

*Tanzania Food, Drugs and Cosmetics (Fees and Charges)
Regulations, 2019*

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THE TANZANIA FOOD, DRUGS AND COSMETICS ACT
(CAP 219)

REGULATIONS

(Made under Section 122(1) (i))

THE TANZANIA FOOD, DRUGS AND COSMETICS (FEES AND CHARGES)
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- Citation 1. These Regulations may be cited as the Tanzania Food, Drugs and Cosmetics (Fees and Charges) Regulations, 2019.
- Application 2. These Regulations shall apply in charging fees for all regulatory activities relating to food, medicines, cosmetics, medical devices and diagnostics in Tanzania Mainland.
- Interpretation 3. In these Regulations unless the context otherwise requires:
- Cap 219 “Act” means the Tanzania Food, Drugs and Cosmetics Act,;
“alteration or variation fee” means a fee paid by a marketing authorisation holder in relation to alteration to be made regarding product composition, formulation, packaging, labelling or any other changes relating to alteration made to a registered product;
“annual retention fee” means a fee paid by a marketing authorisation holder for the purpose of retaining a registered product in the register of the Authority;
“Authority” means the Tanzania Food and Drugs Authority or in its acronym “TFDA” established under the Act;
‘donation’ means medicines, medical devices and diagnostics supplied by donor agencies recognized by the Authority but excluding medicines, medical devices and diagnostics supplied through vertical programmes;
“fees” includes any charge made or levied in connections to services rendered by the Authority;
“Freight on Board or Free on Board or its acronym FoB” means a value of regulated product to be imported into Tanzania mainland;

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“Good Manufacturing Practices (GMP) means practices as described in Tanzania Food, Drugs and Cosmetics (Good Manufacturing Practices) Regulations, 2018;

“large scale enterprise” means an enterprise with capital investment exceeding eight hundred million shillings;

Cap .287, Cap 288

“Local Government Authority” means City Council, Municipal Council, Town Council or District Council as described in Urban and District Authorities Acts;

“manufacturer” means person or firm that is engaged in the manufacture of a product regulated under the Act;

“manufacturing” means all operations involved in the product preparation, processing compounding, formulating, filling, refining, transformation, packing and labelling of product regulated under the Act;

“marketing authorisation holder” means a company, firm or organisation that has been granted a marketing authorisation which allows the holder to market a product regulated under the Act;

“medium scale enterprise ” means an enterprise with capital investment of not less than two hundred million but not exceeding eight hundred million shillings;

“micro scale enterprise” means an enterprise with capital investment of not exceeding five million shillings;

“pre- licensing or registration inspection” means inspection carried out on premises to verify compliance with set requirements prior to granting of a license or permit or registration certificate;

“product carrier” means any box detachable compartment, tank or container, receptacle, or any other arrangement in which a product may be carried in;

“product dealer” means a product manufacturer, packer, importer, exporter, distributor, seller or any other dealer in any product business to which the Act applies;

“products” means food, medicines, antiseptics, disinfectants, medicated soaps, cosmetics, medical devices, diagnostics and medical laboratory equipment;

“registration certificate” means a certificate issued by the Authority in respect of a registered product or premises;

“small scale enterprises” means an enterprise with capital investment exceeding five million shillings but less than two hundred million shillings; and

“vertical programmes” means national disease control programmes for malaria, HIV/AIDS, tuberculosis and leprosy, immunization, neglected tropical diseases and any other programme for diseases of public health importance recognised by the Authority.

Fees and charges
Cap.219

4.-(1) Any person who intends to conduct business related to products regulated under the Act, shall pay fees and charges as prescribed in the First

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Schedule of these Regulations;

(2) Subject to sub-regulation (1), a person may submit samples for laboratory analysis and pay fees and charges as prescribed in the Second Schedule of these Regulations provided that such sample is not for regulatory decision making.

(3) Fees and charges shall be paid in Tanzanian shillings or US\$ equivalent to the amount of Tanzanian shillings or any convertible currency equal to the amount payable in Tanzanian shillings.

(4) The Minister may upon advice of the Director General, change or vary any fees and charges in force at any time.

Appropriation of fees
and charges

5.-(1) Fees and charges paid under these Regulations shall be collected and appropriated by the Authority.

