RIM Bio, Inc

Single Use Bio-process Containers

Validation Guide

Table of Contents

Validation Checklist

▪ USP Class VI, USP <88>	Yes
▪ Cytotoxicity, USP <87>	Yes
▪ Physicochemical, USP<661>	Yes
▪ ADCF	Yes
▪ Bioburden	Yes
▪ Bacterial Endotoxin LAL	Yes
▪ Long Term Sterility	In Progress
▪ Leak Testing Integrity	Yes
▪ Long Term Shelf Life	In Progress
▪ Seal Strength	Yes
▪ Horizontal Impact	Yes
▪ Drop Test	Yes
▪ Film Cycle Testing	Yes
▪ Film Physical Testing	Yes

Quality Control

- **GMP Compliant Facility** **Yes**
- **ISO 9001:2008** **Yes**
- **ISO 7, Class 10,000 Cleanroom** **Yes**
- **Supply Chain Backup:**
  - **Resins** **No**
  - **Films** **Yes**
  - **Converters** **Yes**
  - **Processes** **Yes**
- **All products fully traceable**
- **All products 100% Leak Tested**
- **All products 100% Light Board Visually Inspected**

Quality Assurance

RIM Bio is ISO 9001:2008 certified

All drawings and product specifications are reviewed.

All components and raw materials are inspected before use.

All manufacturing and inspection standards are validated before production begins.

All Bio-Process products and components are assembled in the Clean room.

All components have strict lot control and traceability.

RIM Bio performs extensive component and product reliability testing in-house and through certified third party laboratories.

RIM Bio utilizes inspection and test methods to specific industry requirements.

RIM Bio test methods include but are not limited to:

Class VI Toxicity
Cytotoxicity
Hemolysis
Physicochemical
Heavy Metals
Bacterial Endotoxin LAL
Particulate Control
Mechanical Properties
Water Vapor Transmission Rate
Oxygen Transmission Rate
Film Transparency

Certificate of
Management System Certification

This is to certify the quality management system of

CHANGZHOU RM BIO CO., LTD.

Unified Social Credit Code : 913204116925860136

ADDRESS: NO.6, HUANBAO YI ROAD, XINBEI DISTRICT, CHANGZHOU, JIANGSU PROVINCE P.C.: 213000

Is in conformity with

ISO 9001:2008

This certificate covers the following area

PRODUCTION AND SALE OF DISPOSABLE BIOCHEMICAL LIQUID STORAGE BAG (EXCEPT FOR LICENSED PRODUCT)

Initial Certification Date: NOV. 19, 2013 Issue Date: From OCT. 10, 2016

Validity Period: From OCT. 10, 2016 To SEP. 15, 2018

Certificate No.: M43116Q20884R1M General Manager: 郑宇兵

MANAGEMENT SYSTEM

M4310809CB

Certified client shall receive at least one surveillance audit every year within the validity period, the certificate shall only be valid when used in conjunction with the Notice Letter of Annual Surveillance Certification Decision Information on this certificate could be verified on the official website of Certification and Accreditation Administration of the People's Republic of China (www.cnca.gov.cn) and http://www.jas-anz.org/register and www.hxqc.cn

Beijing Daluhangxing Quality Certification Center Co.,Ltd.

Address: No.Jia 12, Yuquan road, Haidian district, Beijing, P.R. China P.C.: 100143

Gamma Irradiation Certificate

原子辐照

常州原子高科辐照有限公司

Changzhou Atomic Hi-tech Radiation Co., Ltd.

国家环保产业园内

Environmental Protection Industry

NO:040481

辐 照 证 明

CERTIFICATE OF IRRADIATION

常州原子高科辐照有限公司执照登记号（Irradiation License No）：320407000012923
客户名称(Customer)：瑞牡生化（常州）有限公司
产品名称(Description)：20LBioprocss Container
产品批号(Lot No)：20140211-1
辐照日期（Radiation Date）：20140214
辐照批号（Radiation Lot）：140214004
辐照数量(Quantity):20pcs
客户要求剂量（Sterilization Dose Required Customer）
最低剂量（Minimum Dose）：25 KGy　最高剂量（Maximum Dose ）:37.5KGy

常州原子高科辐照有限公司特此证明上述产品已经本公司钴-60γ 射线辐照装置辐照，且满足了客户的剂量要求。通过可接受精度和准确度的剂量测量系统的测量，其实际吸收剂量如下：
Changzhou Atomic Hi-tech Radiation Co., Ltd. hereby certifies that the above products had been irradiated by the ^{60}Co γ-ray and meet the dose requirement from customer. Actual absorbed dose had been measured through our dosimetric system with acceptable precision and accuracy is as follows:

产品实际最低吸收剂量（Minimum Absorbed Dose）:26.8KGy
剂量计名称（Dosimeter Name）：$K_2Cr_2O_7$(Ag)　剂量计不确定度（Dosimeter uncertainty）:-2.0%
剂量计批号（Dosimeter Lot No.）：20131015　签发（Issued by）：
日期（Date）：2014.2.16

Effective: Jan 1, 2012

Subject: Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE)

TSE/BSE Statement

All materials used by RIM Bio, Inc. for the manufacture of single-use BioProcess containers are required to be free from any raw materials or substances derived of animal origin. Additionally, our manufacturing process does not use any ingredients of animal origin, nor do our products come in contact with animal products during storage and transportation. RIM Bio maintains Certificate of Origin information for all raw materials and components used in all manufacturing Lots for full product traceability.

