

NMRA Monthly fee for Medicines - Effective from 01/09/2026 to 30/09/2026

Dollar rates are converted at the selling rate on last working day of the preceding month (31.08.2026) which was published by the Central Bank of Sri Lanka.

Daily Exchange Rates	2026/08/31	
Currency	Buying Rate (Rs.)	Selling Rate (Rs.)
Dollar (USD)	323.4208	332.4895

(I) Processing fee for applications for registrations of medicines

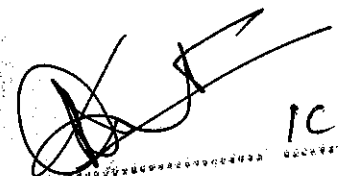
	Type of evaluation	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)	
1	New Molecule Entity (A chemical moiety which has not been previously registered in Sri Lanka, including a new salt, an ester or complex of a previously approved Chemical moiety)	Part 1 Application for Initial decision on Molecule (process or decline)	500	166,244.75	30,672.16	-	4,156.12	201,073.03
		Part 2 Evaluation (if accepted)	1500	498,734.25	92,016.47	-	12,468.36	603,219.08
2	New Dosage Form (Any physical form of a registered medicine in Sri Lanka other than the available registered forms)	1000	332,489.50	61,344.31	-	8,312.24	402,146.05	


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NMRA Monthly fee for Medicines - Effective from 01/09/2026 to 30/09/2026

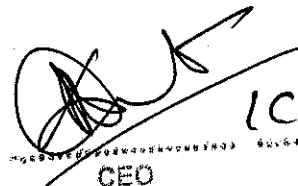
3	New Combination Product (A new combination product is a formulation of two or more medicines in a single dosage form which has not been previously registered in Sri Lanka.)		1500	498,734.25	92,016.47	-	12,468.36	603,219.08
4	New Product (Any new product of an already registered medicine in Sri Lanka.)	Foreign	750	249,367.13	46,008.24	-	6,234.18	301,609.55
		(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	166,244.75	30,672.16	-	4,156.12	201,073.03
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal products.	200	66,497.90	12,268.86	-	1,662.45	80,429.21
			2000	664,979.00	122,688.63	-	16,624.48	804,292.11
5	Therapeutic Biological and Biotechnological Product.							
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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NMRA Monthly fee for Medicines - Effective from 01/09/2026 to 30/09/2026

7	Application for renewal of registration after five years	Foreign	750	249,367.13	46,008.24	-	6,234.18	301,609.55
		(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	166,244.75	30,672.16	-	4,156.12	201,073.03
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product.	200	66,497.90	12,268.86	-	1,662.45	80,429.21


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NMRA Monthly fee for Medicines - Effective from 01/09/2026 to 30/09/2026

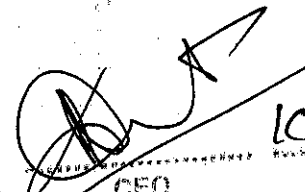
(II) Processing fee for applications for licenses and others

	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	16,624.48	3,067.22	-	415.61	20,107.31
2	Application for Manufacturing Premises (MP) approval -	2000	654,979.00	122,688.63	-	16,624.48	804,292.11
3	Renewal application for Manufacturing Premises (MP) approval - Foreign	500	166,244.75	30,672.16	-	4,156.12	201,073.03
4	Application for Licenses for licensed Importer of Medicines	600	199,493.70	36,806.59	-	4,987.34	241,287.63
5	Renewal for Licenses for licensed Importer of Medicines	200	66,497.90	12,268.86	-	1,662.45	80,429.21
6	Application fee for appointment of New Market Authorization Holder	500	166,244.75	30,672.16	-	4,156.12	201,073.03
7	Application fee for preliminary approval of a local manufacturing plant	100	33,248.95	6,134.43	-	831.22	40,214.60
	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.						
	Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	50	16,624.48	3,067.22	-	415.61	20,107.31


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NMRA Monthly fee for Medicines - Effective from 01/09/2026 to 30/09/2026

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	33,248.95	6,134.43	-	831.22	40,214.60
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	50	16,624.48	3,067.22	-	415.61	20,107.31

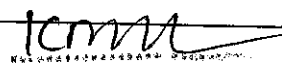

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NMRA Monthly fee for Medicines - Effective from 01/09/2026 to 30/09/2026

(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	166,244.75	30,672.16	-	4,156.12	201,073.03
		(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.						
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	200	66,497.90	12,268.86	-	1,662.45	80,429.21
			100	33,248.95	6,134.43	-	831.22	40,214.60
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).		Free of Charge					
3	Additional data for MP Evaluation - Foreign		500	166,244.75	30,672.16	-	4,156.12	201,073.03
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	33,248.95	6,134.43	-	831.22	40,214.60
		Major Variations						
5	Any variation for medicines required for rare diseases and medicines required in small quantities		250	83,122.38	15,336.08		2,078.06	100,536.52
			Free of Charge					

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NMRA Monthly fee for Medicines - Effective from 01/09/2026 to 30/09/2026

