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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

PROCESSING IN STEAM IN DISCONTINUOUS AGITATING RETORTS

(Retort Survey)

INSTRUCTIONS

Complete the question blocks below. Narrative responses to each item can be entered in the item's "comments" area or where otherwise prompted. Draw a diagram of the retort or obtain one from the firm. Attach the diagram as an exhibit to the EIR. Report all pipe sizes as inside diameter (ID). Refer to 21CFR Part 113.40(d) and p 31 of LACF Guide Part 2.

If problems are found with the firm's retort equipment or processing system, refer the reader to the narrative Turbo EIR under "Objectionable Conditions and Management's Response," and include a narrative explanation of specific problems and evidence under the subheading "Supporting Evidence and Relevance." Submit the completed form as an EIR attachment.

RETORT DESCRIPTION

RETORT NO.	*CAN SIZE	COOKER CAPACITY	STEPS/REEL
	PROCESSING MODE Axial ☐ End-over-End ☐ Rocking ☐		

*List the Can Size covered during the inspection.

COMPUTER CONTROLS

DOES A COMPUTER CONTROL ANY OF THE RETORT FUNCTIONS? ..... Yes ☐ No ☐

EXPLAIN:

DOES THE FIRM HAVE DOCUMENTATION ON HAND THAT INDICATES THAT THE COMPUTER SYSTEM HAS BEEN VALIDATED?

Yes ☐ No ☐

EXPLAIN:

IS RECORD KEEPING PART OF THE COMPUTER FUNCTION? ..... Yes ☐ No ☐

IF YES, DOES THE RECORD KEEPING COMPLY WITH 21 CFR PART 11? ..... Yes ☐ No ☐

COMMENTS:

INDICATING MERCURY IN-GLASS THERMOMETERS (113.40(d)(1))

IS EACH RETORT EQUIPPED WITH AT LEAST ONE MERCURY-IN-GLASS (MIG) THERMOMETER? ..... Yes ☐ No ☐

IS THE RETORT EQUIPPED WITH ANOTHER TYPE OF TEMPERATURE INDICATING DEVICE? ..... Yes ☐ No ☐

IF YES, DESCRIBE THE INDICATOR:

ARE SCALE DIVISIONS EASILY READABLE TO 1°F (.5°C)? ..... Yes ☐ No ☐

NO. OF DEGREES F OR C/IN. OF GRADUATED SCALE: _____. *(TEMP. RANGE MUST NOT EXCEED 17°F(8°C) PER INCH (4°/CM) OF GRADUATED SCALE. SEE LACF GUIDE, P. 14.)*

DATE LAST TESTED FOR ACCURACY:

COMMENTS:

STANDARD USED FOR THE TEST:

NAME AND TITLE OF PERSON WHO PERFORMED TEST:

IS THE LAST TEST DATE IDENTIFIED ON THE THERMOMETER ..... Yes ☐ No ☐

WERE CALIBRATING TEST RECORDS PREPARED/MAINTAINED ..... Yes ☐ No ☐

(SHOULD REQUIREMENT)

DESCRIBE THE FIRM'S ACTIONS REGARDING MIG THERMOMETERS THAT WERE OUT OF CALIBRATION:

IS THE MERCURY UNDIVIDED? ..... Yes ☐ No ☐

*(A THERMOMETER THAT HAS A DIVIDED MERCURY COLUMN OR THAT CANNOT BE ADJUSTED TO THE STANDARD **SHALL** BE REPAIRED OR REPLACED.)*

COMMENTS:

WHEN MIG THERMOMETERS ARE FOUND TO BE PROVIDING READINGS ABOVE THE ACTUAL TEMPERATURES, DOES THE FIRM EVALUATE PRODUCTS PRODUCED USING THOSE THERMOMETERS? ..... Yes ☐ No ☐

DESCRIBE THE FIRM'S PROCEDURES:

IS THE THERMOMETER LOCATED WHERE IT IS EASY TO READ ACCURATELY? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

COMMENTS:

THE SENSOR BULB IS LOCATED IN THE ..... Retort Shell ☐, or External Well ☐

*(**SHALL** REQUIREMENT)*

COMMENTS:

DIAMETER OF OPENING FROM RETORT TO EXTERNAL WELL: _____ BLEEDER SIZE: _____

*(OPENING **SHALL** BE AT LEAST 3/4-IN. DIA.)* *(BLEEDER **SHALL** BE AT LEAST 1/6-IN. DIA.)*

COMMENTS:

DOES THE BLEEDER EMIT STEAM CONTINUOUSLY DURING PROCESSING? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

IF NO, EXPLAIN:

IF A MUFFLER IS USED ON BLEEDER(S), WHAT EVIDENCE DOES THE FIRM HAVE THAT IT DOES NOT RESTRICT FREE FLOW OF STEAM?