It is the position of RIM Bio, that Bovine Spongiform (BSE) / Transmissible Spongiform Encephalopathy (TSE) should not be a concern to any customer using our products or assemblies in their production processes.

If you have any questions or require further information, please contact us or visit our website at www.rimbio.com.

Sincerely,

Steven Spear
Vice President of Sales
RIM Bio, Inc.

This information is considered accurate as of the date appearing above. The Recipient is responsible for determining whether the information in this document is appropriate for the Recipient's use. RIM Bio cannot control how this information is used and therefore, assumes no obligation or liability.

Latex / Phthalate Statement

Effective: Jan 1, 2012

Subject: No Latex and Phthalates in manufacturing process

Latex / Phthalate Statement

All materials used by RIM Bio, Inc. for the manufacture of single-use BioProcess containers are required to be free from Latex and Phthalate plasticizers. Additionally, our manufacturing process does not use any Latex or Phthalate ingredients, nor do our products come in contact with these materials during storage and transportation. RIM Bio maintains Certificate of Origin information for all raw materials and components used in all manufacturing Lots for full product traceability.

It is the position of RIM Bio, that Latex and Phthalate should not be a concern to any customer using our products or assemblies in their production processes.

If you have any questions or require further information, please contact us or visit our website at www.rimbio.com.

Sincerely,

Steven Spear
Vice President of Sales
RIM Bio, Inc.

This information is considered accurate as of the date appearing above. The Recipient is responsible for determining whether the information in this document is appropriate for the Recipient's use. RIM Bio cannot control how this information is used and therefore, assumes no obligation or liability.

NxFlex™ F1000 Film

PRODUCT DESCRIPTION

NxFlex™ F1000 is a clean medical grade multi-layer film designed for bioprocess applications such as 2-D hanging pillow bags for media storage and transport. The film has been developed for mechanical performance and biocompatibility.

FILM CONSTRUCTION

The Inner solution contact layer, is a custom formulated EVA copolymer designed with the purpose of minimizing extractables. An additional polyethylene (PE) layer is then added to this composite film.

To minimize gas diffusion, a layer of polyethylene vinyl alcohol copolymers (EVOH) is coextruded between two layers of medical grade polyethylene (PE) to provide excellent gas barrier properties.

The Outer, non-contact layer is medical grade polyethylene (PE) created from the outer surface of the PE/EVOH coextrusion.

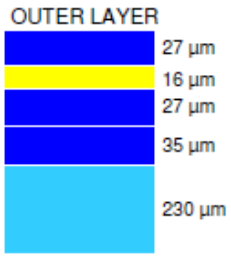
The combination of these specially selected film layers creates a visually clear and flexible multi-layer film that is also mechanically strong and puncture resistant.

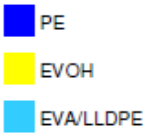
VALIDATION

All NxFlex™ films undergo extensive physical and biocompatibility testing before release. We supply a Certificate of Conformance with each shipment to ensure adherence to specifications and for lot traceability.

ANIMAL DERIVED COMPONENT FREE

In the production of NxFlex™ films, no animal derived components or materials are used in the manufacturing process. The films are considered safe for use in food and bio-pharmaceutical applications.





Physical Data Characteristics		
PROPERTY	**TEST PROTOCOL**	**AVERAGE VALUES**
Film Gauge		335 µm
Tensile Strength (MD) (N/15mm)	ASTM D882	74.1 N/15mm
Tensile Strength (TD) (N/15mm)	ASTM D882	71.5 N/15mm
Ultimate Elongation (MD)(%)	ASTM D882	379%
Ultimate Elongation (TD)(%)	ASTM D882	484%
Oxygen Transmission Rate	ASTM D3985	1.74 cc/m^2/day
Moisture Vapor Transmission Rate	ASTM F1249	1.23 g/m^2 /day
Solution Contact Material		EVA/LLDPE Blend
Temperature Range		-70ºC to 60ºC
Sterilizable Range		25kGy to 50kGy

Biocompatibility Data (Post Gamma Irradiation @ min. 25kGy)*		
PROPERTY	**TEST PROTOCOL**	**AVERAGE VALUES**
USP Class VI	USP 26 <88>	Pass
Cytotoxicity	USP 26 <87>	Pass
Non Volatile Residue	USP 26 <661>	<2 mg
Heavy Metals	USP 26 <661>	<1 ppm
Buffering Capacity	USP 26 <661>	<1 mL

* All biocompatibility testing performed by Toxikon Corporation, Bedford, MA.

RIM Bio, Inc.
Single Use BioProcess Containers

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TEST RESULT CERTIFICATE

Sponsor	RIM Medical, LLC	**Technical Initiation**	1/26/2009
Address	PO Box 880 Inman, South Carolina 29349	**Technical Completion**	2/6/2009
Contact	Scott Warren	**Report Date**	2/17/2009
P.O. Number	P2009-0102	**Project Number**	09-0067-N2

Test Article	NxFlex 2000-2	**Ratio**	120 cm^2/20 mL
Lot/Batch #	Not Supplied by Sponsor	**Vehicles**	USP 0.9% Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1 in 20 Ethanol in NaCl (EtOH), and Polyethylene Glycol 400 (PEG)
Study	Class VI Test – USP	**Extraction Conditions**	70 ± 2 °C for 24 ± 2 hours
Comments	Per Sponsor's specifications, testing was conducted on the opposite side of the surface marked "Test Face".		

