

## NMRA Monthly fee for Borderline Products - 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.)
New Application - Part 1-Initial decision on application (process or decline)	Foreign	500	151,380.00	27,248.40	-	178,628.40
	Local	Free of charge				
New Application - Part 2 - Evaluation (If accepted)	Foreign	1000	302,760.00	54,496.80	-	357,256.80
	Local	750	227,070.00	40,872.60	-	267,942.60
Application for Registration renewal after five years	Foreign	750	227,070.00	40,872.60	-	267,942.60
	Local	500	151,380.00	27,248.40	-	178,628.40
Application for Manufacturing Plant (MP) approval	Foreign Manufacturing plant	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	200	60,552.00	10,899.36	-	71,451.36
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

  
  
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### (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

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	200	60,552.00	10,899.36	2,000.00	73,451.36
Provisional Registration; (may be issued for maximum period of two years)	Foreign	200	60,552.00	10,899.36	2,000.00	73,451.36
	Local	100	30,276.00	5,449.68	2,000.00	37,725.68
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

### (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	100	30,276.00	5,449.68	2,000.00	37,725.68
Amendment of License	100	30,276.00	5,449.68	2,000.00	37,725.68

  
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### (VI) Fees for Other Approvals for Borderline Products

Type of Approval	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	Total (Rs.)	
Formulation Approval of local manufacturer	200	60,552.00	10,899.36	-	71,451.36	
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
	Invoice value USD 2,000-USD 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



### (VII) Fees for Good Manufacturing Practice Inspection (GMP) - Local

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

### (VIII) 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

  
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(IX) 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

(X) Fee for Advertisement

Advertisement	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	Total (Rs.)
Processing fee for an 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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