DDP
Dynamic Design Pharma

DYNAMIC DESIGN PHARMA, Inc.
23332 Madero Road, Suite J
Mission Viejo, California 92691
Phone (949) 643-1120
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Leak Test Certification – 190 XT Transfer System
190 Alpha XT Flange (Only)

System Description: 190 ALPHA XT ASSY - LH VERSION

System date of manufacture 10/13/2011 Alpha Serial Number: 20682/11

Test set up and Procedure

Materials

1. Ammonia 30% concentration: JT Baker Part Number JT9733
2. Ammonia sensitive cloth: La Calhene, P/N LAC-12502
3. Pressure gage: Dwyer #2010C, 0-10 in-H2O – Calibrated by ICC on 12/14/2010

Test Fixture Description

The test fixture consists of a Stainless Steel base (Isolator) plate onto which the Alpha XT Flange is installed. Attached to the base plate is a stainless steel enclosure that permits creating a sealed environment around the sterile side of the assembly.
Connected to the enclosure is a pressure gage capable of measuring up to 10 inches of H2O (2500 Pa). Also connected to the enclosure is a needle valve that is manually adjusted during the test to obtain the desired pressure level inside the chamber.

System Preparation

1. The Alpha XT assembly is installed onto the appropriate test fixture.
2. The Alpha XT flange is locked
3. The funnel is detached to provide clearance for the leak test enclosure
4. See the enclosed figures.

System Certification
190 Alpha XT Flange Only

Date: 10-14-2011 Location: MISSION VIEJO

Print: JOE SACCA Signature: Joe Sacca

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Test procedure

1. Keep the alpha flange door closed
2. Remove the test box from the fixture to gain access to the inside.
3. Place a cup filled with approximately 20ml of ammonia inside the fixture, install the rear wall and tighten in place to create a seal.
4. Using the flow metering valve, allow enough ammonia vapor to escape from the chamber until an internal pressure of 1 In-H2O (250 pa) is achieved. External pressurization may be required.
5. Place the ammonia sensitive cloth over the areas listed in the table below.
6. Allow a minimum of 5 seconds per location. Watch for blue/green discoloration of the cloth at each location.
7. Record findings for each general location of the joints in the table below

Test results summary table – Configuration #2			
Location description	**Pass/Fail**	**Tested by**	**Date tested**
Alpha door seal	PASS	J.S/GM	10-14-11
Alpha flange seal to the isolator wall	PASS	J.S/GM	10-14-11
Mounting frame, XT frame to isolator wall	PASS	J.S/GM	10-14-11
Door lock actuator assembly	PASS	J.S/GM	10-14-11
Door open/close actuator assembly	PASS	J.S/GM	10-14-11
Funnel in/out actuator assembly	PASS	J.S/GM	10-14-11

