

Integrity of seals The integrity of sealing of ampoules should be assessed on an individual basis. Two techniques are available that depend on dye ingress under vacuum or electronic means. With dye intrusion, the ampoules are submerged in a dye solution and under an applied vacuum. Any container that has cracks in its structure or is not sealed will admit the dye when the vacuum is reduced. On washing, badly sealed ampoules will be coloured. This technique underestimates the problem of bad sealing. In the alternative technique, high – frequency spark testing, the presence of a leak causes a change in a high – frequency electrical signal placed across the ampoule. The method is limited to aqueous products with a high conductivity. It is a very sensitive technique and detects weak seals not detected by the dye test. In reality, both tests should be used in parallel