

Ref No	Rev No.	Issue Date

Packaging Validation Report (with clear results)

1. Scope

- 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

- **Operational Qualification (OQ)**
- **Performance Qualification (PQ)** – Test Results:
 - 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)