REFERENCES: The study was conducted based upon the following references: USP 31, NF 26, 2008. <88> Biological Reactivity Tests, *In Vivo*.

ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE: The extraction conditions were performed as stated above. The test article extracts and corresponding blanks were injected systemically and intracutaneously in mice and rabbits, respectively. The injections were in the amounts and routes set forth by USP, including the further dilution of the extracts prepared with PEG. The animals were observed for signs of toxicity and skin reactivity for up to 72 hours post treatment. In addition, the test article was implanted into the paravertebral muscles of rabbits for 7 days and observed macroscopically for signs of hemorrhage, necrosis, discoloration, encapsulation, and infection.

RESULTS: None of the mice injected with the test article extracts exhibited any signs of toxicity in the Systemic Injection Test. In addition, none of the rabbits injected intracutaneously with the test article extracts exhibited any signs of erythema, edema or clinical toxicity. In both the Systemic and Intracutaneous Tests the controls were normal through 72 hours. Also, the implant sites exhibited no significant signs of hemorrhage, necrosis, discoloration, encapsulation, or infection compared with the control sites.

CONCLUSION: The test article meets the requirements of the guidelines for the Biological Test for Plastics, Class VI – 70 °C.

AUTHORIZED PERSONNEL:

Christopher Parker, M.S.
Study Director

Melissa Manning, B.S.
Quality Assurance

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TEST RESULT CERTIFICATE

Sponsor	RIM Medical, LLC	**Technical Initiation**	1/13/2009
Address	PO Box 880 Inman, South Carolina 29349	**Technical Completion**	1/16/2009
Contact	Scott Warren	**Report Date**	1/20/2009
P.O. Number	P2009-0102	**Project Number**	09-0067-N1

Test Article	NxFlex 2000-2	**Ratio**	120 cm^2/20 mL
Lot/Batch #	Not Supplied by Sponsor	**Vehicle**	Serum-Supplemented (Complete) Minimum Essential Medium (MEM)
Study	L929 MEM Elution Test – USP	**Extraction Conditions**	37 ± 1 °C for 24 ± 2 hours
Comments	Per Sponsor's specifications, the exposure ratio was calculated for only one side of the test article.		

REFERENCES: The study was conducted based upon the following references: USP 31, NF 26, 2008. <87> Biological Reactivity Tests, *In Vitro*.

ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE: The biological reactivity of a mammalian monolayer, L929 mouse fibroblast cell culture, in response to the test article extract was determined. Test article extract was prepared as stated above. Positive control (Natural Rubber) and negative control (Negative Control Plastic) articles were prepared to verify the proper functioning of the test system. The test article or control article extracts were used to replace the maintenance medium of the cell culture. All cultures were incubated in duplicate for 48 hours, at 37 ± 1 °C, in a humidified atmosphere containing 5 ± 1% carbon dioxide. Biological reactivity (cellular degeneration and ma formation) was rated on a scale from Grade 0 (No Reactivity) to Grade 4 (Severe Reactivity). The test article met the requirements of the test if none of the cultures exposed to the test article showed greater than a Mild Reactivity (Grade 2).

RESULTS: No signs of reactivity (Grade 0) were exhibited by the cell cultures exposed to the test article extract or the negative control article extract at the 48 hour observations. Severe signs of reactivity (Grade 4) were observed for the positive control article extract at the 48 hour observation.

CONCLUSION: The test article is considered non cytotoxic and meets the requirements of the Elution Test, USP guidelines.

AUTHORIZED PERSONNEL:

Franck Grall, Pharm.D., Ph.D.
Study Director

Wendy Moulton, B.S.
Quality Assurance

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TEST RESULT CERTIFICATE

Sponsor	Rim Medical, LLC	**Technical Initiation**	1/21/2009
Address	PO Box 880 Inman, South Carolina 29349	**Technical Completion**	1/23/2009
Contact	Scott Warren	**Report Date**	1/29/2009
P.O. Number	P2009-0102	**Project Number**	09-0067-N3

Test Article	NxFlex 2000-2	**Ratio**	120 cm²/20.0 mL
Lot/Batch #	Not Supplies	**Vehicle**	Purified Water
Study	Physicochemical Test for Plastics – USP	**Extraction Conditions**	70 ± 2 °C for 24 ± 2 hours
Comments	Side marked Test Face not tested.		

REFERENCES The study was conducted based upon the following references: USP 31, NF 26, 2008. Monograph <661> Containers, Physicochemical Tests–Plastics.

ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE: The test article was extracted in purified water after rinsing in purified water. The following tests were conducted in order to determine physical and chemical properties of the test article's extracts: Nonvolatile Residue, Residue on Ignition, Heavy Metals, and Buffering Capacity.

RESULTS:

TEST	ACCEPTABLE LEVEL	TEST RESULT
Nonvolatile Residue	≤ 15 mg	0.2 mg, Meets Criteria
Residue on Ignition	≤ 5 mg	Not Applicable
Heavy Metals	≤ 1 ppm	Meets Criteria
Buffering Capacity	≤ 10 mL	0.20 mL, Meets Criteria

CONCLUSION: The test article meets criteria of the USP Physicochemical Test for Plastics based upon the methods employed.

AUTHORIZED PERSONNEL

Amtul Qamar

Amtul Qamar, M.S.
Study Director

Katherine Townsend

Katherine Townsend, B.S.
Quality Assurance

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NxFlex™ F1000C1 Film

PRODUCT DESCRIPTION

NxFlex F1000C1 is a medical grade multi-layer film specifically designed for high performance bioprocess applications, particularly cell culture bags on rocking platforms. This film is designated for use in high flexure applications that require exceptional toughness and maximum resistance to flex-cracking.

