

**DEPARTMENT OF HEALTH  
FOOD & DRUG ADMINISTRATION**

Circular No. 1/97 a

**Required quantities of sample drugs for initial registration**

<b>No</b>	<b><u>Drug Category</u></b>	<b><u>Required Quantities</u></b>			
		<b>Tablets/ Capsules/ Unit Dose</b>	<b>Syrup/Sus pension/Elixir (Up to 120ml)</b>	<b>Injection (Ampoules/ Vials)</b>	<b>Topical (Tubes/Bot.) (Bot.) (Tubes/Bot.)</b>
1.	Anti-bacterial	2500	100	350	350
2.	Anti-fungal	2000		350	100
3.	Anti-viral	2000			100
4.	Anti-malarial	2000		350	
5.	Anti-tuberculous	3000		350	
6.	Anti-amoebic	2000	100	300	350
7.	Anthelmintic				
	(a) Single dose	150 doses	100		
	(b) Multiple dose	500 doses	100		
8.	Anti-inflammatory Drugs (Non-Steroidol)	2000	100	300	100
9.	Anti-depressant	3000		300	
10.	Anti-psychotic	3000		300	
11.	Anti-convulsant	2000	100	350	
12.	Anti-parkinsonism	4000			
13.	Anxiolytic	2000		300	
14.	Anti-diabetic	2000		250	
15.	Anti-thyroid	5000			
16.	Anti-emetic	2000	100	350	
17.	Anti-diarrhoeal	2000			
18.	Antispasmodic	2000		150	
19.	Antacid	2000	100		
20.	Anti-ulcer	2000	100	300	
21.	Anti-asthmatic	2000	100	300	
22.	Antitussive	2000	100		
23.	Antihistamine	2000	100	350	100
24.	Mucolytic	2000	100		
25.	Anti-anginal	2000		350	
26.	Anti-hypertensive	2000		300	
27.	Anti-arrhythmic	2000		300	
28.	Beta adenergic blockers	2000		300	
29.	Calcium Antagonnist	2000		300	
30.	Diuretic	2000		200	
31.	Anti-hyperlipidaemic	4000			
32.	Anti-haemorrhoidal	2000			
33.*	Anti-neoplastic				

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34.	Anti-migraine	2000			
35.	Anaesthetics*				
36.	Amino Acids	2000			100(LVP) 350(SVP)
37.	Antianaemic	2000		350	
38.	Cold Remedy	2000	100		
39.	Contraceptive	200 cycles			
40.	Corticosteroids	3000		350	100
41.	Intravenous Replacement Fluids				100(LVP) 350(SVP)
42.	Plasma Expander				100
43.	I/V Glucose (10%, 25%, 50%)			350	
44.	Multivitamin	2000	100	350	
45.	Notropics	3000		450	
46.	(a) Oral Rehydration Salt tablets	700			
	(b) Oral Rehydration Salt Power	200			
		Sachets (One litre Pack)			
		400 Sachets (less than one liter pack)			
47.	Uricosurics	2000			
48.*	Vaccines				
49.	Dematologicals				100
50.	Eye/ Ear Drops				100

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 (or  $\frac{3}{4}$  of \* total shelf life)
- (3) In case of large sized packs (e.g. 500's, 1000's litre pack or jar) the required amounts are 7 bottles or boxes for 500 sized packs 1 litre packs or 1 kg jars & 5 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.