


NMRA Monthly fee for Medicines - 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 fee for applications for registrations of medicines


	Type of evaluation		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
1	New Molecule Entity (A chemical moiety which has not been previously registered in Sri Lanka, including a new salt, an ester or complex of a previously approved Chemical moiety)	Part 1 Application for Initial decision on Molecule (process or decline)	500	155,902.20	28,763.96	-	3,897.56	188,563.72
		Part 2 Evaluation (if accepted)	1500	467,706.60	86,291.87	-	11,692.67	565,691.14
2	New Dosage Form (Any physical form of a registered medicine in Sri Lanka other than the available registered forms)		1000	311,804.40	57,527.91	-	7,795.11	377,127.42



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3	New Combination Product (A new combination product is a formulation of two or more medicines in a single dosage form which has not been previously registered in Sri Lanka.)		1500	467,706.60	86,291.87	-	11,692.67	565,691.14
4	New Product (Any new product of an already registered medicine in Sri Lanka.)	Foreign	750	233,853.30	43,145.93	-	5,846.33	282,845.56
		(Local) Category A- (i) Medicines to be administered internally (e.g. oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (e.g. ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally.	500	155,902.20	28,763.96	-	3,897.56	188,563.72
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal products.	200	62,360.88	11,505.58	-	1,559.02	75,425.48
5	Therapeutic Biological and Biotechnological Product		2000	623,608.80	115,055.82	-	15,590.22	754,254.84
6	Medicines required for rare diseases and medicines required in small quantities (List of products in this category published in the NMRA Official Website.)		Free of Charge					


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			750	233,853.30	43,145.93	-	5,846.33	282,845.56
7	Application for renewal of registration after five years	Foreign						
		(Local) Category A-						
		(i) Medicines to be administered internally (e.g. oral, injectable, inhalational)						
		(ii) Medicines to be administered through other body cavities (e.g. ophthalmic, otological, nasal, rectal, vaginal)						
		(iii) Anti-infective and steroidal products to be applied locally.	500	155,902.20	28,763.96	-	3,897.56	188,563.72
		Category B-						
		Dosage forms applicable on skin other than anti-infective or steroidal product.	200	62,360.88	11,505.58	-	1,559.02	75,425.48


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(II) Processing fee for applications for licenses and others


	Type of evaluation	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
1	Application for Sample Import License	50	15,590.22	2,876.40	-	389.76	18,856.38
2	Application for Manufacturing Premises (MP) approval -	2000	623,608.80	115,055.82	-	15,590.22	754,254.84
3	Renewal application for Manufacturing Premises (MP) approval - Foreign	500	155,902.20	28,763.96	-	3,897.56	188,563.72
4	Application for Licenses for licensed Importer of Medicines	600	187,082.64	34,516.75	-	4,677.07	226,276.46
5	Renewal for Licenses for licensed Importer of Medicines	200	62,360.88	11,505.58	-	1,559.02	75,425.48
6	Application fee for appointment of New Market Authorization Holder	500	155,902.20	28,763.96	-	3,897.56	188,563.72
7	Application fee for preliminary approval of a local manufacturing plant						
	Category A- (i) Medicines to be administered internally (e.g. oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (e.g. ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally.	100	31,180.44	5,752.79	-	779.51	37,712.74
	Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	50	15,590.22	2,876.40	-	389.76	18,856.38




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8	Application fee for renewal of a local manufacturing Plant approval	Category A- (i) Medicines to be administered internally (e.g. oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (e.g. ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally.	100	31,180.44	5,752.79	-	779.51	37,712.74
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	50	15,590.22	2,876.40	-	389.76	18,856.38



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(III) Fees for additional data evaluation

Type of evaluation		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)	
1	Additional data Evaluation for medicine registration.	Foreign	500	155,902.20	28,763.96	-	3,897.56	188,563.72
		(Local) Category A- (i) Medicines to be administered internally (e.g. oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (e.g. ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally.	200	62,360.88	11,505.58	-	1,559.02	75,425.48
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	100	31,180.44	5,752.79	-	779.51	37,712.74
		Free of Charge						
2	Additional data evaluation for Medicines required for rare diseases and medicines required in Small quantities (List of products in this category is published in the NMRA Official Website).							
3	Additional data for MP Evaluation - Foreign		500	155,902.20	28,763.96	-	3,897.56	188,563.72
4	Variations that require review (except for medicines required for rare diseases and medicines required in small quantities)	Notification	Free of Charge					
		Minor Variations	100	31,180.44	5,752.79	-	779.51	37,712.74
		Major Variations						
			250	77,951.10	14,381.98	-	1,948.78	94,281.86
5	Any variation for medicines required for rare diseases and medicines required in small quantities		Free of Charge					



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(IV) Processing fees for Clinical Trial