FILM CONSTRUCTION

The Inner solution contact layer, is a custom formulated EVA copolymer designed with the purpose of minimizing extractables. An additional polyethylene (PE) tie layer is then added to this composite film during lamination.

To minimize gas diffusion, a layer of polyethylene vinyl alcohol copolymers (EVOH) is coextruded between a PA (nylon) layer and a layer of medical grade polyethylene (PE) to provide enhanced gas barrier properties.

The Outer, non-contact strength layer is the polyamine (Nylon) surface that is coextruded with the EVOH and medical grade polyethylene (PE) layers.

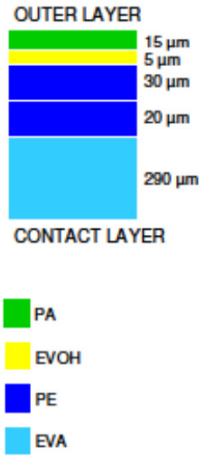
The combination of these specially selected film layers creates a visually clear and flexible multi-layer film that exhibits maximum flex-crack resistance.

VALIDATION

All NxFlex™ films undergo extensive physical and biocompatibility testing before release. We supply a Certificate of Conformance with each shipment to ensure adherence to specifications and for lot traceability.

ANIMAL DERIVED COMPONENT FREE

In the production of NxFlex™ films, no animal derived components or materials are used in the manufacturing process. The films are considered safe for use in food and bio-pharmaceutical applications.



Physical Data Characteristics		
PROPERTY	**TEST PROTOCOL**	**AVERAGE VALUES**
Film Gauge		360 µm
Tensile Strength (MD) (N/15mm)	ASTM D882	70 N/15mm
Tensile Strength (TD) (N/15mm)	ASTM D882	62 N/15mm
Ultimate Elongation (MD)(%)	ASTM D882	399%
Ultimate Elongation (TD)(%)	ASTM D882	484%
Oxygen Transmission Rate	ASTM D3985	2.17 cc/m^2/day
Moisture Vapor Transmission Rate	ASTM F1249	2.32 g/m^2/day
Solution Contact Material		EVA
Temperature Range		0ºC to 60ºC
Sterilizable Range		25kGy to 50kGy
Biocompatibility Data (Post Gamma Irradiation @ min. 25kGy)*		
PROPERTY	**TEST PROTOCOL**	**AVERAGE VALUES**
USP Class VI	USP 26 <88>	Pass
Cytotoxicity	USP 26 <87>	Pass
Non Volatile Residue	USP 26 <661>	<2 mg
Heavy Metals	USP 26 <661>	<1 ppm
Buffering Capacity	USP 26 <661>	<1 mL

* All biocompatibility testing performed by Toxikon Corporation, Bedford, MA.

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Single Use BioProcess Containers

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TEST RESULT CERTIFICATE

Sponsor	RIM Bio, Incorporated	**Technical Initiation**	7/26/2010
Address	1332 235th Place SE Sammamish, Washington 98075	**Technical Completion**	8/5/2010
Contact	Steven Spear	**Report Date**	8/20/2010
P.O. Number	071910	**Project Number**	10-3140-N3

Test Article	NxFlex F1000C Film	**Ratio**	120 cm^2/20 mL
Lot/Batch #	Not Supplied by Sponsor	**Vehicles**	USP 0.9% Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1 in 20 Ethanol in NaCl (EtOH), and Polyethylene Glycol 400 (PEG)
Study	Class VI Test – USP	**Extraction Conditions**	70 ± 2 °C for 24 ± 2 hours
Comments	None		

REFERENCES: The study was conducted based upon the following references: USP 32, NF 27, 2009. <88> Biological Reactivity Tests, *In Vivo*.

ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE: The extraction conditions were performed as stated above. The test article extracts and corresponding blanks were injected systemically and intracutaneously in mice and rabbits, respectively. The injections were in the amounts and routes set forth by USP, including the further dilution of the extracts prepared with PEG. The animals were observed for signs of toxicity and skin reactivity for up to 72 hours post treatment. In addition, the test article was implanted into the paravertebral muscles of rabbits for 7 days and observed macroscopically for signs of hemorrhage, necrosis, discoloration, encapsulation, and infection.

RESULTS: None of the mice injected with the test article extracts exhibited any signs of toxicity in the Systemic Injection Test. In addition, none of the rabbits injected intracutaneously with the test article extracts exhibited any signs of erythema, edema or clinical toxicity. In both the Systemic and Intracutaneous Tests, the controls were normal through 72 hours. Also, the implant sites exhibited no significant signs of hemorrhage, necrosis, discoloration, encapsulation, or infection compared with the control sites.

CONCLUSION: The test article meets the requirements of the guidelines for the Biological Test for Plastics, Class VI – 70 °C.

