



Parker Hannifin Manufacturing Limited

Bioscience Filtration Europe

Inspection Procedure

Revision Status

Rev No.	Rev Note No.	Date	Prepared By	Authorised by		Remarks
				Technical Director	Quality Manager	
1	IN531	21/11/01	[Redacted]	[Redacted]	[Redacted]	New Issue.
2	IN554	16/4/02	[Redacted]	[Redacted]	[Redacted]	Ammendments assed in response to comments from Philip Hall of Eli Lilly. The changes have been approved by the customer / contractor.
			Quality Engineer	Manufacturing Manager	Operations Manager	
3		13/10/08	[Redacted]	[Redacted]	[Redacted]	General review and new document format
4		19/3/13	[Redacted]	[Redacted]	[Redacted]	Company name and logo change

Title: Riboflavin testing of Turbosep and general vessels

IP No. 126

Revision No. 4

*Printed copy uncontrolled
Unless stamped 'Controlled Copy' in RED*

Page 1 of 9



Parker Hannifin Manufacturing Limited

Bioscience Filtration Europe

Inspection Procedure

1 Purpose

The purpose of this document is to describe the method for undertaking Riboflavin testing upon Turbosep vessels, and general vessels where this test has been requested.

2 Scope

- 2.1 This procedure demonstrates how to perform a test to qualify the coverage of the three spray balls mounted in the head of all Turboseps of sizes ZVT 5K and above and general vessels where this test has been requested. Through this, the design of the Turbosep / vessel can be shown to be hygienic.
- 2.2 No definite recognised test procedure exists at present but a review of current methodologies has been undertaken in formulating this procedure.
- 2.3 A demonstration of complete coverage of all components followed by evidence of complete removal will be taken as proof of the Turbosep / vessel design being fully cleanable.
- 2.4 This procedure is only applicable for Turboseps / vessels with flanged body closures.

3 Documents

Appendix A – Riboflavin Testing of Turbosep /Vessel Inspection Report

4 References

- ISPE Technical Article September 1999 “ CIP/COP Validation Test Procedure” by Jon R.Voss
- Personnel communication with employees of Merck and Martek

5 Responsibilities

This procedure is to be conducted on site at dh Fabrication under the direction of their QA Manager / Engineer.

6 Procedure

6.1 Equipment

- Centrifugal Pump : (capable of delivering 25m³/hr)

Title: Riboflavin testing of Turbosep and general vessels	IP No. 126	Revision No. 4
	<i>Printed copy uncontrolled Unless stamped 'Controlled Copy' in RED</i>	Page 2 of 9

