

NMRA Monthly fee for Medical Device - Effective from 01/09/2025 to 30/09/2025

Dollar rates are converted at the selling rate on last working day of the preceding month (29.08.2025) which was published by the Central Bank of Sri Lanka.

Daily Exchange Rates	2025/08/29	
Currency	Buying Rate (Rs.)	Selling Rate (Rs.)
Dollar (USD)	298.6273	306.1596

(I) Processing fee

Type		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
New Application	Foreign	1000	306,159.60	56,486.45	-	7,653.99	370,300.04
	Local - Category A	750	229,619.70	42,364.83	-	5,740.49	277,725.02
	Local - Category B	250	76,539.90	14,121.61	-	1,913.50	92,575.01
Application for Registration renewal after five years	Foreign	750	229,619.70	42,364.83	-	5,740.49	277,725.02
	Local - Category A	500	153,079.80	28,243.22	-	3,827.00	185,150.02
	Local - Category B	200	61,231.92	11,297.29	-	1,530.80	74,060.01
Application for Manufacturing Plant (MP) approval - Foreign		1500	459,239.40	84,729.67	-	11,480.99	555,450.06

(II) Fees for additional data evaluation

Type of evaluation		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
Additional data evaluation	Foreign	500	153,079.80	28,243.22	-	3,827.00	185,150.02
	Local - Category A	200	61,231.92	11,297.29	-	1,530.80	74,060.01
	Local - Category B	100	30,615.96	5,648.64	-	765.40	37,030.00
Additional data for Manufacturing Plant (MP) Evaluation		300	91,847.88	16,945.93	-	2,296.20	111,090.01
Variations that require review		200	61,231.92	11,297.29	-	1,530.80	74,060.01



 CEO Accountant
 National Medicines Regulatory Authority

NMRA Monthly fee for Medical Device - Effective from 01/09/2025 to 30/09/2025

(III) Processing fees for Clinical Trial

Type of Evaluation	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
Industry Sponsored	1000	306,159.60	56,486.45	-	7,653.99	370,300.04
Local Investigator Sponsored	Free of Charge					
Academic with International Sponsorship	250	76,539.90	14,121.61	-	1,913.50	92,575.01
Amendments that require review	250	76,539.90	14,121.61	-	1,913.50	92,575.01

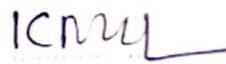
(IV) Fees for Certificates of Registration

Types of Registration Certificates		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
Certificate of Registration for five years	Foreign	400	122,463.84	22,594.58	2,000.00	3,061.60	150,120.02
	Local Category A	200	61,231.92	11,297.29	2,000.00	1,530.80	76,060.01
	Local Category B	100	30,615.96	5,648.64	2,000.00	765.40	39,030.00
Provisional Registration (may be issued for a maximum of two years)	Foreign	200	61,231.92	11,297.29	2,000.00	1,530.80	76,060.01
	Local Category A	100	30,615.96	5,648.64	2,000.00	765.40	39,030.00
	Local Category B	50	15,307.98	2,824.32	1,530.80	382.70	20,045.80
Duplicate Copy of Registration Certificate		250	76,539.90	14,121.61	2,000.00	1,913.50	94,575.01
Amendment of Registration Certificate		100	30,615.96	5,648.64	2,000.00	765.40	39,030.00

(V) Fees for License

) Fees for License

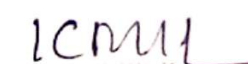
Types of licenses		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
Sample Import license		100	30,615.96	5,648.64	2,000.00	765.40	39,030.00
Import License		100	30,615.96	5,648.64	2,000.00	765.40	39,030.00
Manufacturing License	Local Category A	100	30,615.96	5,648.64	2,000.00	765.40	39,030.00
	Local Category B	50	15,307.98	2,824.32	1,530.80	382.70	20,045.80
Ammendment of License		100	30,615.96	5,648.64	2,000.00	765.40	39,030.00


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 National Medicines Regulatory Authority