	Type of Evaluation		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
1	Industry Sponsored		1000	311,804.40	57,527.91	-	7,795.11	377,127.42
2	Academic with International Sponsorship		250	77,951.10	14,381.98	-	1,948.78	94,281.86
3	Local Investigator Sponsored		Free of Charge					
4	Amendments that require review	Industry Sponsored	250	77,951.10	14,381.98	-	1,948.78	94,281.86
		Academic with International Sponsorship	50	15,590.22	2,876.40	-	389.76	18,856.38
		Local Investigator Sponsored	Free of Charge					


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(V) Fees for Certificates of Registration

Types of Registration Certificates		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)	
1	Full registration (issued for five years)	Foreign	400	124,721.76	23,011.16	2,000.00	3,118.04	152,850.96
		(Local)						
		Category A-						
		(i) Medicines to be administered internally (e.g. oral, injectable, inhalational)						
		(ii) Medicines to be administered through other body cavities (e.g. ophthalmic, otological, nasal, rectal, vaginal)						
	(iii) Anti-infective and steroidal products to be applied locally.	200	62,360.88	11,505.58	2,000.00	1,559.02	77,425.48	
	Category B-							
	Dosage forms applicable on skin other than anti-infective or steroidal product.	100	31,180.44	5,752.79	2,000.00	779.51	39,712.74	
	Medicines required for rare diseases and medicines required in Small quantities	Free of Charge						
	Provisional Registration (issued for a maximum period of two years)	Foreign	200	62,360.88	11,505.58	2,000.00	1,559.02	77,425.48


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2	(Local) Category A- (i) Medicines to be administered internally (e.g. oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (e.g. ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally.	100	31,180.44	5,752.79	2,000.00	779.51	39,712.74
	Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	50	15,590.22	2,876.40	1,559.02	389.76	20,415.40
	Medicines required for rare diseases and medicines required in Small quantities	Free of Charge					
3	Approval for a foreign manufacturing premises	250	77,951.10	14,381.98	2,000.00	1,948.78	96,281.86
4	GMP Certificate for foreign manufacturing premises (on request)	250	77,951.10	14,381.98	2,000.00	1,948.78	96,281.86
5	Duplicate Copy of Certificate of Registration	250	77,951.10	14,381.98	2,000.00	1,948.78	96,281.86
6	Amendment of Certificate of Registration/ Approval	100	31,180.44	5,752.79	2,000.00	779.51	39,712.74


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(VI) Fees for License

	Types of licenses		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
1	Sample Import License		50	15,590.22	2,876.40	1,559.02	389.76	20,415.40
2	Import License	for 1 year	100	31,180.44	5,752.79	2,000.00	779.51	39,712.74
		for 2 years	200	62,360.88	11,505.58	2,000.00	1,559.02	77,425.48
3	License for licensed Importer of Medicines		400	124,721.76	23,011.16	2,000.00	3,118.04	152,850.96
4	Manufacturing License (Local)	Category A- (i) Medicines to be administered internally (e.g. oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (e.g. ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally.	100	31,180.44	5,752.79	2,000.00	779.51	39,712.74
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product.	50	15,590.22	2,876.40	1,559.02	389.76	20,415.40



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5	License for licensed local manufacture of medicine	Category A – (i) Medicines to be administered internally (e.g. oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (e.g. ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally	300	93,541.32	17,258.37	2,000.00	2,338.53	115,138.22
		Category B – Dosage forms applicable on skin other than anti-infective or steroidal product	200	62,360.88	11,505.58	2,000.00	1,559.02	77,425.48
6	Duplicate copy of the License		250	77,951.10	14,381.98	2,000.00	1,948.78	96,281.86
7	Amendment of License		100	31,180.44	5,752.79	2,000.00	779.51	39,712.74



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(VII) Fees for Other Approvals

	Type of Approval		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
1	Application for Formulation Approval (local Manufacturing)		25	7,795.11	1,438.20	-	194.88	9,428.19
2	Application for Formulation Approval (local Manufacturing) of medicines required for rare diseases and medicines required in small quantities .		Free of charge					
3	Application for Approval of Repackaging Sites		50	15,590.22	2,876.40	-	389.76	18,856.38
4	(i) Approval for waiver of registration for the government supplies	Invoice Value (USD) 2,000 or below	50	15,590.22	2,876.40	-	389.76	18,856.38
		Invoice Value (USD) 2,000-15,000	100	31,180.44	5,752.79	-	779.51	37,712.74
		Invoice Value (USD) 15,000 or above						
			200	62,360.88	11,505.58	-	1,559.02	75,425.48
5	Any Clarification Letter		10	3,118.04	575.28	-	77.95	3,771.27
6	GMP certificate for a local manufacturing site		100	31,180.44	5,752.79	2,000.00	779.51	39,712.74
7	Certificate of Pharmaceutical Product (COPP)		50	15,590.22	2,876.40	1,559.02	389.76	20,415.40
8	Free Sale Certificate		50	15,590.22	2,876.40	1,559.02	389.76	20,415.40
9	Appointment of New marketing Authorization Holder (Agency Transfer)	From Manufacturer	1000	311,804.40	57,527.91	-	7,795.11	377,127.42
		From Each new marketing authorization holder	500	155,902.20	28,763.96	-	3,897.56	188,563.72