AUTHORIZED PERSONNEL:

Sarah Goulet

Sarah Goulet, M.S.
Study Director

Stacy Hubbard

Stacy Hubbard, M.S.
Quality Assurance

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TEST RESULT CERTIFICATE

Sponsor	RIM Bio, Incorporated	**Technical Initiation**	7/12/2010
Address	1332 235th Place South East Sammamish, Washington 98075	**Technical Completion**	7/15/2010
Contact	Steven Spear	**Report Date**	7/23/2010
P.O. Number	07062010	**Project Number**	10-3140-N1

Test Article	NxFlex F1000C Film	**Ratio**	120 cm^2/20 mL
Lot/Batch #	Not Supplied by Sponsor	**Vehicle**	Serum–Supplemented (Complete) Minimum Essential Medium (MEM)
Study	L929 MEM Elution Test – USP	**Extraction Conditions**	37 ± 1 °C for 24 ± 2 hours
Comments	None		

REFERENCES: The study was conducted based upon the following references: USP 32, NF 27, 2009. <87> Biological Reactivity Tests, *In Vitro*.

ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE: The biological reactivity of a mammalian monolayer, L929 mouse fibroblast cell culture, in response to the test article extract was determined. Test article extract was prepared as stated above. Positive control (Natural Rubber) and negative control (Negative Control Plastic) articles were prepared to verify the proper functioning of the test system. The test article or control article extracts were used to replace the maintenance medium of the cell culture. All cultures were incubated in duplicate for 48 hours, at 37 ± 1 °C, in a humidified atmosphere containing 5 ± 1% carbon dioxide. Biological reactivity (cellular degeneration and malformation) was rated on a scale from Grade 0 (No Reactivity) to Grade 4 (Severe Reactivity). The test article met the requirements of the test if none of the cultures exposed to the test article showed greater than a Mild Reactivity (Grade 2).

RESULTS: No signs of reactivity (Grade 0) were exhibited by the cell cultures exposed to the test article extract or the negative control article extract at the 48 hour observations. Severe signs of reactivity (Grade 4) were observed for the positive control article extract at the 48 hour observation.

CONCLUSION: The test article is considered non–cytotoxic and meets the requirements of the Elution Test, USP guidelines.

AUTHORIZED PERSONNEL:

Franck Grall, Pharm.D., Ph.D.
Study Director

Allison Lyons-Hook, B.A.
Quality Assurance

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TEST RESULT CERTIFICATE

Sponsor	RIM Bio, Inc	**Technical Initiation**	7/12/2010
Address	1332 235th Place SE Sammamish, Washington 98075	**Technical Completion**	7/14/2010
Contact	Steven Spear	**Report Date**	7/15/2010
P.O. Number	07062010	**Project Number**	10-3140-N2

Test Article	NxFlex F1000C Film	**Ratio**	120 cm²/20 mL
Lot/Batch #	Not Supplied By Sponsor	**Vehicle**	Water For Injection (WFI)
Study	Physicochemical Test for Plastics – USP	**Extraction Conditions**	70 ± 2 °C for 24 ± 2 hours
Comments	None		

REFERENCES The study was conducted based upon the following references: USP 32, NF 27, 2009. Monograph <661> Containers, Physicochemical Tests–Plastics.

ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE: The test article was extracted in WFI after rinsing in WFI. The following tests were conducted in order to determine physical and chemical properties of the test article's extracts: Nonvolatile Residue, Residue on Ignition, Heavy Metals, and Buffering Capacity.

RESULTS:

TEST	ACCEPTABLE LEVEL	TEST RESULT
Nonvolatile Residue	≤ 15 mg	0.2 mg, Meets Criteria
Residue on Ignition	≤ 5 mg	Not Applicable
Heavy Metals	≤ 1 ppm	Meets Criteria
Buffering Capacity	≤ 10 mL	0.015 mL, Meets Criteria

CONCLUSION: The test article meets criteria of the USP Physicochemical Test for Plastics based upon the methods employed.

AUTHORIZED PERSONNEL

Amtul Qamar, M.S.
Study Director

Felice Randi LaMadeleine, B.S., RQAP-GLP
Quality Assurance

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NxFlex™ F4000D1 Film

PRODUCT DESCRIPTION

NxFlex F4000D1 is a medical grade, 5-Layer film specifically designed for bioprocess applications such as large 2-D Pillow Bags (50L and larger) and for 3-D bioprocess containers. This film utilizes an extremely inert PE solution contact layer to minimize extractables. This film has been developed for clarity, high mechanical performance, puncture and tear resistance, and bio-compatibility.

FILM CONSTRUCTION

The Inner solution contact layer, is a highly inert, medical grade polyethylene (PE) custom formulated with the purpose of minimizing extractables. An additional thin tie layer is incorporated in this composite film during lamination.

To minimize gas diffusion, a layer of polyethylene vinyl alcohol copolymers (EVOH) is coextruded between a PA (Nylon) layer and a layer of medical grade polyethylene (PE) to provide excellent gas barrier properties.

The Outer, non-contact strength layer is the polyamide (Nylon) surface that is coextruded with the EVOH and medical grade polyethylene (PE) layers.

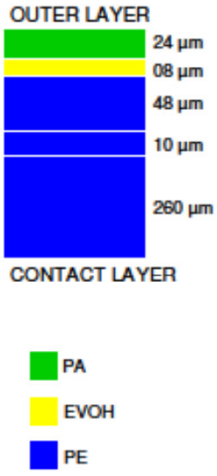
This 5-layer composite construction creates a visually clear and flexible film with very high mechanical strength and good impact and tear resistance. This film offers an excellent solution for large BPC's that require the most inert solution contact layer for the highest bio-compatibility requirements.

VALIDATION

All NxFlex™ films undergo extensive physical and biocompatibility testing before release. We supply a Certificate of Conformance with each shipment to ensure adherence to specifications and for lot traceability.

ANIMAL DERIVED COMPONENT FREE

In the production of NxFlex™ films, no animal derived components or materials are used in the manufacturing process. The films are considered safe for use in food and bio-pharmaceutical applications.



