

NMRA Monthly fee for Medical Device - Effective from 01/12/2025 to 31/12/2025

Dollar rates are converted at the selling rate on last working day of the preceding month (28.11.2025) which was published by the Central Bank of Sri Lanka.

Daily Exchange Rates	2025/11/28	
Currency	Buying Rate (Rs.)	Selling Rate (Rs.)
Dollar (USD)	304 2467	311 8044

(I) Processing fee

Type		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
New Application	Foreign	1000	311,804.40	57,527.91	-	7,795.11	377,127.42
	Local - Category A	750	233,853.30	43,145.93	-	5,846.33	282,845.56
	Local - Category B	250	77,951.10	14,381.98	-	1,948.78	94,281.86
Application for Registration renewal after five years	Foreign	750	233,853.30	43,145.93	-	5,846.33	282,845.56
	Local - Category A	500	155,902.20	28,763.96	-	3,897.56	188,563.72
	Local - Category B	200	62,360.88	11,505.58	-	1,559.02	75,425.48
Application for Manufacturing Plant (MP) approval - Foreign		1500	467,706.60	86,291.87	-	11,692.67	565,691.14

(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	155,902.20	28,763.96	-	3,897.56	188,563.72
	Local - Category A	200	62,360.88	11,505.58	-	1,559.02	75,425.48
	Local - Category B	100	31,180.44	5,752.79	-	779.51	37,712.74
Additional data for Manufacturing Plant (MP) Evaluation		300	93,541.32	17,258.37	-	2,338.53	113,138.22
Variations that require review		200	62,360.88	11,505.58	-	1,559.02	75,425.48


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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	311,804.40	57,527.91	-	7,795.11	377,127.42
Local Investigator Sponsored		Free of Charge				
Academic with International Sponsorship	250	77,951.10	14,381.98	-	1,948.78	94,281.86
Amendments that require review	250	77,951.10	14,381.98	-	1,948.78	94,281.86

(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	124,721.76	23,011.16	2,000.00	3,118.04	152,850.96
	Local Category A	200	62,360.88	11,505.58	2,000.00	1,559.02	77,425.48
	Local Category B	100	31,180.44	5,752.79	2,000.00	779.51	39,712.74
Provisional Registration (may be issued for a maximum of two years)	Foreign	200	62,360.88	11,505.58	2,000.00	1,559.02	77,425.48
	Local Category A	100	31,180.44	5,752.79	2,000.00	779.51	39,712.74
	Local Category B	50	15,590.22	2,876.40	1,559.02	389.76	20,415.40
Duplicate Copy of Registration Certificate		250	77,951.10	14,381.98	2,000.00	1,948.78	96,281.86
Amendment of Registration Certificate		100	31,180.44	5,752.79	2,000.00	779.51	39,712.74

(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	31,180.44	5,752.79	2,000.00	779.51	39,712.74
Import License		100	31,180.44	5,752.79	2,000.00	779.51	39,712.74
Manufacturing License	Local Category A	100	31,180.44	5,752.79	2,000.00	779.51	39,712.74
	Local Category B	50	15,590.22	2,876.40	1,559.02	389.76	20,415.40
Amendment of License		100	31,180.44	5,752.79	2,000.00	779.51	39,712.74


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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	15,590.22	2,876.40	-	389.76	18,856.38
Submission/ Approval fee for waiver of registration	Invoice value USD 2000 or below	50	15,590.22	2,876.40	-	389.76	18,856.38
	Invoice value USD 2,000-USD 10,000	100	31,180.44	5,752.79	-	779.51	37,712.74
	Invoice value USD 10,000-USD 15,000	200	62,360.88	11,505.58	-	1,559.02	75,425.48
	Invoice value USD 15,000-USD 20,000	500	155,902.20	28,763.96	-	3,897.56	188,563.72
	Invoice value USD 20,000 or above	750	233,853.30	43,145.93	-	5,846.33	282,845.56
Any clarification letter		10	3,118.04	575.28	-	77.95	3,771.27
WHO GMP certificate		100	31,180.44	5,752.79	2,000.00	779.51	39,712.74
Free Sale Certificate		50	15,590.22	2,876.40	1,559.02	389.76	20,415.40
Agency Transfer per each party	Manufacturer	1000	311,804.40	57,527.91	-	7,795.11	377,127.42
	Each new marketing authorization holder	1000	311,804.40	57,527.91	-	7,795.11	377,127.42



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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	77,951.10	14,381.98	-	1,948.78	94,281.86
2 (b)	Microbiological Test		250	77,951.10	14,381.98	-	1,948.78	94,281.86
3 (c)	Assay Test (Chemical, Microbiological, Biological)		250	77,951.10	14,381.98	-	1,948.78	94,281.86
4 (d)	Limit Test (performed using Analytical Equipment - HPLC,AAS etc.)		250	77,951.10	14,381.98	-	1,948.78	94,281.86
5 (e)	Three tests or less than three tests	i). If all three tests are in categories (a), (b), (c) & (d) specified above	750	233,853.30	43,145.93	-	5,846.33	282,845.56
		(ii). Otherwise	500	155,902.20	28,763.96	-	3,897.56	188,563.72
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	467,706.60	86,291.87	-	11,692.67	565,691.14
		(ii). Otherwise	1000	311,804.40	57,527.91	-	7,795.11	377,127.42
7 (g)	Single test	Test other than the categories (a), (b), (c), & (d) specified above	175	54,565.77	10,067.38	-	1,364.14	65,997.29


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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	93,541.32	17,258.37	-	2,338.53	113,138.22
	Category B	100	31,180.44	5,752.79	-	779.51	37,712.74
A Packaging/ Repackaging site		100	31,180.44	5,752.79	-	779.51	37,712.74

(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	4,677,066.00	862,918.68	-	116,926.65	5,656,911.33
Other Countries	20000	6,236,088.00	1,150,558.24	-	155,902.20	7,542,548.44

* 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	31,180.44	5,752.79	2,000.00	779.51	39,712.74

(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	311,804.40	57,527.91	-	7,795.11	377,127.42

* Separate Applications should be submitted for each advertisement.


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