

Dollar rates are converted at the selling rate on last working day of the preceding month (30.09.2025) which was published by the Central Bank of Sri Lanka.

Daily Exchange Rates	¥	2025/09/30
Currency	Buying Rate (Rs.)	Selling Rate (Rs.)
Dollar (USD)	298.7784	306.2994

(I)Processing fee for applications for registrations of medicines

		Type of evaluation	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)		Total (Rs.)
1		Part 1 Application for Initial decision on Molecule (process or decline)	500	153,149.70	28,256.12	-	3,828.74	185,234.56
	in Sri Lanka, including a new salt, an ester or complex of a previously	Part 2 Evaluation (if accepted)				-		
,	approved Chemical moiety)	1 100	1500	459,449.10	84,768.36	* %:	11,486.23	555,703.69
2	New Dosage Form (Any physical form o other than the availab	f a registered medicine in Sri Lanka le registered forms)	1000	306,299.40	56,512.24	_	7,657.49	370,469.13





		That infolicing ice for infection	ilcincs - Li	ilective ii on	1 01/10/202	0 00 02/20	72020	
3	New Combination P							
	(A new combination	product is a formulation of two or more						
		e dosage form which has not been						
	previously registered	l in Sri Lanka.)						
			1500	459,449.10	84,768.36	- 1.00	11,486.23	370,470.13
4	New Product						5 5 40 11	277 951 94
	(Any new product	Foreign	750	229,724.55	42,384.18	-	5,743.11	277,851.84
	of an already	(Local) Category A-						
		(i) Medicines to be administered						
	in Sri Lanka.)	internally						
		(e.g. oral, injectable, inhalational)						
		(ii) Medicines to be administered					1	
		through other body cavities (e.g.		*				
		ophthalmic, otological, nasal, rectal,						
		vaginal)						
		(iii) Anti-infective and steroidal						
		products to be applied locally.	500	153,149.70	28,256.12	-	3,828.74	185,234.56
		Category B-			4			
		Dosage forms applicable on skin						
		other than anti-infective or steroidal			1			
		products.	200	61,259.88	11,302.45	-	1,531.50	74,093.83
, 5	Therapeutic Biologica	l and Biotechnological Product	2000	612,598.80	113,024.48	-	15,314.97	740,938.25
6	Medicines required for	or rare diseases and medicines required						
		ist of products in this category			Free of Ch	narge		
	published in the NMF	RA Official Website.)				=>		-

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7	Application for	Foreign	750	229,724.55	42,384.18	-	5,743.11	277,851.84
	renewal of	(Local) Category A-						
,	registration after five	(i) Medicines to be administered						
	years	internally						
		(e.g. oral, injectable, inhalational)						
		(ii) Medicines to be administered						
		through other body cavities (e.g.						
		ophthalmic, otological, nasal, rectal,						
		vaginal)						
		(iii) Anti-infective and steroidal						
		products to be applied locally.						
			500	153,149.70	28,256.12		3,828.74	185,234.56
		Category B-						
		Dosage forms applicable on skin						
		other than anti-infective or steroidal						74 000 00
		product.	200	61,259.88	11,302.45	-	1,531.50	74,093.83

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(II) Processing fee for applications for licenses and others

1-	~, ^ ;	occasing fee for applie	ations for ficenses and others						
_		T	ype of evaluation	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	I otal (Rs.)
	1	Application for Sample	Import License	50	15,314.97	2,825.61	•	382.87	18,523.45
	2	Application for Manufa	acturing Premises (MP) approval -	2000	612,598.80	113,024.48	-	15,314.97	740,938.25
			r Manufacturing Premises (MP)						
		approval - Foreign		500	153,149.70	28,256.12	-	3,828.74	185,234.56
	4	Application for License	es for licensed Importer of Medicines	600	183,779.64	33,907.34	-	4,594.49	222,281.47
	5	Renewal for Licenses f	or licensed Importer of Medicines	200	61,259.88	11,302.45	-	1,531.50	74,093.83
	6	Application fee for app Holder	pointment of New Market Authorization	500	153,149.70	28,256.12	-	3,828.74	185,234.56
	, 7	Application fee for preliminary approval of a local manufacturing plant	Category A- (i) Medicines to be administered internally (e.g. oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (e.g. ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally.	100	30,629.94	5,651.22	-	765.75	37,046.91
			Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	50	15,314.97	2,825.61	-	382.87	18,523.45

