


NMRA Monthly fee for Medicines - Effective from 01/05/2024 to 31/05/2024

Dollar rates are converted at the selling rate on last working day of the preceding month (30.04.2024) which was published by the Central Bank of Sri Lanka.


Daily Exchange Rates	2024/04/30	
Currency	Buying Rate (Rs.)	Selling Rate (Rs.)
Dollar (USD)	293.4489	302.7600

(I) Processing Fees

	Type of evaluation	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	Total (Rs.)	
1	New Molecule Entity (NCE)	Part 1-Initial decision on application (process or decline)	500	151,380.00	27,248.40	-	178,628.40
		Part 2 - Evaluation (if accepted)	1500	454,140.00	81,745.20	-	535,885.20
2	New Dosage Form	1000	302,760.00	54,496.80	-	357,256.80	
3	New Product (Existing chemicals)	Foreign	750	227,070.00	40,872.60	-	267,942.60
		Local - Category A	500	151,380.00	27,248.40	-	178,628.40
		Local - Category B	200	60,552.00	10,899.36	-	71,451.36
4	New Combination Product	1500	454,140.00	81,745.20	-	535,885.20	
5	Therapeutic Biological and Biotechnological Product	2000	605,520.00	108,993.60	-	714,513.60	
6	Application for Registration renewal after 5 years	Foreign	750	227,070.00	40,872.60	-	267,942.60
		Local - Category A	500	151,380.00	27,248.40	-	178,628.40
		Local - Category B	200	60,552.00	10,899.36	-	71,451.36
7	Application for Manufacturing Plant (MP) approval - Foreign	2000	605,520.00	108,993.60	-	714,513.60	



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 National Medicines Regulatory Authority

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(II) Fees for additional data evaluation



Type of evaluation		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	Total (Rs.)
Additional data evaluation	Foreign	500	151,380.00	27,248.40	-	178,628.40
	Local - Category A	200	60,552.00	10,899.36	-	71,451.36
	Local - Category B	100	30,276.00	5,449.68	-	35,725.68
Additional data for MP Evaluation		500	151,380.00	27,248.40	-	178,628.40
Variations that require review		200	60,552.00	10,899.36	-	71,451.36

(III) Processing fees for Clinical Trial

Type of Evaluation	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	Total (Rs.)
Industry Sponsored	1000	302,760.00	54,496.80	-	357,256.80
Local Investigator Sponsored		Free of Charge			
Academic with International Sponsorship	250	75,690.00	13,624.20	-	89,314.20
Amendments that require review	250	75,690.00	13,624.20	-	89,314.20

(IV) Fees for Certificates of Registration

Types of Registration Certificates		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	Total (Rs.)
Certificate of Registration for five years	Foreign	400	121,104.00	21,798.72	2,000.00	144,902.72
	Local Category A	200	60,552.00	10,899.36	2,000.00	73,451.36
	Local Category B	100	30,276.00	5,449.68	2,000.00	37,725.68
Provisional Registration (may be issued for a maximum of two years)	Foreign	200	60,552.00	10,899.36	2,000.00	73,451.36
	Local Category A	100	30,276.00	5,449.68	2,000.00	37,725.68
	Local Category B	50	15,138.00	2,724.84	1,513.80	19,376.64
Duplicate Copy of Registration Certificate		250	75,690.00	13,624.20	2,000.00	91,314.20
Amendment of Registration Certificate		100	30,276.00	5,449.68	2,000.00	37,725.68


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(V) Fees for License

Types of licenses		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	Total (Rs.)
Sample Import License		100	30,276.00	5,449.68	2,000.00	37,725.68
Import License		100	30,276.00	5,449.68	2,000.00	37,725.68
Manufacturing License (Local)	Category A	100	30,276.00	5,449.68	2,000.00	37,725.68
	Category B	50	15,138.00	2,724.84	1,513.80	19,376.64
Amendment of License		100	30,276.00	5,449.68	2,000.00	37,725.68

(VI) Fees for Other Approvals

Type of Approval		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	Total (Rs.)
Formulation Approval of local manufacturer		25	7,569.00	1,362.42	-	8,931.42
Approval for Packaging / Repackaging		50	15,138.00	2,724.84	-	17,862.84
Submission/ approval fee for Waiver of Registration	Invoice value USD 2,000 or below	50	15,138.00	2,724.84	-	17,862.84
	15,000	100	30,276.00	5,449.68	-	35,725.68
	Invoice value USD 15,000 or above	200	60,552.00	10,899.36	-	71,451.36
Any Clarification Letter		10	3,027.60	544.97	-	3,572.57
WHO GMP certificate		100	30,276.00	5,449.68	2,000.00	37,725.68
Certificate of Pharmaceutical Product (COPP)		50	15,138.00	2,724.84	1,513.80	19,376.64
Free Sale Certificate		50	15,138.00	2,724.84	1,513.80	19,376.64
Agency Transfer per each party	Manufacturer	1000	302,760.00	54,496.80	-	357,256.80
	Each new marketing authorization holder	1000	302,760.00	54,496.80	-	357,256.80

NMRA Monthly fee for Medicines - Effective from 01/05/2024 to 31/05/2024

(VII) Fees for Analysis

	Analysis	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	Total (Rs.)	
(a)	Biological Test	250	75,690.00	13,624.20	-	89,314.20	
(b)	Microbiological Test	250	75,690.00	13,624.20	-	89,314.20	
(c)	Assay Test (Chemical, Microbiological, Biological)	250	75,690.00	13,624.20	-	89,314.20	
(d)	Limit Test (performed using Analytical Equipment - HPLC,AAS etc.)	250	75,690.00	13,624.20	-	89,314.20	
(e)	Dissolution Test	250	75,690.00	13,624.20	-	89,314.20	
(f)	Three tests or less than three tests	i). If all three tests are in categories (a), (b), (c), (d) & (e) specified above	750	227,070.00	40,872.60	-	267,942.60
		(ii). Otherwise	500	151,380.00	27,248.40	-	178,628.40
(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 above	1500	454,140.00	81,745.20	-	535,885.20
		(ii). Otherwise	1000	302,760.00	54,496.80	-	357,256.80
(h)	Single Test						
		Test other than the categories (a), (b), (c), (d) & (e) specified above	175	52,983.00	9,536.94	-	62,519.94

(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.)	Total (Rs.)
Wholesale License	60	18,165.60	3,269.81	1,816.56	23,251.97
Retail License	45	13,624.20	2,452.36	1,362.42	17,459.83
Transport License	30	9,082.80	1,634.90	908.28	11,625.98
Amended License	30	9,082.80	1,634.90	908.28	11,625.98


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(IX) Fee for Good Manufacturing Practice Inspection (GMP) - Local

Type		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	Total (Rs.)
A Manufacturing site	Category A	300	90,828.00	16,349.04	-	107,177.04
	Category B	100	30,276.00	5,449.68	-	35,725.68
Repackaging site		100	30,276.00	5,449.68	-	35,725.68

(X) Fee for Good Manufacturing Practice Inspection (GMP) - Foreign

Country	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	Total (Rs.)
SAARC Countries	15000	4,541,400.00	817,452.00	-	5,358,852.00
Other Countries	20000	6,055,200.00	1,089,936.00	-	7,145,136.00

* 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.)	Total (Rs.)
Fee for sample import license for clinical trials	100	30,276.00	5,449.68	2,000.00	37,725.68

(XII) Fee for Advertisement

Advertisement	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	Total (Rs.)
Processing fee for Advertisement (All categories)	1000	302,760.00	54,496.80	-	357,256.80

* Separate Applications should be submitted for each advertisement.


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