PSS™ engineering

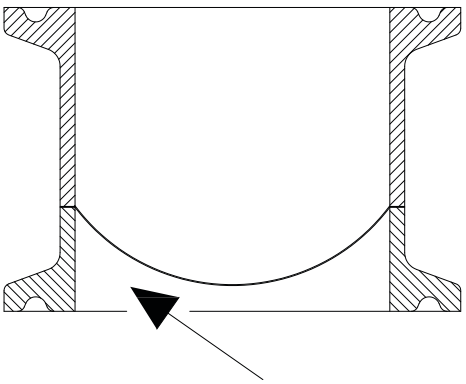
RIBOFLAVIN TEST VALIDATION; A NOVEL RUPTURE DISC ASSEMBLY FOR THE SANITARY PROCESS INDUSTRY

Introduction

Rupture discs are an integral part of any process system delivering immediate overpressure protection of equipment and most commonly used on pressure vessels as the primary safety device. Within the hygienic process industries (Pharma, Biopharma, Food & Beverage, etc.) rupture discs must operate both as safety devices and as part of a hygienic or aseptic envelope.

Part of what constitutes an aseptic envelope is the equipment's ability to be cleaned by dismantling in-situ or by a clean-in-place (CIP) protocol when the equipment is too complex, or it is too costly or time-consuming to be disassembled. The validation of cleanability is confirmed via a spray device coverage test (more commonly known as "Riboflavin test") using a system's current or proposed CIP parameters (cleaning media, flow rates, cleaning device/sprayball, etc.).

Elfab has designed and constructed a novel device incorporating a rupture disc foil within 2 connection flanges. The unit is externally electron beam welded, fusing the foil to the inlet and outlet, creating a robust cartridge-type assembly.



PROCESS SIDE

Figure 1 – Rupture disc with Tri-Clover carriage/stem assembly (scale 1:1)

This novel rupture disc assembly has been designed for the hygienic process industry, however due to the nature of rupture disc design, the disc or "foil" has a convex geometry which could potentially create a crevice at the intersection of the carriage (See Fig. 2). The electron beam welding process developed at Elfab's manufacturing facility has created a penetrative smooth weld bead on the external surface of the assembly but eliminating potential crevices on the process side of the disc (see Fig. 2). The cleanability of the device will be presented later in this paper.

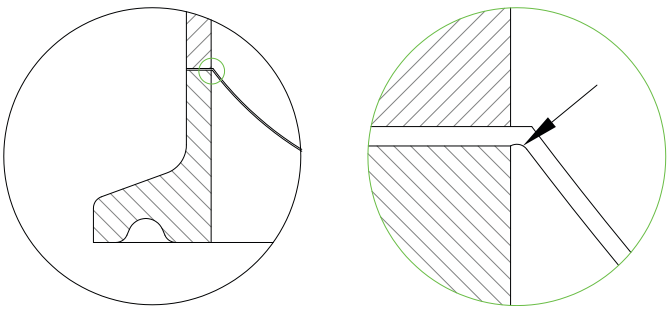


Figure 2 – Rupture Disc foil-Carriage Intersection

Spray device coverage test setup (Riboflavin test)

To qualify the rupture disc to fulfil the requirements of a general Riboflavin test, the process parameters must be based on a system where the general operating conditions are selected to match a variety of best practice and realistic in-service equipment.

Riboflavin tests are primarily designed to test an equipment's cleanability in an existing or new system as part of a factory/ site acceptance test (FAT/SAT). The Riboflavin test for this report is focused on the rupture device (as an attachment) solely, therefore the system it's tested in must be of a form which covers a multitude of realistic processing equipment features.

PSS Engineering Ltd. is a manufacturer of processing vessels, process pipework and process equipment for the pharmaceutical industry. Their work catalogue of process vessels allowed the testing of Elfab's device in a real-life system on a purified water storage vessel currently in production at their manufacturing facility. PSS's experience both in manufacture and commissioning of stainless-steel processing equipment makes them an ideal facilitator for this technical review of Elfab's rupture disc.