*(**SHALL** REQUIREMENT – 113.87(G))*

COMMENTS:

IS THE MERCURY THERMOMETER USED AS THE REFERENCED INSTRUMENT DURING PROCESSING? ... Yes ☐ No ☐

(***SHALL*** *REQUIREMENT)*

COMMENTS:

TEMERATURE RECORDING DEVICE (113.40(d)(2))

IS EACH RETORT EQUIPPED WITH A TEMPERATURE RECORDING DEVICE? ..... Yes ☐ No ☐

TYPE OF TEMPERATURE RECORDER ..... Round Circular Chart ☐ Strip Chart ☐ Other ☐

IF OTHER, EXPLAIN:

DO THE CHART SPECIFICATIONS MEET THE REQUIREMENTS OF PART 113.40(D)(2)? ..... Yes ☐ No ☐

(GRADUATIONS ON THE TEMPERATURE-RECORDING DEVICE SHALL NOT EXCEED 2°F (1°C) WITHIN A RANGE OF 10°F (5.5°C) OF THE PROCESSING TEMPERATURE. EACH CHART SHALL HAVE A WORKING SCALE OF NOT MORE THAN 55°F/IN (12°C/CM) WITHIN A RANGE OF 20°F (10°C) OF THE PROCESSING TEMPERATURE – 113.40(B)(2). ALSO, SEE P. 14 OF LACF FIELD GUIDE-PART 2.)

COMMENTS:

IS THE TEMPERATURE CHART ADJUSTED TO AGREE AS NEARLY AS POSSIBLE WITH BUT NOT HIGHER THAN THE KNOWN ACCURATE MERCURY-IN-GLASS THERMOMETER DURING THE PROCESSING PERIOD? ..... Yes ☐ No ☐

(SHALL REQUIREMENT; NOTE ANY DIFFERENCE BETWEEN THE RECORDING THERMOMETER AND THE MERCURY-IN-GLASS THERMOMETER AND WHICH READING IS HIGHER.)

COMMENTS:

IS THERE A MEANS FOR PREVENTING UNAUTHORIZED ADJUSTMENTS? ..... Yes ☐ No ☐

*(A MEANS OF PREVENTING UNAUTHORIZED CHANGES IN ADJUSTMENTS **SHALL** BE PROVIDED; A LOCK OR NOTICE FROM MANAGEMENT STATING "ONLY AUTHORIZED PERSONS ARE PERMITTED TO MAKE ADJUSTMENTS" & POSTED AT OR NEAR THE RECORDING DEVICE IS A SATISFACTORY MEANS FOR PREVENTING UNAUTHORIZED CHANGES.)*

COMMENTS:

IS THE CHART DRIVE TIMING MECHANISM ACCURATE? ..... Yes ☐ No ☐

IF NO, EXPLAIN:

IS THE RECORDER COMBINED WITH A STEAM CONTROLLER TO FUNCTION AS A RECORDING/CONTROLLING INSTRUMENT? ..... Yes ☐ No ☐

COMMENTS:

THE TEMPERATURE SENSING BULB IS INSTALLED IN THE ..... Retort Shell ☐ , or External Well ☐

*(THE TEMPERATURE-RECORDER BULB **SHALL** BE INSTALLED EITHER WITHIN THE RETORT SHELL OR IN A WELL ATTACHED TO THE SHELL.)*

COMMENTS:

DOES THE TEMPERATURE RECORDER BULB WELL HAVE A 1/16-IN. DIA. OR LARGER BLEEDER THAT EMITS STEAM CONTINUOUSLY DURING THE PROCESSING PERIOD? ..... Yes ☐ No ☐ N/A ☐

*(**SHALL** REQUIREMENT)*

COMMENTS:

IF A MUFFLER IS USED ON THE BLEEDER, DOES THE FIRM HAVE DOCUMENTED EVIDENCE THAT IT DOES NOT BLOCK THE FLOW OF STEAM? ..... Yes ☐ No ☐ N/A ☐

(SHALL REQUIREMENT – 113.87(G))

COMMENTS:

PRESSURE GAGE (113.40(d)(3))

IF A PRESSURE GAGE IS PRESENT ON THE RETORT COOKER SHELL, IS IT GRADUATED IN DIVISIONS OF 2 LBS. OR LESS?

