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Title: Technical Quality Agreement for Contract Manufacturing	Implementation Date:	Version Number 1.0

may be based on the levels specified for the area in which the product is manufactured.

Any critical products running on the same equipment, as PRODCUT shall be pre approved by contract giver.

The hold time duration between the end-of-manufacturing and the beginning-of-cleaning should be discussed and evaluated during the development of the cleaning process. A maximum allowable hold time shall be established for routine production.

7.3 Facility and Utilities Qualification (DQ, IQ, OQ)

SUPPLIER shall be responsible for the qualification of all relevant utility, equipment, computer systems and facilities associated with the manufacture, storage or testing of PRODUCT. Qualification/ Validation is a prerequisite for any equipment or systems used to manufacture or package PRODUCT prior to the initiation of the Process Validation. The qualification shall include but is not limited to Design Qualification (DQ), Installation Qualification (IQ) and Operational Qualification (OQ).

7.4 Process Validation (PQ)

SUPPLIER shall be responsible for the process validation of PRODUCT. The number of batches included in the process validation should be three as a minimum and the measurements performed must be sufficient to allow the normal extent of variation and trends to be established and to provide sufficient data for evaluation. Validation batches should be consecutive. The process validation exercise should demonstrate the consistency and reproducibility of the defined process by using validated analytical methods.

[Optional: CONTRACT GIVER must approve all process validation protocols and reports.](#)

8 Laboratories

8.1 Compliance

SUPPLIER and its subcontractors shall be responsible for ensuring that all laboratories are compliant with relevant cGMP's, and are qualified in all of the methodology associated with PRODUCT.

8.2 Equipment

SUPPLIER and its subcontractors shall be responsible for ensuring that all equipment is properly maintained and calibrated and that appropriate qualification has been conducted.