

NMRA Monthly fee for Medicines - Effective from 01/08/2026 to 31/08/2026

Dollar rates are converted at the selling rate on last working day of the preceding month (31.07.2026) which was published by the Central Bank of Sri Lanka.

Daily Exchange Rates	2026/07/31	
Currency	Buying Rate (Rs.)	Selling Rate (Rs.)
Dollar (USD)	331.206	340.3301

(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	170,165.05	31,395.45	-	4,254.13	205,814.63
		Part 2 Evaluation (if accepted)	1500	510,495.15	94,186.36	-	12,762.38	617,443.89
2	New Dosage Form (Any physical form of a registered medicine in Sri Lanka other than the available registered forms)	1000	340,330.10	62,790.90	-	8,508.25	411,629.25	

K. M. T. K. Karunaratne
Accountant
National Medicines Regulatory Authority
No. 120, North Canal Road,
Colombo 10

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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	510,495.15	94,186.36	-	12,762.38	617,443.89
4	New Product (Any new product of an already registered medicine in Sri Lanka.)	Foreign	750	255,247.58	47,093.18	-	6,381.19	308,721.95
		(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	170,165.05	31,395.45	-	4,254.13	205,814.63
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal products.	200	68,066.02	12,558.18	-	1,701.65	82,325.85
5	Therapeutic Biological and Biotechnological Product		2000	680,660.20	125,581.81	-	17,016.50	823,258.52
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					


 K. M. A. B. Dissanayake
 Accountant
 National Medicines Regulatory Authority
 No. 120, Norris Circular Road
 Colombo 10

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7	Application for renewal of registration after five years	Foreign	750	255,247.58	47,993.18	-	6,381.19	308,721.95
		(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	170,165.05	31,395.45	-	4,254.13	205,814.63
		Category B-						
		Dosage forms applicable on skin other than anti-infective or steroidal product.	200	68,066.02	12,558.18	-	1,701.65	82,325.85

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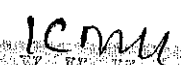
K. H. V. K. MarudanChinn
Accountant
National Medicines Regulatory Authority
No. 120, Morris Canal Road,
Colombo 10

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(II) Processing fee for applications for licenses and others

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	17,016.51	3,139.55	-	425.41	20,581.47	
2	Application for Manufacturing Premises (MP) approval -	2000	680,660.20	125,581.81	-	17,016.51	823,258.52	
3	Renewal application for Manufacturing Premises (MP) approval - Foreign	500	170,165.05	31,395.45	-	4,254.13	205,814.63	
4	Application for Licenses for licensed Importer of Medicines	600	204,198.06	37,674.54	-	5,104.95	246,977.55	
5	Renewal for Licenses for licensed Importer of Medicines	200	68,066.02	12,558.18	-	1,701.65	82,325.85	
6	Application fee for appointment of New Market Authorization Holder	500	170,165.05	31,395.45	-	4,254.13	205,814.63	
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	34,033.01	6,279.09	-	850.83	41,162.93
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	50	17,016.51	3,139.55	-	425.41	20,581.47


 K. M. Y. H. Rajapaksa
 Accountant
 National Medicines Regulatory Authority
 No. 120, Morris Quay
 Colombo 10

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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	34,033.01	6,279.09	-	850.83	41,162.93
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	50	17,016.51	3,139.55	-	425.41	20,581.47

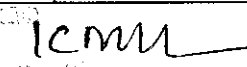
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23. 57. N. 57. EDWARDS, J. L.
Accountant
National Medicines Regulatory Authority
No. 125, Morris Quay, 11th
Colombo 10

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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	170,165.05	31,395.45	-	4,254.13	205,814.63
		(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	68,066.02	12,558.18	-	1,701.65	82,325.85
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	100	34,033.01	6,279.09	-	850.83	41,162.93
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	170,165.05	31,395.45	-	4,254.13	205,814.63
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	34,033.01	6,279.09	-	850.83	41,162.93
		Major Variations	250	85,082.53	15,697.73	-	2,127.06	102,907.32
5	Any variation for medicines required for rare diseases and medicines required in small quantities		Free of Charge					


