

<b>Company Name</b>	Procedure Number:	Page 9 of 19
Title: <b>Validation Master Plan Drug Product Manufacturing</b>	Implementation Date:	Version Number 1.0

- UV lamps

Installation Qualification (IQ) and Operational Qualification (OQ) will be performed on this system and concluded in an IQ an OQ summary report. The Performance Qualification (PQ) will be conducted in III Phases:

#### Performance Qualification

PQ Phase I: 2 weeks daily all monitoring points  
PQ Phase II: 2 weeks daily all monitoring points  
PQ Phase III: 11 month's daily, all monitoring points

Water specifications will be set according to USP and Ph. Eur.

### **3.2.2 WFI Water**

WFI water is feed from the Purified water loop. The pipe work forms a continuous 20mm 316 L stainless steel loop with no separate branches and no dead legs. The pipe work will be passivated on completion and routinely sanitized with clean steam (WFI water treatment and loop drawing Attachment 12).

IQ and OQ will be performed on this system and concluded in an IQ an OQ summary report. PQ will be conducted in III Phases:

#### Performance Qualification

PQ Phase I: 2 weeks daily all monitoring points  
PQ Phase II: 2 weeks daily all monitoring points  
PQ Phase III: 11 month's daily, all monitoring points

Water specifications will be set according to USP and Ph. Eur.

### **3.2.3 Heating, ventilation and air-conditioning (HVAC)**

There are [XY \(please enter the number\)](#) air conditioning (HVAC) units in the facility. The HVAC units supply air to the production workshops. The filtered air supply is temperature and humidity controlled.

The main purpose of the HVAC system is to:

- Prevent product contamination,
- Protect of the environment,
- Protect of manufacturing personnel,
- Prevent of the ingress of vermin, insects, birds etc.

There is no extract air from any room's feed back without filtration to the HVAC system as intake air.

Applicable Limits for the manufacturing areas ([examples](#)):

Air changes: [> 20 AC/h](#)

Temperature: [20 +/- 2°C](#)

Relative humidity: [30-60% RH](#)

Airflow rates, pressurization, and airflow directions will be defined and indicated.