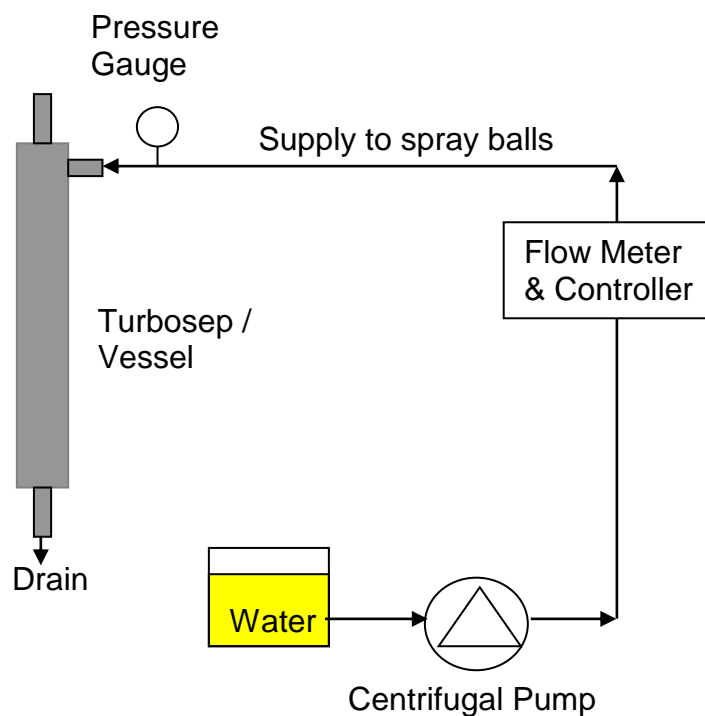
Parker Hannifin Manufacturing Limited

Bioscience Filtration Europe

Inspection Procedure

- Pressure Gauge 0-1.6barg
- Flow controller
- Flow Meter
- 1" flexible reinforced tubing
- Tubing/ pump adapters
- 1 m³ Supply Tank
- 1 m³ Return tank
- U.V.Light Magnaflux Blacklight : ZB100-F UV(A) 100W Euro spec(wavelength 365nm)
- Digital Camera
- Turbosep
- Riboflavin (Supplier P&R Labs : code 18.1220.16)
- Mains water
- Calibrated Scales

6.2 Refer to the diagram below





Parker Hannifin Manufacturing Limited

Bioscience Filtration Europe

Inspection Procedure

- 6.2.1 Measure out 2 grams of Riboflavin using calibrated scales. Record the scales i.d. and calibration date on the results sheet.
- 6.2.2 Mix 10 litres of 0.02 % Riboflavin (0.2 grams / litre of mains water) Stir for a minimum of 2 minutes to ensure all solids have dissolved. The mixture should be used within a period of 24hrs.
- 6.2.3 While the Turbosep / vessel is disassembled coat the internals of the Turbosep / vessel with the 0.02% Riboflavin solution using a tank sprayer. Note the internal surfaces of the vortex finder should not be coated as this will be cleaned via a sprayball on the outlet of the Turbosep that is not under the scope of supply from Parker domnick hunter. This is not applicable for other vessels as there is no vertex finder. The cleaning of this should be verified on site at Eli Lilly for the turboseps only.
- 6.2.4 Take photographs under the U.V. light to demonstrate Riboflavin coverage. (refer to Results section 7.1). To ensure optimum visibility of the Riboflavin the surface should be not be allowed to dry out. If require lightly spray with a water mist to moisten the surface. Re-assemble the vessel.
- 6.2.5 Fill the supply tank with mains water
- 6.2.6 Connect the inlet of the pump to the outlet of the supply tank
- 6.2.7 Connect the outlet of the pump to the 1" flexible pipe and attach this to the spray ball ring main. The ring main connection type will depend on the customer specification.
- 6.2.8 Hoist the Turbosep / vessel into the vertical position
- 6.2.9 Direct the return of the Turbosep / vessel to a suitable container. This will be used to verify the flow rate through the system.
- 6.2.10 Turn on the pump and pass water through the spray balls in the Turbosep / vessel. The water should be pumped through the system in (4) controlled bursts of (2) minutes each.(NOTE: This procedure is customer specific. If a different protocol is required record the parameters on the test results sheet). During this time the pressure should be monitored and recorded at the spray balls. The target pressure is 25 psig. For Turboseps, the pump will be regulated to give 15m³/hr. (66 gpm) to

Title: Riboflavin testing of
Turbosep and general
vessels

IP No. 126

Revision No. 4

*Printed copy uncontrolled
Unless stamped 'Controlled Copy' in RED*

Page 4 of 9



Parker Hannifin Manufacturing Limited

Bioscience Filtration Europe

Inspection Procedure

the combination of the 3 spray balls and the flow rate recorded. If more or less than 3 are used in the design the flow will be altered to give 5 m³/hr (22 gmp) per spray ball. Generally, for other vessels this will be 5 m³/hr (22 gmp) as only one spray ball is used.

6.2.11 Disassemble and photograph the areas described in the results section under the U.V. light to demonstrate removal. (refer to Results section 7.2)

6.2.12 Re assemble and conduct hydrotest.

7.0 Reports

The results of the test are recorded by taking photographs of

7.1 The Riboflavin coating under an ultraviolet light. The areas that are coated are highlighted by a bright luminous yellow colour.

