

NMRA Monthly fee for Medicines - Effective from 01/04/2024 to 30/04/2024

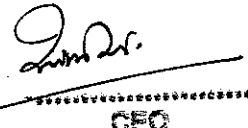
Dollar rates are converted at the selling rate on last working day of the preceding month (28.03.2024) which was published by the Central Bank of Sri Lanka.

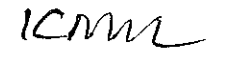
Daily Exchange Rates	2024-03-28	
Currency	Buying Rate (Rs.)	Selling Rate (Rs.)
Dollar (USD)	295.5429	305.3339

(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	152,666.95	27,480.05	-	180,147.00
		Part 2 - Evaluation (if accepted)	1500	458,000.85	82,440.15	-	540,441.00
2	New Dosage Form	1000	305,333.90	54,960.10	-	360,294.00	
3	New Product (Existing chemicals)	Foreign	750	229,000.43	41,220.08	-	270,220.51
		Local - Category A	500	152,666.95	27,480.05	-	180,147.00
		Local - Category B	200	61,066.78	10,992.02	-	72,058.80
4	New Combination Product	1500	458,000.85	82,440.15	-	540,441.00	
5	Therapeutic Biological and Biotechnological Product	2000	610,667.80	109,920.20	-	720,588.00	
6	Application for Registration renewal after 5 years	Foreign	750	229,000.43	41,220.08	-	270,220.51
		Local - Category A	500	152,666.95	27,480.05	-	180,147.00
		Local - Category B	200	61,066.78	10,992.02	-	72,058.80
7	Application for Manufacturing Plant (MP) approval - Foreign	2000	610,667.80	109,920.20	-	720,588.00	

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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	152,666.95	27,480.05	-	180,147.00
	Local - Category A	200	61,066.78	10,992.02	-	72,058.80
	Local - Category B	100	30,533.39	5,496.01	-	36,029.40
Additional data for MP Evaluation		500	152,666.95	27,480.05	-	180,147.00
Variations that require review		200	61,066.78	10,992.02	-	72,058.80


(III) Processing fees for Clinical Trial

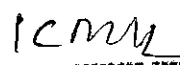
Type of Evaluation	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	Total (Rs.)
Industry Sponsored	1000	305,333.90	54,960.10	-	360,294.00
Local Investigator Sponsored	Free of Charge				
Academic with International Sponsorship	250	76,333.48	13,740.03	-	90,073.51
Amendments that require review	250	76,333.48	13,740.03	-	90,073.51

(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	122,133.56	21,984.04	2,000.00	146,117.60
	Local Category A	200	61,066.78	10,992.02	2,000.00	74,058.80
	Local Category B	100	30,533.39	5,496.01	2,000.00	38,029.40
Provisional Registration (may be issued for a maximum of two years)	Foreign	200	61,066.78	10,992.02	2,000.00	74,058.80
	Local Category A	100	30,533.39	5,496.01	2,000.00	38,029.40
	Local Category B	50	15,266.70	2,748.01	1,526.67	19,541.38
Duplicate Copy of Registration Certificate		250	76,333.48	13,740.03	2,000.00	92,073.51
Amendment of Registration Certificate		100	30,533.39	5,496.01	2,000.00	38,029.40

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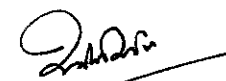
(V) Fees for License

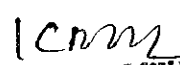
Types of licenses		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	Total (Rs.)
Sample Import License		100	30,533.39	5,496.01	2,000.00	38,029.40
Import License		100	30,533.39	5,496.01	2,000.00	38,029.40
Manufacturing License (Local)	Category A	100	30,533.39	5,496.01	2,000.00	38,029.40
	Category B	50	15,266.70	2,748.01	1,526.67	19,541.38
Amendment of License		100	30,533.39	5,496.01	2,000.00	38,029.40

(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	7,633.35	1,374.00	-	9,007.35
Approval for Packaging / Repackaging		50	15,266.70	2,748.01	-	18,014.71
Submission/ approval fee for Waiver of Registration	Invoice value USD 2,000 or below	50	15,266.70	2,748.01	-	18,014.71
	15,000	100	30,533.39	5,496.01	-	36,029.40
	Invoice value USD 15,000 or above	200	61,066.78	10,992.02	-	72,058.80
Any Clarification Letter		10	3,053.34	549.60	-	3,602.94
WHO GMP certificate		100	30,533.39	5,496.01	2,000.00	38,029.40
Certificate of Pharmaceutical Product (COPP)		50	15,266.70	2,748.01	1,526.67	19,541.38
Free Sale Certificate		50	15,266.70	2,748.01	1,526.67	19,541.38
Agency Transfer per each party	Manufacturer	1000	305,333.90	54,960.10	-	360,294.00
	Each new marketing authorization holder	1000	305,333.90	54,960.10	-	360,294.00

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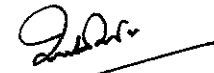
(VII) Fees for Analysis


	Analysis		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	Total (Rs.)
(a)	Biological Test		250	76,333.48	13,740.03	-	90,073.51
(b)	Microbiological Test		250	76,333.48	13,740.03	-	90,073.51
(c)	Assay Test (Chemical, Microbiological, Biological)		250	76,333.48	13,740.03	-	90,073.51
(d)	Limit Test (performed using Analytical Equipment - HPLC, AAS etc.)		250	76,333.48	13,740.03	-	90,073.51
(e)	Dissolution Test		250	76,333.48	13,740.03	-	90,073.51
(f)	Three tests or less than three tests	i). If all three tests are in categories (a), (b), (c), (d) & (e) specified above	750	229,000.43	41,220.08	-	270,220.51
		(ii). Otherwise	500	152,666.95	27,480.05	-	180,147.00
(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	458,000.85	82,440.15	-	540,441.00
		(ii). Otherwise	1000	305,333.90	54,960.10	-	360,294.00
(h)	Single Test	Test other than the categories (a), (b), (c), (d) & (e) specified above	175	53,433.43	9,618.02	-	63,051.45

(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	18,320.03	3,297.61	1,832.00	23,449.64
Retail License	45	13,740.03	2,473.21	1,374.00	17,587.24
Transport License	30	9,160.02	1,648.80	916.00	11,724.82
Amended License	30	9,160.02	1,648.80	916.00	11,724.82

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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	91,600.17	16,488.03	-	108,088.20
	Category B	100	30,533.39	5,496.01	-	36,029.40
Repackaging site		100	30,533.39	5,496.01	-	36,029.40

(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	4,580,008.50	824,401.53	-	5,404,410.03
Other Countries	20000	6,106,678.00	1,099,202.04	-	7,205,880.04

* 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

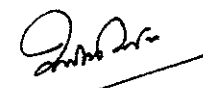
Category	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	Total (Rs.)
Fee for sample import license for clinical trials	100	30,533.39	5,496.01	2,000.00	38,029.40


(XII) Fee for Advertisement

Advertisement	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	Total (Rs.)
Processing fee for Advertisement (All categories)	1000	305,333.90	54,960.10	-	360,294.00

* Separate Applications should be submitted for each advertisement.

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