

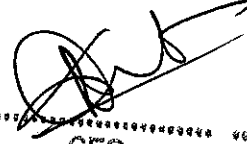
## NMRA Monthly fee for Medicines - Effective from 01/06/2026 to 30/06/2026

Dollar rates are converted at the selling rate on last working day of the preceding month (29.05.2026) which was published by the Central Bank of Sri Lanka.

Daily Exchange Rates	2026/05/29	
Currency	Buying Rate (Rs.)	Selling Rate (Rs.)
Dollar (USD)	324.455	334.2444

### (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)	<b>Part 1</b> Application for Initial decision on Molecule (process or decline)	500	167,122.20	30,834.05	-	4,178.06	202,134.31
		<b>Part 2</b> Evaluation (if accepted)	1500	501,366.60	92,502.14	-	12,534.17	606,402.91
2	New Dosage Form (Any physical form of a registered medicine in Sri Lanka other than the available registered forms)	1000	334,244.40	61,668.09	-	8,356.11	404,268.60	

  
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7	Application for renewal of registration after five years	Foreign	750	250,683.30	46,251.07	-	6,267.08	303,201.45
		(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	167,122.20	30,834.05	-	4,178.06	202,134.31
	Category B- Dosage forms applicable on skin other than anti-infective or steroidal product.	200	66,848.88	12,333.62	-	1,671.22	80,853.72	

  
  
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## NMRA Monthly fee for Medicines - Effective from 01/06/2026 to 30/06/2026

### (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	16,712.22	3,083.41	-	417.81	20,213.44	
2	Application for Manufacturing Premises (MP) approval -	2000	668,488.80	123,336.18	-	16,712.22	808,537.20	
3	Renewal application for Manufacturing Premises (MP) approval - Foreign	500	167,122.20	30,834.05	-	4,178.06	202,134.31	
4	Application for Licenses for licensed Importer of Medicines	600	200,546.64	37,000.86	-	5,013.67	242,561.17	
5	Renewal for Licenses for licensed Importer of Medicines	200	66,848.88	12,333.62	-	1,671.22	80,853.72	
6	Application fee for appointment of New Market Authorization Holder	500	167,122.20	30,834.05	-	4,178.06	202,134.31	
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	33,424.44	6,166.81	-	835.61	40,426.86
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	50	16,712.22	3,083.41	-	417.81	20,213.44

  
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**NMRA Monthly fee for Medicines - Effective from 01/06/2026 to 30/06/2026**

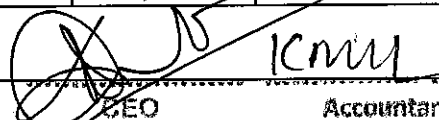
8	Application fee for renewal of a local manufacturing Plant approval	Category A- (i) Medicines to be administered internally (e.g. oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (e.g. ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally.	100	33,424.44	6,166.81	-	835.61	40,426.86
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	50	16,712.22	3,083.41	-	417.81	20,213.44

  
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### (III) Fees for additional data evaluation

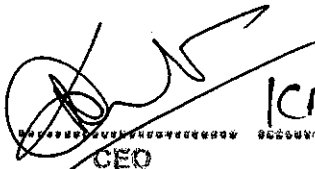
	Type of evaluation	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)	
1	Additional data Evaluation for medicine registration.	500	167,122.20	30,834.05	-	4,178.06	202,134.31	
	(Local) Category A- (i) Medicines to be administered internally (e.g. oral, injectable, inhalational) (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	66,848.88	12,333.62	-	1,671.22	80,853.72	
	Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	100	33,424.44	6,166.81	-	835.61	40,426.86	
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	167,122.20	30,834.05	-	4,178.06	202,134.31	
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	33,424.44	6,166.81	-	835.61	40,426.86
		Major Variations	250	83,561.10	15,417.02	-	2,089.03	101,067.15
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	334,244.40	61,668.09	-	8,356.11	404,268.60	
2	Academic with International Sponsorship	250	83,561.10	15,417.02	-	2,089.03	101,067.15	
3	Local Investigator Sponsored	Free of Charge						
4	Amendments that require review	Industry Sponsored	250	83,561.10	15,417.02	-	2,089.03	101,067.15
		Academic with International Sponsorship	50	16,712.22	3,083.41	-	417.81	20,213.44
		Local Investigator Sponsored	Free of Charge					

