

NMRA Monthly fee for Borderline Products - 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 Fees

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	155,902.20	28,763.96	-	3,897.56	188,563.72
	Local	Free of charge					
New Application - Part 2 - Evaluation (If accepted)	Foreign	1000	311,804.40	57,527.91	-	7,795.11	377,127.42
	Local	750	233,853.30	43,145.93	-	5,846.33	282,845.56
Application for Registration renewal after five years	Foreign	750	233,853.30	43,145.93	-	5,846.33	282,845.56
	Local	500	155,902.20	28,763.96	-	3,897.56	188,563.72
Application for Manufacturing Plant (MP) approval	Foreign Manufacturing plant	1500	467,706.60	86,291.87	-	11,692.67	565,691.14

(II) Fees for additional data evaluation

1) 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	188,563.71
	Local	200	62,360.88	11,505.58	-	1,559.02	75,425.48
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


 CEO
 National Medicines Regulatory Authority


 Accountant

NMRA Monthly fee for Borderline Products - Effective from 01/12/2025 to 31/12/2025

(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

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	200	62,360.88	11,505.58	2,000.00	1,559.02	77,425.48
Provisional Registration; (may be issued for maximum period of two years)	Foreign	200	62,360.88	11,505.58	2,000.00	1,559.02	77,425.48
	Local	100	31,180.44	5,752.79	2,000.00	779.51	39,712.74
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	100	31,180.44	5,752.79	2,000.00	779.51	39,712.74
Amendment of License	100	31,180.44	5,752.79	2,000.00	779.51	39,712.74


 CEO
 National Medicines Regulatory Authority


 Accountant

NMRA Monthly fee for Borderline Products - Effective from 01/12/2025 to 31/12/2025

(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	62,360.88	11,505.58	-	1,559.02	75,425.48
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 2,000 or below	50	15,590.22	2,876.40	-	18,856.38
	Invoice value USD 2,000-USD 15,000	100	31,180.44	5,752.79	-	37,712.74
	Invoice value USD 15,000 or above	200	62,360.88	11,505.58	-	75,425.48
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
Certificate of Pharmaceutical Product (COPP)	50	15,590.22	2,876.40	1,559.02	389.76	20,415.40
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	-	377,127.42
	Each new marketing authorization holder	1000	311,804.40	57,527.91	-	377,127.42

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

(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	4,677,066.00	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


 CEO
 National Medicines Regulatory Authority


 Accountant

NMRA Monthly fee for Borderline Products - Effective from 01/12/2025 to 31/12/2025

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

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

* Separate Applications should be submitted for each advertisement.


 CEO
 National Medicines Regulatory Authority


 Accountant
 National Medicines Regulatory Authority