

NMRA Monthly fee for Medicines - Effective from 01/02/2026 to 28/02/2026

Dollar rates are converted at the selling rate on last working day of the preceding month (30.01.2026) which was published by the Central Bank of Sri Lanka.

Daily Exchange Rates		2026/01/30	
Currency	Buying Rate (Rs.)	Selling Rate (Rs.)	
Dollar (USD)	305.6681	313.2039	

(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	156,601.95	28,893.06	-	3,915.05
		Part 2 Evaluation (if accepted)	1500	469,805.85	86,679.18	-	11,745.15
2	New Dosage Form (Any physical form of a registered medicine in Sri Lanka other than the available registered forms)	1000	313,203.90	57,786.12	-	7,830.10	378,820.12

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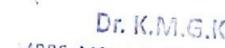
3	New Combination Product (A new combination product is a formulation of two or more medicines in a single dosage form which has not been previously registered in Sri Lanka.)		1500	469,805.85	86,679.18	-	11,745.15	568,230.18
4	New Product (Any new product of an already registered medicine in Sri Lanka.)		750	234,902.93	43,339.59	-	5,872.57	284,115.09
	(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 steroid products to be applied locally.	500	156,601.95	28,893.06	-	3,915.05	189,410.06	
	Category B- Dosage forms applicable on skin other than anti-infective or steroid products.	200	62,640.78	11,557.22	-	1,566.02	75,764.02	
5	Therapeutic Biological and Biotechnological Product		2000	626,407.80	115,572.24	-	15,660.20	757,640.24
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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7	Application for renewal of registration after five years	Foreign	750	234,902.93	43,339.59	-	5,872.57	284,115.09
		(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 steroid products to be applied locally.						
			500	156,601.95	28,893.06	-	3,915.05	189,410.06
		Category B- Dosage forms applicable on skin other than anti-infective or steroid product.	200	62,640.78	11,557.22	-	1,566.02	75,764.02


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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	15,660.20	2,889.31	-	391.50	18,941.02
2	Application for Manufacturing Premises (MP) approval -	2000	626,407.80	115,572.24	-	15,660.20	757,640.24
3	Renewal application for Manufacturing Premises (MP) approval - Foreign	500	156,601.95	28,893.06	-	3,915.05	189,410.06
4	Application for Licenses for licensed Importer of Medicines	600	187,922.34	34,671.67	-	4,698.06	227,292.07
5	Renewal for Licenses for licensed Importer of Medicines	200	62,640.78	11,557.22	-	1,566.02	75,764.02
6	Application fee for appointment of New Market Authorization Holder	500	156,601.95	28,893.06	-	3,915.05	189,410.06
7	Application fee for preliminary approval of a local manufacturing plant	100	31,320.39	5,778.61	-	783.01	37,882.01
	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 steroid products to be applied locally.						
	Category B- Dosage forms applicable on skin other than anti-infective or steroid product	50	15,660.20	2,889.31	-	391.50	18,941.02


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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 steroid products to be applied locally.	100	31,320.39	5,778.61	-	783.01	37,882.01
		50	15,660.20	2,889.31		391.50	18,941.02


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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	156,601.95	28,893.06	-	3,915.05	189,410.06
	(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 steroid products to be applied locally.	200	62,640.78	11,557.22	-	1,566.02	75,764.02
	Category B- Dosage forms applicable on skin other than anti-infective or steroid product	100	31,320.39	5,778.61	-	783.01	37,882.01
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						
4 Variations that require review (except for medicines required for rare diseases and medicines required in small quantities)	Notification	500	156,601.95	28,893.06	-	3,915.05	189,410.06
	Minor Variations	100	31,320.39	5,778.61	-	783.01	37,882.01
	Major Variations	250	78,300.98	14,446.53	-	1,957.52	94,705.03
5	Any variation for medicines required for rare diseases and medicines required in small quantities						

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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	313,203.90	57,786.12	-	7,830.10	378,820.12
2	Academic with International Sponsorship	250	78,300.98	14,446.53	-	1,957.52	94,705.03
3	Local Investigator Sponsored			Free of Charge			
4	Amendments that require review	Industry Sponsored	250	78,300.98	14,446.53	-	1,957.52
		Academic with International Sponsorship	50	15,660.20	2,889.31	-	391.50
		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 (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.	400	125,281.56	23,114.45	2,000.00	3,132.04	153,528.05
	200	62,640.78	11,557.22	2,000.00	1,566.02	77,764.02	
	100	31,320.39	5,778.61	2,000.00	783.01	39,882.01	
	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	62,640.78	11,557.22	2,000.00	1,566.02	77,764.02

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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. <i>ophthalmic, otological, nasal, rectal, vaginal</i>) (iii) Anti-infective and steroid products to be applied locally.	100	31,320.39	5,778.61	2,000.00	783.01	39,882.01
	Category B- Dosage forms applicable on skin other than anti-infective or steroid product	50	15,660.20	2,889.31	1,566.02	391.50	20,507.04
	Medicines required for rare diseases and medicines required in Small quantities	Free of Charge					
3	Approval for a foreign manufacturing premises	250	78,300.98	14,446.53	2,000.00	1,957.52	96,705.03
4	GMP Certificate for foreign manufacturing premises (on request)	250	78,300.98	14,446.53	2,000.00	1,957.52	96,705.03
5	Duplicate Copy of Certificate of Registration	250	78,300.98	14,446.53	2,000.00	1,957.52	96,705.03
6	Amendment of Certificate of Registration/ Approval	100	31,320.39	5,778.61	2,000.00	783.01	39,882.01