(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	332,489.50	61,344.31	-	8,312.24	402,146.05
2	Academic with International Sponsorship	250	83,122.38	15,336.08	-	2,078.06	100,536.52
3	Local Investigator Sponsored	Free of Charge					
4	Industry Sponsored	250	83,122.38	15,336.08	-	2,078.06	100,536.52
	Academic with International Sponsorship	50	16,624.48	3,067.22	-	415.61	20,107.31
	Local Investigator Sponsored	Free of Charge					

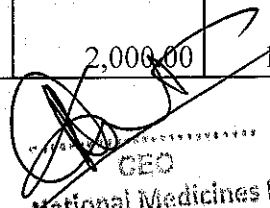

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NMRA Monthly fee for Medicines - Effective from 01/09/2026 to 30/09/2026

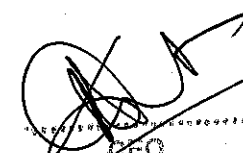
(V) Fees for Certificates of Registration

	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	132,995.80	24,537.73	2,000.00	3,324.90	162,858.43
		(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. <i>ophthalmic, otological, nasal, rectal, vaginal</i>) (iii) Anti-infective and steroidal products to be applied locally.	200	66,497.90	12,268.86	2,000.00	1,662.45	82,429.21
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product.	100	33,248.95	6,134.43	2,000.00	831.22	42,214.60
		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	66,497.90	12,268.86	2,000.00	1,662.45	82,429.21


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NMRA Monthly fee for Medicines - Effective from 01/09/2026 to 30/09/2026

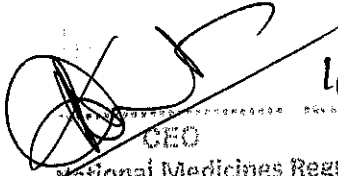
2	(Local) Category A- (i) Medicines to be administered internally (e.g. oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (e.g. ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally.	100	33,248.95	6,134.43	2,000.00	831.22	42,214.60
	Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	50	16,624.48	3,067.22	1,662.45	415.61	21,769.76
	Medicines required for rare diseases and medicines required in Small quantities	Free of Charge					
3	Approval for a foreign manufacturing premises	250	83,122.38	15,336.08	2,000.00	2,078.06	102,536.52
4	GMP Certificate for foreign manufacturing premises (on request)	250	83,122.38	15,336.08	2,000.00	2,078.06	102,536.52
5	Duplicate Copy of Certificate of Registration	250	83,122.38	15,336.08	2,000.00	2,078.06	102,536.52
6	Amendment of Certificate of Registration/ Approval	100	33,248.95	6,134.43	2,000.00	831.22	42,214.60

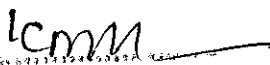

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NMRA Monthly fee for Medicines - Effective from 01/09/2026 to 30/09/2026

(VI) Fees for License

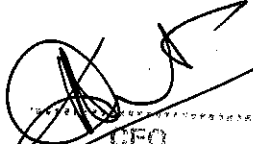
	Types of licenses		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
1	Sample Import License		50	16,624.48	3,067.22	1,662.45	415.61	21,769.76
2	Import License	for 1 year	100	33,248.95	6,134.43	2,000.00	831.22	42,214.60
		for 2 years	200	66,497.90	12,268.86	2,000.00	1,662.45	82,429.21
3	License for licensed Importer of Medicines		400	132,995.80	24,537.73	2,000.00	3,324.90	162,858.43
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	33,248.95	6,134.43	2,000.00	831.22	42,214.60
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product.	50	16,624.48	3,067.22	1,662.45	415.61	21,769.76


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NMRA Monthly fee for Medicines - Effective from 01/09/2026 to 30/09/2026

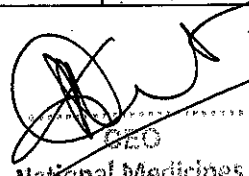
5	License for licensed local manufacture of medicine	Category A – (i) Medicines to be administered internally (e.g. oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (e.g. ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally	300	99,746.85	18,403.29	2,000.00	2,493.67	122,643.81
		Category B – Dosage forms applicable on skin other than anti-infective or steroidal product	200	66,497.90	12,268.86	2,000.00	1,662.45	82,429.21
6	Duplicate copy of the License		250	83,122.38	15,336.08	2,000.00	2,078.06	102,536.52
7	Amendment of License		100	33,248.95	6,134.43	2,000.00	831.22	42,214.60


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NMRA Monthly fee for Medicines - Effective from 01/09/2026 to 30/09/2026

