

NMRA Monthly fee for Medicines - 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.

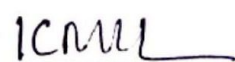
Daily Exchange Rates		2025/08/29
Currency	Buying Rate (Rs.)	Selling Rate (Rs.)
Dollar (USD)	298.6273	306.1596

(I) Processing Fees

	Type of evaluation		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
1	New Molecule Entity (NCE)	Part 1-Initial decision on application (process or decline)	500	153,079.80	28,243.22	-	3,827.00	185,150.02
		Part 2 - Evaluation (if accepted)	1500	459,239.40	84,729.67	-	11,480.99	555,450.06
2	New Dosage Form		1000	306,159.60	56,486.45	-	7,653.99	370,300.04
3	New Product (Existing chemicals)	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
4	New Combination Product		1500	459,239.40	84,729.67	-	11,480.99	555,450.06
5	Therapeutic Biological and Biotechnological Product		2000	612,319.20	112,972.89	-	15,307.98	740,600.07
6	Application for Registration renewal after 5 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
7	Application for Manufacturing Plant (MP) approval - Foreign		2000	612,319.20	112,972.89	-	15,307.98	740,600.07



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(II) Fees for additional data evaluation

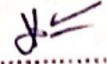
Type of evaluation		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
Additional data evaluation	Foreign	500	153,079.80	28,243.22	-	3,827.00	185,150.02
	Local - Category A	200	61,231.92	11,297.29	-	1,530.80	74,060.01
	Local - Category B	100	30,615.96	5,648.64	-	765.40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

(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



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(V) 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
	Category B	50	15,307.98	2,824.32	1,530.80	382.70	20,045.80
Amendment of License		100	30,615.96	5,648.64	2,000.00	765.40	39,030.00

(VI) Fees for Other Approvals

Type of Approval		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
Formulation Approval of local manufacturer		25	7,653.99	1,412.16	-	191.35	9,257.50
Approval for Packaging / Repackaging		50	15,307.98	2,824.32	-	382.70	18,515.00
Submission/ approval fee for Waiver of Registration	Invoice value USD 2,000 or below	50	15,307.98	2,824.32	-	382.70	18,515.00
	15,000	100	30,615.96	5,648.64	-	765.40	37,030.00
	above	200	61,231.92	11,297.29	-	1,530.80	74,060.01
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
Certificate of Pharmaceutical Product (COPP)		50	15,307.98	2,824.32	1,530.80	382.70	20,045.80
Free Sale Certificate		50	15,307.98	2,824.32	1,530.80	382.70	20,045.80
Agency Transfer per each party	Manufacturer	1000	306,159.60	56,486.45	-	7,653.99	370,300.04
	Each new marketing authorization holder	1000	306,159.60	56,486.45	-	7,653.99	370,300.04




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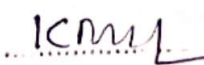
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(VII) Fees for Analysis

	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)	Dissolution Test	250	76,539.90	14,121.61	-	1,913.50	92,575.01
(f)	Three tests or less than three tests	i). If all three tests are in categories (a), (b), (c), (d) & (e) specified above					
		750	229,619.70	42,364.83	-	5,740.49	277,725.02
(g)	Four tests or more than four tests	(ii). Otherwise					
		500	153,079.80	28,243.22	-	3,827.00	185,150.02
(g)	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) & (e) specified					
		1500	459,239.40	84,729.67	-	11,480.99	555,450.06
(h)	Single Test	(ii). Otherwise					
		1000	306,159.60	56,486.45	-	7,653.99	370,300.04
(h)	Single Test	Test other than the categories (a), (b), (c), (d) & (e) specified above					
		175	53,577.93	9,885.13	-	1,339.45	64,802.51

(VIII) Fees for License 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.)
Wholesale License	60	18,369.58	3,389.19	1,836.96	459.24	24,054.97
Retail License	45	13,777.18	2,541.89	1,377.72	344.43	18,041.22
Transport License	30	9,184.79	1,694.59	918.48	229.62	12,027.48
Amended License	30	9,184.79	1,694.59	918.48	229.62	12,027.48



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(IX) 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	Category A	300	91,847.88	16,945.93	-	2,296.20	111,090.01
	Category B	100	30,615.96	5,648.64	-	765.40	37,030.00
Repackaging site		100	30,615.96	5,648.64	-	765.40	37,030.00

(X) 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

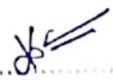
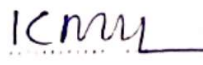
(XI) Fee for sample import license for clinical trials

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

(XII) 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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