Each surface of the Turbosep / vessel should be photographed with a digital camera. The critical areas are highlighted by the numbers and diagram detailed on the test results sheet.

For this part to be successful all internal surfaces should be coated with Riboflavin

7.2 The same critical surfaces following the clean water flush under an ultraviolet light.

For this part to be successful internal surfaces should be free from Riboflavin. This will be indicated by a lack of bright luminous yellow colour. (i.e. no luminescence generated by the Riboflavin reaction to UV light) The limit of sensitivity of the test has been shown to be 1microgram / 25cm². Carry-over levels can be calculated by using the internal surface area of the specific Turbosep / vessel. This is recorded on the results sheet.

Note: This does not include the internal surface of impinger assembly, which will be cleaned using an external CIP source, not provided by Parker domnick hunter.

The record sheet should have five A4 photographs attached as proof of coverage and five as proof of subsequent cleaning.

Title: Riboflavin testing of
Turbosep and general
vessels

IP No. 126

Revision No. 4

*Printed copy uncontrolled
Unless stamped 'Controlled Copy' in RED*

Page 5 of 9



Parker Hannifin Manufacturing Limited

Bioscience Filtration Europe

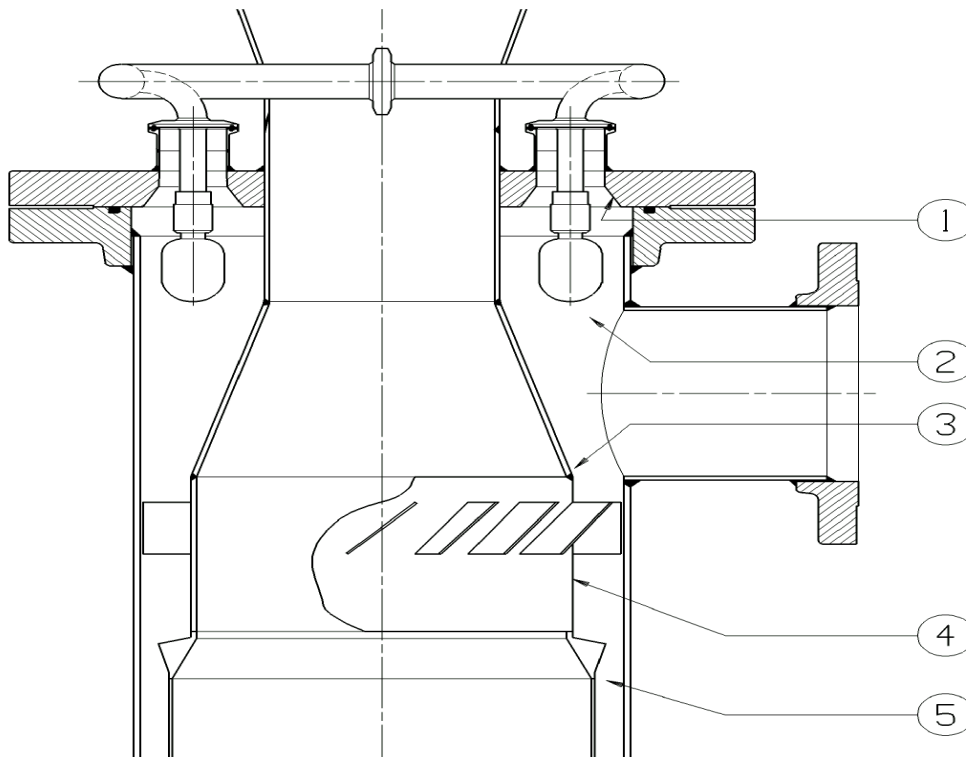
Inspection Procedure

Appendix A – Riboflavin Testing of Turbosep Inspection Report

The record sheet should have five A4 photographs attached as proof of coverage and five as proof of subsequent cleaning.