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NM	RA Monthly fee for Med	icines - Ei	iective irom	01/10/2020			
Application fee for renewal of a local manufacturing Plant approval	Category A- (i) Medicines to be administered internally (e.g. oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (e.g. ophthalmic, otological, nasal, rectal, yaginal)						
	(iii) Anti-infective and steroidal products to be applied locally.	100	30,629.94	5,651.22	-	765.75	37,046.91
	Category B- Dosage forms applicable on skin other than anti-infective or steroidal product	50	15,314.97	2,825.61		382.87	18,523.45
	127	50	15,314.97	2,825.61	-		382.87

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(III) Fees for additional data evaluation

Additional data		Fee (USD)	Amount (Rs.)	(Rs.) @ 18%	(Rs.)		Total (Rs.)
	Foreign	500	153,149.70	28,256.12	•	3,828.74	185,234.56
	(Local) Category A-			21			
	(i) Medicines to be administered	1					
registration.	internally		-				
	(e.g. oral, injectable, inhalational)						
	(ii) Medicines to be administered	1					
	through other body cavities (e.g.						
	ophthalmic, otological, nasal, rectal,					1	
	vaginal)			* * *			
	products to be applied locally.	200	61,259.88	11,302.45	-	1,531.50	74,093.83
	Category B-				,	1	
	Dosage forms applicable on skin other					1	
	than anti-infective or steroidal product	100	30,629.94	5,651.22	-	765.75	37,046.91
Additional data evalu	ation for Medicines required for rare						
diseases and medicine	es required in Small quantities (List of			Free of (Charge		
products in this categ	ory is published in the NMRA Official						
Website).	A Production Foreign	500	153 149 70	28 256 12	Τ .	3.828.74	185,234.56
		300	155,147.70				
		100	30 629 94			765.75	37,046.9
		100	30,027.71	3,031.22			
	Wajor variations						
	1						
small quantities)		250	76,574.83	14,128.0	06	- 1,914.37	92,617.
			A.	Free o	f Charge		140011
	Additional data evaludiseases and medicine Website). Additional data for Mariations that require review (except for medicine required for rare diseases and medicines required in small quantities) Any variation for medicine to the small quantities	(e.g. oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (e.g. ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally. Category B- Dosage forms applicable on skin other than anti-infective or steroidal product Additional data evaluation for Medicines required for rare diseases and medicines required in Small quantities (List of products in this category is published in the NMRA Official Website). Additional data for MP Evaluation - Foreign Variations that require review (except for medicines required in Minor Variations Major Variations Major Variations	(e.g. oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (e.g. ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally. Category B- Dosage forms applicable on skin other than anti-infective or steroidal product Additional data evaluation for Medicines required for rare diseases and medicines required in Small quantities (List of products in this category is published in the NMRA Official Website). Additional data for MP Evaluation - Foreign Variations that require review (except for medicines required in Small quantities) Major Variations Major Variations Any variation for medicines required for rare diseases and	(e.g. oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (e.g. ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally. Category B- Dosage forms applicable on skin other than anti-infective or steroidal product Additional data evaluation for Medicines required for rare diseases and medicines required in Small quantities (List of products in this category is published in the NMRA Official Website). Additional data for MP Evaluation - Foreign Variations that require review (except for medicines required in Small quantities) Major Variations Major Variations Any variation for medicines required for rare diseases and Major Variations required for rare diseases and	(e.g. oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (e.g. ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally. Category B- Dosage forms applicable on skin other than anti-infective or steroidal product International data evaluation for Medicines required for rare diseases and medicines required in Small quantities (List of products in this category is published in the NMRA Official Website). Additional data for MP Evaluation - Foreign Variations that require review (except for medicines required in small quantities) Any variation for medicines required for rare diseases and medicines required in small quantities Any variation for medicines required for rare diseases and medicines required in small quantities	(e.g. oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (e.g. ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally. Category B- Dosage forms applicable on skin other than anti-infective or steroidal product Additional data evaluation for Medicines required for rare diseases and medicines required in Small quantities (List of products in this category is published in the NMRA Official Website). Additional data for MP Evaluation - Foreign Notification Free of Charge Minor Variations Major Variations Major Variations Any variation for medicines required for rare diseases and medicines required in small quantities Any variation for medicines required for rare diseases and medicines required in small quantities The control of the product o	(e.g. oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (e.g. ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally. Category B- Dosage forms applicable on skin other than anti-infective or steroidal product Additional data evaluation for Medicines required for rare diseases and medicines required in Small quantities (List of products in this category is published in the NMRA Official Website). Additional data for MP Evaluation - Foreign Notification Tree of Charge Free of Charge Minor Variations Major Variations The Charge The Charge

