

Mechanical Demand Specification

(Reference SOP: _____)

All mechanical adjustments are to be designed with the ability to carry out fine adjustment without the need to strip down or remove other equipment to carry out the desired function.

Where intricate adjustment is required consideration shall be given to complete removal of an assembly so that adjustment can be carried out off line prior to assembly or inclusion in the machine.

1.4.1. Special tools

Special tools for maintenance shall be furnished with the equipment.

1.4.2. Clearances Under Equipment

Equipment shall be free standing above the floor with at least 150mm clear space beneath items for cleaning. Where equipment is lower than 150mm from the floor the space beneath this item shall be closed and sealed to the floor with a secure coving strip. Suitable coving shall be for permanent fixtures, an epoxy material or semipermanent items, a silicon coving strip or similar.

The operation side of equipment shall allow for operators to have clearance to clear away fallen items from the floor.

1.5. Component Materials Selection

Equipment will be used to manufacture pharmaceuticals. The cleanliness of the machine operating environment will be specified for specific applications. As a minimum the equipment shall not generate particles or breakdown surface finishes due to exposure to salt solutions or abrasion.

1.5.1. Product Components.

Where Product, solutions or powders without primary packaging are in contact with the equipment. The materials shall be selected with consideration of the intended use of equipment. There shall be no chance of cross contamination, possibility of residual product being retained or transfer of component materials into the product. Product seals and gaskets selected should be verified for use. The use of triclover style gaskets for connection of pipes is acceptable. For example, use the yellow & white dot Vitron material as a standard on all connections where steam will be present.

A list of the materials in contact with solutions or powders shall be prepared with the design for approval by the project co-ordinator before implementation.

1.5.2. Components not in direct product contact.