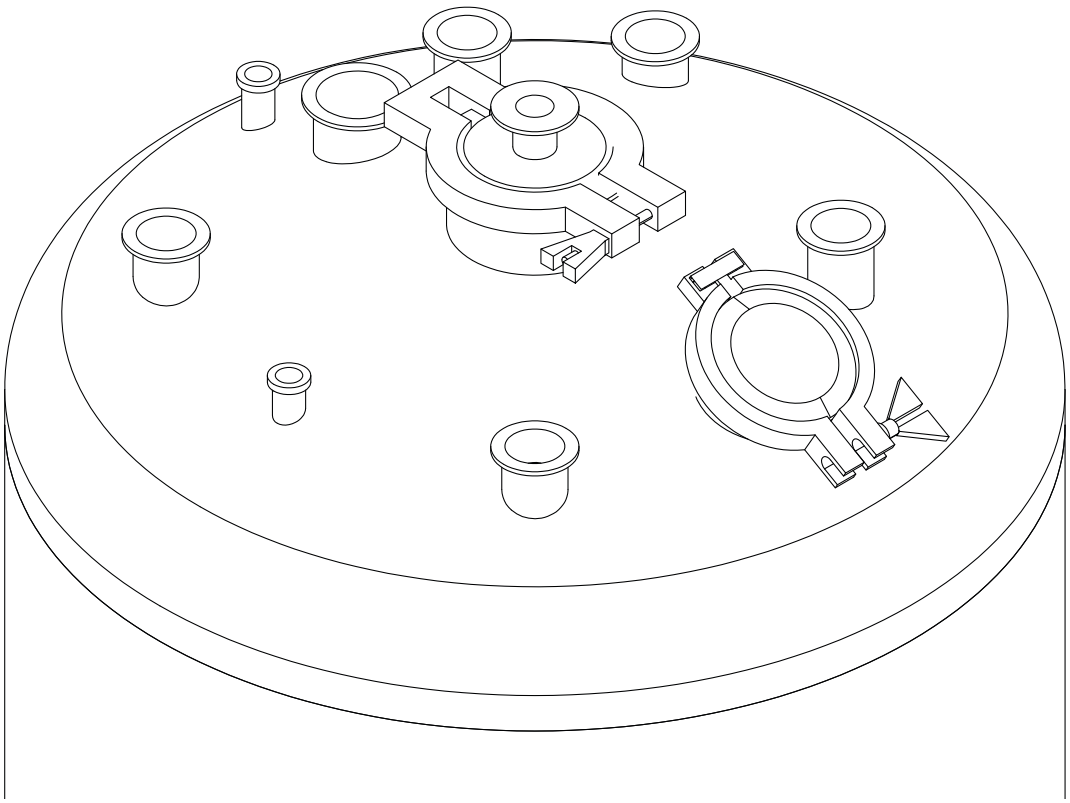


Figure 3 – Test Vessel Head with Tri-Clover Pt3 Flanged Connections

Spray device coverage test setup (Riboflavin test) cont...

A typical design procedure for vessel spray lance piping and positioning minimises CIP shadowing and maximises fluid storage without submerging the spray device itself. The positioning of the rupture disc (see Fig. 4) on this vessel has been selected to ensure the most difficult cleaning angle and was chosen to provide rigour to the cleaning cycle ensuring the device is subjected to a worst-case position. It is generally accepted that between the two most popular cleaning devices; static and rotary, static is the least effective but still increasingly common due to the simple design and ease of validation. Selecting a static sprayball satisfies the current industry standard for a spray device in the hygienic industry and ensures that following a successful test, performance with a rotary spray device will produce similar or superior cleaning results.

The test was carried out with a static spray ball cleaning device with design data shown in Table 1.

Hole Dia	Ball Dia	Connection	Height	Flow	Cleaning Radius
mm	mm		mm	m3/hr	m
1.6	50	1" OD Clip On	75	3.7	5.0

Table 1 – Spray Device Design Data (HPE, 2018)

