

NMRA Monthly fee for Medical Device - Effective from 01/10/2026 to 31/10/2026

Dollar rates are converted at the selling rate on last working day of the preceding month (31.08.2026) which was published by the Central Bank of Sri Lanka.

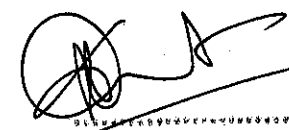
Daily Exchange Rates	2026/09/30	
Currency	Buying Rate (Rs.)	Selling Rate (Rs.)
Dollar (USD)	326.2849	335.3368

(I) Processing fee

Type	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
New Application	Foreign	1000	335,336.80	61,869.64	-	405,589.86
	Local - Category A	750	251,502.60	46,402.23	-	304,192.40
	Local - Category B	250	83,834.20	15,467.41	-	101,397.47
Application for Registration renewal after five years	Foreign	750	251,502.60	46,402.23	-	304,192.40
	Local - Category A	500	167,668.40	30,934.82	-	202,794.93
	Local - Category B	200	67,067.36	12,373.93	-	81,117.97
Application for Manufacturing Plant (MP) approval - Foreign	1500	503,005.20	92,804.46	-	12,575.13	608,384.79

(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	167,668.40	30,934.82	-	202,794.93
	Local - Category A	200	67,067.36	12,373.93	-	81,117.97
	Local - Category B	100	33,533.68	6,186.96	-	40,558.98
Additional data for Manufacturing Plant (MP) Evaluation	300	100,601.04	18,560.89	-	2,515.03	121,676.96
Variations that require review	200	67,067.36	12,373.93	-	1,676.68	81,117.97


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(III) Processing fees for Clinical Trial

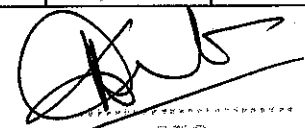
Type of Evaluation	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
Industry Sponsored	1000	335,336.80	61,869.64	-	8,383.42	405,589.86
Local Investigator Sponsored		Free of Charge				
Academic with International Sponsorship	250	83,834.20	15,467.41	-	2,095.86	101,397.47
Amendments that require review	250	83,834.20	15,467.41	-	2,095.86	101,397.47

(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	134,134.72	24,747.86	2,000.00	3,353.37	164,235.95
	Local Category A	200	67,067.36	12,373.93	2,000.00	1,676.68	83,117.97
	Local Category B	100	33,533.68	6,186.96	2,000.00	838.34	42,558.98
Provisional Registration (may be issued for a maximum of two years)	Foreign	200	67,067.36	12,373.93	2,000.00	1,676.68	83,117.97
	Local Category A	100	33,533.68	6,186.96	2,000.00	838.34	42,558.98
	Local Category B	50	16,766.84	3,093.48	1,676.68	419.17	21,956.17
Duplicate Copy of Registration Certificate		250	83,834.20	15,467.41	2,000.00	2,095.86	103,397.47
Amendment of Registration Certificate		100	33,533.68	6,186.96	2,000.00	838.34	42,558.98

(V) Fees for License

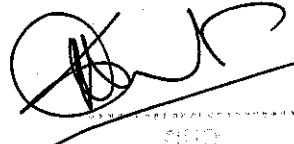
Types of licenses		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
Sample Import license		100	33,533.68	6,186.96	2,000.00	838.34	42,558.98
Import License		100	33,533.68	6,186.96	2,000.00	838.34	42,558.98
Manufacturing License	Local Category A	100	33,533.68	6,186.96	2,000.00	838.34	42,558.98
	Local Category B	50	16,766.84	3,093.48	1,676.68	419.17	21,956.17
Amendment of License		100	33,533.68	6,186.96	2,000.00	838.34	42,558.98


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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	16,766.84	3,093.48	-	419.17	20,279.49
Submission/ Approval fee for waiver of registration	Invoice value USD 2000 or below	50	16,766.84	3,093.48	-	419.17	20,279.49
	Invoice value USD 2,000-USD 10,000	100	33,533.68	6,186.96	-	838.34	40,558.98
	Invoice value USD 10,000-USD 15,000	200	67,067.36	12,373.93	-	1,676.68	81,117.97
	Invoice value USD 15,000-USD 20,000	500	167,668.40	30,934.82	-	4,191.71	202,794.93
	Invoice value USD 20,000 or above	750	251,502.60	46,402.23	-	6,287.57	304,192.40
Any clarification letter		10	3,353.37	618.70	-	83.83	4,055.90
WHO GMP certificate		100	33,533.68	6,186.96	2,000.00	838.34	p
Free Sale Certificate		50	16,766.84	3,093.48	1,676.68	419.17	21,956.17
Agency Transfer per each party	Manufacturer	1000	335,336.80	61,869.64	-	8,383.42	405,589.86
	Each new marketing authorization holder	1000	335,336.80	61,869.64	-	8,383.42	405,589.86


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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	83,834.20	15,467.41	-	2,095.86	101,397.47
2 (b)	Microbiological Test		250	83,834.20	15,467.41	-	2,095.86	101,397.47
3 (c)	Assay Test (Chemical, Microbiological, Biological)		250	83,834.20	15,467.41	-	2,095.86	101,397.47
4(d)	Limit Test (performed using Analytical Equipment - HPLC,AAS etc.)		250	83,834.20	15,467.41	-	2,095.86	101,397.47
5 (e)	Three tests or less than three tests	i). If all three tests are in categories (a), (b), (c) & (d) specified above	750	251,502.60	46,402.23	-	6,287.57	304,192.40
		(ii). Otherwise	500	167,668.40	30,934.82	-	4,191.71	202,794.93
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	503,005.20	92,804.46	-	12,575.13	608,384.79
		(ii). Otherwise	1000	335,336.80	61,869.64	-	8,383.42	405,589.86
7 (g)	Single test	Test other than the categories (a), (b), (c), & (d) specified above	175	58,683.94	10,827.19	-	1,467.10	70,978.23



 Director General

 Medical Research and Regulatory Authority

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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	100,601.04	18,560.89	-	121,676.96
	Category B	100	33,533.68	6,186.96	-	40,558.98
A Packaging/ Repackaging site		100	33,533.68	6,186.96	-	40,558.98

(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	5,030,052.00	928,044.59	-	125,751.30	6,083,847.89
Other Countries	20000	6,706,736.00	1,237,392.79	-	167,668.40	8,111,797.19

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

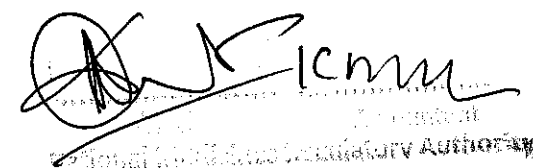
(X) Fee for sample import license for clinical trials

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	33,533.68	6,186.96	2,000.00	838.34	42,558.98

(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	335,336.80	61,869.64	-	8,383.42	405,589.86

* Separate Applications should be submitted for each advertisement.


 Director General
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