Topic – Test item characterization

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Test item characterization

- **Test item is identified as an article that is the subject of a study. This includes synthetic and naturally occurring chemicals, biologicals agents, live organism and medical devices.**
- **It should be noted that test item is also referred to as "test chemical" in some of the OECD Test guidelines.**

Characterization:-

- **Characterization is attributes of the test item which collectively provide evidence that is suitable to fulfil the objectives of a GLP study.**

Importance of this guideline

- **This guidance provides clarity for test facilities on the expectations of national good laboratory practice (GLP) compliance monitoring authorities and how test item are received, characterized, sampled, handled, stored, archived and destroyed.**
- **The document consolidates existing OECD guidance on test items that are used in studies conducted in accordance with the principles of GLP.**

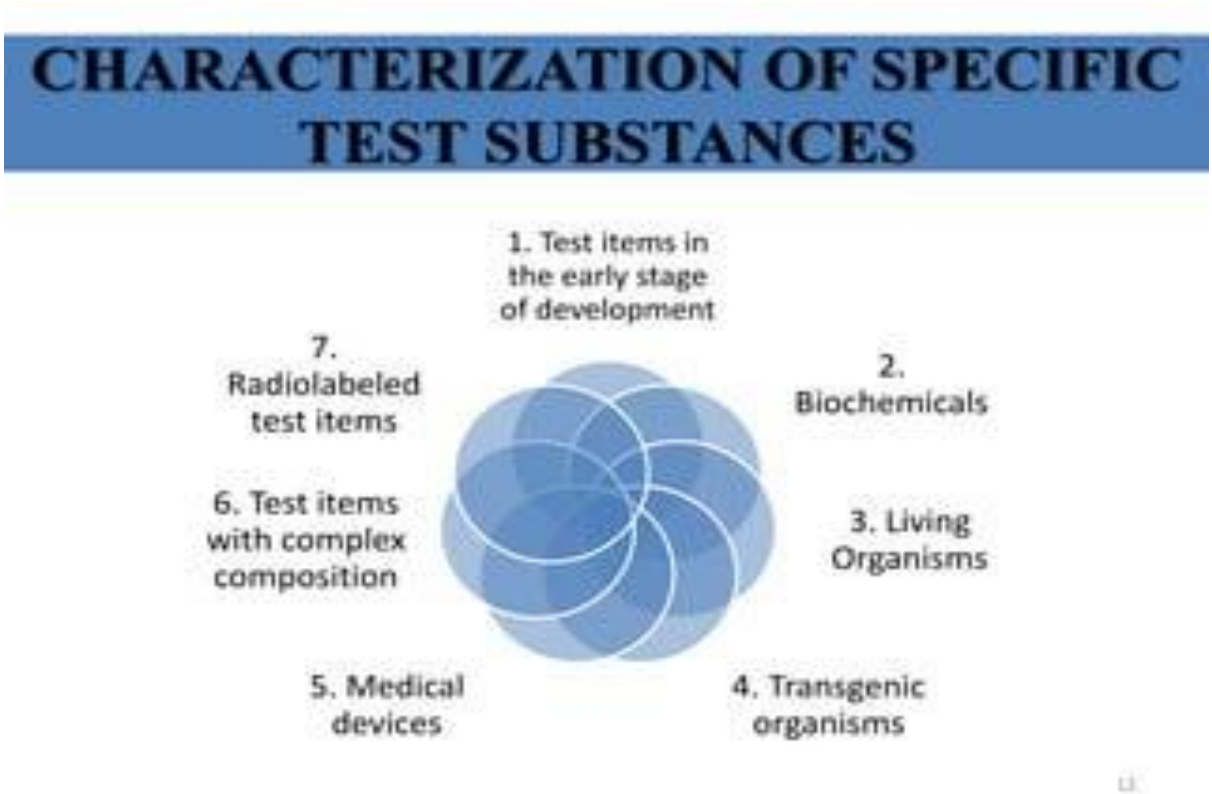
- **It also aims to promote a consistent approach that is appropriate to the objective of the study and the nature of the test item.**

Basic terminologies

- **Batch :- Batch is defined as a specific quantity or lot of a test item produced during a defined cycle of manufacture in such a way that it could be expected to be a uniform character and should be designated as such.**
- **Vehicle : - Vehicle is defined as any agent that serves as a carrier and is used to mix, disperse, or solubilize the test item to facilitate the administration /application to the test item.**
- **Identification : - Identification of the test item means the process of assessing and checking information including labelling, prior to undertaking a GLP study.**
- **Test system :- Test system means any biological, chemical or physical system or a combination thereof used in a study.**

Preparation of the test item

- Preparation of test item (or prepared test item) could be a formulation (or mixture) containing the test item or the test item in a vehicle, where the combination is obtained by dilution, mixing, dispersion, suspension, solubilization and another process with the intention to be administered to the test system.
- A test item which is encapsulated or packed in some other way, in the absence of excipients or a vehicle, for the purpose of delivery to the test system is not regarded as a prepared item as per these guidelines.



Test item in early stage

1. **The extent to which a test item will be characterized may be commensurate with the stage of product development.**

2. **In the earlier stage of test item development there may be less characterization information available.**

3. **However, the study director should always be able to demonstrate that the test item used in the study is what is required in the study plan.**

2. Biochemicals

➨ **If the test item is a biochemical, for example an antibody, a peptide, a protein, a viral vector or an enzyme, the need for information to verify biological activity should always be considered, including the determination method and its qualification as part of the characterization process.**

- **If no information is provided to demonstrate the biological activity of the test item ,the reasons why the test item is still considered suitable for use in the study should be clearly outlined in the study plan and in the final study report .**

Living organism

- **If the test item is a living organism , for example a cell line, a virus or a microorganism, the characterization may require specific information on properties which are unique to the test item.**
- **If a test item is a cell line, it may be appropriate to confirm passage number.**
- **If the organisms are derived from a culture collection, such collection typically maintain detailed records of suppliers of cultures showing the material sent (with strain and batch number where appropriate), method and date shipment, and name and address of the person who sent it.**

4. Medical device

For studies on medical devices, characterization data can include the description of

The device

The lot number

The type of materials the device is made of (and method of manufacture and name of the manufacturer of any polymers, colorants, metal)

The methods of manufacture and synthesis of the final device (inj. Modeling)

Location of manufacturing facilities