 No. 129, Nanda ...
 Colombo 10

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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	340,330.10	62,790.90	-	8,508.25	411,629.25
2	Academic with International Sponsorship	250	85,082.53	15,697.73	-	2,127.06	102,907.32
3	Local Investigator Sponsored	Free of Charge					
4	Amendments that require review	Industry Sponsored	250	85,082.53	15,697.73	-	102,907.32
		Academic with International Sponsorship	50	17,016.51	3,139.55	-	20,581.47
		Local Investigator Sponsored	Free of Charge				

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Dr. S. D. M. Mahipala
Accountant
National Medicines Regulatory Authority
No. 120, Morris Place, Colombo
Colombo 10

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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	136,132.04	25,116.36	2,000.00	3,403.30	166,651.70
		(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	68,066.02	12,558.18	2,000.00	1,701.65	84,325.85
		Category B-						
		Dosage forms applicable on skin other than anti-infective or steroidal product.	100	34,033.01	6,279.09	2,000.00	850.83	43,162.93
		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	68,066.02	12,558.18	2,000.00	1,701.65	84,325.85

Accountant
National Medicines Regulatory Authority
No. 120, Morris Canal Road,
Colombo 10'

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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	34,033.01	6,279.09	2,000.00	850.83	43,162.93
	Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	50	17,016.51	3,139.55	1,701.65	425.41	22,283.12
	Medicines required for rare diseases and medicines required in Small quantities	Free of Charge					
3	Approval for a foreign manufacturing premises	250	85,082.53	15,697.73	2,000.00	2,127.06	104,907.32
4	GMP Certificate for foreign manufacturing premises (on request)	250	85,082.53	15,697.73	2,000.00	2,127.06	104,907.32
5	Duplicate Copy of Certificate of Registration	250	85,082.53	15,697.73	2,000.00	2,127.06	104,907.32
6	Amendment of Certificate of Registration/ Approval	100	34,033.01	6,279.09	2,000.00	850.83	43,162.93


 K. M. Y. K. Karunaratne
 Accountant
 National Medicines Regulatory Authority
 No. 428, Newlands Road,
 Colombo 10

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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	17,016.51	3,139.55	1,701.65	425.41	22,283.12
2	Import License	for 1 year	100	34,033.01	6,279.09	2,000.00	850.83	43,162.93
		for 2 years	200	68,066.02	12,558.18	2,000.00	1,701.65	84,325.85
3	License for licensed Importer of Medicines		400	136,132.04	25,116.36	2,000.00	3,403.30	166,651.70
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	34,033.01	6,279.09	2,000.00	850.83	43,162.93
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product.	50	17,016.51	3,139.55	1,701.65	425.41	22,283.12

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Dr. B. V. R. Thirumangalakudi
Secretary
National Medicines Regulatory Authority
No. 12, Noida
Gurgaon

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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)	300	102,099.03	18,837.27	2,000.00	2,552.48	
		(iii) Anti-infective and steroidal products to be applied locally						125,488.78
		Category B –						
		Dosage forms applicable on skin other than anti-infective or steroidal product	200	68,066.02	12,558.18	2,000.00	1,701.65	84,325.85
6	Duplicate copy of the License		250	85,082.53	15,697.73	2,000.00	2,127.06	104,907.32
7	Amendment of License		100	34,033.01	6,279.09	2,000.00	850.83	43,162.93

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Dr. D. B. S. Fernando
Accountant
National Medicines Regulatory Authority
No. 100, Moria Centre, 1st Floor,
Colombo 10