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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	15,660.20	2,889.31	1,566.02	391.50	20,507.04
2	Import License for 1 year	100	31,320.39	5,778.61	2,000.00	783.01	39,882.01
	for 2 years	200	62,640.78	11,557.22	2,000.00	1,566.02	77,764.02
3	License for licensed Importer of Medicines	400	125,281.56	23,114.45	2,000.00	3,132.04	153,528.05
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 steroid products to be applied locally.	100	31,320.39	5,778.61	2,000.00	783.01
			50	15,660.20	2,889.31	1,566.02	391.50
							20,507.04

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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	93,961.17	17,335.84	2,000.00	2,349.03	115,646.04
		(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	62,640.78	11,557.22	2,000.00	1,566.02	77,764.02
6	Duplicate copy of the License		250	78,300.98	14,446.53	2,000.00	1,957.52	96,705.03
7	Amendment of License		100	31,320.39	5,778.61	2,000.00	783.01	39,882.01

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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	7,830.10	1,444.65	-	195.75	9,470.50
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	15,660.20	2,889.31	-	391.50	18,941.02
4	(i) Approval for waiver of registration for the government supplies	Invoice Value (USD) 2,000 or below	50	15,660.20	2,889.31	-	391.50
		Invoice Value (USD) 2,000-15,000	100	31,320.39	5,778.61	-	783.01
	(ii) Application for waiver of registration for the private supplies	Invoice Value (USD) 15,000 or above	200	62,640.78	11,557.22	-	1,566.02
5	Any Clarification Letter	10	3,132.04	577.86	-	78.30	3,788.20
6	GMP certificate for a local manufacturing site	100	31,320.39	5,778.61	2,000.00	783.01	39,882.01
7	Certificate of Pharmaceutical Product (COPP)	50	15,660.20	2,889.31	1,566.02	391.50	20,507.04
8	Free Sale Certificate	50	15,660.20	2,889.31	1,566.02	391.50	20,507.04
9	Appointment of New marketing Authorization Holder (Agency Transfer)	From Manufacturer					
		1000	313,203.90	57,786.12	-	7,830.10	378,820.12
	From Each new marketing authorization holder	500	156,601.95	28,893.06	-	3,915.05	189,410.06

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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	78,300.98	14,446.53	-	1,957.52	94,705.03
2(b)	Microbiological Test	250	78,300.98	14,446.53	-	1,957.52	94,705.03
3(c)	Assay Test (Chemical, Microbiological, Biological)	250	78,300.98	14,446.53	-	1,957.52	94,705.03
4(d)	Limit test (performed using Analytical Equipment- HPLC, AAS etc.)	250	78,300.98	14,446.53	-	1,957.52	94,705.03
5 (e)	Dissolution Test	250	78,300.98	14,446.53	-	1,957.52	94,705.03
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 (II) Otherwise	750 500	234,902.93 156,601.95	43,339.59 28,893.06	5,872.57 3,915.05	284,115.09 189,410.06
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 (II) Otherwise tests other than items 1, 2, 3, 4 and 5 in Column 1	1500 1000	469,805.85 313,203.90	86,679.18 57,786.12	11,745.15 7,830.10	568,230.18 378,820.12
8(h)	Single Test	tests other than items 1, 2, 3, 4 and 5 in Column 1	175	54,810.68	10,112.57	1,370.27	66,293.52

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(15)

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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	18,792.23	3,467.17	1879.22	469.81	24,608.43
2	Retail License	45	14,094.18	2,600.38	1409.42	352.35	18,456.33
3	Transport License	10	3,132.04	577.86	313.20	78.30	4,101.40
4	Duplicate of License	50	15,660.20	2,889.31	1566.02	391.50	20,507.04
5	Amended License	30	9,396.12	1,733.58	939.61	234.90	12,304.21
6	TELE Pharmacy (Home Delivery) License (Period of one Year)	100	31,320.39	5,778.61	2000	783.01	39,882.01

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	37,584.47	6,934.33	-	939.61	45,458.41
2	Application fee for Retail License	90	28,188.35	5,200.75	-	704.71	34,093.81
3	Application fee for Transport License for therapeutic goods	20	6,264.08	1,155.72	-	156.60	7,576.40

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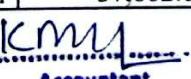
(X) Fee for Pharmacy and Good Distribution Practice Inspection (GDP)

	Type	Fee (USD)	Amount in (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs. 2.5%)	Total (Rs.)
1	Good Distribution Practice Inspection	100	31,320.39	5,778.61	2000	783.01	39,882.01
2	Pharmacovigilance Inspection	100	31,320.39	5,778.61	2000	783.01	39,882.01

(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	93,961.17	17,335.84	-	2,349.03
	Category B- Dosage forms applicable on skin other than anti- infective or steroidal product.	100	31,320.39	5,778.61	-	783.01	37,882.01
2	A Repackaging site	100	31,320.39	5,778.61	-	783.01	37,882.01

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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	4,698,058.50	866,791.79	-	117,451.46	5,682,301.75
2	Other Countries	20000	6,264,078.00	1,155,722.39	-	156,601.95	7,576,402.34
3	Follow up inspection (All countries)	5000	1,566,019.50	288,930.60	-	39,150.49	1,894,100.59

* 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	219,242.73	40,450.28	-	5,481.07	265,174.08
2	Approval of Advertisement (All categories)	300	93,961.17	17,335.84	-	2,349.03	113,646.04

* Separate Applications should be submitted for each advertisement.

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