TEST RESULTS SHEET FOR RIBOFLAVIN TESTING OF TURBOSEP (pre clean water flush)

Turbosep Model		Turbosep Part No		Date of Test		Signature of Tester	
Riboflavin Supplier		Riboflavin Lot number		Pressure Gauge	ID	Weigh scales	ID
					Cal Date		Cal date
CIP Flow		% Riboflavin		Inlet pressure		Internal Surface area	



Photograph	View	Thumbnail Image	Signature of photographer
1	Above spray ball		
2	Spray ball and		

Title: Riboflavin testing of Turbosep and general vessels

IP No. 126

Revision No. 4

*Printed copy uncontrolled
Unless stamped 'Controlled Copy' in RED*

Page 6 of 9



Parker Hannifin Manufacturing Limited

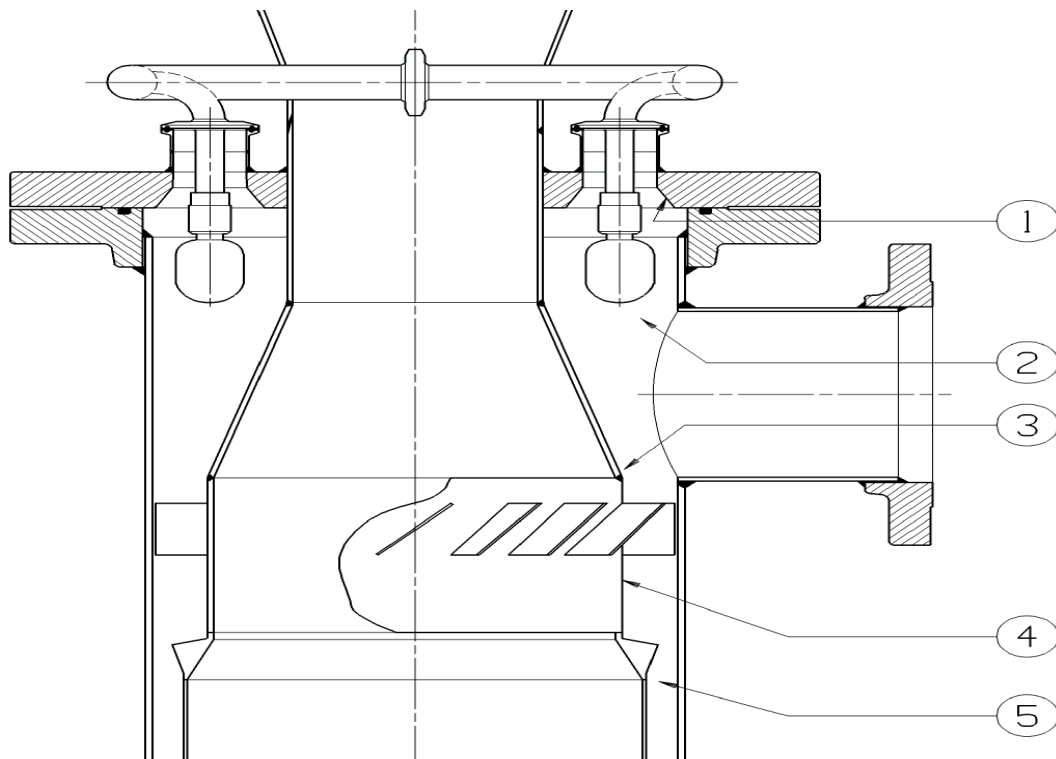
Bioscience Filtration Europe

Inspection Procedure

	surrounding area		
3	Top of turbine blades		
4	Bottom of turbine blades		
5	Below impinger		

TEST RESULTS SHEET FOR RIBOFLAVIN TESTING OF TURBOSEP (post clean water flush)

Turbosep Model		Turbosep Part No		Date of Test		Signature of Tester	
Riboflavin Supplier		Riboflavin Lot number		Pressure Gauge	ID	Weigh scales	ID
					Cal date		Cal date
CIP Flow		% Riboflavin		Inlet pressure		Internal Surface area	



