NMRA Monthly fee for Medicines - Effective from 01/11/2026 to 30/11/2026

Dollar rates are converted at the selling rate on last working day of the preceding month (30.10.2026) which was published by the Central Bank of Sri Lanka.

Daily Exchange Rates	2026.10.30	
Currency	**Buying Rate (Rs.)**	**Selling Rate (Rs.)**
Dollar (USD)	328.0447	337.1431

(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	168,571.55	31,101.45	-	4,214.29	203,887.29
		Part 2 Evaluation (if accepted)	1500	505,714.65	93,304.35	-	12,642.87	611,661.87
2	New Dosage Form (Any physical form of a registered medicine in Sri Lanka other than the available registered forms)		1000	337,143.10	62,202.90	-	8,428.58	407,774.58

CEO

Accountant

National Medicines Regulatory Author

NMRA Monthly fee for Medicines - Effective from 01/11/2026 to 30/11/2026

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	505,714.65	93,304.35	-	12,642.87	611,661.87
4	New Product - (Any new product of an already registered medicine in Sri Lanka.)	Foreign	750	252,857.33	46,652.18	-	6,321.43	305,830.94
		(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	168,571.55	31,101.45	-	4,214.29	203,887.29
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal products.	200	67,428.62	12,440.58	-	1,685.72	81,554.92
5	Therapeutic Biological and Biotechnological Product		2000	674,286.20	124,405.80	-	16,857.16	815,549.16
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					

CEO
National Medicines Regulatory Authority

Accountant

NMRA Monthly fee for Medicines - Effective from 01/11/2026 to 30/11/2026

7	Application for renewal of registration after five years	Foreign	750	252,857.33	46,652.18	-	6,321.43	305,830.94
		(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	168,571.55	31,101.45	-	4,214.29	203,887.29
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product.	200	67,428.62	12,440.58	-	1,685.72	81,554.92

CEO

Accountant

National Medicines Regulatory Authority

NMRA Monthly fee for Medicines - Effective from 01/11/2026 to 30/11/2026

(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	16,857.16	3,110.15	-	421.43	20,388.74
2	Application for Manufacturing Premises (MP) approval -		2000	674,286.20	124,405.80	-	16,857.16	815,549.16
3	Renewal application for Manufacturing Premises (MP) approval - Foreign		500	168,571.55	31,101.45	-	4,214.29	203,887.29
4	Application for Licenses for licensed Importer of Medicines		600	202,285.86	37,321.74	-	5,057.15	244,664.75
5	Renewal for Licenses for licensed Importer of Medicines		200	67,428.62	12,440.58	-	1,685.72	81,554.92
6	Application fee for appointment of New Market Authorization Holder		500	168,571.55	31,101.45	-	4,214.29	203,887.29
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	33,714.31	6,220.29	-	842.86	40,777.46
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	50	16,857.16	3,110.15	-	421.43	20,388.74

CEO

Accountant

National Medicines Regulatory Authority

NMRA Monthly fee for Medicines - Effective from 01/11/2026 to 30/11/2026

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	33,714.31	6,220.29	-	842.86	40,777.46
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	50	16,857.16	3,110.15	-	421.43	20,388.74

CEO
National Medicines Regulatory Authority

Accountant

NMRA Monthly fee for Medicines - Effective from 01/11/2026 to 30/11/2026

(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	168,571.55	31,101.45	-	4,214.29	203,887.29
		(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	67,428.62	12,440.58	-	1,685.72	81,554.92
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	100	33,714.31	6,220.29	-	842.86	40,777.46
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	168,571.55	31,101.45	-	4,214.29	203,887.29
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	33,714.31	6,220.29	-	842.86	40,777.46
		Major Variations	250	84,285.78	15,550.73		2,107.14	101,943.65
5	Any variation for medicines required for rare diseases and medicines required in small quantities		Free of Charge					

Accountant
National Medicines Regulatory Author

NMRA Monthly fee for Medicines - Effective from 01/11/2026 to 30/11/2026

(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	337,143.10	62,202.90	-	8,428.58	407,774.58
2	Academic with International Sponsorship		250	84,285.78	15,550.73	-	2,107.14	101,943.65
3	Local Investigator Sponsored		Free of Charge					
4	Amendments that require review	Industry Sponsored	250	84,285.78	15,550.73	-	2,107.14	101,943.65
		Academic with International Sponsorship	50	16,857.16	3,110.15	-	421.43	20,388.74
		Local Investigator Sponsored	**Free of Charge**					

