

NMRA Monthly fee for Borderline Products - Effective from 01/08/2026 to 31/08/2026

Dollar rates are converted at the selling rate on last working day of the preceding month (31.07.2026) which was published by the Central Bank of Sri Lanka.

Daily Exchange Rates		2026/07/31
Currency	Buying Rate (Rs.)	Selling Rate (Rs.)
Dollar (USD)	331.206	340.3301

(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	170,165.05	31,395.45	-	4,254.13	205,814.63
	Local	Free of charge					
New Application - Part 2 - Evaluation (If accepted)	Foreign	1000	340,330.10	62,790.90	-	8,508.25	411,629.25
	Local	750	255,247.58	47,093.18	-	6,381.19	308,721.95
Application for Registration renewal after five years	Foreign	750	255,247.58	47,093.18	-	6,381.19	308,721.95
	Local	500	170,165.05	31,395.45	-	4,254.13	205,814.63
Application for Manufacturing Plant (MP) approval	Foreign Manufacturing plant	1500	510,495.15	94,186.36	-	12,762.38	617,443.89

(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	170,165.05	31,395.45	-	4,254.13	205,814.63
	Local	200	68,066.02	12,558.18	-	1,701.65	82,325.85
Additional data for Manufacturing plant (MP) Evaluation		300	102,099.03	18,837.27	-	2,552.48	123,488.78
Variations that require review		200	68,066.02	12,558.18	-	1,701.65	82,325.85

Dr. P. V. M. Mahipala
 Director
 National Medicines Regulatory Authority
 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100

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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	340,330.10	62,790.90	-	8,508.25	411,629.25
Local Investigator Sponsored		Free of Charge				
Academic with International Sponsorship	250	85,082.53	15,697.73	-	2,127.06	102,907.32
Amendments that require review	250	85,082.53	15,697.73	-	2,127.06	102,907.32

(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	136,132.04	25,116.36	2,000.00	3,403.30	166,651.70
	Local	200	68,066.02	12,558.18	2,000.00	1,701.65	84,325.85
Provisional Registration; (may be issued for maximum period of two years)	Foreign	200	68,066.02	12,558.18	2,000.00	1,701.65	84,325.85
	Local	100	34,033.01	6,279.09	2,000.00	850.83	43,162.93
Duplicate Copy of Registration Certificate		250	85,082.53	15,697.73	2,000.00	2,127.06	104,907.32
Amendment of Registration Certificate		100	34,033.01	6,279.09	2,000.00	850.83	43,162.93

(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	34,033.01	6,279.09	2,000.00	850.83	43,162.93
Import License	100	34,033.01	6,279.09	2,000.00	850.83	43,162.93
Manufacturing License	100	34,033.01	6,279.09	2,000.00	850.83	43,162.93
Amendment of License	100	34,033.01	6,279.09	2,000.00	850.83	43,162.93

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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	68,066.02	12,558.18	-	1,701.65	82,325.85
Approval for Packaging/ Repackaging		50	17,016.51	3,139.55	-	425.41	20,581.47
Submission/ Approval fee for waiver of registration	Invoice value USD 2,000 or below	50	17,016.51	3,139.55	-	425.41	20,581.47
	Invoice value USD 2,000-USD 15,000	100	34,033.01	6,279.09	-	850.83	41,162.93
	Invoice value USD 15,000 or above	200	68,066.02	12,558.18	-	1,701.65	82,325.85
Any Clarification letter		10	3,403.30	627.91	-	85.08	4,116.29
WHO GMP certificate		100	34,033.01	6,279.09	2,000.00	850.83	43,162.93
Certificate of Pharmaceutical Product (COPP)		50	17,016.51	3,139.55	1,701.65	425.41	22,283.12
Free Sale Certificate		50	17,016.51	3,139.55	1,701.65	425.41	22,283.12
Agency Transfer per each party	Manufacturer	1000	340,330.10	62,790.90	-	8,508.25	411,629.25
	Each new marketing authorization holder	1000	340,330.10	62,790.90	-	8,508.25	411,629.25

(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	102,099.03	18,837.27	-	2,552.48	123,488.78
A Packaging / Repackaging site	100	34,033.01	6,279.09	-	850.83	41,162.93

(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	5,104,951.50	941,863.55	-	127,623.79	6,174,438.84
Other Countries	20000	6,806,602.00	1,255,818.07	-	170,165.05	8,232,585.12

* 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	34,033.01	6,279.09	2,000.00	850.83	43,162.93

(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	340,330.10	62,790.90	-	8,508.25	411,629.25

* Separate Applications should be submitted for each advertisement.

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