

NMRA Monthly fee for Medical Device - Effective from 01/07/2026 to 31/07/2026

Dollar rates are converted at the selling rate on last working day of the preceding month (30.06.2026) which was published by the Central Bank of Sri Lanka.

Daily Exchange Rates	2026/06/30	
Currency	Buying Rate (Rs.)	Selling Rate (Rs.)
Dollar (USD)	331.6619	341.3051

(I) Processing fee

Type	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
New Application	Foreign	1000	341,305.10	62,970.79	-	412,808.52
	Local - Category A	750	255,978.83	47,228.09	-	309,606.39
	Local - Category B	250	85,326.28	15,742.70	-	103,202.14
Application for Registration renewal after five years	Foreign	750	255,978.83	47,228.09	-	309,606.39
	Local - Category A	500	170,652.55	31,485.39	-	206,404.25
	Local - Category B	200	68,261.02	12,594.16	-	82,561.71
Application for Manufacturing Plant (MP) approval - Foreign	1500	511,957.65	94,456.19	-	619,212.78	

(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	170,652.55	31,485.39	-	206,404.25
	Local - Category A	200	68,261.02	12,594.16	-	82,561.71
	Local - Category B	100	34,130.51	6,297.08	-	41,280.85
Additional data for Manufacturing Plant (MP) Evaluation	300	102,391.53	18,891.24	-	123,842.56	
Variations that require review	200	68,261.02	12,594.16	-	82,561.71	

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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	341,305.10	62,970.79	-	8,532.63	412,808.52
Local Investigator Sponsored		Free of Charge				
Academic with International Sponsorship	250	85,326.28	15,742.70	-	2,133.16	103,202.14
Amendments that require review	250	85,326.28	15,742.70	-	2,133.16	103,202.14

(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	136,522.04	25,188.32	2,000.00	3,413.05	167,123.41
	Local Category A	200	68,261.02	12,594.16	2,000.00	1,706.53	84,561.71
	Local Category B	100	34,130.51	6,297.08	2,000.00	853.26	43,280.85
Provisional Registration (may be issued for a maximum of two years)	Foreign	200	68,261.02	12,594.16	2,000.00	1,706.53	84,561.71
	Local Category A	100	34,130.51	6,297.08	2,000.00	853.26	43,280.85
	Local Category B	50	17,065.26	3,148.54	1,706.53	426.63	22,346.96
Duplicate Copy of Registration Certificate		250	85,326.28	15,742.70	2,000.00	2,133.16	105,202.14
Amendment of Registration Certificate		100	34,130.51	6,297.08	2,000.00	853.26	43,280.85

(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	34,130.51	6,297.08	2,000.00	853.26	43,280.85
Import License		100	34,130.51	6,297.08	2,000.00	853.26	43,280.85
Manufacturing License	Local Category A	100	34,130.51	6,297.08	2,000.00	853.26	43,280.85
	Local Category B	50	17,065.26	3,148.54	1,706.53	426.63	22,346.96
Amendment of License		100	34,130.51	6,297.08	2,000.00	853.26	43,280.85

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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	17,065.26	3,148.54	-	426.63	20,640.43	
Submission/ Approval fee for waiver of registration	Invoice value USD 2000 or below	50	17,065.26	3,148.54	-	426.63	20,640.43
	Invoice value USD 2,000- USD 10,000	100	34,130.51	6,297.08	-	853.26	41,280.85
	Invoice value USD 10,000- USD 15,000	200	68,261.02	12,594.16	-	1,706.53	82,561.71
	Invoice value USD 15,000- USD 20,000	500	170,652.55	31,485.39	-	4,266.31	206,404.25
	Invoice value USD 20,000 or above	750	255,978.83	47,228.09	-	6,399.47	309,606.39
Any clarification letter	10	3,413.05	629.71	-	85.33	4,128.09	
WHO GMP certificate	100	34,130.51	6,297.08	2,000.00	853.26	43,280.85	
Free Sale Certificate	50	17,065.26	3,148.54	1,706.53	426.63	22,346.96	
Agency Transfer per each party	Manufacturer	1000	341,305.10	62,970.79	-	8,532.63	412,808.52
	Each new marketing authorization holder	1000	341,305.10	62,970.79	-	8,532.63	412,808.52

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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	102,391.53	18,891.24	-	123,842.56
	Category B	100	34,130.51	6,297.08	-	41,280.85
A Packaging/ Repackaging site	100	34,130.51	6,297.08	-	853.26	41,280.85

(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	5,119,576.50	944,561.86	-	127,989.41	6,192,127.77
Other Countries	20000	6,826,102.00	1,259,415.82	-	170,652.55	8,256,170.37

* 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	34,130.51	6,297.08	2,000.00	853.26	43,280.85

(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	341,305.10	62,970.79	-	8,532.63	412,808.52

* Separate Applications should be submitted for each advertisement.

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