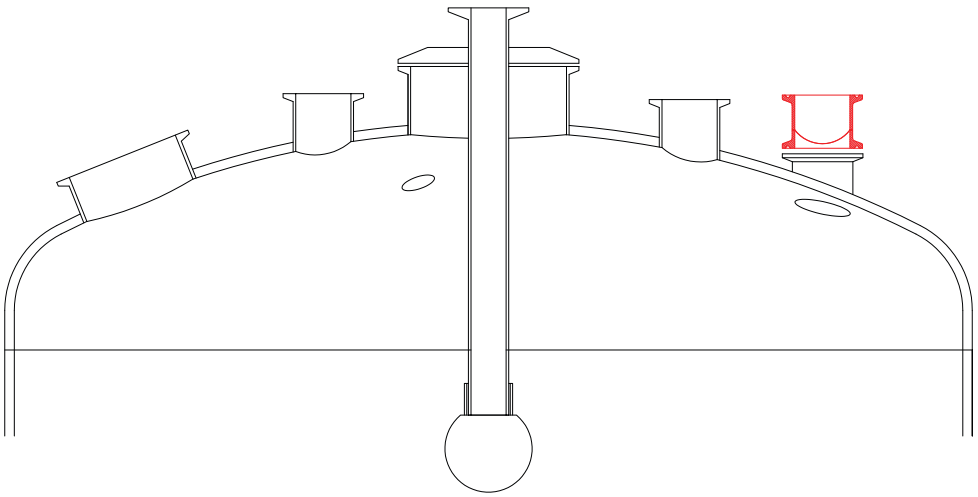


Figure 4 – Test Vessel Head in Section with Rupture Disc in Position (Red)

Spray device coverage test setup (Riboflavin test) cont...

The spray device is sized for and served by a dedicated pumping system with a centrifugal pump. The Riboflavin test system design is shown below in Fig. 5 (pumping skid shown outlined, parts 2-5):

1. IBC (de-ionised (DI) water of quality: <2µS/m)
2. Pump priming valve (ball)
3. Centrifugal pump (MDM 40H161/3 – 5400l/hr @ 2 barg)
4. Flow meter 0 – 10,000 l/hr (GEMU, variable area)
5. Water delivery valve (diaphragm)
6. Process vessel
7. **Elfab Test Piece**
8. Access manway for Riboflavin application
9. Drain

