                | 152,937.95      | 7,399,138.02 |

\* Air Tickets, Visa fees and Transport cost within that country should be borne by the Applicant

## (X) Fee for sample import license for clinical trials

| Category                                          | Fee (USD) | Amount (Rs.) | VAT (Rs.) @ 18% | Stamp Duty (Rs.) | SSCL (Rs.) 2.5% | Total (Rs.) |
|---------------------------------------------------|-----------|--------------|-----------------|------------------|-----------------|-------------|
| Fee for sample import license for clinical trials | 100       | 30,587.59    | 5,643.41        | 2,000.00         | 764.69          | 38,995.69   |

## (XI) Fee for Advertisement

| Advertisement                                     | Fee (USD) | Amount (Rs.) | VAT (Rs.) @ 18% | Stamp Duty (Rs.) | SSCL (Rs.) 2.5% | Total (Rs.) |
|---------------------------------------------------|-----------|--------------|-----------------|------------------|-----------------|-------------|
| Processing fee for Advertisement (All categories) | 1000      | 305,875.90   | 56,434.10       | -                | 7,646.90        | 369,956.90  |

\* Separate Applications should be submitted for each advertisement.

  
 Chairman  
 National Medicines Regulatory Authority