Appendix II Facilities and Equipment Standards

1. Medical institutions must provide adequate facilities to ensure the orderly handling of equipment, materials or product, and the prevention of contamination by substances, personnel, or environmental conditions that could be expected to have an adverse effect on product quality.
2. Medical institutions must establish written specifications for the cleanliness classifications of dispensing sites, and take the measures to maintain cleanliness.
3. Dispensing sites

3.1 The cleanliness classifications of the dispensing site:

Grade	Maximum permitted number of particles/m^3 equal to or greater than the tabulated size			
	At rest		In operation	
	0.5 μm	5.0 μm	0.5 μm	5.0 μm
A	3,520	20	3,520	20
B	3,520	29	352,000	2,900
C	352,000	2,900	3,520,000	29,000
D	3,520,000	29,000	-	-

3.2 Limits for microbial contamination of cleans areas in operation:

Grade	Limits for microbial contamination			
	Air sample cfu/m^3	Settle plates (diam. 90 mm), cfu/4hours	Contact plates (diam. 55 mm), cfu/plate	Glove print 5 fingers cfu/glove
A	<1	<1	<1	<1
B	10	5	5	5
C	100	50	25	-
D	200	100	50	-

4. The cleanliness of the dispensing site should be carried out in accordance with the following provisions:

4.1 The work area for product synthesis, purification, and final sterile filtration of the formula preparation should be at least grade C.

4.2 The aseptic laminar airflow workstation or isolator for sterile filtration and final dispensing operations is grade A

5. The area where the aseptic laminar airflow workstation is set up should be controlled by personnel.

6. The equipment and the internal surface of the aseptic laminar airflow workstation should be easy to clean and disinfect. Before daily use, the internal surface of the workstation should be in accordance with sterile specifications or cleaned with a disinfectant that has been properly sterile filtered; And the equipment inside the workstation is the same.

7. Areas with cleanliness classification requirements should be regularly monitored for microbes and airborne particles.

8. The monitoring of settle plates, particulate matters and airborne microbes should be complied with the following provisions:

8.1 The area for sterile filtration and final dispensing operations of PET drug products should be daily carried out the monitoring of settle plates before the start of the first batch of operations, including aseptic assembly and dynamic operations; And the monitoring implementation method for particulate matters and airborne microbes may be confirmed based on the results of the periodic risk assessment.

8.2 Medical institutions must have written procedures that monitoring the environmental operation in paragraph 8.1 of this appendix, and record the monitoring results and corrective and preventive actions for abnormal situations.

9. The surfaces of equipment that contact components, in-process materials, or PET drugs must not be reactive, additive, or

absorptive so as to alter the quality of PET drugs.