

NMRA Monthly fee for Borderline Products - Effective from 01/08/2025 to 31/08/2025

Dollar rates are converted at the selling rate on last working day of the preceding month (31.07.2025) which was published by the Central Bank of Sri Lanka.

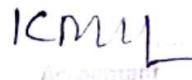
Daily Exchange Rates	2025/07/31	
Currency	Buying Rate (Rs.)	Selling Rate (Rs.)
Dollar (USD)	298.3293	305.8759

(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	152,937.95	28,217.05	-	3,823.45	184,978.45
	Local		Free of charge				
New Application - Part 2 - Evaluation (If accepted)	Foreign	1000	305,875.90	56,434.10	-	7,646.90	369,956.90
	Local	750	229,406.93	42,325.58	-	5,735.17	277,467.68
Application for Registration renewal after five years	Foreign	750	229,406.93	42,325.58	-	5,735.17	277,467.68
	Local	500	152,937.95	28,217.05	-	3,823.45	184,978.45
Application for Manufacturing Plant (MP) approval	Foreign Manufacturing plant	1500	458,813.85	84,651.16	-	11,470.35	554,935.36

(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	152,937.95	28,217.05	-	3,823.45	184,978.45
	Local	200	61,175.18	11,286.82	-	1,529.38	73,991.38
Additional data for Manufacturing plant (MP) Evaluation		300	91,762.77	16,930.23	-	2,294.07	110,987.07
Variations that require review		200	61,175.18	11,286.82	-	1,529.38	73,991.38


 Cashier

 Accountant
 For NMRA, Ministry of Health, Sri Lanka

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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	305,875.90	56,434.10	-	7,646.90	369,956.90
Local Investigator Sponsored		Free of Charge				
Academic with International Sponsorship	250	76,468.98	14,108.53	-	1,911.72	92,489.23
Amendments that require review	250	76,468.98	14,108.53	-	1,911.72	92,489.23

(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	122,350.36	22,573.64	2,000.00	3,058.76	149,982.76
	Local	200	61,175.18	11,286.82	2,000.00	1,529.38	75,991.38
Provisional Registration; (may be issued for maximum period of two years)	Foreign	200	61,175.18	11,286.82	2,000.00	1,529.38	75,991.38
	Local	100	30,587.59	5,643.41	2,000.00	764.69	38,995.69
Duplicate Copy of Registration Certificate		250	76,468.98	14,108.53	2,000.00	1,911.72	94,489.23
Amendment of Registration Certificate		100	30,587.59	5,643.41	2,000.00	764.69	38,995.69

(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	30,587.59	5,643.41	2,000.00	764.69	38,995.69
Import License	100	30,587.59	5,643.41	2,000.00	764.69	38,995.69
Manufacturing License	100	30,587.59	5,643.41	2,000.00	764.69	38,995.69
Amendment of License	100	30,587.59	5,643.41	2,000.00	764.69	38,995.69


 Chairman
 National Medicines Regulatory Authority

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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	61,175.18	11,286.82	-	1,529.38	73,991.38
Approval for Packaging/ Repackaging	50	15,293.80	2,821.71	-	382.34	18,497.86
Submission/ Approval fee for waiver of registration	Invoice value USD 2,000 or below	50	15,293.80	2,821.71	-	18,497.86
	Invoice value USD 2,000-USD 15,000	100	30,587.59	5,643.41	-	36,995.69
	Invoice value USD 15,000 or above	200	61,175.18	11,286.82	-	73,991.38
Any Clarification letter	10	3,058.76	564.34	-	76.47	3,699.57
WHO GMP certificate	100	30,587.59	5,643.41	2,000.00	764.69	38,995.69
Certificate of Pharmaceutical Product (COPP)	50	15,293.80	2,821.71	1,529.38	382.34	20,027.24
Free Sale Certificate	50	15,293.80	2,821.71	1,529.38	382.34	20,027.24
Agency Transfer per each party	Manufacturer	1000	305,875.90	56,434.10	-	369,956.90
	Each new marketing authorization holder	1000	305,875.90	56,434.10	-	369,956.90

(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	91,762.77	16,930.23	-	2,294.07	110,987.07
A Packaging / Repackaging site	100	30,587.59	5,643.41	-	764.69	36,995.69

(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	4,588,138.50	846,511.55	-	114,703.46	5,549,353.51
Other Countries	20000	6,117,518.00	1,128,682.07	-	152,937.95	7,399,138.02

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


 K. M. L.
 Assistant
 National Medicines Regulatory Authority

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(IX) Fee for sample import license for clinical trials

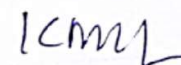
Category	Fee (USD)	Amount (Rs.)	VAT (Rs.) @18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
Fee for sample import license for clinical trials	100	30,587.59	5,643.41	2,000.00	764.69	38,995.69

(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	305,875.90	56,434.10	-	7,646.90	369,956.90

* Separate Applications should be submitted for each advertisement.


Chairman
National Medicines Regulatory Authority


Accountant
National Medicines Regulatory Authority