(2) Fees and charges payable under these Regulations shall not be refundable.

(3) Failure to pay in time the fees and charges in force shall attract a penalty of 25% of the total amount payable.

(4) The Authority, where satisfied that the declared value do not reflect the actual cost which were to be used to calculate FoB, may reject the importation approval or uplift the value of consignment to the cost that would be the valued amount of the product or consignment.

Payment by order of
the court

6.-(1) When an order of the court requires a person to pay for fees and charges retrospectively for any regulated product or services, such pay shall include the calculated 25% of the total amount ought to have been paid prior to the court order.

(2) The FoB charges shall be paid before importation of the respective consignment declared by the importer.

Fees and charges
prescribed by other
Regulations

7.-(1) Any other Regulations made under the Act for which fees and charges are prescribed, shall be deemed to have been part of these Regulations.

(2) A person who shall be charged to pay fees and charges in force under any other regulations made under the Act, shall be deemed to have been complied with these regulations and shall have the same legal effect as charged under these Regulations.

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Fees for GMP
inspection

8.-(1) Fees paid for Good Manufacturing Practice inspections shall be determined and charged basing on the manufacturing sites.

(2) The Authority shall charge additional fees not exceeding 25% for each additional production line or block.

Revocation of GN
No. 464 of 2015 and
428 of 2017

9. The Tanzania Food, Drugs and Cosmetics (Fees and Charges) Regulations, 2015 and The Tanzania Food, Drugs and Cosmetics (Fees and Charges Amendment) Regulations, 2017 are hereby revoked.

Offence and Penalty

10. Any person who-

(a) contravenes or fails to comply with these Regulations;

(b) Aid another person to commit an offence, commits an offence and shall, on conviction, be liable to the penalty prescribed under the Act.

Saving provision

11. All fees, charges, orders or action made under the revoked Regulations shall be deemed to have been made under these Regulations.

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FIRST SCHEDULE

(Made under regulation 4(1))

Human and Veterinary Medicines (Domestic)				
	Service	Currency		
			Fee	
1.	Registration	TZS	1,000,000	
2.	Variation -Major	TZS	200,000	
3.	Variation -Minor	TZS	100,000	
Human, Veterinary Medicines and Biologicals (Imported)				
4.	Registration	USD	2,000	
5.	Registration – biologicals	USD	3,500	
6.	Retention	USD	300	
7.	Variation – Major	USD	1,000	
8.	Variation – Minor	USD	300	
9.	Fast track registration	USD	Double the respective fee	
Registration for domestic and imported food products				
			Domestic	Imported
10.	Milk and milk products	TZS	600,000	1,000,000
11.	Cereal and cereal products	TZS	700,000	900,000
12.	Pulses	TZS	500,000	800,000
13.	Nuts	TZS	400,000	700,000
14.	Tuber and roots	TZS	600,000	800,000
15.	Non- alcoholic beverages	TZS	600,000	800,000

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16.	Alcoholic beverages	TZS	400,000	600,000
17.	Sugar and honeys	TZS	500,000	800,000
18.	Iodated salt	TZS	300,000	500,000
19.	Fats and oils	TZS	400,000	600,000
20.	Tea and coffee	TZS	600,000	1,000,000
21.	Cocoa and cocoa products	TZS	600,000	1,000,000
22.	Spices and herbs	TZS	600,000	900,000
23.	Vinegar	TZS	300,000	500,000
24.	Fish and fish products	TZS	600,000	800,000
25.	Meat and meat products	TZS	500,000	900,000
26.	Fruits and fruit products	TZS	400,000	700,000
27.	Drinking water	TZS	600,000	900,000
28.	Vegetable and vegetable products	TZS	400,000	700,000
29.	Food for infants and follow up formula	TZS	1,400,000	2,000,000
30.	Food supplements	TZS	1,400,000	2,000,000
31.	Processed cereal based foods for children	TZS	1,400,000	2,000,000
32.	Food additives	TZS	300,000	500,000
33.	Confectionaries	TZS	600,000	800,000
34.	Alteration –major	TZS	50,000	100,000
35.	Food sold in supermarkets	TZS	0	200,000
36.	Pre – shipment samples for non-registrable food	TZS	0	500,000
37.	Registration fees for food products manufactured by micro and small manufacturing enterprises (Analysis fees inclusive)	TZS	50,000	0