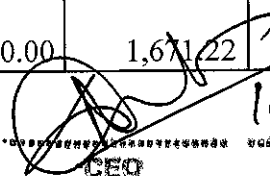
  
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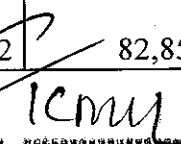
  
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## NMRA Monthly fee for Medicines - Effective from 01/06/2026 to 30/06/2026

### (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)	400	133,697.76	24,667.24	2,000.00	3,342.44	163,707.44
	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.	200	66,848.88	12,333.62	2,000.00	1,671.22	82,853.72
	Category B- Dosage forms applicable on skin other than anti-infective or steroidal product.	100	33,424.44	6,166.81	2,000.00	835.61	42,426.86
	Medicines required for rare diseases and medicines required in Small quantities	<b>Free of Charge</b>					
	Provisional Registration (issued for a maximum period of two years)						
	Foreign	200	66,848.88	12,333.62	2,000.00	1,671.22	82,853.72

  
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## NMRA Monthly fee for Medicines - Effective from 01/06/2026 to 30/06/2026

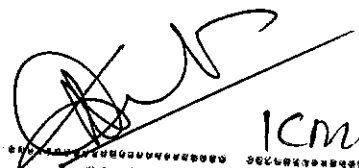
### (VI) Fees for License

	Types of licenses		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
1	Sample Import License		50	16,712.22	3,083.41	1,671.22	417.81	21,884.66
2	Import License	for 1 year	100	33,424.44	6,166.81	2,000.00	835.61	42,426.86
		for 2 years	200	66,848.88	12,333.62	2,000.00	1,671.22	82,853.72
3	License for licensed Importer of Medicines		400	133,697.76	24,667.24	2,000.00	3,342.44	163,707.44
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	33,424.44	6,166.81	2,000.00	835.61	42,426.86
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product.	50	16,712.22	3,083.41	1,671.22	417.81	21,884.66

  
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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)	300	100,273.32	18,500.43	2,000.00	2,506.83	123,280.58
		(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	66,848.88	12,333.62	2,000.00	1,671.22	82,853.72
6	Duplicate copy of the License		250	83,561.10	15,417.02	2,000.00	2,089.03	103,067.15
7	Amendment of License		100	33,424.44	6,166.81	2,000.00	835.61	42,426.86

  
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## NMRA Monthly fee for Medicines - Effective from 01/06/2026 to 30/06/2026

### (VII) Fees for Other Approvals

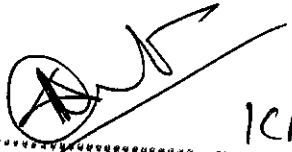
	Type of Approval	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)	
1	Application for Formulation Approval (local Manufacturing)	25	8,356.11	1,541.70	-	208.90	10,106.71	
2	Application for Formulation Approval (local Manufacturing) of medicines required for rare diseases and medicines required in small quantities .	<b>Free of charge</b>						
3	Application for Approval of Repackaging Sites	50	16,712.22	3,083.41	-	417.81	20,213.44	
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	16,712.22	3,083.41	-	417.81	20,213.44
		Invoice Value (USD) 2,000-15,000	100	33,424.44	6,166.81	-	835.61	40,426.86
		Invoice Value (USD) 15,000 or above	200	66,848.88	12,333.62	-	1,671.22	80,853.72
5	Any Clarification Letter	10	3,342.44	616.68	-	83.56	4,042.68	
6	GMP certificate for a local manufacturing site	100	33,424.44	6,166.81	2,000.00	835.61	42,426.86	
7	Certificate of Pharmaceutical Product (COPP)	50	16,712.22	3,083.41	1,671.22	417.81	21,884.66	
8	Free Sale Certificate	50	16,712.22	3,083.41	1,671.22	417.81	21,884.66	
9	Appointment of New marketing Authorization Holder (Agency Transfer)	From Manufacturer	1000	334,244.40	61,668.09	-	8,356.11	404,268.60
		From Each new marketing authorization holder	500	167,122.20	30,834.05	-	4,178.06	202,134.31