Yes ☐ No ☐

*(**SHOULD** REQUIREMENT)*

IS THE PRESSURE COOLING SHELL EQUIPPED WITH A PRESSURE GAGE? ..... Yes ☐ No ☐

COMMENTS:

STEAM CONTROLLER (113.40(d)(4))

IS THE STEAM CONTROLLER AUTOMATIC? ..... Yes ☐ No ☐

*(EACH RETORT **SHALL** BE EQUIPPED WITH AN AUTOMATIC STEAM CONTROLLER TO MAINTAIN THE RETORT TEMPERATURE)*

COMMENTS:

IS THE STEAM CONTROLLER TEMPERATURE OR PRESSURE ACTUATED? ..... Temp. ☐ Press. ☐

(THE STEAM CONTROLLER MAY BE ACTIVATED BY A TEMPERATURE SENSOR POSITIONED NEAR THE MERCURY-IN-GLASS THERMOMETER; A STEAM CONTROLLER ACTIVATED BY THE STEAM PRESSURE OF THE RETORT IS ACCEPTABLE IF IT IS CAREFULLY MAINTAINED SO IT OPERATES SATISFACTORILY.)

COMMENTS:

REPORT THE **MANUFACTURER**, **MODEL**, **TYPE** AND **SIZE** OF THE AUTOMATIC STEAM CONTROL VALVE:

IF THE TEMPERATURE (STEAM) CONTROLLER IS AIR OPERATED, DOES THE SYSTEM HAVE AN ADEQUATE FILTER TO ASSURE A SUPPLY OF CLEAN, DRY AIR? ..... Yes ☐ No ☐

*(AIR OPERATED TEMPERATURE CONTROLLERS **SHOULD** HAVE ADEQUATE FILTER SYSTEMS TO ASSURE A SUPPLY OF CLEAN, DRY AIR – 113.40(d)(2).)*

COMMENTS:

BLEEDERS (113.40(d)(5))

ARE BLEEDERS (EXCEPT THOSE FOR THERMOMETER WELLS) 1/8-INCH OR LARGER IN DIAMETER? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

COMMENTS:

ARE THESE BLEEDERS LOCATED ALONG THE TOP OF THE RETORT NO MORE THAN 8 FT. APART AND WITHIN APPROXIMATELY 1 FT. OF THE OUTERMOST LOCATION OF CONTAINERS AT EACH END? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

COMMENTS:

ARE THE BLEEDERS ARRANGED SO THE OPERATOR CAN OBSERVE THAT THEY ARE OPERATING PROPERLY?

Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

COMMENTS:

ARE THE BLEEDERS WIDE OPEN DURING THE ENTIRE PROCESS INCLUDING THE COME-UP TIME? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

COMMENTS:

IF A MUFFLER IS USED ON BLEEDERS, DOES THE FIRM HAVE DOCUMENTED EVIDENCE THAT IT DOES NOT RESTRICT FREE FLOW OF STEAM? ..... Yes ☐ No ☐ N/A ☐

(SHALL REQUIREMENT – 113.87(G))

COMMENTS:

VENTING & CONDENSATE REMOVAL (113.40(d)(5&6))

IS THE RETORT VENTED TO REMOVE AIR PRIOR TO PROCESSING? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

NUMBER OF VENTS: _____ DIAMETER: _____ LENGTH: _____

LOCATION:

WHAT IS THE TYPE OF VENT VALVE? ..... Gate ☐ Plug Cock ☐ Other ☐

IF OTHER, SPECIFY:

ARE VENTS FULLY OPEN DURING VENTING? ..... Yes ☐ No ☐

IF NO, EXPLAIN:

DOES THE FIRM HAVE ON FILE DOCUMENTARY PROOF DEMONSTRATING THAT ADEQUATE VENTING IS ACHIEVED?