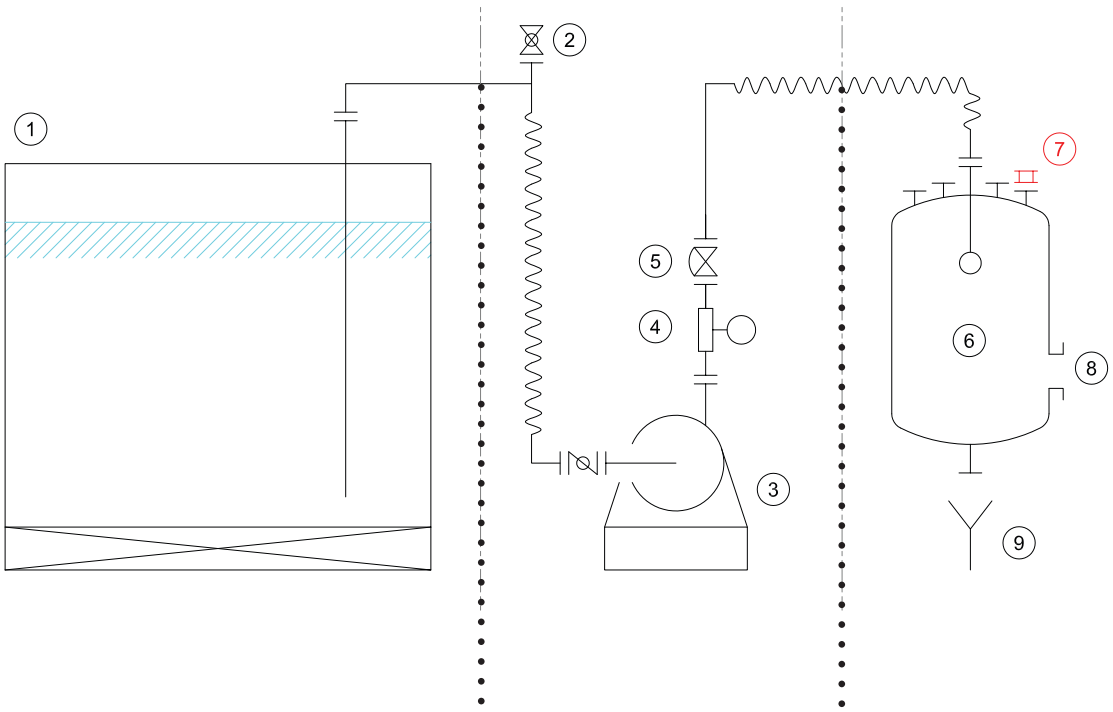


Figure 5 – Riboflavin Test Setup with Rupture Disc in Position

Test Procedure

In accordance with ASME BPE, Riboflavin tests follow the owner/user agreed procedure with all process data documented for ease of replication. The procedure was executed in accordance with ASME BPE Appendix L (ASME, 2016).

The duration of the cleaning rinse was set at 2 minutes (PSS Engineering Ltd., 2014) based on a catalogue of previously commissioned equipment/end user feedback. All other process data was matched to the spray device's design data.

Cleanability

All sample rupture devices were sprayed with Riboflavin mixture whilst dry and viewed under UV light to check their application and fluorescence. The devices were then affixed to the tank nozzle (with all tank internal surfaces dry).

After each sample device was cleaned for 2 minutes, the rupture disc carriages were removed and inspected with a UV light. Each device displayed no signs of any fluorescence, indicating removal of all Riboflavin.

After the device was left to dry in ambient air, it was inspected using a 6mm borescope to ensure any crevices were fully cleaned and all Riboflavin residue was washed away.

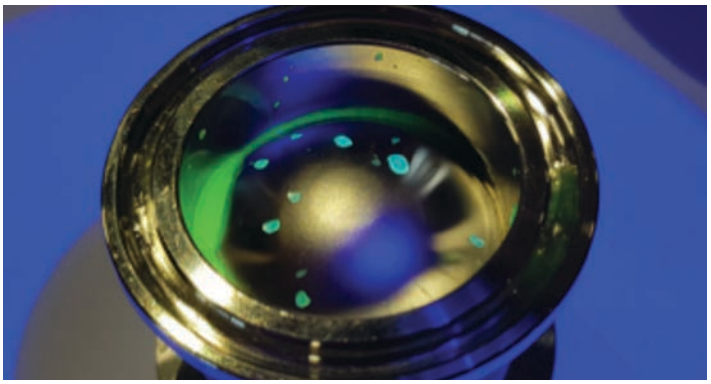


Figure 6 – Rupture Disc Carriage Applied with Riboflavin (UV lighting)

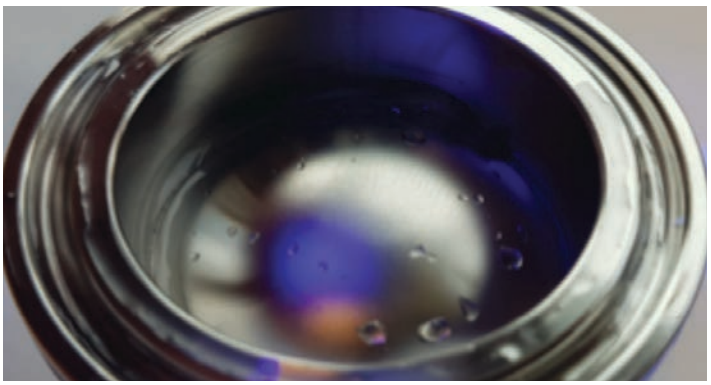


Figure 7 – Rupture Disc Carriage after Cleaning Cycle (UV lighting)

Figure 8 – Crevice View - Post Test & Rupture Disc Joining Weld (Dry) – (White lighting)

Review

The devices displayed excellent cleanability and performed well under the cleaning method used. All evidence of the Riboflavin had been removed after a cleaning cycle of 2 minutes. During the cleaning cycle, it was observed through a sightglass that the spray pattern from the cleaning device rebounds from the opposite side of the nozzle to the shadowed area and wets the inaccessible surfaces. This rebounding spray was enough to generate a cleaning action on the shadowed part of the device. **Fig. 9 illustrates this action.**