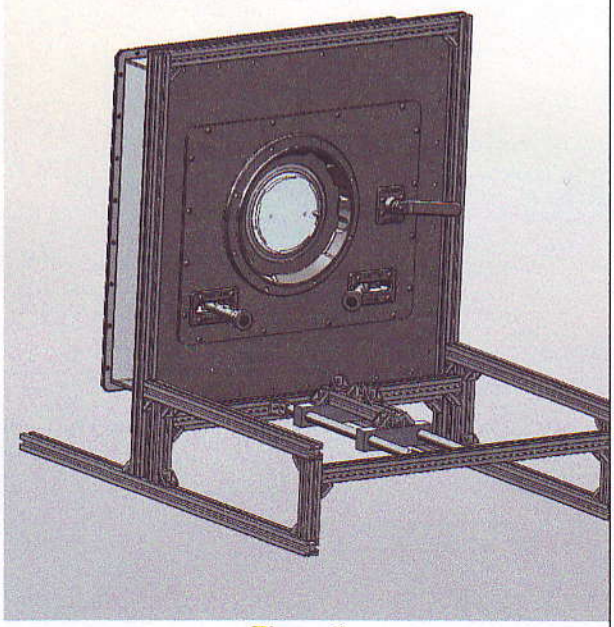

Figure 1
Operator side access
Alpha door closed

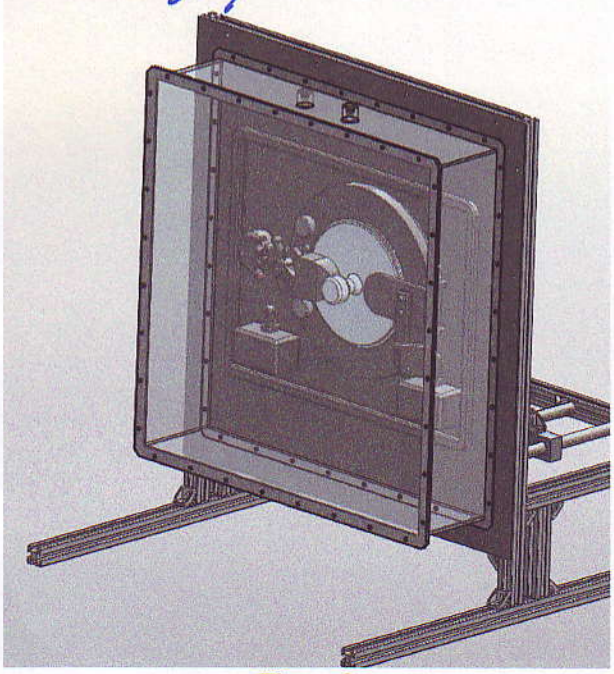

Figure 2
Enclosure installed, funnel removed for clearance

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Leak Test Certification – 190 XT Transfer System
190 Alpha XT Flange docked with
190 Beta NR-HP Flange

System Description: 190 ALPHA XT ASSY - LH VERSION WITH DOCKED 190BETA NR-HP FLANGE

System date of manufacture 10/13/2011

Alpha Serial Number: 20682/11 Beta Serial Number: 10242/11

Test set up and Procedure

Materials

1. Ammonia 30% concentration: JT Baker Part Number JT9733
2. Ammonia sensitive cloth: La Calhene, P/N LAC-12502
3. Pressure gage: Dwyer #2010C, 0-10 in-H2O – Calibrated by ICC on 12/14/2010

Test Fixture Description

The test fixture consists of a Stainless Steel base (Isolator) plate onto which the Alpha XT Flange is installed. Attached to the base plate is a stainless steel enclosure that permits creating a sealed environment around the sterile side of the assembly.
Connected to the enclosure is a pressure gage capable of measuring up to 10 inches of H2O (2500 Pa). Also connected to the enclosure is a needle valve that is manually adjusted during the test to obtain the desired pressure level inside the chamber.

System Preparation

1. The Alpha XT assembly must be installed onto the appropriate test fixture.
2. The beta NR-HP must be docked and the alpha/beta door slightly opened
3. The funnel is detached to provide clearance for the leak test enclosure
4. See the enclosed figures.

System Certification
Alpha X Flange and Beta NR-HP flange connected

Date: 10-14-2011 Location: MISSION VIEJO

Print: JOE SACCA Signature: Joe Sacca

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Test procedure

1. Dock the beta flange with sealed canister adapter attached
2. Remove the test box from the fixture to gain access to the inside.
3. Open the alpha/beta door slightly
4. Place a cup filled with approximately 20ml of ammonia inside the fixture, install the rear wall and tighten in place to create a seal.
5. Using the flow metering valve, allow enough ammonia vapor to escape from the chamber until an internal pressure of 1 In-H2O (250 pa) is achieved. External pressurization may be required.
6. Place the ammonia sensitive cloth over the areas of the assembly listed in the table below
7. Allow a minimum of 5 seconds per location. Watch for blue/green discoloration of the cloth at each location.
8. Record findings for each general location of the joints in the table below

