AB FIA Odarslövs mölla
Vinkelhaken 1D
S- 247 32 Södra Sandby
Sweden

Instrument Qualification

Dissolution Testers for Chewing Gums DRT1, DRT2 and DRT3

Addendum: Pressure control and torque mesurements, pH and temperature logging

version 1.1
Valid from 080630

AB FIA Odarslövs mölla
Vinkelhaken 1D
S- 247 32 Södra Sandby
Sweden

Instrument Type		Serial Number	
DRT1-3			
	Name	**Name Ref.**	**Signature**
Tested by			
Checked by :			
Authorised by :			

Installation Qualification is in this case simplified. A control is made that the instrument is of the correct type with pressure and torque load cells mounted on all cells of the DRT. The loggers are there and electrical connections complete and undamaged. A computer with the relevant programs installed.

Operation Qualification follows SOP 010 and SOP 011 with their test protocols.

AB FIA Odarslövs mölla
Vinkelhaken 1D
S- 247 32 Södra Sandby
Sweden

Standard Operation Procedure:

SOP-No: F010

Check of Pressure control and torque monitoring

1. Aim

The purpose of this SOP is to ensure that the pressure and torque values represent the actual values that are exposed by the DRT on any formulation like for example a chewing gum.

2. Scope

The performance of this check should be performed at least every six months.

3. Responsibility

The system user or an authorised FIA engineer has the responsibility for this check.

4. Description and Performance

Use a weight, weighed on a certified balance and a calibrated dynamometric wrench to perform this test.

- Follow instructions in the manual for pressure and torque measurements.
- Register the values that are monitored for pressure while the weight of known value is put on the base chamber surface for the lower jaws.
- Mount adapters for torque measurements on the base chambers.
- Register the values at a setting on the dynamometric wrench for about 100 Ncm.
- Check that when the preset pressure limit is exceeded, a "**!**" mark is displayed in the logg-data.

The monitored values should not deviate more than 20% from the applied pressure (weights) or torque. To increase accuracy in the measurements it is possible to set up calibration curves. That is beyond the scope of the OQ.

5. Reference Documents

Please study the appropriate instruction manuals carefully. The test protocol should be filled in completely before proceeding further.

AB FIA Odarslövs mölla
Vinkelhaken 1D
S- 247 32 Södra Sandby
Sweden

Test Protocol:

PP-No.: F010

Check of Pressure control and torque monitoring

Pressure

Applied weight (N)			Monitored pressure (N)		
Cell 1	**Cell 2**	**Cell 3**	**Cell 1**	**Cell 2**	**Cell 3**

When the preset pressure limit is exceeded, a "**!**" mark is displayed in the logg-data.

Monitored **!** OK		
Cell 1	**Cell 2**	**Cell 3**

Torque

Applied torque (Ncm)			Monitored torque (Ncm)		
Cell 1	**Cell 2**	**Cell 3**	**Cell 1**	**Cell 2**	**Cell 3**

	Tested by:	Approved by:
Date:		

AB FIA Odarslövs mölla
Vinkelhaken 1D
S- 247 32 Södra Sandby
Sweden

Standard Operation Procedure:

SOP-No: F011

Check of pH and temperature logging

1. Aim

The purpose of this SOP is to ensure that the pH and temperature values that are logged represent the actual values in the dissolution medium in cells of the DRT.

2. Scope

The performance of this check should be performed at least every six months.

3. Responsibility

The system user or an authorised FIA engineer has the responsibility for this check.

4. Description and Performance

Use a certified thermometer and controlled pH buffers to perform this test.

- Check that the Water bath temperature is stable.
- Mount the test cells.
- Fill the Test Cell with 50 ml of pH-buffer.
- Introduce the thermometer into the Test Cells.
- Let the temperature stabilize for about 15 minutes.
- Note the value from the thermometer in the test protocol.
- Start the logger wait a few seconds and stop the logger.
- Empty test cells and repeat the procedure for the next pH-buffers and temperatures.

For OQ it is only necessary that the temperature does not deviate more than 1 degrees and that the pH does not deviate more than 1 unit.

To increase accuracy in the measurements it is necessary to set up calibration curves. That is beyond the scope of the OQ.

5. Reference Documents

Please study the appropriate instruction manuals carefully. The test protocol should be filled in completely before proceeding further.

AB FIA Odarslövs mölla
Vinkelhaken 1D
S- 247 32 Södra Sandby
Sweden

Test Protocol:

PP-No.: F011

Check of pH and temperature logging

Please ensure that any validation tools deployed in these checks are noted in the test protocol.

Temperature

Temperature read in cell			Monitored temperature		
Cell 1	**Cell 2**	**Cell 3**	**Cell 1**	**Cell 2**	**Cell 3**

pH

pH in buffer/temp			Monitored pH/temp		
Cell 1	**Cell 2**	**Cell 3**	**Cell 1**	**Cell 2**	**Cell3**

	Tested by:	Approved by:
Date:		

AB FIA Odarslövs mölla
Vinkelhaken 1D
S- 247 32 Södra Sandby
Sweden

Standard Operation Procedure:

SOP-No: F012

Check of emergency stop, front door and rear door of safety cupboard

- At the Electronic Control Device: ensure switches on top are set in down positions (lift and lower surface. Switch on "Main" (a green lamp indicates power on).
- A Safety cupboard is mounted to cover the Chewing module and to eliminate the clamping risk between the jaws. There is always a door on the front. Special versions may have a rear door.
  The doors of the cupboard must be closed before the instrument can operate. While either or both of the doors are opened, the power is shut down and at the same time the supply of compressed air to all pneumatic cylinders is shut. The lamp on the control box is put out and a puffing sound is heard. The pneumatic cylinders are kept in their positions.
- An Emergency Stop is placed by the Control Device. While the emergency stop is pressed down, the power is shut down and at the same time the supply of compressed air to all pneumatic cylinders is shut. The lamp is put out and a puffing sound is heard. The pneumatic cylinders are kept in their positions.
- The Emergency Stop is reset by turning it Counter Clock Wise.

1. Reference Documents

Please study the appropriate instruction manuals carefully. The test protocol should be filled in completely before proceeding further.

AB FIA Odarslövs mölla
Vinkelhaken 1D
S- 247 32 Södra Sandby
Sweden

Test Protocol:

PP-No.: F012

Control of safety

	Power cut to control box	Compressed air cut out
Open front door		
Open rear door		
Press the Emergrency Stop		

	Tested by:	Approved by:
Date:		