

## **ANNEX B**

### **RISK CATEGORIZATION**

Drug Manufacturer Risk Classification will be based on type of products manufactured:

#### **Low Risk:**

- Manufacturers and Packers:
  - Human – All External Preparations (Non-sterile and Household Remedy), Medicinal Gas
  - Veterinary – External Preparations
- Manufacturer and packers of drug substance/starting materials under this category
- Repackers of Pharmaceutical Products

#### **Medium Risk:**

- Manufacturers and Packers:
  - Human - Non-Sterile and Household Remedy Products (Except external preparations)
  - Veterinary – Non-sterile Products (Except external preparations)
- Manufacturer and packers of drug substance/starting materials under this category

#### **High Risk:**

- Manufacturers and Packers
  - Human - Sterile Products
  - Veterinary – Sterile Products
- Manufacturer and packers of drug substance/starting materials under this category

*Note: In the case of more than one product line in a manufacturer with a different identified risk category, the highest risk shall prevail.*