  
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## NMRA Monthly fee for Medicines - Effective from 01/06/2026 to 30/06/2026

### (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	83,561.10	15,417.02	-	2,089.03	101,067.15	
2(b)	Microbiological Test	250	83,561.10	15,417.02	-	2,089.03	101,067.15	
3©	Assay Test (Chemical, Microbiological, Biological)	250	83,561.10	15,417.02	-	2,089.03	101,067.15	
4(d)	Limit test (performed using Analytical Equipment- HPLC, AAS etc.)	250	83,561.10	15,417.02	-	2,089.03	101,067.15	
5 (e)	Dissolution Test	250	83,561.10	15,417.02	-	2,089.03	101,067.15	
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	250,683.30	46,251.07	-	6,267.08	303,201.45
		(II) Otherwise	500	167,122.20	30,834.05	-	4,178.06	202,134.31
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	501,366.60	92,502.14	-	12,534.17	606,402.91
		(II) Otherwise tests other than items 1, 2, 3, 4 and 5 in Column 1	1000	334,244.40	61,668.09	-	8,356.11	404,268.60
8(h)	Single Test	175	58,492.77	10,791.92	-	1,462.32	70,747.01	

  
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## NMRA Monthly fee for Medicines - Effective from 01/06/2026 to 30/06/2026

(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	20,054.66	3,700.09	2000.00	501.37	26,256.12
2	Retail License	45	15,041.00	2,775.07	1504.10	376.03	19,696.20
3	Transport License	10	3,342.44	616.68	334.24	83.56	4,376.92
4	Duplicate of License	50	16,712.22	3,083.40	1671.22	417.81	21,884.65
5	Amended License	30	10,027.33	1,850.04	1002.73	250.68	13,130.78
6	TELE Pharmacy (Home Delivery) License (Period of one Year)	100	33,424.44	6,166.81	2000	835.61	42,426.86

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	40,109.33	7,400.17	-	1,002.73	48,512.23
2	Application fee for Retail License	90	30,082.00	5,550.13	-	752.05	36,384.18
3	Application fee for Transport License for therapeutic goods	20	6,684.89	1,233.36	-	167.12	8,085.37

  
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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	33,424.44	6,166.81	2000	835.61	42,426.86
2	Pharmacovigilance Inspection	100	33,424.44	6,166.81	2000	835.61	42,426.86

**(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	100,273.32	18,500.43	-	2,506.83	121,280.58
		100	33,424.44	6,166.81	-	835.61	40,426.86
2	A Repackaging site	100	33,424.44	6,166.81	-	835.61	40,426.86

  
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## NMRA Monthly fee for Medicines - Effective from 01/06/2026 to 30/06/2026

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

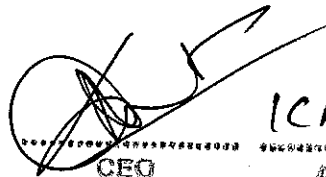
	Country	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
1	SAARC Countries	15000	5,013,666.00	925,021.38	-	125,341.65	6,064,029.03
2	Other Countries	20000	6,684,888.00	1,233,361.84	-	167,122.20	8,085,372.04
3	Follow up inspection (All countries)	5000	1,671,222.00	308,340.46	-	41,780.55	2,021,343.01

\* 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	233,971.08	43,167.66	-	5,849.28	282,988.02
2	Approval of Advertisement (All categories)	300	100,273.32	18,500.43	-	2,506.83	121,280.58

\* Separate Applications should be submitted for each advertisement.

  
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