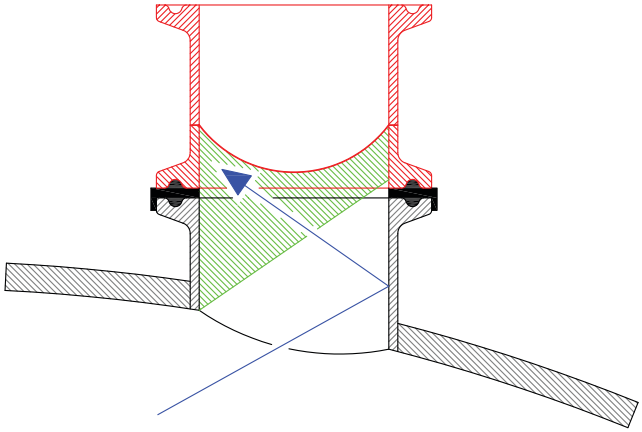


Figure 9 – Primary Cleaning Action - Rebound (Carriage, Shadow, Spray + Rebound)

Design Considerations

As the rupture disc is an attachment on a non-flow through nozzle (i.e. dead end) the L/D ratio for the nozzle must conform to ASME BPE specification for vessel openings "SD-3.4.2." In order for the design to be considered hygienic, its integration into a vessel must follow the below design recommendations:

- Minimise the L/D to 2 or less in accordance with SD-3.4.2(a) – See Fig. 10
- Sized greater than 1in (25mm) in accordance with SD-3.4.2(b)
- Match the same internal finish as installed equipment in accordance with SD-3.4.2(e)
- Positioning of rupture disc close to the centreline of the spray device for reduction of shadowing angle

For the rupture disc installation, L/D shall be measured from the intersection (see Fig. 2) of the device to the lowest part of the vessel opening.Elfab's new rupture disc assembly is compatible with hygienic pad flanges which provide optimum positioning within a vessel shell to ASME BPE, it is recommended that any non-flow nozzles including attachments such as rupture discs be installed within a hygienic pad flange, such as Neumo AWH-Connect (AWH, 2019), etc. to minimise L/D (See Fig. 11).

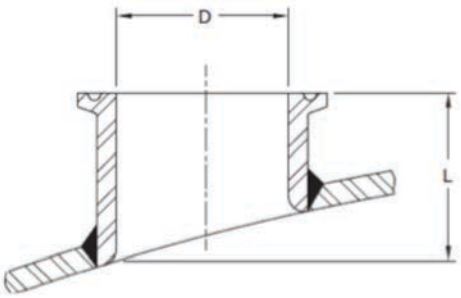


Figure 10 - L/D for Vessel Openings
Source: ASME 2016, Fig. c SD-3.4.2-1

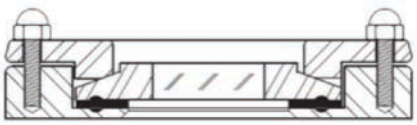


Figure 11 - Hygienic Pad Flange
Source: ASME 2016, Fig. b SD-3.4.6-1

Conclusion

From this test report, Elfab's new rupture disc assembly is shown to have exceptional cleanability against the benchmark sanitary cleaning test to ASME BPE standards. Its assembly within a flanged carriage ensures it remains robust in operation and maintenance activities whilst the process side of the disc is a hygienic and cleanable aseptic surface.

The design of this new rupture disc assembly has been thoughtfully considered to minimise L/D ratios to allow the process side of the disc to be fully exposed to a cleaning device.

Its design has many far-reaching applications in the hygienic process industry both as a newly specified product and as a retrofit product to deliver a robust solution to maintenance and changeover activities.

References:

- ASME. (2016). Bio Processing Equipment. ***Appendix L***, 318-319.
- AWH. (2019). ***https://www.awh.eu/***. Retrieved from AWH Connect: https://www.awh.eu/fileadmin/downloads/Broschueren_und_Kataloge/AWH_Catalog_AWH-Connect.pdf
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About the Author:

Gwyn Jones is a Chartered design engineer currently working for PSS Engineering Ltd. designing and manufacturing high purity processing equipment for the Pharmaceutical industry. Gwyn has over 15 years' experience of hygienic equipment design and has worked at the forefront of engineering design and manufacturing processes with world leading names in the Pharmaceutical industry. He is currently engaged in a novel material finishing technique with a renowned manufacturing research institute which it is hoped will challenge the Pharma industry standard electropolishing method.