

NMRA Monthly fee for Medical Device - Effective from 01/08/2026 to 31/08/2026

Dollar rates are converted at the selling rate on last working day of the preceding month (31.07.2026) which was published by the Central Bank of Sri Lanka.

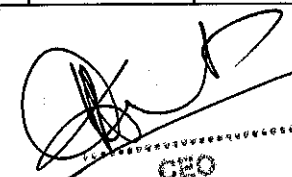
Daily Exchange Rates		2026/07/31
Currency	Buying Rate (Rs.)	Selling Rate (Rs.)
Dollar (USD)	331.206	340.3301

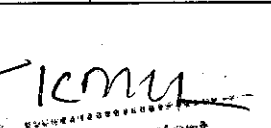
(I) Processing fee

Type		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
New Application	Foreign	1000	340,330.10	62,790.90	-	8,508.25	411,629.25
	Local - Category A	750	255,247.58	47,093.18	-	6,381.19	308,721.95
	Local - Category B	250	85,082.53	15,697.73	-	2,127.06	102,907.32
Application for Registration renewal after five years	Foreign	750	255,247.58	47,093.18	-	6,381.19	308,721.95
	Local - Category A	500	170,165.05	31,395.45	-	4,254.13	205,814.63
	Local - Category B	200	68,066.02	12,558.18	-	1,701.65	82,325.85
Application for Manufacturing Plant (MP) approval - Foreign		1500	510,495.15	94,186.36	-	12,762.38	617,443.89

(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	170,165.05	31,395.45	-	4,254.13	205,814.63
	Local - Category A	200	68,066.02	12,558.18	-	1,701.65	82,325.85
	Local - Category B	100	34,033.01	6,279.09	-	850.83	41,162.93
Additional data for Manufacturing Plant (MP) Evaluation		300	102,099.03	18,837.27	-	2,552.48	123,488.78
Variations that require review		200	68,066.02	12,558.18	-	1,701.65	82,325.85


CEO
 National Medicines Regulatory Authority


Accountant
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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	340,330.10	62,790.90	-	8,508.25	411,629.25
Local Investigator Sponsored		Free of Charge				
Academic with International Sponsorship	250	85,082.53	15,697.73	-	2,127.06	102,907.32
Amendments that require review	250	85,082.53	15,697.73	-	2,127.06	102,907.32

(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	136,132.04	25,116.36	2,000.00	3,403.30	166,651.70
	Local Category A	200	68,066.02	12,558.18	2,000.00	1,701.65	84,325.85
	Local Category B	100	34,033.01	6,279.09	2,000.00	850.83	43,162.93
Provisional Registration (may be issued for a maximum of two years)	Foreign	200	68,066.02	12,558.18	2,000.00	1,701.65	84,325.85
	Local Category A	100	34,033.01	6,279.09	2,000.00	850.83	43,162.93
	Local Category B	50	17,016.51	3,139.55	1,701.65	425.41	22,283.12
Duplicate Copy of Registration Certificate		250	85,082.53	15,697.73	2,000.00	2,127.06	104,907.32
Amendment of Registration Certificate		100	34,033.01	6,279.09	2,000.00	850.83	43,162.93

(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	34,033.01	6,279.09	2,000.00	850.83	43,162.93
Import License	100	34,033.01	6,279.09	2,000.00	850.83	43,162.93
Manufacturing License	Local Category A	100	34,033.01	6,279.09	2,000.00	43,162.93
	Local Category B	50	17,016.51	3,139.55	1,701.65	22,283.12
Amendment of License	100	34,033.01	6,279.09	2,000.00	850.83	43,162.93

Director
 Ministry of Health and Family Welfare
 Government of India
 New Delhi


 Date: 12/08/2026

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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	17,016.51	3,139.55	-	425.41	20,581.47
Submission/ Approval fee for waiver of registration	Invoice value USD 2000 or below	50	17,016.51	3,139.55	-	425.41	20,581.47
	Invoice value USD 2,000-USD 10,000	100	34,033.01	6,279.09	-	850.83	41,162.93
	Invoice value USD 10,000-USD 15,000	200	68,066.02	12,558.18	-	1,701.65	82,325.85
	Invoice value USD 15,000-USD 20,000	500	170,165.05	31,395.45	-	4,254.13	205,814.63
	Invoice value USD 20,000 or above	750	255,247.58	47,093.18	-	6,381.19	308,721.95
Any clarification letter		10	3,403.30	627.91	-	85.08	4,116.29
WHO GMP certificate		100	34,033.01	6,279.09	2,000.00	850.83	43,162.93
Free Sale Certificate		50	17,016.51	3,139.55	1,701.65	425.41	22,283.12
Agency Transfer per each party	Manufacturer	1000	340,330.10	62,790.90	-	8,508.25	411,629.25
	Each new marketing authorization holder	1000	340,330.10	62,790.90	-	8,508.25	411,629.25

ICM

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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.)
1 (a)	Biological test		250	85,082.53	15,697.73	-	2,127.06	102,907.32
2 (b)	Microbiological Test		250	85,082.53	15,697.73	-	2,127.06	102,907.32
3 (c)	Assay Test (Chemical, Microbiological, Biological)		250	85,082.53	15,697.73	-	2,127.06	102,907.32
4(d)	Limit Test (performed using Analytical Equipment - HPLC,AAS etc.)		250	85,082.53	15,697.73	-	2,127.06	102,907.32
5 (e)	Three tests or less than three tests	i). If all three tests are in categories (a), (b), (c) & (d) specified above	750	255,247.58	47,093.18	-	6,381.19	308,721.95
		(ii). Otherwise	500	170,165.05	31,395.45	-	4,254.13	205,814.63
6 (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	510,495.15	94,186.36	-	12,762.38	617,443.89
		(ii). Otherwise	1000	340,330.10	62,790.90	-	8,508.25	411,629.25
7 (g)	Single test	Test other than the categories (a), (b), (c), & (d) specified above	175	59,557.77	10,988.41	-	1,488.94	72,035.12

ICMU

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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	102,099.03	18,837.27	-	123,488.78
	Category B	100	34,033.01	6,279.09	-	41,162.93
A Packaging/ Repackaging site		100	34,033.01	6,279.09	-	41,162.93

(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	5,104,951.50	941,863.55	-	127,623.79	6,174,438.84
Other Countries	20000	6,806,602.00	1,255,818.07	-	170,165.05	8,232,585.12

* 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	34,033.01	6,279.09	2,000.00	850.83	43,162.93

(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	340,330.10	62,790.90	-	8,508.25	411,629.25

* Separate Applications should be submitted for each advertisement.


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