

Ref No	Rev No.	Issue Date

Packaging validation protocol

1. Scope of the Protocol

- Manufacturer Name
- Product Name & Description

2. International References

- Relevant Standards (ISO/ASTM)

3. Packaging System Description

- Packaging Specifications & Dimensions
- Sterile Barrier System Description
- Packaging Process Description
- Welding Parameters:
 - Machine Description
 - Welding Temperature & Time

4. Test Ambient Conditions

- Temperature & Relative Humidity

5. Packaging System Validation

- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ) – Test Methods:
 - Visual Inspection
 - Dye Migration Test
 - Seal Peel Test
 - Or equivalent tests based on product nature, referring to relevant standards

6. Enclosures

- Packaging Samples
- Test Equipment Printouts
- Accreditation Certificate (for External Lab)