TABLE B: GMP STANDARDS FOR FPPS, EXCLUDING BIOLOGICALS, BLOOD PRODUCTS, AND RADIOPHARMACEUTICALS

	PIC/S	WHO	US FDA	CFDA	CDSCO	SID and GP
Personnel						
Qualifications	Similar					
Experience	Similar					
Training	Similar					
Premises						
Pest control	Similar					
Clean air/room classification*	Grades A–D	Grades A–D	Classes 100–100,000 and ISO Grades 5–8	Grades A–D	Grades A–D	Grades A–D
Microbial monitoring limits*	Grades A–D	Grades A–D	Classes 100–100 000 and ISO Grades 5–8	Grades A–D	Grades A–D	Grades A–D
Air pressure differential*	10–15 Pascal	10–15 Pascal	10–15 Pascal	Not specified	≥ 15 Pascal	10–15 Pascal
Monitoring frequency						
Particulate count*	Routinely	Routinely	Every production shift	Daily	Every 6 months	Routinely
Air change rate*	Not specified	Not specified	Every production shift	Not specified	Every 6 months	Not specified
Air pressure differential*	Not specified	Not specified	Every production shift	Not specified	Daily	Routinely
Temperature and humidity*	Based on product and nature of operations	Based on product and nature of operations	Every production shift	Based on product and nature of operations	Daily	Based on product and nature of operations
HEPA filter integrity testing*	Not specified	Every 6–12 months	Twice a year	Routinely; frequency not specified	Every year	Routinely; frequency not specified
Production						
Qualification and validation	Similar					
Quality control						
Reference/retention samples	Similar					
Stability testing	Similar					
Pharmacopeia standards	European or other pharmacopoeias	International Pharmacopoeia	United States Pharmacopeia	Chinese Pharmacopoeia	Indian Pharmaco-poeia	Russian Federation State Pharmacopoeia
Other						
Self-inspection	Similar					
Quality risk management	Similar				QRM con-cepts not mentioned	Similar
Documentation and data integrity	Similar					

**GMP components or subcomponents applicable only to sterile products manufacture.*