Physical Data Characteristics		
PROPERTY	**TEST PROTOCOL**	**AVERAGE VALUES**
Film Gauge		350 µm
Tensile Strength (MD) (N/15mm)	ASTM D882	80.4 N/15mm
Tensile Strength (TD) (N/15mm)	ASTM D882	76.9 N/15mm
Ultimate Elongation (MD)(%)	ASTM D882	406%
Ultimate Elongation (TD)(%)	ASTM D882	481%
Oxygen Transmission Rate	ASTM D3985	1.46 cc/m^2/day
Moisture Vapor Transmission Rate	ASTM F1249	1.06 g/m^2/day
Solution Contact Material		PE
Temperature Range		0ºC to 60ºC
Sterilizable Range		25kGy to 50kGy

Biocompatibility Data (Post Gamma Irradiation @ min. 25kGy)*		
PROPERTY	**TEST PROTOCOL**	**AVERAGE VALUES**
USP Class VI	USP 26 <88>	Pass
Cytotoxicity	USP 26 <87>	Pass
Non Volatile Residue	USP 26 <661>	<2 mg
Heavy Metals	USP 26 <661>	<1 ppm
Buffering Capacity	USP 26 <661>	<1 mL

* All biocompatibility testing performed by Toxikon Corporation, Bedford, MA.

RIM Bio, Inc.
Single Use BioProcess Containers

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TEST RESULT CERTIFICATE

Sponsor	RIM Medical, LLC	**Technical Initiation**	1/21/2009
Address	PO Box 880 Inman, South Carolina 29349	**Technical Completion**	1/30/2009
Contact	Scott Warren	**Report Date**	2/17/2009
P.O. Number	P2009-0101	**Project Number**	09-0034-N2

Test Article	Nx FLM-1005	**Ratio**	120 cm^2/20 mL
Lot/Batch #	Not Supplied by Sponsor	**Vehicles**	USP 0.9% Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1 in 20 Ethanol in NaCl (EtOH), and Polyethylene Glycol 400 (PEG)
Study	Class VI Test – USP	**Extraction Conditions**	70 ± 2 °C for 24 ± 2 hours
Comments	Per Sponsor's specifications, testing was conducted on the marked side of the film.		

REFERENCES: The study was conducted based upon the following references: USP 31, NF 26, 2008. <88> Biological Reactivity Tests, *in Vivo*.

ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE: The extraction conditions were performed as stated above. The test article extracts and corresponding blanks were injected systemically and intracutaneously in mice and rabbits, respectively. The injections were in the amounts and routes set forth by USP, including the further dilution of the extracts prepared with PEG. The animals were observed for signs of toxicity and skin reactivity for up to 72 hours post treatment. In addition, the test article was implanted into the paravertebral muscles of rabbits for 7 days and observed macroscopically for signs of hemorrhage, necrosis, discoloration, encapsulation, and infection.

RESULTS: None of the mice injected with the test article extracts exhibited any signs of toxicity in the Systemic Injection Test. In addition, none of the rabbits injected intracutaneously with the test article extracts exhibited any signs of erythema, edema or clinical toxicity. In both the Systemic and Intracutaneous Tests the controls were normal through 72 hours. Also, the implant sites exhibited no significant signs of hemorrhage, necrosis, discoloration, encapsulation, or infection compared with the control sites.

CONCLUSION: The test article meets the requirements of the guidelines for the Biological Test for Plastics, Class VI – 70 °C.

AUTHORIZED PERSONNEL:

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Melissa Manning, B.S.
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TEST RESULT CERTIFICATE

Sponsor	RIM Medical, LLC	**Technical Initiation**	1/19/2009
Address	PO Box 880 Inman, South Carolina 29349	**Technical Completion**	1/21/2009
Contact	Scott Warren	**Report Date**	1/23/2009
P.O. Number	P2009-0101	**Project Number**	09-0034-N3

Test Article	Nx FLM-1005	**Ratio**	120 cm²/20 mL
Lot/Batch #	Not supplied By Sponsor	**Vehicle**	Purified Water
Study	Physicochemical Test for Plastics USP	**Extraction Conditions**	70 ± 2 °C for 24 ± 2 hours
Comments	Tested 1 side only.		

REFERENCES The study was conducted based upon the following references: USP 31, NF 26, 2008. Monograph <661> Containers, Physicochemical Tests–Plastics.

ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE: The test article was extracted in purified water after rinsing in purified water. The following tests were conducted in order to determine physical and chemical properties of the test article's extracts: Nonvolatile Residue, Residue on Ignition, Heavy Metals, and Buffering Capacity.

RESULTS:

TEST	ACCEPTABLE LEVEL	TEST RESULT
Nonvolatile Residue	≤ 15 mg	0.0 mg, Meets Criteria
Residue on Ignition	≤ 5 mg	Not Applicable
Heavy Metals	≤ 1 ppm	Meets Criteria
Buffering Capacity	≤ 10 mL	0.0 mL, Meets Criteria

CONCLUSION: The test article meets criteria of the USP Physicochemical Test for Plastics based upon the methods employed.