NMRA Monthly fee for Medical Device - Effective from 01/09/2025 to 30/09/2025

(VI) Fees for Other Approvals

Type of Approval		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
Free of charge							
Formulation Approval for local manufacturer		50	15,307.98	2,824.32	-	382.70	18,515.00
Approval for Packaging / Repackaging							
Submission/ Approval fee for waiver of registration	Invoice value USD 2000 or below	50	15,307.98	2,824.32	-	382.70	18,515.00
	Invoice value USD 2,000- USD 10,000	100	30,615.96	5,648.64	-	765.40	37,030.00
	Invoice value USD 10,000- USD 15,000	200	61,231.92	11,297.29	-	1,530.80	74,060.01
	Invoice value USD 15,000- USD 20,000	500	153,079.80	28,243.22	-	3,827.00	185,150.02
	Invoice value USD 20,000 or above	750	229,619.70	42,364.83	-	5,740.49	277,725.02
Any clarification letter		10	3,061.60	564.86	-	76.54	3,703.01
WHO GMP certificate		100	30,615.96	5,648.64	2,000.00	765.40	39,030.00
Free Sale Certificate		50	15,307.98	2,824.32	1,530.80	382.70	20,045.80
Agency Transfer per each party		1000	306,159.60	56,486.45	-	7,653.99	370,300.04
	Manufacturer						
	Each new marketing authorization holder	1000	306,159.60	56,486.45	-	7,653.99	370,300.04

 
 CEO Accountant
 National Medicines Regulatory Authority

NMRA Monthly fee for Medical Device - Effective from 01/09/2025 to 30/09/2025

(VII) Fees for Analysis

	Analysis	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
(a)	Biological test	250	76,539.90	14,121.61	-	1,913.50	92,575.01
(b)	Microbiological Test	250	76,539.90	14,121.61	-	1,913.50	92,575.01
(c)	Assay Test (Chemical, Microbiological, Biological)	250	76,539.90	14,121.61	-	1,913.50	92,575.01
(d)	Limit Test (performed using Analytical Equipment - HPLC, AAS etc.)	250	76,539.90	14,121.61	-	1,913.50	92,575.01
(e)	Three tests or less than three tests	i). If all three tests are in categories (a), (b), (c) & (d) specified above					
		750	229,619.70	42,364.83	-	5,740.49	277,725.02
		(ii). Otherwise					
		500	153,079.80	28,243.22	-	3,827.00	185,150.02
(f)	Four tests or more than four tests	(i). If all four tests or more than four tests are in the categories (a), (b), (c) & (d) specified above					
		1500	459,239.40	84,729.67	-	11,480.99	555,450.06
		(ii). Otherwise					
		1000	306,159.60	56,486.45	-	7,653.99	370,300.04
(g)	Single test	Test other than the categories (a), (b), (c), & (d) specified above					
		175	53,577.93	9,885.13	-	1,339.45	64,802.51


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(VIII) 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.)
A Manufacturing site	300	91,847.88	16,945.93	-	2,296.20	111,090.01
	Category A	100	30,615.96	-	765.40	37,030.00
	Category B	100	30,615.96	-	765.40	37,030.00
A Packaging/ Repackaging site						

(IX) 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.)
SAARC Countries	15000	4,592,394.00	847,296.69	-	114,809.85	5,554,500.54
Other Countries	20000	6,123,192.00	1,129,728.92	-	153,079.80	7,406,000.72

* Air Tickets, Visa fees and Transport cost within that country should be borne by the Applicant

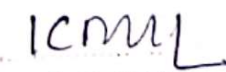
(X) Fee for sample import license for clinical trials

Category	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
Fee for sample import license for clinical trials	100	30,615.96	5,648.64	2,000.00	765.40	39,030.00

(XI) Fee for Advertisement

Advertisement	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
Processing fee for Advertisement (All categories)	1000	306,159.60	56,486.45	-	7,653.99	370,300.04

* Separate Applications should be submitted for each advertisement.


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