



National Drug Authority

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Revised April 25, 2007

SAMPLING PLAN FOR MEDICINES

S/No.	Dosage Form	Minimum Sample Size (per batch/lot)
1	Tablets	100 tablets
2	Capsules	100 capsules
3	Oral solution / suspension <i>(bottles of 100 ml and above)</i>	10 bottles
4	Oral solution / suspension <i>(bottles below 100 ml)</i>	20 bottles
5	Powder for oral suspension	20 bottles
6	Sterile solution injection / IV fluids / eye drops	60 ampoules / vials / bottles
7	Sterile suspension injection	20 ampoules / vials
8	Sterile powder for injection	25 vials <i>(see No. 9 for exception)</i>
9	Streptomycin sterile powder for injection	50 vials
10	Eye ointment	12 tubes
11	Creams / gels / ointments (for topical use)	5 tubes / containers
12	Powders packed in sachets	25 sachets

Notes:

1. All samples must be picked in their intact (un-opened, un-tampered) primary packaging materials (primary containers).
2. For tablets and capsules where the primary packaging ((primary container) contains more than 100 tablets or capsules, the entire container should be sampled.
3. The recommended storage conditions should be observed during sampling and delivery of the samples to the laboratory.
4. The minimum sample sizes shown above are derived with consideration for the requirements of the out-of-specifications (OOS) results investigation procedure and possible re-testing in case results are disputed by the client.