Yes ☐ No ☐

*(**SHALL** REQUIREMENT (113.40(D)(6); HEAT DISTRIBUTION DATA AND/OR A LETTER FROM A COMPETENT PROCESS AUTHORITY DOCUMENTING THE LAST HEAT DISTRIBUTION TEST PERFORMED ON THE RETORT (DATE OF TEST, WHO PERFORMED THE TEST, THE RESULTING VENT SCHEDULE, ETC) WOULD BE ACCEPTABLE DOCUMENTATION.)*

COMMENTS:

IS A STEAM BY-PASS VALVE USED DURING VENTING? ..... Yes ☐ No ☐

IF YES, EXPLAIN:

(NOTE: VENTING PROCEDURES AND ARRANGEMENTS MUST BE THE SAME AS USED DURING THE TEMPERATURE DISTRIBUTION STUDY THAT WAS CONDUCTED ON THE RETORT TO ESTABLISH THE VENT SCHEDULE.)

IF VENTS ARE EQUIPPED WITH MUFFLERS, SPECIFY TYPE AND PERFORMANCE CHARACTERISTICS. DOES THE FIRM HAVE DOCUMENTED EVIDENCE THAT THE MUFFLER ALLOWS ADEQUATE VENTING? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT – 113.87(G))*

COMMENTS:

WHEN THE STEAM IS TURNED ON, IS THE DRAIN OPENED FOR A TIME SUFFICIENT TO REMOVE STEAM CONDENSATE FROM THE RETORT? ..... Yes ☐ No ☐

*(**SHOULD** REQUIREMENT)*

COMMENTS:

IS PROVISION MADE FOR CONTAINING DRAINAGE OF CONDENSATE DURING THE RETORT OPERATION?

Yes ☐ No ☐

*(**SHOULD** REQUIREMENT; IN RETORTS HAVING TOP STEAM INLET AND BOTTOM VENTING, A BLEEDER **SHALL** BE INSTALLED IN THE BOTTOM OF THE RETORT TO REMOVE CONDENSATE – 113.40(d)(5).)*

(NOTE: A CONDENSATE TRAP OR BLEEDER LOCATED AT THE BOTTOM OF THE RETORT WOULD BE SUFFICIENT TO ASSURE CONTINUAL CONDENSATE REMOVAL.)

COMMENTS:

DESCRIBE THE PROCEDURES USED FOR CONDENSATE REMOVAL:

IF A CONDENSATE BLEEDER IS PRESENT AT THE BOTTOM OF THE RETORT, IS IT VISIBLE TO THE RETORT OPERATOR?

Yes ☐ No ☐

DOES IT CONTINUOUSLY EMIT STEAM DURING THE COME-UP AND THERMAL PROCESS? ..... Yes ☐ No ☐

COMMENTS:

IS THE CONDENSATE BLEEDER CHECKED WITH SUFFICIENT FREQUENCY DURING THE PROCESSING OF EACH RETORT LOAD TO ASSURE ADEQUATE REMOVAL OF CONDENSATE? ..... Yes ☐ No ☐

ARE THESE OBSERVATIONS RECORDED AT THE TIME THEY ARE MADE? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT – 113.100(a))*

COMMENTS:

RETORT SPEED TIMING (113.40(d)(7)

*IS THE ROTATIONAL SPEED OF THE RETORT ADJUSTED AS NECESSARY, TO ENSURE THAT THE SPEED IS AS SPECIFIED IN THE SCHEDULED PROCESS? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

COMMENTS:

IS THE ROTATIONAL SPEED OF THE RETORT AND THE PROCESS TIME RECORDED FOR EACH RETORT LOAD PROCESSED?

Yes ☐ No ☐

*(**SHALL** REQUIREMENT)*

IF NO, IS A RECORDING TACHOMETER USED TO PROVIDE A CONTINUOUS RECORD OF THE SPEED? ... Yes ☐ No ☐

IF NO, HOW DOES THE FIRM MONITOR AND RECORD THE RETORT SPEED AND PROCESS TIME OF EACH RETORT LOAD PROCESSED?

