Lead Site (where it exists), or by the manufacturing site (if there is no Lead Site);

- The stability profile of the product; and a comparison of the analytical results on return and on release;
- The Lead Site should confirm the result of the analysis.

5.1.10 Product should only be considered for redistribution, reworking or repackaging if the examination, testing or other investigations outlined above prove the drug meets appropriate standards of safety, strength and quality.

5.1.11 All actions, inspections and analysis shall be documented, and shall ensure traceability to the original batch.

5.1.12 If the assessment confirms the quality of the product, the product can be re-released for redistribution, reworking or repackaging using the defined QA and site procedures.

5.1.13 Reworking or repackaging operations shall be carried out in compliance with the regulatory application by the unit originally responsible for the operation.

5.1.14 If reworking or repackaging operations are not performed at the unit originally responsible for the operations, the operations should be performed in a facility approved by International Compliance Group, QA & Dossier Management, Manufacturing Strategy Group or the Lead Audit site.

5.2 Salvaged Goods

5.2.1 Returned goods that have been subjected to improper storage and/or transportation conditions, including extremes in temperature, humidity, smoke fumes, pressure, age, or radiation due to natural disasters, fires, accidents or equipment failures shall not be salvaged or returned to the market place.