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(IV) Processing fees for Clinical Trial

	7	Type of Evaluation	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
1	Industry Sponsored		1000	306,299.40	56,512.24	-	7,657.49	370,469.13
	Academic with Interna	ational Sponsorship	250	76,574.85	14,128.06	-	1,914.37	92,617.28
	Local Investigator Spo				Free of Cl	narge		
	Local investigator ope	Industry Sponsored	250	76,574.85	14,128.06	-	1,914.37	92,617.28
	Amendments that	Academic with International Sponsorship	50	15,314.97	2,825.61	-	382.87	18,523.45
	require review	Local Investigator Sponsored			Free of Cl	harge		

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(V) 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.)
	Full registration	Foreign	400	122,519.76	22,604.90	2,000.00	3,062.99	150,187.65
1	(issued for five years)	(Local) Category A- (i) Medicines to be administered internally (e.g. oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (e.g. ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal	700	122,017110	14.2			
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product.	200	61,259.88	11,302.45	2,000.00	1,531.50	76,093.83
	a	Medicines required for rare diseases and medicines required in Small quantities	100	30,629.94	5,651.22 Free of Ch	2,000.00 narge	765.75	39,046.91
R (i m	rovisional Legistration ssued for a maximum period of vo years)	oreign						
			200	61,259.88	11,302.45	2,000.00	1,531.50	76,093.82

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NMRA Monthly fee for Medicines - Effective from 01/10/2025 to 31/10/2025 (Local) Category A-(i) Medicines to be administered internally (e.g. oral, injectable, inhalational) (ii) Medicines to be administered 2 through other body cavities (e.g. ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally. 100 30,629.94 5,651.22 2,000.00 765.75 39,046.91 Category B-Dosage forms applicable on skin other than anti-infective or steroidal product 50 15,314.97 2,825.61 1,531.50 382.87 Medicines required for rare diseases 20,054.95 and medicines required in Small Free of Charge quantities Approval for a foreign manufacturing premises 3 250 76,574.85 14,128.06 2,000.00 1,914.37 GMP Certificate for foreign manufacturing premises (on 94,617.28 4 request) 250 76,574.85 14,128.06 2,000.00 1,914.37 94,617.28 Duplicate Copy of Certificate of Registration

250

100

Amendement of Certificate of Registration/ Approval

76,574.85

30,629.94

14,128.06

5,651.22

2,000.00

2,000.00

1,914.37

765.75

94,617.28

39,046.91

(VI) Fees for License

		Types of licenses	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	2.5%	Total (Rs.)
1	Sample Import Licen	se	50	15,314.97	2,825.61	1,531.50	382.87	20,054.95
2	Import License	for 1 year	100	30,629.94	5,651.22	2,000.00	765.75	39,046.91
		for 2 years	200	61,259.88	11,302.45	2,000.00	1,531.50	76,093.83
3	License for licensed	Importer of Medicines	400	122,519.76	22,604.90	2,000.00	3,062.99	150,187.65
4	Manufacturing License (Local)	Category A- (i) Medicines to be administered internally (e.g. oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (e.g. ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally.	100	30,629.94	5,651.22	2,000.00	765.75	39,046.91
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product.	50	15,314.97	2,825.61	1,531.50	382.87	20,054.95



