

NMRA Monthly fee for Medical Device - Effective from 01/01/2026 to 31/01/2026

Dollar rates are converted at the selling rate on last working day of the preceding month (31.12.2025) which was published by the Central Bank of Sri Lanka.

Daily Exchange Rates		2025/12/31
Currency	Buying Rate (Rs.)	Selling Rate (Rs.)
Dollar (USD)	306.2933	313.8313

(I) Processing fee

Type		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
New Application	Foreign	1000	313,831.30	57,901.87	-	7,845.78	379,578.95
	Local - Category A	750	235,373.48	43,426.41	-	5,884.34	284,684.23
	Local - Category B	250	78,457.83	14,475.47	-	1,961.45	94,894.75
Application for Registration renewal after five years	Foreign	750	235,373.48	43,426.41	-	5,884.34	284,684.23
	Local - Category A	500	156,915.65	28,950.94	-	3,922.89	189,789.48
	Local - Category B	200	62,766.26	11,580.37	-	1,569.16	75,915.80
Application for Manufacturing Plant (MP) approval - Foreign		1500	470,746.95	86,852.81	-	11,768.67	569,368.43

(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	156,915.65	28,950.94	-	3,922.89	189,789.48
	Local - Category A	200	62,766.26	11,580.37	-	1,569.16	75,915.80
	Local - Category B	100	31,383.13	5,790.19	-	784.58	37,957.90
Additional data for Manufacturing Plant (MP) Evaluation		300	94,149.39	17,370.56	-	2,353.73	113,873.68
Variations that require review		200	62,766.26	11,580.37	-	1,569.16	75,915.80


 CEO
 National Medicines Regulatory Authority


 Accountant

NMRA Monthly fee for Medical Device - Effective from 01/01/2026 to 31/01/2026

(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	313,831.30	57,901.87	-	7,845.78	379,578.95
Local Investigator Sponsored		Free of Charge				
Academic with International Sponsorship	250	78,457.83	14,475.47	-	1,961.45	94,894.75
Amendments that require review	250	78,457.83	14,475.47	-	1,961.45	94,894.75

(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	Foreign	400	125,532.52	23,160.75	2,000.00	3,138.31	153,831.58
	Local Category A	200	62,766.26	11,580.37	2,000.00	1,569.16	77,915.80
	Local Category B	100	31,383.13	5,790.19	2,000.00	784.58	39,957.90
Provisional Registration (may be issued for a maximum of two years)	Foreign	200	62,766.26	11,580.37	2,000.00	1,569.16	77,915.79
	Local Category A	100	31,383.13	5,790.19	2,000.00	784.58	39,957.90
	Local Category B	50	15,691.57	2,895.09	1,569.16	392.29	20,548.11
Duplicate Copy of Registration Certificate		250	78,457.83	14,475.47	2,000.00	1,961.45	96,894.75
Amendment of Registration Certificate		100	31,383.13	5,790.19	2,000.00	784.58	39,957.90

(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	31,383.13	5,790.19	2,000.00	784.58	39,957.90
Import License	100	31,383.13	5,790.19	2,000.00	784.58	39,957.90
Manufacturing License	Local Category A	100	31,383.13	5,790.19	2,000.00	39,957.90
	Local Category B	50	15,691.57	2,895.09	1,569.16	20,548.11
Amendment of License	100	31,383.13	5,790.19	2,000.00	784.58	39,957.90



 CEO Accountant
 National Medicines Regulatory Authority

NMRA Monthly fee for Medical Device - Effective from 01/01/2026 to 31/01/2026

20

(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	15,691.57	2,895.09	-	392.29	18,978.95
Submission/ Approval fee for waiver of registration	Invoice value USD 2000 or below	50	15,691.57	2,895.09	-	392.29	18,978.95
	Invoice value USD 2,000- USD 10,000	100	31,383.13	5,790.19	-	784.58	37,957.90
	Invoice value USD 10,000- USD 15,000	200	62,766.26	11,580.37	-	1,569.16	75,915.80
	Invoice value USD 15,000- USD 20,000	500	156,915.65	28,950.94	-	3,922.89	189,789.48
	Invoice value USD 20,000 or above	750	235,373.48	43,426.41	-	5,884.34	284,684.23
Any clarification letter		10	3,138.31	579.02	-	78.46	3,795.79
WHO GMP certificate		100	31,383.13	5,790.19	2,000.00	784.58	39,957.90
Free Sale Certificate		50	15,691.57	2,895.09	1,569.16	392.29	20,548.11
Agency Transfer per each party	Manufacturer	1000	313,831.30	57,901.87	-	7,845.78	379,578.95
	Each new marketing authorization holder	1000	313,831.30	57,901.87	-	7,845.78	379,578.95


 CEO

 Accountant
 National Medicines Regulatory Authority

NMRA Monthly fee for Medical Device - Effective from 01/01/2026 to 31/01/2026

(VII) Fees for Analysis

	Analysis	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
1 (a)	Biological test	250	78,457.83	14,475.47	-	1,961.45	94,894.75
2 (b)	Microbiological Test	250	78,457.83	14,475.47	-	1,961.45	94,894.75
3 (c)	Assay Test (Chemical, Microbiological, Biological)	250	78,457.83	14,475.47	-	1,961.45	94,894.75
4 (d)	Limit Test (performed using Analytical Equipment - HPLC, AAS etc.)	250	78,457.83	14,475.47	-	1,961.45	94,894.75
5 (e)	Three tests or less than three tests	i). If all three tests are in categories (a), (b), (c) & (d) specified above					
		750	235,373.48	43,426.41	-	5,884.34	284,684.23
6 (f)	Four tests or more than four tests	(ii). Otherwise					
		500	156,915.65	28,950.94	-	3,922.89	189,789.48
7 (g)	Single test	(i). If all four tests or more than four tests are in the categories (a), (b), (c) & (d) specified above					
		1500	470,746.95	86,852.81	-	11,768.67	569,368.43
7 (g)	Single test	(ii). Otherwise					
		1000	313,831.30	57,901.87	-	7,845.78	379,578.95
7 (g)	Test other than the categories (a), (b), (c), & (d) specified above	175	54,920.48	10,132.83	-	1,373.01	66,426.32


 CEO
 National Medicine Regulatory Authority


 Accountant

NMRA Monthly fee for Medical Device - Effective from 01/01/2026 to 31/01/2026

(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	94,149.39	17,370.56	-	2,353.73	113,873.68
	Category B	100	31,383.13	5,790.19	-	784.58	37,957.90
A Packaging/ Repackaging site		100	31,383.13	5,790.19	-	784.58	37,957.90

(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	4,707,469.50	868,528.12	-	117,686.74	5,693,684.36
Other Countries	20000	6,276,626.00	1,158,037.50	-	156,915.65	7,591,579.15

* 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	31,383.13	5,790.19	2,000.00	784.58	39,957.90

(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	313,831.30	57,901.87	-	7,845.78	379,578.95

* Separate Applications should be submitted for each advertisement.


 CEO
 National Medicines Regulatory Authority


 Accountant