

NMRA Monthly fee for Borderline Products - Effective from 01/05/2026 to 31/05/2026

Dollar rates are converted at the selling rate on last working day of the preceding month (30.04.2026) which was published by the Central Bank of Sri Lanka.

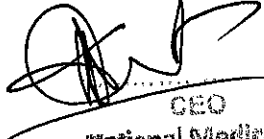
Daily Exchange Rates	2026/04/30	
Currency	Buying Rate (Rs.)	Selling Rate (Rs.)
Dollar (USD)	315.8712	323.8049


(I) Processing Fees

Type of evaluation		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
New Application - Part 1-Initial decision on application (process or decline)	Foreign	500	161,902.45	29,871.00	-	4,047.56	195,821.01
	Local	Free of charge					
New Application - Part 2 - Evaluation (If accepted)	Foreign	1000	323,804.90	59,742.00	-	8,095.12	391,642.02
	Local	750	242,853.68	44,806.50	-	6,071.34	293,731.52
Application for Registration renewal after five years	Foreign	750	242,853.68	44,806.50	-	6,071.34	293,731.52
	Local	500	161,902.45	29,871.00	-	4,047.56	195,821.01
Application for Manufacturing Plant (MP) approval	Foreign Manufacturing plant	1500	485,707.35	89,613.01	-	12,142.68	587,463.04

(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	161,902.45	29,871.00	-	4,047.56	195,821.01
	Local	200	64,760.98	11,948.40	-	1,619.02	78,328.40
Additional data for Manufacturing plant (MP) Evaluation		300	97,141.47	17,922.60	-	2,428.54	117,492.61
Variations that require review		200	64,760.98	11,948.40	-	1,619.02	78,328.40


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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	323,804.90	59,742.00	-	8,095.12	391,642.02
Local Investigator Sponsored			Free of Charge			
Academic with International Sponsorship	250	80,951.23	14,935.50	-	2,023.78	97,910.51
Amendments that require review	250	80,951.23	14,935.50	-	2,023.78	97,910.51

(IV) Fees for Certificates

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	129,521.96	23,896.80	2,000.00	3,238.05	158,656.81
	Local	200	64,760.98	11,948.40	2,000.00	1,619.02	80,328.40
Provisional Registration; (may be issued for maximum period of two years)	Foreign	200	64,760.98	11,948.40	2,000.00	1,619.02	80,328.40
	Local	100	32,380.49	5,974.20	2,000.00	809.51	41,164.20
Duplicate Copy of Registration Certificate		250	80,951.23	14,935.50	2,000.00	2,023.78	99,910.51
Amendment of Registration Certificate		100	32,380.49	5,974.20	2,000.00	809.51	41,164.20

(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	32,380.49	5,974.20	2,000.00	809.51	41,164.20
Import License	100	32,380.49	5,974.20	2,000.00	809.51	41,164.20
Manufacturing License	100	32,380.49	5,974.20	2,000.00	809.51	41,164.20
Amendment of License	100	32,380.49	5,974.20	2,000.00	809.51	41,164.20


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(VI) Fees for Other Approvals for Borderline Products

Type of Approval	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)	
Formulation Approval of local manufacturer	200	64,760.98	11,948.40	-	1,619.02	78,328.40	
Approval for Packaging/ Repackaging	50	16,190.25	2,987.10	-	404.76	19,582.11	
Submission/ Approval fee for waiver of registration	Invoice value USD 2,000 or below	50	16,190.25	2,987.10	-	404.76	19,582.11
	Invoice value USD 2,000-USD 15,000	100	32,380.49	5,974.20	-	809.51	39,164.20
	Invoice value USD 15,000 or above	200	64,760.98	11,948.40	-	1,619.02	78,328.40
Any Clarification letter	10	3,238.05	597.42	-	80.95	3,916.42	
WHO GMP certificate	100	32,380.49	5,974.20	2,000.00	809.51	41,164.20	
Certificate of Pharmaceutical Product (COPP)	50	16,190.25	2,987.10	1,619.02	404.76	21,201.13	
Free Sale Certificate	50	16,190.25	2,987.10	1,619.02	404.76	21,201.13	
Agency Transfer per each party	Manufacturer	1000	323,804.90	59,742.00	-	8,095.12	391,642.02
	Each new marketing authorization holder	1000	323,804.90	59,742.00	-	8,095.12	391,642.02

(VII) Fees 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	300	97,141.47	17,922.60	-	2,428.54	117,492.61
A Packaging / Repackaging site	100	32,380.49	5,974.20	-	809.51	39,164.20

(VIII) 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	4,857,073.50	896,130.06	-	121,426.84	5,874,630.40
Other Countries	20000	6,476,098.00	1,194,840.08	-	161,902.45	7,832,840.53

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


 Director General
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(IX) 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	32,380.49	5,974.20	2,000.00	809.51	41,164.20

(X) Fee for Advertisement

Advertisement	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
Processing fee for an Advertisement (All categories)	1000	323,804.90	59,742.00	-	8,095.12	391,642.02

* Separate Applications should be submitted for each advertisement.


 CEO Accountant
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