	1 (11)	that infolithly tee for 1,2000					1	1
5		 (i) Medicines to be administered internally (e.g. oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (e.g. ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal 	300	91,889.82	16,953.67	2,000.00	2,297.25	113,140.74
,		products to be applied locally Category B — Dosage forms applicable on skin other than anti-infective or steroidal product	200	61,259.88	11,302.45	2,000.00	1,531.50	76,093.82
				76,574.85	14,128.06	2,000.00	1,914.37	94,617.28
6	Duplicate copy of the	e License	25			-		39,046.91
7	Amendment of Licer	nca	10	30,029.94	3,051122			

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(VII) Fees for Other Approvals

	Type of Approval	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
	Application for Formulation Approval (local Manufactu	ring) 25	7,657.49	1,412.81		191.44	9,261.74
2	Application for Formulation Approval (local Manufactur of medicines required for rare diseases and medicines recommendation)	ring)		Free of ch	iarge		a.
	in small quantities	50	15,314.97	2,825.61	-	382.87	18,523.45
′ 3	Application for Approval of Repackaging Sites (i) Approval for Invoice Value	50	15,314.97	2,825.61	-	382.87	18,523.45
	waiv- er of registration for the Invoice Value (USD) 2,000 or below Invoice Value (USD) 2,000-15,000	0 100	30,629.94	5,651.22	-	765.75	37,046.91
4	government supplies (ii) Application for waiver of registration Invoice Value (USD) 15,000 or above						
	for the private	200	61,259.88	11,302.45	-	1,531.50	74,093.83
	supplies	10	3,062.99	565.12	-	76.57	3,704.68
5	Any Clarification Letter	100	30,629.94	5,651.22	2,000.00	765.75	37,046.91
7	GMP certificate for a local manufacturing site Certificate of Pharmaceutical Product (COPP)	50	15,314.97	2,825.61	1,531.50	382.87	18,523.45 18,523.45
		50	15,314.97	2,825.61	1,531.50	382.87	10,323.43
8	Free Sale Certificate Appointment of New From Manufacturer marketing	1000	306,299.40	56,512.24	_	7,657.49	370,469.1 3
9	Authorization Holder (Agency Transfer) From Each new marketing authorization holder	500	153,149.70	28,256.12	•	3,828.74	185,234.56

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(VII	I) Fees for Analysis		Т		VAT	Stamp Duty	SSCL (Rs.)	Total (Rs.)
			Fee (USD)	Amount (Rs.)	(Rs.) @ 18%	(Rs.)	2.5%	Total (13.)
_		Analysis						
1	Biological Test		250	76,574.85	14,128.06	-	1,914.37	92,617.28
			250	76,574.85	14,128.06		1,914.37	92,617.28
2	Microbiological Test		250	76,574.85	14,128.06	-	1,914.37	92,617.28
3	Assay Test (Chemica	II, Microbiological, Biological)		76,574.85	14,128.06	-	1,914.37	92,617.28
, 4	Limit test (performed t	using Analytical Equipment- HPLC, AAS etc.)	250	70,374.63	14,120.00			
5	Dissolution Test		250	76,574.85	14,128.06	-	1,914.37	92,617.28
	Three or less than	(I) If all three tests comprise from						
	three tests	items 1, 2, 3, 4 and						
6		5 in Column 1	750	229,724.55	42,384.18	-	5,743.11	277,851.84
		(II) Otherwise	500	153,149.70	28,256.12	-	3,828.74	185,234.56
7		(I) If all four tests comprise from items						
		1, 2, 3, 4 and 5	,				1	
		in Column 1						
	Four tests or more		1500	459,449.10	84,768.36	-	11,486.23	555,703.69
	than four tests	(II) Otherwise tests other than items 1,					,	
		2, 3, 4 and 5 in	1000 mg 1000 m 1000	183.			7 (57 (0)	270 460 12
		Column 1	1000	306,299.40	56,512.24	-	7,657.49	370,469.13
	Cinala Tost	tests other than items 1, 2, 3, 4 and 5 in		50 500 10	0.000 (4		1 240 00	64 922 10
8	Single Test	Column 1	175	53,602.40	9,889.64	-	1,340.06	64,832.10



(LX) Fees for Licenses to deal in medicines in Retail Pharmacies, Wholesale Establishments and Transporting of Medicines.

