

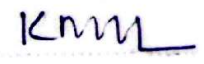
NMRA Monthly fee for Medicines - Effective from 01/10/2025 to 31/10/2025

Dollar rates are converted at the selling rate on last working day of the preceding month (30.09.2025) which was published by the Central Bank of Sri Lanka.

Daily Exchange Rates	2025/09/30	
Currency	Buying Rate (Rs.)	Selling Rate (Rs.)
Dollar (USD)	298.7784	306.2994

(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	153,149.70	28,256.12	-	3,828.74	185,234.56
		Part 2 Evaluation (if accepted)	1500	459,449.10	84,768.36	-	11,486.23	555,703.69
2	New Dosage Form (Any physical form of a registered medicine in Sri Lanka other than the available registered forms)		1000	306,299.40	56,512.24	-	7,657.49	370,469.13



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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	459,449.10	84,768.36	- 1.00	11,486.23	370,470.13
4	New Product (Any new product of an already registered medicine in Sri Lanka.)	Foreign	750	229,724.55	42,384.18	-	5,743.11	277,851.84
		(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	153,149.70	28,256.12	-	3,828.74	185,234.56
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal products.	200	61,259.88	11,302.45	-	1,531.50	74,093.83
5	Therapeutic Biological and Biotechnological Product		2000	612,598.80	113,024.48	-	15,314.97	740,938.25
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	229,724.55	42,384.18	-	5,743.11	277,851.84
		(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	153,149.70	28,256.12	-	3,828.74	185,234.56
		Category B-						
		Dosage forms applicable on skin other than anti-infective or steroidal product.	200	61,259.88	11,302.45	-	1,531.50	74,093.83


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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	15,314.97	2,825.61	-	382.87	18,523.45
2	Application for Manufacturing Premises (MP) approval -	2000	612,598.80	113,024.48	-	15,314.97	740,938.25
3	Renewal application for Manufacturing Premises (MP) approval - Foreign	500	153,149.70	28,256.12	-	3,828.74	185,234.56
4	Application for Licenses for licensed Importer of Medicines	600	183,779.64	33,907.34	-	4,594.49	222,281.47
5	Renewal for Licenses for licensed Importer of Medicines	200	61,259.88	11,302.45	-	1,531.50	74,093.83
6	Application fee for appointment of New Market Authorization Holder	500	153,149.70	28,256.12	-	3,828.74	185,234.56
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	30,629.94	5,651.22	-	765.75	37,046.91
	Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	50	15,314.97	2,825.61	-	382.87	18,523.45


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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	30,629.94	5,651.22	-	765.75	37,046.91
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	50	15,314.97	2,825.61	-	382.87	18,523.45



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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	153,149.70	28,256.12	-	3,828.74	185,234.56
	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	61,259.88	11,302.45	-	1,531.50	74,093.83
	Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	100	30,629.94	5,651.22	-	765.75	37,046.91
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	153,149.70	28,256.12	-	3,828.74	185,234.56
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	30,629.94	5,651.22	-	37,046.91
		Major Variations	250	76,574.85	14,128.06	-	92,617.28
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	306,299.40	56,512.24	-	7,657.49	370,469.13
2	Academic with International Sponsorship	250	76,574.85	14,128.06	-	1,914.37	92,617.28
3	Local Investigator Sponsored	Free of Charge					
	Industry Sponsored	250	76,574.85	14,128.06	-	1,914.37	92,617.28
4	Amendments that require review	50	15,314.97	2,825.61	-	382.87	18,523.45
	Local Investigator Sponsored	Free of Charge					


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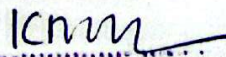

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(V) Fees for Certificates of Registration

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)	400	122,519.76	22,604.90	2,000.00	3,062.99	150,187.65
	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	61,259.88	11,302.45	2,000.00	1,531.50	76,093.83
	Category B-						
	Dosage forms applicable on skin other than anti-infective or steroidal product.	100	30,629.94	5,651.22	2,000.00	765.75	39,046.91
	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	61,259.88	11,302.45	2,000.00	1,531.50	76,093.82


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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	30,629.94	5,651.22	2,000.00	765.75	39,046.91
	Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	50	15,314.97	2,825.61	1,531.50	382.87	20,054.95
	Medicines required for rare diseases and medicines required in Small quantities	Free of Charge					
3	Approval for a foreign manufacturing premises	250	76,574.85	14,128.06	2,000.00	1,914.37	94,617.28
4	GMP Certificate for foreign manufacturing premises (on request)	250	76,574.85	14,128.06	2,000.00	1,914.37	94,617.28
5	Duplicate Copy of Certificate of Registration	250	76,574.85	14,128.06	2,000.00	1,914.37	94,617.28
6	Amendment of Certificate of Registration/ Approval	100	30,629.94	5,651.22	2,000.00	765.75	39,046.91


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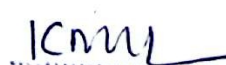

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(VI) Fees for License

	Types of licenses		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
1	Sample Import License		50	15,314.97	2,825.61	1,531.50	382.87	20,054.95
2	Import License	for 1 year	100	30,629.94	5,651.22	2,000.00	765.75	39,046.91
		for 2 years	200	61,259.88	11,302.45	2,000.00	1,531.50	76,093.83
3	License for licensed Importer of Medicines		400	122,519.76	22,604.90	2,000.00	3,062.99	150,187.65
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	30,629.94	5,651.22	2,000.00	765.75	39,046.91
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product.	50	15,314.97	2,825.61	1,531.50	382.87	20,054.95