(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	8,312.24	1,533.61	-	207.81	10,053.66
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	16,624.48	3,067.22	-	415.61	20,107.31
4	(i) Approval for waiver of registration for the government supplies (ii) Application for waiver of registration for the private supplies	Invoice Value (USD) 2,000 or below	50	16,624.48	3,067.22	-	415.61	20,107.31
		Invoice Value (USD) 2,000-15,000	100	33,248.95	6,134.43	-	831.22	40,214.60
		Invoice Value (USD) 15,000 or above						
			200	66,497.90	12,268.86	-	1,662.45	80,429.21
5	Any Clarification Letter		10	3,324.90	613.44	-	83.12	4,021.46
6	GMP certificate for a local manufacturing site		100	33,248.95	6,134.43	2,000.00	831.22	42,214.60
7	Certificate of Pharmaceutical Product (COPP)		50	16,624.48	3,067.22	1,662.45	415.61	21,769.76
8	Free Sale Certificate		50	16,624.48	3,067.22	1,662.45	415.61	21,769.76
9	Appointment of New marketing Authorization Holder (Agency Transfer)	From Manufacturer	1000	332,489.50	61,344.31	-	8,312.24	402,146.05
		From Each new marketing authorization holder	500	166,244.75	30,672.16	-	4,156.12	201,073.03

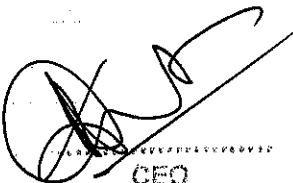

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NMRA Monthly fee for Medicines - Effective from 01/09/2026 to 30/09/2026

(VIII) Fees for Analysis

VIII) Fees for Analysis

	Analysis		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
1 (a)	Biological Test		250	83,122.38	15,336.08	-	2,078.06	100,536.52
2(b)	Microbiological Test		250	83,122.38	15,336.08	-	2,078.06	100,536.52
3©	Assay Test (Chemical, Microbiological, Biological)		250	83,122.38	15,336.08	-	2,078.06	100,536.52
4(d)	Limit test (performed using Analytical Equipment- HPLC, AAS etc.)		250	83,122.38	15,336.08	-	2,078.06	100,536.52
5 (e)	Dissolution Test		250	83,122.38	15,336.08	-	2,078.06	100,536.52
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	249,367.13	46,008.23	-	6,234.18	301,609.55
		(II) Otherwise	500	166,244.75	30,672.16	-	4,156.12	201,073.03
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	498,734.25	92,016.47	-	12,468.36	603,219.08
		(II) Otherwise tests other than items 1, 2, 3, 4 and 5 in Column 1	1000	332,489.50	61,344.31	-	8,312.24	402,146.05
8(h)	Single Test	tests other than items 1, 2, 3, 4 and 5 in Column 1	175	58,185.66	10,735.25	-	1,454.64	70,375.55


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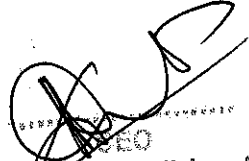
NMRA Monthly fee for Medicines - Effective from 01/09/2026 to 30/09/2026

(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	19,949.37	3,680.66	1994.94	498.73	26,123.70
2	Retail License	45	14,962.03	2,760.49	1496.20	374.05	19,592.77
3	Transport License	10	3,324.90	613.44	332.49	83.12	4,353.95
4	Duplicate of License	50	16,624.48	3,067.22	1662.45	415.61	21,769.76
5	Amended License	30	9,974.69	1,840.33	997.47	249.37	13,061.86
6	TELE Pharmacy (Home Delivery) License (Period of one Year)	100	33,248.95	6,134.43	2000.00	831.22	42,214.60

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	39,898.74	7,361.32	-	997.47	48,257.53
2	Application fee for Retail License	90	29,924.06	5,520.99	-	748.10	36,193.15
3	Application fee for Transport License for therapeutic goods	20	6,649.79	1,226.89	-	166.24	8,042.92


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NMRA Monthly fee for Medicines - Effective from 01/09/2026 to 30/09/2026

(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	33,248.95	6,134.43	2000	831.22	42,214.60
2	Pharmacovigilance Inspection	100	33,248.95	6,134.43	2000	831.22	42,214.60

(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	99,746.85	18,403.29	-	2,493.67	120,643.81
	Category B- Dosage forms applicable on skin other than anti-infective or steroidal product.	100	33,248.95	6,134.43	-	831.22	40,214.60
2	A Repackaging site	100	33,248.95	6,134.43	-	831.22	40,214.60


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NMRA Monthly fee for Medicines - Effective from 01/09/2026 to 30/09/2026

(XII) Fee for Good Manufacturing Practice Inspection (GMP) – Foreign

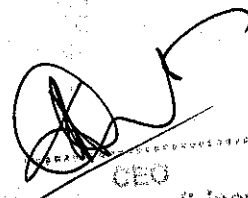
	Country	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
1	SAARC Countries	15000	4,987,342.50	920,164.69	-	124,683.56	6,032,190.75
2	Other Countries	20000	6,649,790.00	1,226,886.26	-	166,244.75	8,042,921.01
3	Follow up inspection (All countries)	5000	1,662,447.50	306,721.56	-	41,561.19	2,010,730.25

* 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	232,742.65	42,941.02	-	5,818.57	281,502.24
2	Approval of Advertisement (All categories)	300	99,746.85	18,403.29	-	2,493.67	120,643.81

* Separate Applications should be submitted for each advertisement.


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