

<b>Title: Hose Management</b>					
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**Introduction**

What minimum standards should be considered by an API manufacturing site for the storage, handling and cleaning of hoses used during cleaning or production of Intermediates or final Active Pharmaceutical Ingredients (APIs)?

This guidance will only deal with hoses that can be moved and used for multiple purposes rather than flexible lines that are permanently fixed to the equipment (e.g. flanged). A flexible line that is permanently fixed to the equipment should be managed and maintained in accordance with the site maintenance practices.

This document is intended to provide general guidance on:

- Hose Use Procedure
- Considerations When Developing Site Hose Specifications
- Preventive Maintenance
- Visual Inspection (Verification) Prior to Use or Storage
- When and how often should hose inspection be done?
- Labeling and Traceability
- Cleaning of Hoses
- Storage and Handling
- Managing Hose Failure Incidents

This document will assist Site API manufacturing facilities in developing and implementing site-specific hose management practices, if not currently existing, or enhance prevailing hose practices that put emphasis on both Quality and Operational efficiency.

**Recommendations & Rationale for Recommendations**

***Hose Use Procedure:***

GMP sites should have procedures defining the use, specification, storage, handling, cleaning and maintenance of hoses used in cleaning and production of intermediates and APIs in accordance with cGMP guidelines. Flexible hoses should be adequately identified, maintained, and cleaned.

Section 5.2 - Q7A, emphasizes written procedures should be established for cleaning equipment and its subsequent release for use in manufacture of intermediates and APIs. In addition, sites should have standardized hose management practices, including management of change, with written procedures that identify factors to be considered and evaluated.

***Considerations When Developing Site Hose Specifications:***

Each hose assembly should meet or exceed the applicable requirements in functionality, dimension, characteristic or industry standards. A cross-functional evaluation and approval on hose specifications among site's responsible personnel (i.e., engineering, quality, production/operations, maintenance, and safety representatives) and collaboration with

major information areas ó Size, Temperature, Application, Material, Pressure, Ends, and Delivery ó required for specification of a suitable hose assembly.

***Preventive Maintenance:***

Detection of early warning signs of hose deterioration or loss of performance before conditions leading to malfunction or failure should be the primary goal of a hose preventive maintenance program. A good hose preventive maintenance program should include the following:

- An SOP that sets processing requirements to ensure hose integrity;
- A program that provides documented tracking of the age and conditions throughout the life cycle of the hose;
- A plan that defines maintenance requirements based on engineering and safety best practices;
- Standardization of hoses and end fitting types when at all possible Specifically, a hose preventive maintenance program is expected to set minimum requirements calling for tests including:
  - Visual inspection ó each hose assembly is inspected for damage to the cover or body of the hose. Kinks, cuts, abrasions, and crushed areas are reasons for failures. An internal visual inspection of the end fitting will reveal if tube failure has occurred. A damaged hose body makes the hose susceptible to leaks or ruptures.
  - Continuity test ó performing this test on each hose assembly will eliminate ungrounded hoses.
- Hydrostatic test ó performing this test will help remove leaking hose assemblies from service.

If failure in one or all of the above tests is experienced, prompt replacement or repair of hose is recommended. There should be a procedure that ensures consistent hose preventive maintenance, inspection and replacement practices. A reliable hose preventive maintenance program will promote a longer hose life cycle and establish hose replacement frequency in the most economical way.

***Visual Inspection (Verification) Prior to Use or Storage:***

Early detection of a flawed hose prior to use can ultimately avoid implicating lots of material in the event of a hose failure. Performing a verification of hose integrity and configuration of connections just prior to use and storage is certainly an added value, as it will prevent costly material spills, cleanup, downtime and potential injury.

Visually inspect all chemical hoses prior to use or storage by examining the interior of the hose ends, especially near the coupling for possible damage to the Teflon inner lining. Check the gasket area and the hose exterior for cracks, cuts, kinks, flattening, broken kamlock ears, etc. If any damage is detected, initiate the necessary repair or replacement.

***When and how often should hose inspection be done?***

Inspection requirements will vary with each application type. The following factors should be considered:

- Critical nature of application
- Operating temperatures