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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) (iii) Anti-infective and steroidal products to be applied locally	300	91,889.82	16,953.67	2,000.00	2,297.25	113,140.74
		Category B – Dosage forms applicable on skin other than anti-infective or steroidal product	200	61,259.88	11,302.45	2,000.00	1,531.50	76,093.82
			250	76,574.85	14,128.06	2,000.00	1,914.37	94,617.28
6	Duplicate copy of the License		100	30,629.94	5,651.22	2,000.00	765.75	39,046.91
7	Amendment of License							



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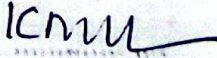
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(VII) Fees for Other Approvals

	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	7,657.49	1,412.81	-	191.44	9,261.74
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	15,314.97	2,825.61	-	382.87	18,523.45
4	(i) Approval for waiver of registration for the government supplies	Invoice Value (USD) 2,000 or below	50	15,314.97	2,825.61	-	382.87	18,523.45
		Invoice Value (USD) 2,000-15,000	100	30,629.94	5,651.22	-	765.75	37,046.91
		Invoice Value (USD) 15,000 or above						
			200	61,259.88	11,302.45	-	1,531.50	74,093.83
5	Any Clarification Letter		10	3,062.99	565.12	-	76.57	3,704.68
6	GMP certificate for a local manufacturing site		100	30,629.94	5,651.22	2,000.00	765.75	37,046.91
7	Certificate of Pharmaceutical Product (COPP)		50	15,314.97	2,825.61	1,531.50	382.87	18,523.45
			50	15,314.97	2,825.61	1,531.50	382.87	18,523.45
8	Free Sale Certificate							
9	Appointment of New marketing Authorization Holder (Agency Transfer)	From Manufacturer	1000	306,299.40	56,512.24	-	7,657.49	370,469.13
		From Each new marketing authorization holder	500	153,149.70	28,256.12	-	3,828.74	185,234.56


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(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	Biological Test		250	76,574.85	14,128.06	-	1,914.37	92,617.28
2	Microbiological Test		250	76,574.85	14,128.06	-	1,914.37	92,617.28
3	Assay Test (Chemical, Microbiological, Biological)		250	76,574.85	14,128.06	-	1,914.37	92,617.28
4	Limit test (performed using Analytical Equipment- HPLC, AAS etc.)		250	76,574.85	14,128.06	-	1,914.37	92,617.28
5	Dissolution Test		250	76,574.85	14,128.06	-	1,914.37	92,617.28
6	Three or less than three tests	(I) If all three tests comprise from items 1, 2, 3, 4 and 5 in Column 1	750	229,724.55	42,384.18	-	5,743.11	277,851.84
		(II) Otherwise	500	153,149.70	28,256.12	-	3,828.74	185,234.56
7	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	459,449.10	84,768.36	-	11,486.23	555,703.69
		(II) Otherwise tests other than items 1, 2, 3, 4 and 5 in Column 1	1000	306,299.40	56,512.24	-	7,657.49	370,469.13
8	Single Test	tests other than items 1, 2, 3, 4 and 5 in Column 1	175	53,602.40	9,889.64	-	1,340.06	64,832.10


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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	18,377.96	3,390.73	1837.80	459.45	24,065.94
2	Retail License	45	13,783.47	2,543.05	1378.35	344.59	18,049.46
3	Transport License	10	3,062.99	565.12	306.30	76.57	4,010.98
4	Duplicate of License	50	15,314.97	2,825.61	1531.50	382.87	20,054.95
5	Amended License	30	9,188.98	1,695.37	918.90	229.72	12,032.97
6	TELE Pharmacy (Home Delivery) License (Period of one Year)	100	30,629.94	5,651.22	2000	765.75	39,046.91

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	36,755.93	6,781.47	-	918.90	44,456.30
2	Application fee for Retail License	90	27,566.95	5,086.10	-	689.17	33,342.22
3	Application fee for Transport License for therapeutic goods	20	6,125.99	1,130.25	-	153.15	7,409.39



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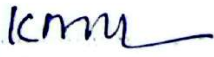
(X) Fee for Pharmacy and Good Distribution Practice Inspection (GDP)

	Type	Fee (USD)	Amount in (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
1	Good Distribution Practice Inspection	100	30,629.94	5,651.22	2000	765.75	39,046.91
2	Pharmacovigilance Inspection	100	30,629.94	5,651.22	2000	765.75	39,046.91

(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	91,889.82	16,953.67	-	2,297.25	111,140.74
	Category B- Dosage forms applicable on skin other than anti- infective or steroidal product.	100	30,629.94	5,651.22	-	765.75	37,046.91
2	A Repackaging site	100	30,629.94	5,651.22	-	765.75	37,046.91


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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	4,594,491.00	847,683.59	-	114,862.28	5,557,036.87
2	Other Countries	20000	6,125,988.00	1,130,244.79	-	153,149.70	7,409,382.49
3	Follow up inspection (All countries)	5000	1,531,497.00	282,561.20	-	38,287.43	1,852,345.63

* 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	214,409.58	39,558.57	-	5,360.24	259,328.39
2	Approval of Advertisement (All categories)	300	91,889.82	16,953.67	-	2,297.25	111,140.74

* Separate Applications should be submitted for each advertisement.


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