CEO
National Medicines Regulatory Authority

Accountant

NMRA Monthly fee for Medicines - Effective from 01/11/2026 to 30/11/2026

(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	134,857.24	24,881.16	2,000.00	3,371.43	165,109.83
		(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	67,428.62	12,440.58	2,000.00	1,685.72	83,554.92
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product.	100	33,714.31	6,220.29	2,000.00	842.86	42,777.46
		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	67,428.62	12,440.58	2,000.00	1,685.72	83,554.92

2026 ICMM

Accountant

National Medicines Regulatory Author

NMRA Monthly fee for Medicines - Effective from 01/11/2026 to 30/11/2026

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	33,714.31	6,220.29	2,000.00	842.86	42,777.46
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	50	16,857.16	3,110.15	1,685.72	421.43	22,074.46
		Medicines required for rare diseases and medicines required in Small quantities	**Free of Charge**					
3	Approval for a foreign manufacturing premises		250	84,285.78	15,550.73	2,000.00	2,107.14	103,943.65
4	GMP Certificate for foreign manufacturing premises (on request)		250	84,285.78	15,550.73	2,000.00	2,107.14	103,943.65
5	Duplicate Copy of Certificate of Registration		250	84,285.78	15,550.73	2,000.00	2,107.14	103,943.65
6	Amendement of Certificate of Registration/ Approval		100	33,714.31	6,220.29	2,000.00	842.86	42,777.46

CEO

Accountant

National Medicines Regulatory Authority

NMRA Monthly fee for Medicines - Effective from 01/11/2026 to 30/11/2026

(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	16,857.16	3,110.15	1,685.72	421.43	22,074.46
2	Import License	for 1 year	100	33,714.31	6,220.29	2,000.00	842.86	42,777.46
		for 2 years	200	67,428.62	12,440.58	2,000.00	1,685.72	83,554.92
3	License for licensed Importer of Medicines		400	134,857.24	24,881.16	2,000.00	3,371.43	165,109.83
4	2026	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	33,714.31	6,220.29	2,000.00	842.86	42,777.46
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product.	50	16,857.16	3,110.15	1,685.72	421.43	22,074.46

CEO

Accountant

National Medicines Regulatory Author

NMRA Monthly fee for Medicines - Effective from 01/11/2026 to 30/11/2026

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	101,142.93	18,660.87	2,000.00	2,528.57	124,332.37
		Category B – Dosage forms applicable on skin other than anti-infective or steroidal product	200	67,428.62	12,440.58	2,000.00	1,685.72	83,554.92
6	Duplicate copy of the License		250	84,285.78	15,550.73	2,000.00	2,107.14	103,943.65
7	Amendment of License		100	33,714.31	6,220.29	2,000.00	842.86	42,777.46

CEO

Accountant

National Medicines Regulatory Authority

NMRA Monthly fee for Medicines - Effective from 01/11/2026 to 30/11/2026

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	33,714.31	6,220.29	-	842.86	40,777.46
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	50	16,857.16	3,110.15	-	421.43	20,388.74

CEO
Accountant
National Medicines Regulatory Authority

NMRA Monthly fee for Medicines - Effective from 01/11/2026 to 30/11/2026

(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	8,428.58	1,555.07	-	210.71	10,194.36
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	16,857.16	3,110.15	-	421.43	20,388.74
4	(i) Approval for waiv- er of registration for the government supplies (ii) Application for waiver of registration for the private supplies	Invoice Value (USD) 2,000 or below	50	16,857.16	3,110.15	-	421.43	20,388.74
		Invoice Value (USD) 2,000-15,000	100	33,714.31	6,220.29	-	842.86	40,777.46
		Invoice Value (USD) 15,000 or above	200	67,428.62	12,440.58	-	1,685.72	81,554.92
5	Any Clarification Letter		10	3,371.43	622.03	-	84.29	4,077.75
6	GMP certificate for a local manufacturing site		100	33,714.31	6,220.29	2,000.00	842.86	42,777.46
7	Certificate of Pharmaceutical Product (COPP)		50	16,857.16	3,110.15	1,685.72	421.43	22,074.46
8	Free Sale Certificate		50	16,857.16	3,110.15	1,685.72	421.43	22,074.46
9	Appointment of New marketing Authorization Holder (Agency Transfer)	From Manufacturer	1000	337,143.10	62,202.90	-	8,428.58	407,774.58
		From Each new marketing authorization holder	500	168,571.55	31,101.45	-	4,214.29	203,887.29

