

NMRA Monthly fee for Medical Device - 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 fee

Type	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	Total (Rs.)	
New Application	Foreign	1000	302,760.00	54,496.80	-	357,256.80
	Local - Category A	750	227,070.00	40,872.60	-	267,942.60
	Local - Category B	250	75,690.00	13,624.20	-	89,314.20
Application for Registration renewal after five 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
Application for Manufacturing Plant (MP) approval - Foreign	1500	454,140.00	81,745.20	-	535,885.20	

(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 Manufacturing Plant (MP) Evaluation	300	90,828.00	16,349.04	-	107,177.04	
Variations that require review	200	60,552.00	10,899.36	-	71,451.36	


 CEO

 Accountant
National Medicines Regulatory Authority

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

(VI) Fees for Other Approvals

Type of Approval		Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	Total (Rs.)
Formulation Approval for local manufacturer			Free of charge			
Approval for Packaging / Repackaging		50	15,138.00	2,724.84	-	17,862.84
Submission/ Approval fee for waiver of registration	Invoice value USD 2000 or below	50	15,138.00	2,724.84	-	17,862.84
	Invoice value USD 2,000- USD 10,000	100	30,276.00	5,449.68	-	35,725.68
	Invoice value USD 10,000- USD 15,000	200	60,552.00	10,899.36	-	71,451.36
	Invoice value USD 15,000- USD 20,000	500	151,380.00	27,248.40	-	178,628.40
	Invoice value USD 20,000 or above	750	227,070.00	40,872.60	-	267,942.60
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
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


 CEO

 Accountant
National Medicines Regulatory Authority

NMRA Monthly fee for Medical Device - 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)	Three tests or less than three tests	i). If all three tests are in categories (a), (b), (c) & (d) specified above	750	227,070.00	40,872.60	-	267,942.60
		(ii). Otherwise	500	151,380.00	27,248.40	-	178,628.40
(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	454,140.00	81,745.20	-	535,885.20
		(ii). Otherwise	1000	302,760.00	54,496.80	-	357,256.80
(g)	Single test						
		Test other than the categories (a), (b), (c), & (d) specified above	175	52,983.00	9,536.94	-	62,519.94



CEO **Accountant**
 National Medicines Regulatory Authority

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

(VIII) 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
A Packaging/ Repackaging site		100	30,276.00	5,449.68	-	35,725.68

(IX) 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

(X) 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

(XI) 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.



 CEO
 National Medicines Regulatory Authority



 Accountant
 National Medicines Regulatory Authority