NMRA Monthly fee for Borderline Products - 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 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	168,571.55	31,101.45	-	4,214.29	203,887.29
	Local	Free of charge					
New Application - Part 2 - Evaluation (If accepted)	Foreign	1000	337,143.10	62,202.90	-	8,428.58	407,774.58
	Local	750	252,857.33	46,652.18	-	6,321.43	305,830.94
Application for Registration renewal after five years	Foreign	750	252,857.33	46,652.18	-	6,321.43	305,830.94
	Local	500	168,571.55	31,101.45	-	4,214.29	203,887.29
Application for Manufacturing Plant (MP) approval	Foreign Manufacturing plant	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	200	67,428.62	12,440.58	-	1,685.72	81,554.92
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

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	200	67,428.62	12,440.58	2,000.00	1,685.72	83,554.92
Provisional Registration; (may be issued for maximum period of two years)	Foreign	200	67,428.62	12,440.58	2,000.00	1,685.72	83,554.92
	Local	100	33,714.31	6,220.29	2,000.00	842.86	42,777.46
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	100	33,714.31	6,220.29	2,000.00	842.86	42,777.46
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 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	67,428.62	12,440.58	-	1,685.72	81,554.92
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 2,000 or below	50	16,857.16	3,110.15	-	421.43	20,388.74
	Invoice value USD 2,000-USD 15,000	100	33,714.31	6,220.29	-	842.86	40,777.46
	Invoice value USD 15,000 or above	200	67,428.62	12,440.58	-	1,685.72	81,554.92
Any Clarification 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
Certificate of Pharmaceutical Product (COPP)		50	16,857.16	3,110.15	1,685.72	421.43	22,074.46
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

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

(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	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

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

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

* Separate Applications should be submitted for each advertisement.

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