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(VIII) Fees for Analysis

(VIII) Fees for Analysis			Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
	Analysis							
1 (a)	Biological Test		250	77,951.10	14,381.98	-	1,948.78	94,281.86
2(b)	Microbiological Test		250	77,951.10	14,381.98	-	1,948.78	94,281.86
3©	Assay Test (Chemical, Microbiological, Biological)		250	77,951.10	14,381.98	-	1,948.78	94,281.86
4(d)	Limit test (performed using Analytical Equipment- HPLC, AAS etc.)		250	77,951.10	14,381.98	-	1,948.78	94,281.86
5 (e)	Dissolution Test		250	77,951.10	14,381.98	-	1,948.78	94,281.86
6(f)	Three or less than three tests	(I) If all three tests comprise from items 1, 2, 3, 4 and 5 in Column 1	750	233,853.30	43,145.93	-	5,846.33	282,845.56
		(II) Otherwise	500	155,902.20	28,763.96	-	3,897.56	188,563.72
7(g)	Four tests or more than four tests	(I) If all four tests comprise from items 1, 2, 3, 4 and 5 in Column 1	1500	467,706.60	86,291.87	-	11,692.67	565,691.14
		(II) Otherwise tests other than items 1, 2, 3, 4 and 5 in Column 1	1000	311,804.40	57,527.91	-	7,795.11	377,127.42
8(h)	Single Test	tests other than items 1, 2, 3, 4 and 5 in Column 1	175	54,565.77	10,067.38	-	1,364.14	65,997.30


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(IX) Fees for Licenses to deal in medicines in Retail Pharmacies, Wholesale Establishments and Transporting of Medicines.

	Type	Fee (USD)	Amount in (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
1	Wholesale License	60	18,708.26	3,451.67	1870.83	467.71	24,498.47
2	Retail License	45	14,031.20	2,588.76	1403.12	350.78	18,373.86
3	Transport License	10	3,118.04	575.28	311.80	77.95	4,083.07
4	Duplicate of License	50	15,590.22	2,876.40	1559.02	389.76	20,415.40
5	Amended License	30	9,354.13	1,725.84	935.41	233.85	12,249.23
6	TELE Pharmacy (Home Delivery) License (Period of one Year	100	31,180.44	5,752.79	2000	779.51	39,712.74

Processing Fee for application for Licenses and others

	Type	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty	SSCL (Rs.) 2.5%	Total (Rs.)
1	Application fee for Wholesale License	120	37,416.53	6,903.35	-	935.41	45,255.29
2	Application fee for Retail License	90	28,062.40	5,177.51	-	701.56	33,941.47
3	Application fee for Transport License for therapeutic goods	20	6,236.09	1,150.56	-	155.90	7,542.55


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(X) Fee for Pharmacy and Good Distribution Practice Inspection (GDP)

	Type	Fee (USD)	Amount in (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
1	Good Distribution Practice Inspection	100	31,180.44	5,752.79	2000	779.51	39,712.74
2	Pharmacovigilance Inspection	100	31,180.44	5,752.79	2000	779.51	39,712.74

(XI) Fee for Good Manufacturing Practice Inspection (GMP) – Local

	Type	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
1	A Manufacturing site Category A- Manufacturers whose product range include: - (i) Medicines to be administered internally (e.g. oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (e.g. ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally.	300	93,541.32	17,258.37	-	2,338.53	113,138.22
	Category B- Dosage forms applicable on skin other than anti- infective or steroidal product.	100	31,180.44	5,752.79	-	779.51	37,712.74
2	A Repackaging site	100	31,180.44	5,752.79	-	779.51	37,712.74


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(XII) 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.)
1	SAARC Countries	15000	4,677,066.00	862,918.68	-	116,926.65	5,656,911.33
2	Other Countries	20000	6,236,088.00	1,150,558.24	-	155,902.20	7,542,548.44
3	Follow up inspection (All countries)	5000	1,559,022.00	287,639.56	-	38,975.55	1,885,637.11

* Air tickets, Visa fees should be borne by the Applicant.


(XIII) Fee for advertisement

	Advertisement	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
1	Processing fee for the application of an Advertisement (All categories)	700	218,263.08	40,269.54	-	5,456.58	263,989.20
2	Approval of Advertisement (All categories)	300	93,541.32	17,258.37	-	2,338.53	113,138.22

* Separate Applications should be submitted for each advertisement.



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