

V. Professional information—Continued

B. Manufacturing plant:

1. Equipment:

a. Type and make of equipment (Tablet machines, homogenizers, etc.)-----

	Yes	No
(1) Properly located?	-----	-----
(2) Adequate for required operations?	-----	-----
(3) Constructed to facilitate cleaning?	-----	-----
(4) Properly maintained?	-----	-----

2. Personnel:

a. List number of employees:-----

b. Percentage of Professional Employees:-----

c. List name, education and experience of the head of the manufacturing operation:-----

d. List qualifications of all other professional employees in the manufacturing operation: (i.e., B.Sc. Pharmacy, B.Sc. Chemistry, etc.) (Use back of page, if necessary):

3. Are manufacturing operations controlled by: (Determine by following a specific item during manufacturing)

	Yes	No
a. Use of suitable batch numbering system	-----	-----
b. Preparation of formula or batch records	-----	-----
c. Checking of ingredients (Identity, weight, measure)	-----	-----
d. Maintaining identity during processing	-----	-----
e. Checking yield against theory	-----	-----
f. Checking quality during processing	-----	-----
g. Adequate sampling and testing	-----	-----
h. Compliance with specifications	-----	-----
i. Maintaining of appropriate records and samples	-----	-----

C. Packaging operations:

(Determine by following a specific item during packaging)

1. Does company use only new containers?	-----	-----
2. Are packaging and finishing procedures controlled by establishment of specifications	-----	-----
3. A formal procedure providing for the inspection and issue of packaging materials including labels and labeling	-----	-----
4. Provisions for proper disposition of unused labels	-----	-----
5. Use of suitable batch, lot, or control numbers	-----	-----
6. Maintaining identity before and during packaging	-----	-----
7. Checking yield against theory	-----	-----
8. Sampling and checking	-----	-----
9. Provision for release by quality control	-----	-----
10. Maintaining of adequate records and samples	-----	-----
(a) List name and title of person interviewed	-----	-----