

**DEPARTMENT OF HEALTH
FOOD & DRUG ADMINISTRATION**

Circular No. 1/97 b

Required quantities of sample drugs for Renewal

No	<u>Drug Category</u>	<u>Required Quantities</u>			
		Tablets/ Capsules/ Unit Dose	Syrup/Sus pension/Elixir (Up to 120ml)	Injection (Ampoules/ Vials)	Topical (Tubes/Bot.) (Bot.) (Tubes/Bot.)
1.	Anti-bacterial	500	20	50	20
2.	Anti-fungal	500	20	50	15
3.	Anti-viral	500	20	50	15
4.	Anti-malarial	500		50	
5.	Anti-tuberculous	500		50	
6.	Anti-amoebic	500	20	50	20
7.	Anthelmintic				
	(a) Single dose	50	20		
	(b) Multiple dose	50	20		
8.	Anti-inflammatory Drugs (Non-Steroidol)	500	20	50	15
9.	Anti-depressant	500	20	50	
10.	Anti-psychotic	500	20	50	
11.	Anti-convulsant	500	20	50	
12.	Anti-parkinsonism	500	20	50	
13.	Anxiolytic	500	20	50	
14.	Anti-diabetic	500		50	
15.	Anti-thyroid	500			
16.	Anti-emetic	500	20	50	
17.	Anti-diarrhoeal	500	20		
18.	Antispasmodic	500	20	50	
19.	Antacid	500	20		
20.	Anti-ulcer	500	20	50	
21.	Anti-asthmatic	500	20	50	
22.	Antitussive	500	20		
23.	Antihistamine	500	20	50	
24.	Mucolytic	500	20		
25.	Anti-anginal	500		50	
26.	Anti-hypertensive	500		50	
27.	Anti-arrhythmic	500		50	
28.	Beta adenergic blockers	500		50	
29.	Calcium Antagonnist	500		50	
30.	Diuretic	500		50	
31.	Anti-hyperlipidaemic	500			
32.	Anti-haemorrhoidal	500			
33.*	Anti-neoplastic				

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34.	Anti-migraine	500	20	50	
35.*	Anaesthetics				
36.	Amino Acids	500			10(LVP) 50(LVP) 15
37.	Antianaemic	500	20	50	
38.	Cold Remedy	500	20		
39.	Contraceptive	50 cycles			
40.	Corticosteroids	500		50	
41.	Intravenous Replacement Fluids				10(LVP) 50(SVP)
42.	Multivitamin	500	20	50	
43.	Notropics	500	20	50	
44.	(a) Oral Rehydration Salt tablets (b) Oral Rehydration Salt Power	100 30			
		Sachets (One litre Pack) 50 Sachets (less than one liter pack)			
45.	Uricosurics	500			
46.*	Vaccines				
47.	Dematologicals				15
48.	Eye/ Ear Drops				15

LVP= Large Volume Parenteral,
(500 ml & above)

SVP= Small Volume Parenteral,
(less than 500 ml)

- Note: (1) For those with (*)markings and for controlled medicine please check with FDA for exact number
- (2) All the submitted sample drugs must have a minimum of two years' shelf - life
- (3) In case of large sized packs (e.g. 500's, 1000's litre pack or jar) the required amounts are 3 bottles & 2 bottles or boxes for 1000 sized packs and packs which are more than 1 litre or 1 kg sizes.
- (4) If more than one type of packagings or pack sizeds are applied simultaneously for registration any one of small sized packs may conform to the prescribed amounts. The remainings have to be submitted in a minium of four unit-pack each if it is a small sized pack and two unit-pack each if it is a large sized pack.