	Туре	Fee (USD)	Amount in (Rs.)	VAT (Rs.) @ 18%		SSCL (Rs.) 2.5%	Total (Rs.)
1	Wholesale License	60	18,377.96	3,390.73	1837.80	459.45	24,065.94
′ 2	Retail License	45	13,783.47	2,543.05	1378.35	344.59	18,049.46
3	Transport License	10	3,062.99	565.12	306.30	76.57	4,010.98
4	Duplicate of License	50	15,314.97	2,825.61	1531.50	382.87	20,054.95
5	Amended License	30	9,188.98	1,695.37	918.90	229.72	12,032.97
6	TELE Pharmacy (Home Delivery) License (Period of one Year	100	30,629.94	5,651.22	2000	765.75	39,046.91

Processing Fee for application for Licenses and others

Type	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%		SSCL (Rs.) 2.5%	Total (Rs.)
1 Application fee for Wholesale License	120	36,755.93	6,781.47	-	918.90	44,456.30
2 Application fee for Retaill License	90	27,566.95	5,086.10	-	689.17	33,342.22
3 Application fee for Transport License for therapeutic goods	20	6,125.99	1,130.25	-	153.15	7,409.39

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(X) Fee for Pharmacy and Good Distribution Practice Inspection (GDP)

(A)	ree for r narmacy and coop a			VAT	Stamp Duty	SSCL (Rs.)	Total (Rs.)
	· Type	Fee (USD)	Amount in (Rs.)	(Rs.) @ 18%	(Rs.)	2.5%	39,046.91
	Good Distribution Practice Inspection	100	(22.01	5,651.22 5,651.22	2000 2000	765.75 765.75	39,046.91
1 2	Pharmacovigilance Inspection						

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

	Туре	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5%	Total (Rs.)
i - (i i (t	Category A- Manufacturers whose product range include: i) Medicines to be administered internally (e.g. oral, injectable, inhalational) ii) Medicines to be administered internally of the body cavities (e.g. inhalational) phthalmic, otological, nasal, rectal, inaginal) iii) Anti-infective and steroidal incoducts to be applied locally.	300	91,889.82	16,953.67	-	2,297.25	111,140.74
I	Category B- Dosage forms applicable on skin other han anti- infective or steroidal product.	100	30,629.94	5,651.22	-	765.75	37,046.91
	Repackaging site	100	30,629.94	5,651.22		765.75	37,046.9

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

(AI	Country	Fee (USD)	Amount (Rs.)	(Rs.) @ 18%	Stamp Duty (Rs.)	SSCL (Rs.) 2.5% 114,862.28	Total (Rs.) 5,557,036.87
1	SAARC Countries	15000	4,594,491.00	847,683.59	-	114,802.28	3,337,030.07
2	Other Countries	20000	6,125,988.00	1,130,244.79	-	153,149.70	7,409,382.49
3	Follow up inspection (All countries)	5000	1,531,497.00	282,561.20	-	38,287.43	1,852,345.63

^{*} Air tickets, Visa fees should be borne by the Applicant.

(XIII) Fee for advertisement

(2222	Advertisement	Fee (USD)	Amount (Rs.)	VAT (Rs.) @ 18%		SSCL (Rs.) 2.5%	Total (Rs.)
1	Processing fee for the application of an Advertisement (All categories)	700	214,409.58	39,558.57	-	5,360.24	259,328.39
	Approval of Advertisement (All categories)	300	91,889.82	16,953.67	-	2,297.25	111,140.74

^{*} Separate Applications should be submitted for each advertisement.