AUTHORIZED PERSONNEL

Amtul Qamar

Amtul Qamar, M.S.
Study Director

Katherine Townsend

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TEST RESULT CERTIFICATE

Sponsor	RIM Medical, LLC	**Technical Initiation**	1/8/2009
Address	PO Box 880 Inman, South Carolina 29349	**Technical Completion**	1/11/2009
Contact	Scott Warren	**Report Date**	1/16/2009
P.O. Number	P2009-0101	**Project Number**	09-0034-N1

Test Article	Nx FLM-1005	**Ratio**	120 cm^2/20 mL
Lot/Batch #	Not Supplied by Sponsor	**Vehicle**	Serum–Supplemented (Complete) Minimum Essential Medium (MEM)
Study	L929 MEM Elution Test – USP	**Extraction Conditions**	37 ± 1 °C for 24 ± 2 hours
Comments	Per Sponsor request, the extraction ratio was calculated for 1 side of the film only.		

REFERENCES: The study was conducted based upon the following references: USP 31, NF 26, 2008. <87> Biological Reactivity Tests, *In Vitro*.

ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE: The biological reactivity of a mammalian monolayer, L929 mouse fibroblast cell culture, in response to the test article extract was determined. Test article extract was prepared as stated above. Positive control (Natural Rubber) and negative control (Negative Control Plastic) articles were prepared to verify the proper functioning of the test system. The test article or control article extracts were used to replace the maintenance medium of the cell culture. All cultures were incubated in duplicate for 48 hours, at 37 ± 1 °C, in a humidified atmosphere containing 5 ± 1% carbon dioxide. Biological reactivity (cellular degeneration and malformation) was rated on a scale from Grade 0 (No Reactivity) to Grade 4 (Severe Reactivity). The test article met the requirements of the test if none of the cultures exposed to the test article showed greater than a Mild Reactivity (Grade 2).

RESULTS: No signs of reactivity (Grade 0) were exhibited by the cell cultures exposed to the test article extract or the negative control article extract at the 48 hour observations. Severe signs of reactivity (Grade 4) were observed for the positive control article extract at the 48 hour observation.

CONCLUSION: The test article is considered non–cytotoxic and meets the requirements of the Elution Test, USP guidelines.

AUTHORIZED PERSONNEL:

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RIM Bio, Inc.

Single Use Bio-Process Containers

Cell Density Evaluation Comparison

RIM Bio Cell Culture Bag vs. Sartorius Culti-Bag
Bags specifically designed for Rocking Platforms.

Bag Manufacturer	Bag Size	Cell Count
RIM Bio – Test Bag 1	50L (25L working volume)	8.9
RIM Bio – Test Bag 2	50L (25L working volume)	9.1
Sartorius – Culti-Bag	50L (25L working volume)	9.2

Testing Notes:

1. All testing conducted by Scripps Research Institute.
2. All testing was performed on certified GE Wave System 50 Rocking Platforms.
3. Media, Lab, and Test Conditions were constant for all testing.
4. Insect Cell Media used for all tests.
5. All single-use bag details were similar for all testing
6. Testing conducted in December, 2010.

Conclusions:

Test results for the RIM Bio single-use cell culture bags and the single-use Sartorius Culti-Bags show very similar results. It is further concluded that the RIM Bio and Sartorius products are considered equivalent when used in these or similar test conditions.

RIM Bio, Inc.

Single Use Bio-Process Containers

Date: January 26, 2014

Subject: RIM Bio - Film Description and Compatibility with Sartorius Films

The BioProcess Industry has validated two primary polymers for the Contact Layer of Single-Use Containers. The first material is EVA (ethylene vinyl acetate) and is most commonly used for 2-D Bags, and Bags for Rocking Platforms. The second most widely used material is ULDPE which is used as the Contact Layer for large 2-D bags and 3-D Bags.

RIM Bio utilizes both EVA and ULDPE in the manufacture of the following three specialized NxFlex Films that are now used throughout the industry:

- NxFlex F1000 EVA Contact Layer
- NxFlex F1000C1 EVA Contact Layer
- NxFlex F4000D1 ULDPE Contact Layer

These three Films were developed and tested by RIM Bio and designed to be virtually identical to the most commonly used films in the BioProcess industry. Each of these NxFlex Films will be described in more detail below:

NxFlex F1000 and F1000C1

These RIM Bio Films utilize a Medical Grade EVA Contact Layer with the same resin designation as specified by Sartorius Stedim for their FlexBoy 2-D Bags and Culti-Bag products. This contact layer material can be sealed using RF equipment and has been widely uses for over 20 years. RIM Bio has conducted comparative cell-growth density testing against both Sartorius and GE Wave. In both independent tests, the NxFlex F1000 and F1000C1 Film was found to be "equal to, or better" in comparison to the Sartorius FlexBoy and Culti-Bag Films. This RIM Bio film is certified Class VI, USP <87>, and USP <661> by Toxikon Corporation. Data Sheet and testing information is detailed in the RIM Bio Validation Guide available on request.

NxFlex F4000D1

This RIM Bio Film utilizes a Medical Grade ULDPE Contact Layer with the same Dow resin designation as specified by Sartorius and Hyclone for their 2-D and 3-D bags. This Contact Layer material is considered the most inert PE (polyethylene) material in the market today and has a US FDA - DMF listing and EU compliance. This Film has been mechanically tested for containers up to 2000L in size. The F4000D1 Film is certified Class VI, USP <87>, and USP <661> by Toxikon Corporation. Data Sheet and testing information is detailed in the RIM Bio Validation Guide available on request.