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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	8,508.25	1,569.77	-	212.71	10,290.73
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	17,016.51	3,139.55	-	425.41	20,581.47
4	(i) Approval for waiver of registration for the government supplies	Invoice Value (USD) 2,000 or below	50	17,016.51	3,139.55	-	425.41	20,581.47
		Invoice Value (USD) 2,000-15,000	100	34,033.01	6,279.09	-	850.83	41,162.93
		Invoice Value (USD) 15,000 or above	200	68,066.02	12,558.18	-	1,701.65	82,325.85
5	Any Clarification Letter		10	3,403.30	627.91	-	85.08	4,116.29
6	GMP certificate for a local manufacturing site		100	34,033.01	6,279.09	2,000.00	850.83	43,162.93
7	Certificate of Pharmaceutical Product (COPP)		50	17,016.51	3,139.55	1,701.65	425.41	22,283.12
8	Free Sale Certificate		50	17,016.51	3,139.55	1,701.65	425.41	22,283.12
9	Appointment of New marketing Authorization Holder (Agency Transfer)	From Manufacturer	1000	340,330.10	62,790.90	-	8,508.25	411,629.25
		From Each new marketing authorization holder	500	170,165.05	31,395.45	-	4,254.13	205,814.63


 K. M. Y. K. Marimuthu
 Accountant
 National Medicines Regulatory Authority
 No. 120, Route 6
 Colombo 10

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(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	85,082.53	15,697.73	-	2,127.06	102,907.32
2(b)	Microbiological Test		250	85,082.53	15,697.73	-	2,127.06	102,907.32
3©	Assay Test (Chemical, Microbiological, Biological)		250	85,082.53	15,697.73	-	2,127.06	102,907.32
4(d)	Limit test (performed using Analytical Equipment- HPLC, AAS etc.)		250	85,082.53	15,697.73	-	2,127.06	102,907.32
5 (e)	Dissolution Test		250	85,082.53	15,697.73	-	2,127.06	102,907.32
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	255,247.58	47,093.18	-	6,381.19	308,721.95
		(II) Otherwise	500	170,165.05	31,395.45	-	4,254.13	205,814.63
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	510,495.15	94,186.36	-	12,762.38	617,443.89
		(II) Otherwise tests other than items 1, 2, 3, 4 and 5 in Column 1	1000	340,330.10	62,790.90	-	8,508.25	411,629.25
8(h)	Single Test	tests other than items 1, 2, 3, 4 and 5 in Column 1	175	59,557.77	10,988.41	-	1,488.94	72,035.12

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K. B. T. K. Karmacharya
Accountant
National Medicines Regulatory Authority
No. 100, Naraina
Colombo 10

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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	34,033.01	6,279.09	2000	850.83	43,162.93
2	Pharmacovigilance Inspection	100	34,033.01	6,279.09	2000	850.83	43,162.93

(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	102,099.03	18,837.27	-	2,552.48	123,488.78
	Category B- Dosage forms applicable on skin other than anti- infective or steroidal product.	100	34,033.01	6,279.09	-	850.83	41,162.93
2	A Repackaging site	100	34,033.01	6,279.09	-	850.83	41,162.93

Accountant
National Medicines Regulatory Authority
No. 428, Monrovia Street,
Colombo 10

KCMU

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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	5,104,951.50	941,863.55	-	127,623.79	6,174,438.84
2	Other Countries	20000	6,806,602.00	1,255,818.07	-	170,165.05	8,232,585.12
3	Follow up inspection (All countries)	5000	1,701,650.50	313,954.52	-	42,541.26	2,058,146.28

* 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	238,231.07	43,953.63	-	5,955.78	288,140.48
2	Approval of Advertisement (All categories)	300	102,099.03	18,837.27	-	2,552.48	123,488.78

* Separate Applications should be submitted for each advertisement.

ICmm

M. B. T. H. Karunaratne
Accountant
National Medicines Regulatory Authority
No. 429, North Canal Road,
Colombo 10