Photograph	View	Thumbnail Image	Signature of photographer
1	Above spray ball		

Title: Riboflavin testing of Turbosep and general vessels

IP No. 126

Revision No. 4

*Printed copy uncontrolled
Unless stamped 'Controlled Copy' in RED*

Page 7 of 9



Parker Hannifin Manufacturing Limited

Bioscience Filtration Europe

Inspection Procedure

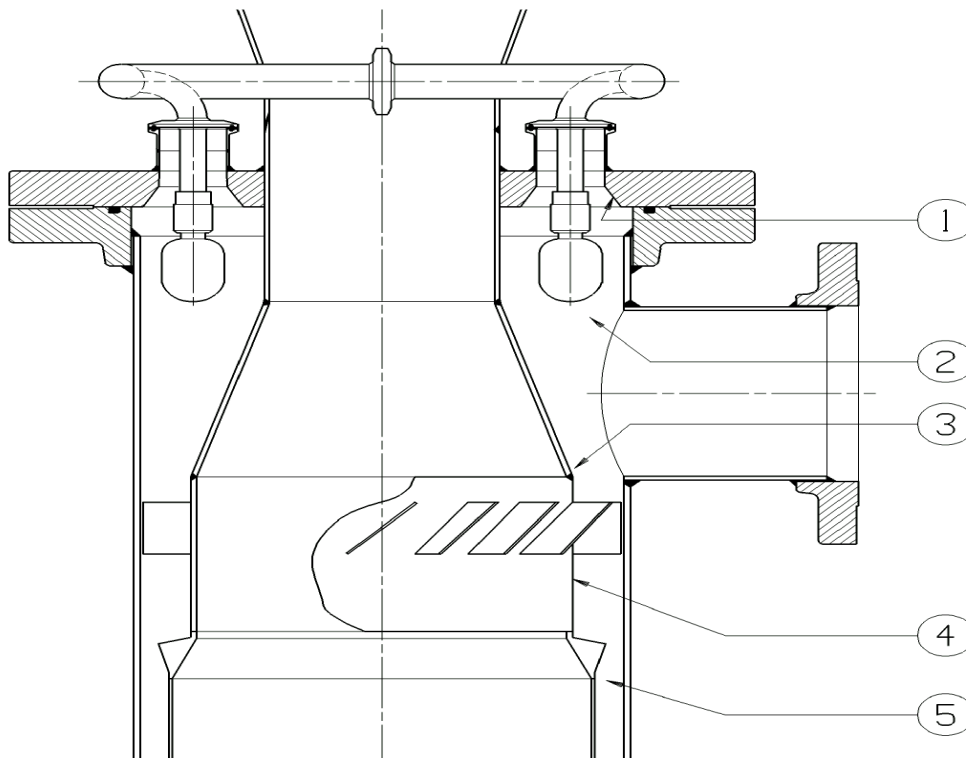
2	Spray ball and surrounding area		
3	Top of turbine blades		
4	Bottom of turbine blades		
5	Below impinger		

Appendix A – Riboflavin Testing of Vessel Inspection Report

The record sheet should have five A4 photographs attached as proof of coverage and five as proof of subsequent cleaning.

TEST RESULTS SHEET FOR RIBOFLAVIN TESTING OF Vessel (pre clean water flush)

Vessel Model		Vessel Part No		Date of Test		Signature of Tester	
Riboflavin Supplier		Riboflavin Lot number		Pressure Gauge	ID	Weigh scales	ID
					Cal Date		Cal date
CIP Flow		% Riboflavin		Inlet pressure		Internal Surface area	



Photograph	View	Thumbnail Image	Signature of photographer
------------	------	-----------------	---------------------------

