

## NMRA Monthly fee for Medicines - Effective from 01/03/2026 to 31/03/2026

Dollar rates are converted at the selling rate on last working day of the preceding month (27.02.2026) which was published by the Central Bank of Sri Lanka.

Daily Exchange Rates	2026/02/27	
Currency	Buying Rate (Rs.)	Selling Rate (Rs.)
Dollar (USD)	305.5642	313.0569

### (D) 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	156,528.45	28,879.50	-	3,913.21	189,321.16
		<b>Part 2</b> Evaluation (if accepted)	1500	469,585.35	86,638.50	-	11,739.63	567,963.48
2	New Dosage Form (Any physical form of a registered medicine in Sri Lanka other than the available registered forms)	1000	313,056.90	57,759.00	-	7,826.42	378,642.32	

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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	469,585.35	86,638.50	-	11,739.63	567,963.48	
4	New Product (Any new product of an already registered medicine in Sri Lanka.)	Foreign	750	234,792.68	43,319.25	-	5,869.82	283,981.75
		<b>(Local) Category A-</b> (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	156,528.45	28,879.50	-	3,913.21	189,321.16
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal products.	200	62,611.38	11,551.80	-	1,565.28	75,728.46
		Therapeutic Biological and Biotechnological Product	2000	626,113.80	115,518.00	-	15,652.85	757,284.65
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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### NMRA Monthly fee for Medicines - Effective from 01/03/2026 to 31/03/2026

7	Application for renewal of registration after five years	Foreign	750	234,792.68	43,319.25	-	5,869.82	283,981.75
		(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	156,528.45	28,879.50	-	3,913.21	189,321.16
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product.	200	62,611.38	11,551.80	-	1,565.28	75,728.46

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## NMRA Monthly fee for Medicines - Effective from 01/03/2026 to 31/03/2026

### (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	15,652.85	2,887.95	-	391.32	18,932.12	
2	Application for Manufacturing Premises (MP) approval -	2000	626,113.80	115,518.00	-	15,652.85	757,284.65	
3	Renewal application for Manufacturing Premises (MP) approval - Foreign	500	156,528.45	28,879.50	-	3,913.21	189,321.16	
4	Application for Licenses for licensed Importer of Medicines	600	187,834.14	34,655.40	-	4,695.85	227,185.39	
5	Renewal for Licenses for licensed Importer of Medicines	200	62,611.38	11,551.80	-	1,565.28	75,728.46	
6	Application fee for appointment of New Market Authorization Holder	500	156,528.45	28,879.50	-	3,913.21	189,321.16	
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	31,305.69	5,775.90	-	782.64	37,864.23
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	50	15,652.85	2,887.95	-	391.32	18,932.12

  
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## NMRA Monthly fee for Medicines - Effective from 01/03/2026 to 31/03/2026

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	31,305.69	5,775.90	-	782.64	37,864.23
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	50	15,652.85	2,887.95	-	391.32	18,932.12

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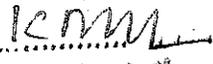
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### (V) Fees for Certificates of Registration

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	125,222.76	23,103.60	2,000.00	3,130.57	153,456.93
	(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	62,611.38	11,551.80	2,000.00	1,565.28	77,728.46	
Category B-							
Dosage forms applicable on skin other than anti-infective or steroidal product.	100	31,305.69	5,775.90	2,000.00	782.64	39,864.23	
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	62,611.38	11,551.80	2,000.00	1,565.28	77,728.46

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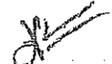
  
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## NMRA Monthly fee for Medicines - Effective from 01/03/2026 to 31/03/2026

2	<b>(Local)</b> 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	31,305.69	5,775.90	2,000.00	782.64	39,864.23
	Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	50	15,652.85	2,887.95	1,565.28	391.32	20,497.40
	Medicines required for rare diseases and medicines required in Small quantities	<b>Free of Charge</b>					
3	Approval for a foreign manufacturing premises	250	78,264.23	14,439.75	2,000.00	1,956.61	96,660.59
4	GMP Certificate for foreign manufacturing premises (on request)	250	78,264.23	14,439.75	2,000.00	1,956.61	96,660.59
5	Duplicate Copy of Certificate of Registration	250	78,264.23	14,439.75	2,000.00	1,956.61	96,660.59
6	Amendment of Certificate of Registration/ Approval	100	31,305.69	5,775.90	2,000.00	782.64	39,864.23

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## NMRA Monthly fee for Medicines - Effective from 01/03/2026 to 31/03/2026

(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	15,652.85	2,887.95	1,565.28	391.32	20,497.40
2	Import License for 1 year	100	31,305.69	5,775.90	2,000.00	782.64	39,864.23
	for 2 years	200	62,611.38	11,551.80	2,000.00	1,565.28	77,728.46
3	License for licensed Importer of Medicines	400	125,222.76	23,103.60	2,000.00	3,130.57	153,456.93
4	Manufacturing License (Local)	Category A-					
		(i) Medicines to be administered internally (e.g. oral, injectable, inhalational)					
		100	31,305.69	5,775.90	2,000.00	782.64	
							39,864.23
		50	15,652.85	2,887.95	1,565.28	391.32	
							20,497.40