CEO
National Medicines Regulatory Author

Accountant

NMRA Monthly fee for Medicines - Effective from 01/11/2026 to 30/11/2026

(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	84,285.78	15,550.73	-	2,107.14	101,943.65
2(b)	Microbiological Test		250	84,285.78	15,550.73	-	2,107.14	101,943.65
3©	Assay Test (Chemical, Microbiological, Biological)		250	84,285.78	15,550.73	-	2,107.14	101,943.65
4(d)	Limit test (performed using Analytical Equipment- HPLC, AAS *etc.*)		250	84,285.78	15,550.73	-	2,107.14	101,943.65
5 (e)	Dissolution Test		250	84,285.78	15,550.73	-	2,107.14	101,943.65
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	252,857.33	46,652.18	-	6,321.43	305,830.94
		(II) Otherwise	500	168,571.55	31,101.45	-	4,214.29	203,887.29
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	505,714.65	93,304.35	-	12,642.87	611,661.87
		(II) Otherwise tests other than items 1, 2, 3, 4 and 5 in Column 1	1000	337,143.10	62,202.90	-	8,428.58	407,774.58
8(h)	Single Test	tests other than items 1, 2, 3, 4 and 5 in Column 1	175	59,000.04	10,885.51	-	1,475.00	71,360.55

CEO

Accountant

National Medicines Regulatory Author

NMRA Monthly fee for Medicines - Effective from 01/11/2026 to 30/11/2026

(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	20,228.59	3,732.17	2000.00	505.71	26,466.47
2	Retail License	45	15,171.44	2,799.13	1517.14	379.29	19,867.00
3	Transport License	10	3,371.43	622.03	337.14	84.29	4,414.89
4	Duplicate of License	50	16,857.16	3,110.15	1685.72	421.43	22,074.44
5	Amended License	30	10,114.29	1,866.09	1011.43	252.86	13,244.67
6	TELE Pharmacy (Home Delivery) License (Period of one Year	100	33,714.31	6,220.29	2000.00	842.86	42,777.46

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	40,457.17	7,464.35	-	1,011.43	48,932.95
2	Application fee for Retaill License	90	30,342.88	5,598.26	-	758.57	36,699.71
3	Application fee for Transport License for therapeutic goods	20	6,742.86	1,244.06	-	168.57	8,155.49

Accountant
National Medicines Regulatory Authority

NMRA Monthly fee for Medicines - Effective from 01/11/2026 to 30/11/2026

(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	33,714.31	6,220.29	2000	842.86	42,777.46
2	Pharmacovigilance Inspection	100	33,714.31	6,220.29	2000	842.86	42,777.46

(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	101,142.93	18,660.87	-	2,528.57	122,332.37
		Category B- Dosage forms applicable on skin other than anti- infective or steroidal product.	100	33,714.31	6,220.29	-	842.86	40,777.46
2	A Repackaging site		100	33,714.31	6,220.29	-	842.86	40,777.46

CEO

Accountant

National Medicines Regulatory Authority

NMRA Monthly fee for Medicines - Effective from 01/11/2026 to 30/11/2026

(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	5,057,146.50	933,043.53	-	126,428.66	6,116,618.69
2	Other Countries	20000	6,742,862.00	1,244,058.04	-	168,571.55	8,155,491.59
3	Follow up inspection (All countries)	5000	1,685,715.50	311,014.42	-	42,148.88	2,038,872.30

* 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	236,000.17	43,542.03	-	5,900.00	285,442.20
2	Approval of Advertisement (All categories)	300	101,142.93	18,660.87	-	2,528.57	122,332.37

* Separate Applications should be submitted for each advertisement.

CEO

Accountant

National Medicines Regulatory Authority