DOES THE FIRM HAVE A MEANS OF PREVENTING UNAUTHORIZED SPEED CHANGES ON THE RETORT? ..... Yes ☐ No ☐

*(**SHALL** REQUIREMENT; A LOCK OR NOTICE FROM MANAGEMENT POSTED AT OR NEAR THE SPEED ADJUSTMENT DEVICE THAT PROVIDES A WARNING THAT ONLY AUTHORIZED PERSONS ARE PERMITTED TO MAKE ADJUSTMENTS, IS A SATISFACTORY MEANS OF PREVENTING UNAUTHORIZED CHANGES.)*

*THE REEL SPEED IS ADJUSTED TO PROVIDE FOR A SPECIFIC PROCESS TIME. MINIMUM REEL SPEEDS ARE NORMALLY DETERMINED DURING PROCESS ESTABLISHMENT TO PROVIDE FOR ADEQUATE PRODUCT AGITATION. REEL SPEEDS WHICH ARE GREATER THAN THE MINIMUM ESTABLISHED PROCESS MAY SHORTEN THE PROCESS TIME. REEL SPEEDS WHICH ARE SLOWER THAN THE MINIMUM REEL SPEED MAY NOT PROVIDE FOR ADEQUATE AGITATION OF THE PRODUCT. REEL SPEED AND PROCESS TIME CAN BE DETERMINED USING THE FOLLOWING FORMULAS. TO USE THESE FORMULAS, KNOWN VALUES CAN BE ENTERED INTO THE FORMULA TO DETERMINE UNKNOWN VALUES OR TO CHECK THE VALUES SUPPLIED BY THE FIRM ON THE PROCESS FILING FORM. THE CAPACITY OF THE RETORT IS NORMALLY STAMPED ON THE END OF THE COOKER REEL SHAFT. THE APPROXIMATE NUMBER OF REEL STEPS FOR THE FMC SYSTEM FOR EACH CONTAINER SIZE IS PROVIDED IN THE TABLE BELOW. PLEASE BE AWARE THAT SOME REELS MAY BE ALTERED. IN SOME CASES, THE FIRM MAY PROCESS A SMALLER CAN SIZE (E.G. 300 IN A 303 X 307 REEL).

CONTAINER SIZE	*NUMBER OF STEPS PER TURN OF REEL*
211	56
300-303	47
303-307	42
401-404	35
603	24

DETERMINE THE REEL SPEED BY TIMING 10 REVOLUTIONS OF
THE RETORT REEL AND REPORT RESULTS (IN SECONDS): _____

CALCULATE THE ACTUAL PROCESS TIME USING THE FORMULA:

SECONDS FOR 10 REVS = (10 RVS)X(60 SECS) X (REEL STEPS) X (PROCESS TIME)/CAPACITY

ACTUAL PROCESS TIME = _____ **MIN**.

IS THE ACTUAL PROCESS TIME AT LEAST EQUAL TO THE MINIMUM PROCESS TIME FILED WITH FDA ..... Yes ☐ No ☐

CALCULATE THE PROCESS SPEED IN CONTAINERS/MIN USING THE FORMULA:

CONTAINERS PER MINUTE = CAPACITY/PROCESS TIME (MIN)

CONTAINERS PER MINUTE = _____

CALCULATE THE REEL SPEED AS REVOLUTIONS PER MINUTE (RPM) USING THE FORUMLA:

RPM = CAPACITY/(REEL STEPS) X (PROCESS TIME)

REEL SPEED (RPM) = _____

IS THE REEL SPEED CALCULATED ABOVE AS CONTAINERS PER MINUTE AND/OR REVOLUTIONS PER MINUTE AT LEAST EQUAL TO THE MINIMUM REEL SPEED FILED WITH FDA? ..... Yes ☐ No ☐

(IF NO, THE LOT COULD BE UNDER PROCESSED AND SHOULD BE HANDLED AS A PROCESS DEVIATION.

ALTERNATE FORMULAS WHICH CAN BE USED TO DETERMINE SECONDS FOR 10 REVOLUTIONS OF THE REEL:

(10 REV) X (60 SECS) X (#REEL STEPS)/(CPM)

(10 RVS) X (60 SEC)/RPM

OTHER CONCERNS AND OBSERVATIONS

EXPLAIN ANY OTHER CONCERNS WITH THE OPERATION OF THIS RETORT SYSTEM: