

NMRA Monthly fee for Medical Device - Effective from 01/04/2026 to 30/04/2026

Dollar rates are converted at the selling rate on last working day of the preceding month (31.03.2026) which was published by the Central Bank of Sri Lanka.

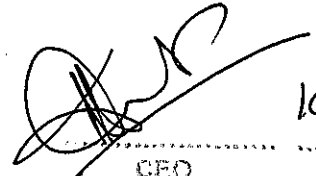
Daily Exchange Rates	2026/03/31	
Currency	Buying Rate (Rs.)	Selling Rate (Rs.)
Dollar (USD)	311.7664	319.312

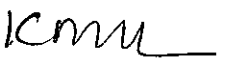
(I) Processing fee

Type		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
New Application	Foreign	1000	319,312.00	58,913.06	-	7,982.80	386,207.86
	Local - Category A	750	239,484.00	44,184.80	-	5,987.10	289,655.90
	Local - Category B	250	79,828.00	14,728.27	-	1,995.70	96,551.97
Application for Registration renewal after five years	Foreign	750	239,484.00	44,184.80	-	5,987.10	289,655.90
	Local - Category A	500	159,656.00	29,456.53	-	3,991.40	193,103.93
	Local - Category B	200	63,862.40	11,782.61	-	1,596.56	77,241.57
Application for Manufacturing Plant (MP) approval - Foreign		1500	478,968.00	88,369.60	-	11,974.20	579,311.80

(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	159,656.00	29,456.53	-	3,991.40	193,103.93
	Local - Category A	200	63,862.40	11,782.61	-	1,596.56	77,241.57
	Local - Category B	100	31,931.20	5,891.31	-	798.28	38,620.79
Additional data for Manufacturing Plant (MP) Evaluation		300	95,793.60	17,673.92	-	2,394.84	115,862.36
Variations that require review		200	63,862.40	11,782.61	-	1,596.56	77,241.57


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(III) Processing fees for Clinical Trial

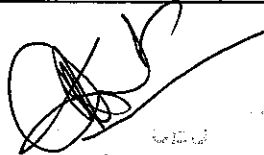
Type of Evaluation	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
Industry Sponsored	1000	319,312.00	58,913.06	-	7,982.80	386,207.86
Local Investigator Sponsored		Free of Charge				
Academic with International Sponsorship	250	79,828.00	14,728.27	-	1,995.70	96,551.97
Amendments that require review	250	79,828.00	14,728.27	-	1,995.70	96,551.97

(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	127,724.80	23,565.23	2,000.00	3,193.12	156,483.15
	Local Category A	200	63,862.40	11,782.61	2,000.00	1,596.56	79,241.57
	Local Category B	100	31,931.20	5,891.31	2,000.00	798.28	40,620.79
Provisional Registration (may be issued for a maximum of two years)	Foreign	200	63,862.40	11,782.61	2,000.00	1,596.56	79,241.57
	Local Category A	100	31,931.20	5,891.31	2,000.00	798.28	40,620.79
	Local Category B	50	15,965.60	2,945.65	1,596.56	399.14	20,906.95
Duplicate Copy of Registration Certificate	250	79,828.00	14,728.27	2,000.00	1,995.70	98,551.97	
Amendment of Registration Certificate	100	31,931.20	5,891.31	2,000.00	798.28	40,620.79	

(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	31,931.20	5,891.31	2,000.00	798.28	40,620.79	
Import License	100	31,931.20	5,891.31	2,000.00	798.28	40,620.79	
Manufacturing License	Local Category A	100	31,931.20	5,891.31	2,000.00	798.28	40,620.79
	Local Category B	50	15,965.60	2,945.65	1,596.56	399.14	20,906.95
Amendment of License	100	31,931.20	5,891.31	2,000.00	798.28	40,620.79	


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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	15,965.60	2,945.65	-	399.14	19,310.39
Submission/ Approval fee for waiver of registration	Invoice value USD 2000 or below	50	15,965.60	2,945.65	-	399.14	19,310.39
	Invoice value USD 2,000- USD 10,000	100	31,931.20	5,891.31	-	798.28	38,620.79
	Invoice value USD 10,000- USD 15,000	200	63,862.40	11,782.61	-	1,596.56	77,241.57
	Invoice value USD 15,000- USD 20,000	500	159,656.00	29,456.53	-	3,991.40	193,103.93
	Invoice value USD 20,000 or above	750	239,484.00	44,184.80	-	5,987.10	289,655.90
Any clarification letter		10	3,193.12	589.13	-	79.83	3,862.08
WHO GMP certificate		100	31,931.20	5,891.31	2,000.00	798.28	40,620.79
Free Sale Certificate		50	15,965.60	2,945.65	1,596.56	399.14	20,906.95
Agency Transfer per each party	Manufacturer	1000	319,312.00	58,913.06	-	7,982.80	386,207.86
	Each new marketing authorization holder	1000	319,312.00	58,913.06	-	7,982.80	386,207.86


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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	95,793.60	17,673.92	-	115,862.36
	Category B	100	31,931.20	5,891.31	-	38,620.79
A Packaging/ Repackaging site	100	31,931.20	5,891.31	-	798.28	38,620.79

(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	4,789,680.00	883,695.96	-	119,742.00	5,793,117.96
Other Countries	20000	6,386,240.00	1,178,261.28	-	159,656.00	7,724,157.28

* 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	31,931.20	5,891.31	2,000.00	798.28	40,620.79

(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	319,312.00	58,913.06	-	7,982.80	386,207.86

* Separate Applications should be submitted for each advertisement.


 CEO
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