(19)

NMRA Monthly fee for Medical Device - Effective from 01/11/2026 to 30/11/2026

Dollar rates are converted at the selling rate on last working day of the preceding month (30.10.2026) which was published by the Central Bank of Sri Lanka.

Daily Exchange Rates	2026/10/30	
Currency	Buying Rate (Rs.)	Selling Rate (Rs.)
Dollar (USD)	328.0447	337.1431

(I) Processing fee

Type		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
New Application	Foreign	1000	337,143.10	62,202.90	-	8,428.58	407,774.58
	Local - Category A	750	252,857.33	46,652.18	-	6,321.43	305,830.94
	Local - Category B	250	84,285.78	15,550.73	-	2,107.14	101,943.65
Application for Registration renewal after five years	Foreign	750	252,857.33	46,652.18	-	6,321.43	305,830.94
	Local - Category A	500	168,571.55	31,101.45	-	4,214.29	203,887.29
	Local - Category B	200	67,428.62	12,440.58	-	1,685.72	81,554.92
Application for Manufacturing Plant (MP) approval - Foreign		1500	505,714.65	93,304.35	-	12,642.87	611,661.87

(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	168,571.55	31,101.45	-	4,214.29	203,887.29
	Local - Category A	200	67,428.62	12,440.58	-	1,685.72	81,554.92
	Local - Category B	100	33,714.31	6,220.29	-	842.86	40,777.46
Additional data for Manufacturing Plant (MP) Evaluation		300	101,142.93	18,660.87	-	2,528.57	122,332.37
Variations that require review		200	67,428.62	12,440.58	-	1,685.72	81,554.92

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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	337,143.10	62,202.90	-	8,428.58	407,774.58
Local Investigator Sponsored	Free of Charge					
Academic with International Sponsorship	250	84,285.78	15,550.73	-	2,107.14	101,943.65
Amendments that require review	250	84,285.78	15,550.73	-	2,107.14	101,943.65

(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	134,857.24	24,881.16	2,000.00	3,371.43	165,109.83
	Local Category A	200	67,428.62	12,440.58	2,000.00	1,685.72	83,554.92
	Local Category B	100	33,714.31	6,220.29	2,000.00	842.86	42,777.46
Provisional Registration (may be issued for a maximum of two years)	Foreign	200	67,428.62	12,440.58	2,000.00	1,685.72	83,554.92
	Local Category A	100	33,714.31	6,220.29	2,000.00	842.86	42,777.46
	Local Category B	50	16,857.16	3,110.15	1,685.72	421.43	22,074.46
Duplicate Copy of Registration Certificate		250	84,285.78	15,550.73	2,000.00	2,107.14	103,943.65
Amendement of Registration Certificate		100	33,714.31	6,220.29	2,000.00	842.86	42,777.46

(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	33,714.31	6,220.29	2,000.00	842.86	42,777.46
Import License		100	33,714.31	6,220.29	2,000.00	842.86	42,777.46
Manufacturing License	Local Category A	100	33,714.31	6,220.29	2,000.00	842.86	42,777.46
	Local Category B	50	16,857.16	3,110.15	1,685.72	421.43	22,074.46
Ammendment of License		100	33,714.31	6,220.29	2,000.00	842.86	42,777.46

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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	16,857.16	3,110.15	-	421.43	20,388.74
Submission/ Approval fee for waiver of registration	Invoice value USD 2000 or below	50	16,857.16	3,110.15	-	421.43	20,388.74
	Invoice value USD 2,000-USD 10,000	100	33,714.31	6,220.29	-	842.86	40,777.46
	Invoice value USD 10,000-USD 15,000	200	67,428.62	12,440.58	-	1,685.72	81,554.92
	Invoice value USD 15,000-USD 20,000	500	168,571.55	31,101.45	-	4,214.29	203,887.29
	Invoice value USD 20,000 or above	750	252,857.33	46,652.18	-	6,321.43	305,830.94
Any clarrification letter		10	3,371.43	622.03	-	84.29	4,077.75
WHO GMP certificate		100	33,714.31	6,220.29	2,000.00	842.86	42,777.46
Free Sale Certificate		50	16,857.16	3,110.15	1,685.72	421.43	22,074.46
Agency Transfer per each party	Manufacturer	1000	337,143.10	62,202.90	-	8,428.58	407,774.58
	Each new marketing authorization holder	1000	337,143.10	62,202.90	-	8,428.58	407,774.58

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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	84,285.78	15,550.73	-	2,107.14	101,943.65
2 (b)	Microbiological Test		250	84,285.78	15,550.73	-	2,107.14	101,943.65
3 (c)	Assay Test (Chemical, Microbiological, Biological)		250	84,285.78	15,550.73	-	2,107.14	101,943.65
4(d)	Limit Test (performed using Analytical Equipment - HPLC,AAS etc.)		250	84,285.78	15,550.73	-	2,107.14	101,943.65
5 (e)	Three tests or less than three tests	i). If all three tests are in categories (a), (b), (c) & (d) specified above	750	252,857.33	46,652.18	-	6,321.43	305,830.94
		(ii). Otherwise	500	168,571.55	31,101.45	-	4,214.29	203,887.29
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	505,714.65	93,304.35	-	12,642.87	611,661.87
		(ii). Otherwise	1000	337,143.10	62,202.90	-	8,428.58	407,774.58
7 (g)	Single test	Test other than the categories (a), (b), (c), & (d) specified above	175	59,000.04	10,885.51	-	1,475.00	71,360.55

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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	101,142.93	18,660.87	-	2,528.57	122,332.37
	Category B	100	33,714.31	6,220.29	-	842.86	40,777.46
A Packaging/ Repackaging site		100	33,714.31	6,220.29	-	842.86	40,777.46

(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	5,057,146.50	933,043.53	-	126,428.66	6,116,618.69
Other Countries	20000	6,742,862.00	1,244,058.04	-	168,571.55	8,155,491.59

* 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	33,714.31	6,220.29	2,000.00	842.86	42,777.46

(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	337,143.10	62,202.90	-	8,428.58	407,774.58

* Separate Applications should be submitted for each advertisement.

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