Title: Riboflavin testing of
Turbosep and general
vessels

IP No. 126

Revision No. 4

*Printed copy uncontrolled
Unless stamped 'Controlled Copy' in RED*

Page 8 of 9



Parker Hannifin Manufacturing Limited

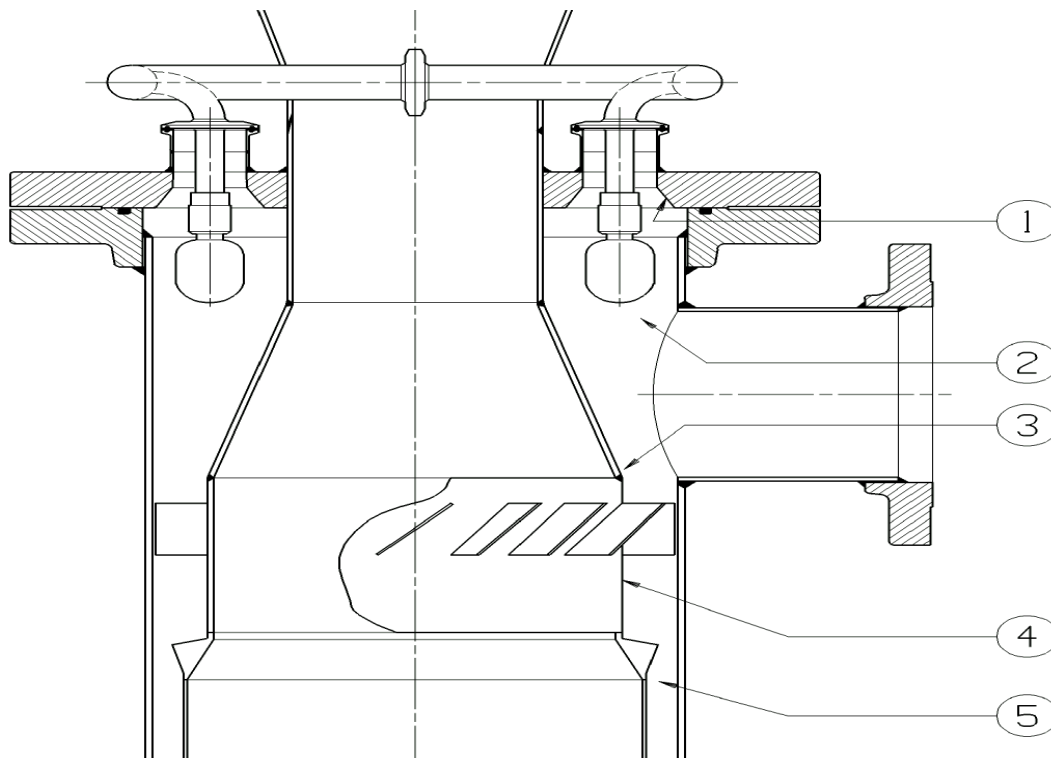
Bioscience Filtration Europe

Inspection Procedure

1	Above spray ball		
2	Spray ball and surrounding area		
3	Top of turbine blades		
4	Bottom of turbine blades		
5	Below impinger		

TEST RESULTS SHEET FOR RIBOFLAVIN TESTING OF Vessel (post clean water flush)

Vessel Model		Vessel Part No		Date of Test		Signature of Tester	
Riboflavin Supplier		Riboflavin Lot number		Pressure Gauge	ID	Weigh scales	ID
					Cal date		Cal date
CIP Flow		% Riboflavin		Inlet pressure		Internal Surface area	



Photograph	View	Thumbnail Image	Signature of photographer
1	Above spray ball		

Title: Riboflavin testing of
Turbosep and general
vessels

IP No. 126

Revision No. 4

*Printed copy uncontrolled
Unless stamped 'Controlled Copy' in RED*

Page 9 of 9



Parker Hannifin Manufacturing Limited

Bioscience Filtration Europe

Inspection Procedure

2	Spray ball and surrounding area		
3	Top of turbine blades		
4	Bottom of turbine blades		
5	Below impinger		

Title: Riboflavin testing of
Turbosep and general
vessels

IP No. 126

Revision No. 4

*Printed copy uncontrolled
Unless stamped 'Controlled Copy' in RED*

Page 10 of 9