CEO



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## NMRA Monthly fee for Medicines - Effective from 01/03/2026 to 31/03/2026

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	93,917.07	17,327.70	2,000.00	2,347.93	115,592.70
		Category B – Dosage forms applicable on skin other than anti-infective or steroidal product	200	62,611.38	11,551.80	2,000.00	1,565.28	77,728.46
6	Duplicate copy of the License		250	78,264.23	14,439.75	2,000.00	1,956.61	96,660.59
7	Amendment of License		100	31,305.69	5,775.90	2,000.00	782.64	39,864.23



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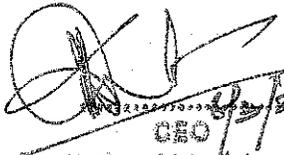
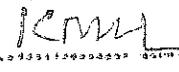
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## NMRA Monthly fee for Medicines - Effective from 01/03/2026 to 31/03/2026

### (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	7,826.42	1,443.97	-	195.66	9,466.05	
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	15,652.85	2,887.95	-	391.32	18,932.12	
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	15,652.85	2,887.95	-	391.32	18,932.12
		Invoice Value (USD) 2,000-15,000	100	31,305.69	5,775.90	-	782.64	37,864.23
		Invoice Value (USD) 15,000 or above	200	62,611.38	11,551.80	-	1,565.28	75,728.46
5	Any Clarification Letter	10	3,130.57	577.59	-	78.26	3,786.42	
6	GMP certificate for a local manufacturing site	100	31,305.69	5,775.90	2,000.00	782.64	39,864.23	
7	Certificate of Pharmaceutical Product (COPP)	50	15,652.85	2,887.95	1,565.28	391.32	20,497.40	
8	Free-Sale Certificate	50	15,652.85	2,887.95	1,565.28	391.32	20,497.40	
9	Appointment of New marketing Authorization Holder (Agency Transfer)	From Manufacturer	1000	313,056.90	57,759.00	-	7,826.42	378,642.32
		From Each new marketing authorization holder	500	156,528.45	28,879.50	-	3,913.21	189,321.16

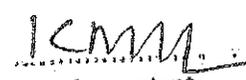
  
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 Accountant  
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## NMRA Monthly fee for Medicines - Effective from 01/03/2026 to 31/03/2026

### (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	78,264.23	14,439.75	-	1,956.61	94,660.59
2(b)	Microbiological Test		250	78,264.23	14,439.75	-	1,956.61	94,660.59
3(c)	Assay Test (Chemical, Microbiological, Biological)		250	78,264.23	14,439.75	-	1,956.61	94,660.59
4(d)	Limit test (performed using Analytical Equipment- HPLC, AAS etc.)		250	78,264.23	14,439.75	-	1,956.61	94,660.59
5 (e)	Dissolution Test		250	78,264.23	14,439.75	-	1,956.61	94,660.59
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	234,792.68	43,319.25	-	5,869.82	283,981.75
		(II) Otherwise	500	156,528.45	28,879.50	-	3,913.21	189,321.16
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	469,585.35	86,638.50	-	11,739.63	567,963.48
		(II) Otherwise tests other than items 1, 2, 3, 4 and 5 in Column 1	1000	313,056.90	57,759.00	-	7,826.42	378,642.32
8(h)	Single Test	tests other than items-1, 2, 3, 4 and 5 in Column 1	175	54,784.96	10,107.82	-	1,369.62	66,262.40

  
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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	31,305.69	5,775.90	2000	782.64	39,864.23
2 Pharmacovigilance Inspection	100	31,305.69	5,775.90	2000	782.64	39,864.23

## (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	93,917.07	17,327.70	-	2,347.93	113,592.70
Category B- Dosage forms applicable on skin other than anti-infective or steroidal product.	100	31,305.69	5,775.90	-	782.64	37,864.23
2 A Repackaging site	100	31,305.69	5,775.90	-	782.64	37,864.23

Dr. K.M.G.K. Bandara  
 MBBS, MSc, MD (Com. Med), MA (Sociology)  
 Chief Executive Officer (Acting) **CEO**  
 National Medicines Regulatory Authority  
 130, W. G. Ramanayake Mawatha, Colombo 02.

  
**Accountant**

## NMRA Monthly fee for Medicines - Effective from 01/03/2026 to 31/03/2026

### (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	4,695,853.50	866,384.97	-	117,396.34	5,679,634.81
2	Other Countries	20000	6,261,138.00	1,155,179.96	-	156,528.45	7,572,846.41
3	Follow up inspection (All countries)	5000	1,565,284.50	288,794.99	-	39,132.11	1,893,211.60

\* 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	219,139.83	40,431.30	-	5,478.50	265,049.63
2	Approval of Advertisement (All categories)	300	93,917.07	17,327.70	-	2,347.93	113,592.70

\* Separate Applications should be submitted for each advertisement.

  
 .....  
**CEO**

  
 .....  
**Accountant**

**National Medicines Regulatory Authority**

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