Test results summary table – Configuration #2			
Location description	**Pass/Fail**	**Tested by**	**Date tested**
Alpha/Beta joint	PASS	J-S/GM	10-14-11
IDF Clamp connection	PASS	J-S/GM	10-14-11
Beta NR Flange	PASS	J-S/GM	10-14-11

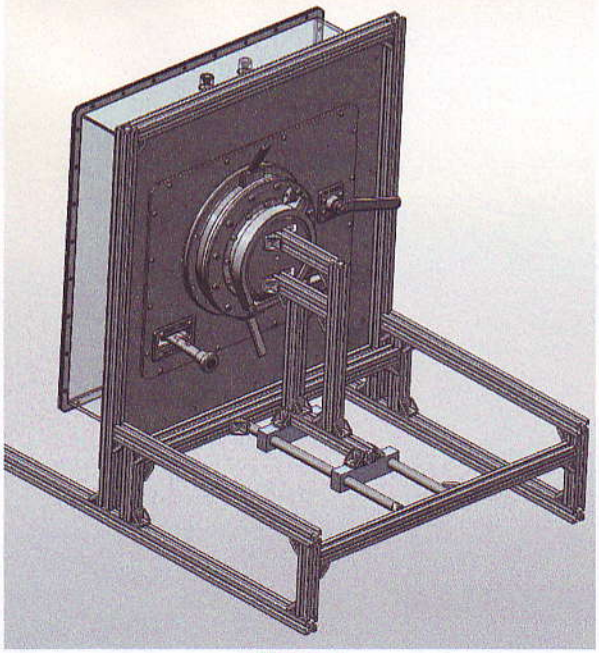

Figure 1
Leak test set up for testing alpha/beta seal connection – beta flange docked

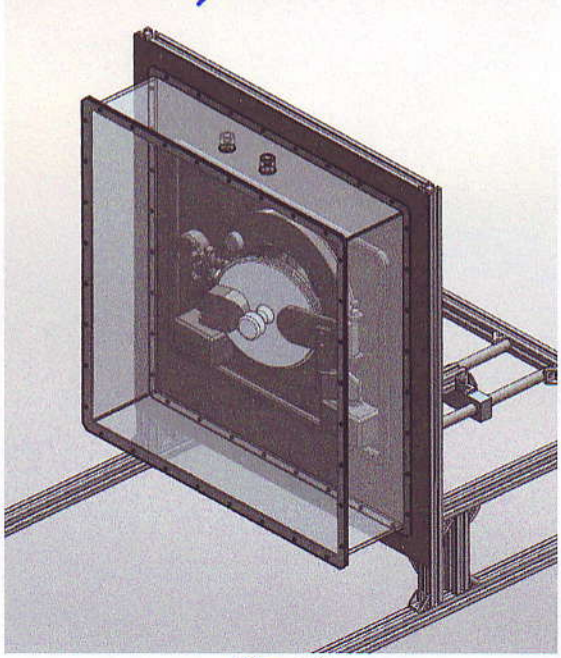

Figure 2
Leak test set up for testing alpha/beta seal – Alpha/Beta door slightly opened

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Leak Test Certification – 190 XT Transfer System
190 Beta NR-HP Flange (High Pressure)

System Description: 190 BETA NR-HP ASSEMBLY

System date of manufacture 10/13/2011 Beta Serial Number: 10-242/11

Test set up and Procedure

Materials

1. Water supply
2. Water basin, large enough to hold the beta NR-HP fully submerged
3. Compressed air supply up to 2 bar (30psi)
4. Pressure gage: generic

Test Fixture Description

A sealing fixture must be installed on the beta door and clamped to the lugs of the beta flange to create a seal simulating the presence of the LAC pressure cap (not available to conduct this test).
The assembly is connected to the air supply via a port located in the 6" IDF closure cap.

System Preparation

1. Install the High Pressure clamp onto the beta NR-HP flange.
2. Install the pressure cap simulator over the beta door and seal.
3. Fill the basic as required.
4. Make the pneumatic connection.
5. See the enclosed figures.