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38.	Fast track registration	TZS	Double respective fee	Double respective fee
MEDICAL DEVICES				
Registration –Imported				
39.	Class A (Registrable)		USD	500
40.	Class B		USD	2,000
41.	Class C		USD	2,000
42.	Class D		USD	2,500
43.	Variation –Minor		USD	200
44.	Variation –Major		USD	500
45.	Retention fee		USD	200
Registration - Domestic				
46.	Class B		TZS	200,000
47.	Class C		TZS	500,000
48.	Class D		TZS	500,000
49.	Variation-minor		TZS	100,000
50.	Variation-major		TZS	150,000
Diagnostics				
Registration of IVD (Imported)				
51.	Class A (Registrable)		USD	300
52.	Class B		USD	1000
53.	Class C		USD	1500
54.	Class D		USD	2000
55.	Variation - Minor		USD	200

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56.	Variation - Major	USD	500
57.	Retention	USD	200
Registration of IVD (Domestic)			
58.	Class B	TZS	200,000
59.	Class C	TZS	500,000
60.	Class D	TZS	500,000
61.	Variation - Minor	TZS	100,000
62.	Variation - Major	TZS	150,000
Performance Evaluation Tests (Diagnostics)			
63.	Haematology Analyzer	USD	3,000
64.	Clinical Chemistry Analyzer	USD	3,500
65.	Molecular Analyzer	USD	5,300
66.	Chemi-luminescent Analyzer	USD	5,300
67.	Chromatography Analyzer	USD	4,800
68.	Molecular Analyzer- Sequencer	USD	5,300
69.	Rapid Diagnostic Tests (Laboratory and Field)	USD	3,000
70.	Staining Reagents, Media and Discs	USD	1,000
71.	Bacteriological Analyzer	USD	4,800
72.	Others	USD	3,000
Cosmetics (Imported)			
73.	Registration	TZS	150,000
74.	Variation	TZS	50,000
75.	Retention	TZS	100,000

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Cosmetics (Domestic)			
76.	Registration	TZS	100,000
77.	Variation	TZS	20,000
78.	Registration fees for cosmetic products manufactured by micro and small manufacturing enterprises (Analysis fees inclusive)	TZS	50,000
Antiseptics, Disinfectants and Medicated Soaps (Imported)			
79.	Registration	TZS	200,000
80.	Variation	TZS	100,000
81.	Retention	TZS	150,000
Antiseptics, Disinfectants and Medicated Soaps (Domestic)			
82.	Registration	TZS	100,000
83.	Variation	TZS	50,000
84.	Registration fees for antiseptics, disinfectants and medicated soaps manufactured by micro and small manufacturing enterprises (Analysis fees inclusive)	TZS	50,000
Authorisation of Clinical Trials			
85.	Application to conduct clinical trials	USD	3000
86.	Amendment-Major	USD	500
87.	Amendment-Minor	USD	300
88.	Fast track	USD	Double authorisation fee
GMP inspection and Quality Audit fee for food, medicines and medical device facilities per block (Foreign)			
89.	East Africa	USD	4,000
90.	Rest of Africa	USD	5,000
91.	Asia	USD	6,000
92.	Europe	USD	6,500
93.	America	USD	7,500

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94.	Australia and New Zealand	USD	7,500
Evaluation and Approval of promotional materials			
Medicinal products			
95.	Promotional material-foreign	USD	100
96.	Abbreviated advert-foreign	USD	50
97.	Promotional material-domestic	TZS	100,000
98.	Abbreviated advert-domestic	TZS	50,000
Food and Food Products			
99.	Label artwork of pre-packaged food	TZS	50,000
100.	Label artwork of high risk food	TZS	100,000
101.	Promotional material		50,000
Permits			
102.	Trade fair permit-Foreign company	USD	200
103.	Change of Local Technical Representative	USD	2,000
104.	Large Pharmaceutical manufacturers	TZS	700,000
105.	Medium Pharmaceutical manufacturers	TZS	500,000
106.	Small Pharmaceutical manufacturers	TZS	300,000
107.	Large cosmetics manufacturers	TZS	500,000
108.	Medium cosmetics manufacturers	TZS	350,000
109.	Small cosmetics manufacturers	TZS	150 000
110.	Pharmaceutical importers	TZS	300,000
111.	Wholesale veterinary outlets	TZS	300,000
112.	Wholesale Medical device outlets	TZS	300,000
113.	Wholesale cosmetics outlets	TZS	300,000

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114.	Retail cosmetic outlets	TZS	50,000
115.	Retail medical device outlets	TZS	100,000
116.	Disposal charge on value of condemned products	TZS	25%
117.	Inspection of consignments at owners premises	TZS	100,000
118.	Inspection of new food processing facilities - large	TZS	250,000
119.	Inspection of new food processing facilities -medium	TZS	200,000
120.	Annual dealers permit for distributors-large scale	TZS	150,000
121.	Annual dealers permit for distributors-Medium	TZS	100,000
122.	Annual dealers permit for distributors-small scale	TZS	50,000
123.	Annual dealers license/permit for Manufacturers-large scale	TZS	300,000
124.	Annual dealers license/permit for Manufacturers-Medium scale	TZS	150,000
125.	Annual dealers license/permit for manufacturers- small scale	TZS	50,000
126.	Registration fees for food premises including mass caterers charged through Local Government Authorities	TZS	60,000
Importation fees			
127.	Food products	FoB	1.5%
128.	Medicinal products	FoB	2.0%
129.	Pharmaceutical raw materials	FoB	0.5%
130.	Medical devices and diagnostics	FoB	2%
131.	Cosmetic products	FoB	1%
132.	Cosmetic raw materials	FoB	1%

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133.	Antiseptics, disinfectants and medicated soaps	FoB	2%
134.	Donated medicines, medical devices and diagnostics	FoB	0.25%
135.	Accessories for medical devices and diagnostics	FoB	0.5%
136.	Medical laboratory equipment	FoB	2%

SECOND SCHEDULE

(Made under regulation 4(2))

LABORATORY COMMERCIAL SAMPLES ANALYSIS

S/N	PARAMETERS	FEES in TZS
FOOD PRODUCTS		
Proximate Analysis		
1.	Free fatty acids in Meat	280,000
2.	Polyaromatic Hydrocarbons (PAH) in water	260,000
3.	Fat in meat	230,000
4.	Peroxide Value	220,000
5.	Atropine level	160,000
6.	Vitamin A	150,000
7.	Vitamin B1 (Thiamine)	150,000
8.	Vitamin B2 (Riboflavin)	150,000
9.	Vitamin B3 (Biotin)	150,000
10.	Vitamin B6 (Pyridoxine)	150,000
11.	Vitamin B12 (Cyanocobalamine)	150,000
12.	Vitamin C (Ascorbic Acid)	150,000
13.	Vitamin D (Cholecalciferol)	150,000
14.	Vitamin E (Tocopherol)	150,000

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S/N	PARAMETERS	FEES in TZS
15.	Vitamin K	150,000
16.	Folic acid	150,000
17.	Butyhydroxyanisole (BHA)	150,000
18.	Butylhydrotoluene (BHT)	150,000
19.	Propylene glycol stearate	150,000
20.	Caffeine	150,000
21.	Beta Carotene	150,000
22.	Nicotinic Acid	150,000
23.	Fibre	150,000
24.	Glucono delta lactones	150,000
25.	Sucrose	150,000
26.	Fructose	150,000
27.	Glucose	150,000
28.	Levulose	150,000
29.	Dextrose	150,000
30.	Nitrites	140,000
31.	Milk fat	140,000
32.	Iodine value	140,000
33.	Protein	120,000
34.	Crude fiber	120,000
35.	Acid Insoluble ash	120,000
36.	Glycosidic cyanide	120,000
37.	Potassium Bromate	120,000
38.	Volatile oils	120,000
39.	Fats	120,000
40.	Lean Meat	120,000
41.	Precipitin	120,000
42.	Meat content	120,000
43.	Total volatile bases	120,000
44.	Solid Not Fat (SNF)	120,000
45.	Total nitrogen	120,000
46.	Proline	120,000

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S/N	PARAMETERS	FEES in TZS
47.	Solid Not Fat (SNF)	120,000
48.	Diastase activity	120,000
49.	Sugar	115,000
50.	Sodium Chloride	115,000
51.	Non Volatile oils	115,000
52.	Water soluble ash	115,000
53.	Methanol	115,000
54.	Reducing sugar	115,000
55.	Histamine	115,000
56.	Trimethylamine	115,000
57.	Indole	115,000
58.	Hydroxyproline	115,000
59.	Boric Acid	115,000
60.	Acetaly esters	115,000
61.	Lecithin	115,000
62.	Acid value	115,000
63.	Peroxide	115,000
64.	Hydroxy Methly Furfuraldehyde (HMF)	115,000
65.	Saponification value	115,000
66.	Unsaponifiable matters	115,000
67.	Total solids	100,000
68.	Ash	100,000
69.	Tannins	100,000
70.	Aldehydes	100,000
71.	Salt	90,000
72.	Thiobarbituric Acid	90,000
73.	Phosphates	90,000
74.	Lactose	90,000
75.	Starch	90,000
76.	Sulphates	90,000
77.	Fluorides	90,000
78.	Free acidity	90,000

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S/N	PARAMETERS	FEES in TZS
79.	Sulphides	90,000
80.	Turbidity	90,000
81.	Beef content	90,000
82.	Starch	90,000
83.	Alcohol extract	90,000
84.	Chlorides	80,000
85.	Talc	80,000
86.	Urease Acidity	80,000
87.	Total carbohydrates	70,000
88.	Moisture Content	70,000
89.	Total solids	70,000
90.	Fixed Acidity	55,000
91.	Free fatty acids in oils and fats	55,000
92.	Insoluble impurities	55,000
93.	Melting point	55,000
94.	Acidity	55,000
95.	Alkalinity	55,000
96.	Total Acidity	55,000
97.	Volatile Acidity	55,000
98.	Chromate test	55,000
99.	Sodium Chloride (NaCl)	55,000
100.	Carbon dioxide	45,000
101.	Soap content	45,000
102.	Viscosity	45,000
103.	pH in milk (at 55°C)	35,000
104.	Glutens	35,000
105.	Microscopic examination	35,000
106.	Sieve test	35,000
107.	Total Dissolved Solids (TDS)	35,000
108.	Total Soluble Solids (TSS)	35,000
109.	Solubility	35,000
110.	Lactose	35,000

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S/N	PARAMETERS	FEES in TZS
111.	Freezing Point	35,000
112.	Specific gravity	20,000
113.	pH (at 20°C)	20,000
114.	Refractive Index	20,000
115.	Relative Density	20,000
116.	Conductivity	20,000
117.	Total Suspended Solids	20,000
118.	Hexabromide	20,000
119.	Polybromide	20,000
120.	Arachidic Acid	20,000
121.	Density	20,000
122.	Flash Point	20,000
123.	Heat damaged seeds	10,000
124.	Immature or shrivelled seeds	10,000
125.	Insect damaged grains	10,000
126.	Immature grains	10,000
127.	Physical inspection	10,000
128.	Extraneous matter	10,000
129.	Visual appearance	10,000
130.	Chalky	10,000
131.	Coloured grains	10,000
132.	Discoloured grains	10,000
133.	Foreign matter	10,000
Contaminants		
Heavy metals		
134.	Mercury (Hg)	125,000
135.	Arsenic (As)	125,000
136.	Nickel (Ni)	125,000
137.	Lead (Pb)	125,000
138.	Cadmium (Cd)	125,000
139.	Copper (Cu)	125,000
140.	Other metals (each)	125,000

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S/N	PARAMETERS	FEES in TZS
	Mycotoxins	
141.	Mycotoxins by LC-MS/MS	480,000
142.	Ochratoxins	270,000
143.	Deoxynivalenol	270,000
144.	Total Aflatoxins	270,000
145.	Aflatoxin B1	270,000
146.	Fumonisin A	270,000
147.	Fumonisin B	270,000
148.	Aflatoxin M1	270,000
149.	T. Toxin	270,000
150.	Zeralenol	270,000
151.	Patulin	270,000
	Drug residues	
152.	Screening	140,000
153.	Drug residues by HPLC	300,000
154.	Quantification each by LC-MS/MS	480,000
	Pesticide residues	
155.	Screening	140,000
156.	Pesticide residue each	270,000
157.	Quantification each by LC-MS/MS	480,000
	Chemicals	
158.	Melamine	300,000
159.	Formalin	200,000
	Microbiological tests	
160.	Total viable aerobic count	300,000
161.	Coliforms	290,000
162.	Faecal coliforms	290,000
163.	<i>Pseudomonas aeruginosa</i>	290,000
164.	Sulphite reducing anaerobes	290,000
165.	Sulphate reducing bacteria	390,000
166.	Moulds and Yeasts	370,000
167.	Acetic acid bacteria	390,000

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S/N	PARAMETERS	FEES in TZS
168.	Lactic acid bacteria	390,000
169.	Salmonella species	350,000
170.	Total viable aerobic count	300,000
171.	<i>Escherichia coli</i>	300,000
172.	Enterobacteriaceae	300,000
173.	Shigella	350,000
174.	<i>Staphylococcus aureus</i>	340,000
175.	<i>Clostridium perfringes</i>	380,000
176.	<i>Bacillus cereus</i>	380,000
177.	<i>Listeria monocytogenes</i>	340,000
	Additives	
178.	Artificial Sweeteners each	150,000
179.	Food colour each	150,000
180.	Preservative each	150,000
	MEDICINES	
	Tablets, Capsules and Sachets	
181.	Physical examination	10,000
	Identification tests	
182.	by UV/VIS	150,000
183.	by HPLC	1,000,000
184.	by FTIR	230,000
185.	by TLC	300,000
186.	by Colour reaction	180,000
187.	by Melting point	70,000
188.	by Optical rotation	70,000
	Assay	
189.	by UV/VIS	400,000
190.	by HPLC	1,500,000
191.	by Titration	500,000
192.	Bioassay	400,000
	Dissolution	
193.	by UV/VIS	300,000

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S/N	PARAMETERS	FEES in TZS
194.	by HPLC	1,600,000
	Uniformity of dosage unit	
195.	Content Uniformity by UV/VIS	740,000
196.	Content Uniformity by HPLC	2,900,000
197.	by Weight Variation	60,000
	Related Substances or impurities	
198.	by HPLC (limit)	1,200,000
199.	by HPLC	1,500,000
200.	by TLC	800,000
201.	by TLC (limit)	150,000
	Moisture Content	
202.	by Loss on drying	160,000
203.	by KF	1,000,000
204.	by direct titration	1,000,000
205.	by distillation	130,000
206.	Other tests	
207.	Disintegration	80,000
208.	Hardness	20,000
209.	Friability	60,000
210.	Sulphated Ash	530,000
211.	Heavy metals by AAS each	580,000
212.	Heavy metals by colour limit	370,000
	Microbiological Tests	
213.	Total Aerial Microbial Count	390,000
214.	Yeast/Mould Count	330,000
215.	<i>Escherichia coli</i>	280,000
216.	<i>Pseudomonas aeruginosa</i>	280,000
217.	Salmonella	350,000
218.	<i>Staphylococcus aureus</i>	350,000
	Syrups, Suspensions, Solutions and Powder or Granules for Suspension	
219.	Physical examination	10,000
	Identification	

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S/N	PARAMETERS	FEES in TZS
220.	by UV/VIS	150,000
221.	by HPLC	1,000,000
222.	by FTIR	240,000
223.	by TLC	400,000
224.	by Colour reaction	180,000
225.	by Optical rotation	70,000
	Assay	
226.	by UV/VIS	400,000
227.	by HPLC	1,500,000
228.	by Titration	500,000
229.	Bioassay	400,000
	Uniformity of dosage unit	
230.	Content Uniformity by UV/VIS	750,000
231.	Content Uniformity by HPLC	2,900,000
232.	by Weight Variation	60,000
	Related Substances or impurities	
233.	by HPLC (limit)	1,170,000
234.	by HPLC	1,480,000
235.	by TLC	800,000
236.	by TLC(limit)	140,000
237.	Deliverable volume	60,000
	Moisture Content	
238.	by Loss on drying	160,000
239.	by KF	1,000,000
240.	by direct titration	1,000,000
241.	by distillation	130,000
	Other Tests	
242.	Sulphated Ash	530,000
243.	Heavy metals by AAS	590,000
244.	Heavy metals by colour limit	350,000
245.	pH	20,000
246.	Weight /mL	55,000

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S/N	PARAMETERS	FEES in TZS
247.	Sulphated Ash	530,000
248.	Heavy metals by AAS	590,000
249.	Heavy metals by colour limit	350,000
250.	pH	20,000
251.	Weight /mL	55,000
252.	Pseudomonas aeruginosa	290,000
253.	Salmonella	350,000
254.	S. aureus	350,000
Injectables (large & small)		
255.	Physical examination	10,000
Assay		
256.	by UV/VIS	400,000
257.	by HPLC @ API	1,450,000
258.	by Titration	500,000
259.	Bioassay	390,000
Identification		
260.	by UV/VIS	150,000
261.	by HPLC @ API	1,000,000
262.	by FTIR	240,000
263.	by TLC	400,000
264.	by Colour reaction	180,000
265.	by Optical rotation	70,000
Moisture Content		
266.	by Loss on drying	160,000
267.	by KF	1,000,000
268.	by direct titration	1,000,000
269.	by distillation	120,000
270.	pH	20,000
Related Substances/impurities		
271.	by HPLC(limit)	1,170,000
272.	by HPLC	1,480,000
273.	by TLC	800,000

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S/N	PARAMETERS	FEES in TZS
274.	by TLC(limit)	140,000
	Uniformity of dosage unit	
275.	Content Uniformity by UV/VIS	700,000
276.	Content Uniformity by HPLC	2,900,000
277.	by Weight Variation	60,000
	Other Tests	
278.	Heavy metals by colour limit	370,000
279.	Sulphated Ashes	530,000
280.	Deliverable volume	60,000
281.	Clarity of solution	60,000
282.	Particulate Matter	60,000
283.	Colour of solution	800,000
	Sterility	
284.	by filtration	320,000
285.	by steritest	350,000
286.	Bacterial endotoxins	350,000
	External Preparations	
	Creams, Ointments, Gels and Lotions (Sterile and Non-Sterile)	
287.	Physical examination	10,000
	Assay	
288.	by UV/VIS	400,000
289.	by HPLC	1,400,000
290.	by Titration	520,000
291.	Bioassay	400,000
	Identification	
292.	by UV/VIS	150,000
293.	by HPLC	1,000,000
294.	by FTIR	240,000
295.	by TLC	400,000
296.	by Colour reaction	180,000
	Uniformity of dosage unit	
297.	by Weight Variation	60,000

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S/N	PARAMETERS	FEES in TZS
	Water content	
298.	by KF	1,000,000
299.	by direct titration	1,000,000
300.	by distillation	130,000
	Limit of other impurities	
301.	Heavy metals by colour limit	370,000
302.	Sulphated Ash	530,000
	Microbial limit	
303.	Total Aerial Microbial Count	390,000
304.	Yeast/Mould Count	330,000
	Inhalers and Aerosols	
305.	Physical examination	10,000
	Identification	
306.	by UV/VIS	150,000
307.	by HPLC @ API	1,000,000
308.	by FTIR	240,000
309.	by TLC	400,000
310.	by Colour reaction	180,000
311.	by Melting point	70,000
312.	by Optical rotation	70,000
	Assay	
313.	by UV/VIS	400,000
314.	by HPLC	1,450,000
315.	by Titration	500,000
316.	Bioassay	390,000
	Uniformity of delivered dose	
317.	by determination of contents	1,450,000
318.	Deposition of the Emitted dose	1,450,000
	Related Substances/impurities	
319.	by HPLC	1,170,000
320.	by HPLC (limit)	1,450,000
321.	by TLC	800,000

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S/N	PARAMETERS	FEES in TZS
322.	by TLC(limit)	140,000
	Moisture Content	
323.	by Loss on drying	160,000
324.	by KF	1,000,000
325.	by direct titration	1,000,000
326.	by distillation	130,000
	Leak test	
327.	Direct measurement	60,000
	Other Tests	
328.	Sulphated Ash	530,000
329.	Heavy metals by AAS each	590,000
330.	Heavy metals by colour limit	370,000
	Microbiological Tests	
331.	Total Aerial Microbial Count	390,000
332.	Yeast/Mould Count	330,000
	Eye, Nose and Ear drops	
333.	Physical examination	10,000
	Assay	
334.	by UV/VIS	400,000
335.	by HPLC	1,000,000
336.	by Titration	500,000
337.	Bioassay	400,000
	Identification	
338.	by UV/VIS	150,000
339.	by HPLC	1,000,000
340.	by FTIR	240,000
341.	by TLC	400,000
342.	by Colour reaction	180,000
343.	by Optical rotation	70,000
	Water Content	
344.	by KF	1,000,000
345.	by direct titration	1,000,000

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S/N	PARAMETERS	FEES in TZS
346.	by distillation	130,000
347.	pH	20,000
	Related Substances or impurities	
348.	by HPLC	1,170,000
349.	by HPLC (limit)	1,500,000
350.	by TLC	800,000
351.	by TLC(limit)	140,000
	Uniformity of dosage unit	
352.	Content Uniformity by UV/VIS	730,000
353.	Content Uniformity by HPLC	2,900,000
354.	by Weight Variation	60,000
	Other Tests	
355.	Heavy metals by colour limit	360,000
356.	Sulphate Ash	530,000
357.	Leakage	60,000
358.	Metal particles	60,000
	Sterility	
359.	by filtration	320,000
360.	by sterility test	350,000
	Raw Materials (Active Pharmaceutical Ingredients and Excipients)	
361.	Appearance/Description	20,000
	Assay	
362.	by UV/VIS	400,000
363.	Bioassay	400,000
364.	by HPLC	1,500,000
365.	by Titration	500,000
	Identification	
366.	by UV/VIS	150,000
367.	by HPLC	1,000,000
368.	by FTIR	240,000
369.	by TLC	400,000
370.	by Colour reaction	180,000

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S/N	PARAMETERS	FEES in TZS
371.	by Optimal rotation	70,000
372.	by melting point	70,000
	Moisture Content	
373.	by Loss on drying	160,000
374.	by KF	1,000,000
375.	by Direct titration	1,000,000
376.	by Distillation	130,000
	Related Substances or impurities	
377.	by HPLC (limit)	1,170,000
378.	by HPLC	1,480,000
379.	by TLC	800,000
380.	by TLC (limit)	140,000
	Other Tests	
381.	Heavy metals by limits test	370,000
382.	Sulphated Ash	530,000
	Microbiological Tests	
383.	Total Aerial Microbial Count	390,000
384.	Yeast/Mould Count	330,000
385.	<i>Escherichia coli</i>	280,000
386.	<i>Pseudomonas aeruginosa</i>	280,000
387.	Salmonella	360,000
388.	<i>Staphylococcus aureus</i>	360,000
	COSMETICS	
	Creams, Ointments, Gels and Lotions	
389.	Physical examination	10,000
	Identification for banned ingredients	
390.	by TLC,	400,000
391.	by HPTLC	400,000
392.	by GC MS	390,000
393.	by HPLC	700,000
	Determination of heavy metal each	
394.	by AAS	360,000

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S/N	PARAMETERS	FEES in TZS
	Microbiological Tests	
395.	Total Aerial Microbial Count	390,000
396.	Yeast/ Mould Count	330,000
	MEDICAL DEVICES AND IN-VITRO DIAGNOSTIC TESTING	
	Condoms and Gloves	
397.	Package Integrity	130,000
398.	Determination of Length	130,000
399.	Determination of Width	130,000
400.	Determination of Thickness	130,000
401.	Determination of Bursting volume and Pressure	500,000
402.	Determination of Tensile properties	320,000
403.	Testing for holes – Water leakage test	500,000
404.	Testing for holes – Electronic testing	500,000
	Syringes	
405.	Determination of Heavy metal	500,000
406.	Determination of Alkalinity and acidity	130,000
407.	Determination of freedom from air	230,000
408.	Determination of freedom from Liquid	230,000
	Surgical blades	
409.	Determination of fitting dimension – 75 \$ USD	
410.	Analysis of Plaster of Paris (POP) and Bandages	
411.	Adhesiveness	230,000
412.	Cotton wool	
413.	Water holding capacity – 50 \$ USD - Sinking time – 50 \$ USD	
	Suture	

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GN. No.

S/N	PARAMETERS	FEES in TZS
414.	Determination of Tensile properties	130,000

Dodoma
February, 2019

UMMY A. MWALIMU
*Minister for Health, Community Development,
Gender, Elderly and Children*