System Certification
190 Beta NR-HP Flange (High pressure)

Date: 10/13/11 Location: MISSION VIEJO

Print: JOE SALCA Signature: Joe Salca

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Test procedure

1. Place the assembly in the water basin with the beta flange down. Make sure that it is fully submerged.
2. Pressurize the assembly slowly and watch for bubbles rising from any of the joints.
3. Once 30 PSI (2 bar) is reached, hold at this pressure and carefully inspect for bubbles for a duration of 5 minutes.
4. Release the internal pressure back down to atmosphere.
5. Flip the assembly over in the basin, beta flange oriented upward.
6. Pressurize the assembly slowly and watch for bubbles rising from any of the joints.
7. Once 30 PSI (2 bar) is reached, hold at this pressure and carefully inspect for bubbles for a duration of 5 minutes.
8. Record findings for each general location of the joints in the table below

Test results summary table – Configuration #2			
Location description	**Pass/Fail**	**Tested by**	**Date tested**
Beta flange down	PASS	J.S/GM	10/13/11
Beta flange up	PASS	J.S/GM	10/13/11
ASSEMBLY SIDEWAYS	PASS	J.S/GM	10/13/11

Comments:
THE ASSEMBLY WAS OBSERVED FOR A MINIMUM OF 5 MINUTES @ EACH ORIENTATION

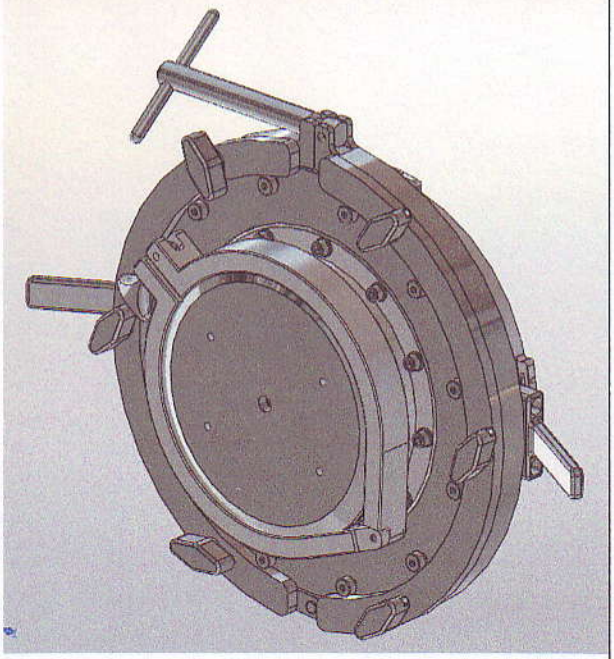

Figure 1
IDF Flange side of the beta NR-HP assembly

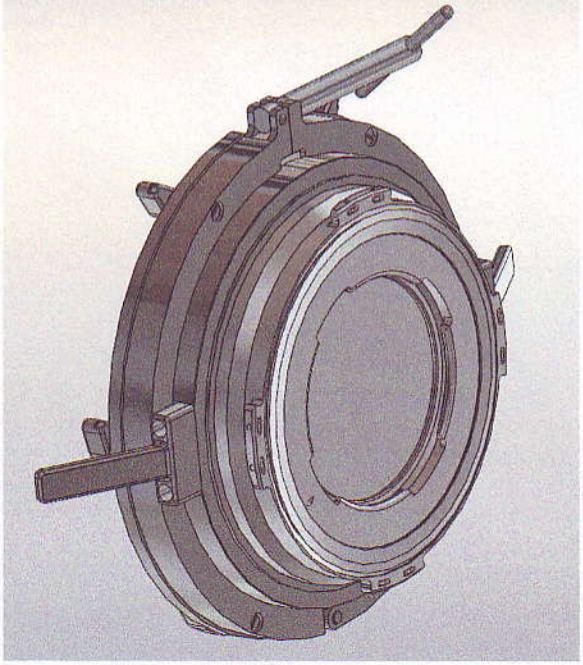

Figure 2
Beta flange side of the beta NR-HP assembly