RIM Bio, Inc.
Single Use Bio-Process Containers

Data Sheet

NxFlex T-9001 Thermoplastic Elastomer (TPE)
For use in Bio-Process applications

NxFlex T-9001 is our alternative to C-Flex. This is a Class VI and ISO 10993-4 material and meets FDA food grade requirements. T-9001 contains special additives to reduce sticking and abrasion of the ID and is recommended for use in peristaltic pumps.
Listed below are additional characteristics:

- **Ease of sterilization (ethylene oxide and gamma ray)**
- **Good chemical resistance**
- **Meets FDA food grade requirements**
- **Translucent**
- **Durometer range 65 ± 5**
- **Suitable for use up to 150° F**
- **Material will provide resistance to creeping at temperatures up to 275° F (135° C)**

T-9001 has all the desirable mechanical properties characteristic of thermoplastic rubbers. This extrusion grade material can be tightly controlled for dimensional stability and cleanliness.

Compatibility for Food and Medical Use – this product meets the requirements of the FDA's Title 21 Section 177.1810 for food grade use and has passed Class VI, USP 87, USP 661 and Hemolysis testing. However, customers are responsible for performing any required biocompatibility testing.

Typical Physical Properties – (ASTM D-412)

Compound	Tensile @ Break	Elongation	300% Modulus	500% Modulus
NxFlex T-9001	1600 min. psi	750 % min	450 avg. psi	800 avg. psi

The technical information supplied consists of typical product data and should not be used for specification purposes.

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TEST RESULT CERTIFICATE

Sponsor	[redacted]	Technical Initiation	3/3/2009
Address		Technical Completion	3/6/2009
Contact		Report Date	7/7/2009
P.O. Number	PR117977	Project Number	09-0798-N1

Test Article	K-9601	Ratio	3 cm^2/1 mL
Lot/Batch #	4004	Vehicle	Serum Supplemented (Complete) Minimum Essential Medium (MEM)
Study	L929 MEM Elution Test – ISO	Extraction Conditions	37 ± 1 °C for 24 ± 2 hours
Comments	None		

REFRENCES: The study was conducted based upon the following references: ISO 10993 -5, 1999, Biological Evaluation of Medical Devices – Part 5: Tests for *In Vitro* Cytotoxicity. ISO 10993-12, 2007, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials.

ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE: The biological reactivity of a mammalian monolayer, L929 mouse fibroblas: cell culture, in response to the test article extract was determined. Test article extract was prepared as stated above. Positive control (Natural Rubber) and negative control (Negative Control Plastic) articles were prepared to verify the proper functioning of the test system. The test article or control article extracts were used to replace the maintenance medium of the cell culture. All cultures were incubated in triplicate for 48 hours, at 37 ± 1 °C, in a humidified atmosphere containing 5 ± 1% carbon dioxide. Biological reactivity (cellular degeneration and malfermation) was rated on a scale from Grade 0 (No Reactivity) to Grade 4 (Severe Reactivity). The test article met the requirements of the test if none of the cultures exposed to the test article showed greater than a Mild Reactivity (Grade 2).

RESULTS: No signs of reactivity (Grade 0) were exhibited by the cell cultures exposed to the test article extract or the negative control article extract at the 48 hour observations. Severe signs of reactivity (Grade 4) were observed for the positive control article extract at the 48 hour observation.

CONCLUSION: The test article is considered non cytotoxic and meets the requirements of the Elution Test, ISO 10993-5 guidelines.

AUTHORIZED PERSONNEL:

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TEST RESULT CERTIFICATE

Sponsor	[redacted]	Technical Initiation	3/4/2009
Address		Technical Completion	3/10/2009
Contact		Report Date	7/6/2009
P.O. Number	PR1117977	Project Number	09-0790-N2

Test Article	K-9001	Ratio	3 cm²/1 mL
Lot/Batch #	14004	Vehicle	USP 0.9% Sodium Chloride for Injection (NaCl)
Study	Hemolysis – Rabbit Blood – ISO Indirect Contact	Extraction Conditions	70 ± 2 °C for 24 ± 2 hours
Comments	None		

REFERENCES: The study was conducted based upon the following references: ISO 10993–4, 2002, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood, as amended 2006. Hemolysis – Rabbit Blood, Evaluation of Hemodialyzers and Dialysis Membranes, DHEW Publication # (NIH) 77–1294, pg. 213, 1977. Author Method, ATTP-1, Material Sciences Toxicology Laboratories, University of Tennessee Center for the Health Sciences, Memphis, TN, April 18, 1977. Feldman, Bernard F., Joseph G. Zinkl, and Nemi C. Jain, eds. Schalm's Veterinary Hematology, 5th edition, Baltimore: Lippincott Williams & Wilkins, 2000: 858 – 859. ISO 10993–12, 2007, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials.

ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE: The test article was added to a test vial containing USP 0.9% Sodium Chloride for Injection (NaCl) and extracted as specified above. The test article extract (10 mL each) was transferred to three test vials. The positive control (10 mL USP Sterile Water for Injection (SWFI)) and negative control (10 mL NaCl) were prepared in triplicate. All tubes were incubated in a 37 ± 2 °C waterbath for 30 ± 2 minutes. The rabbit blood was collected in tubes containing an anticoagulant (EDTA) and diluted in NaCl. After the incubation period, 0.2 mL of fresh diluted rabbit blood was added to all vials. All vials were incubated in a 37 ± 2 °C waterbath for an additional 60 ± 4 minutes. After incubation, the vials were centrifuged. The absorbance of each supernatant was determined spectrophotometrically at 545 nm. The percent hemolysis of the test article was determined.

RESULTS: A test article with a 5% hemolysis or less is considered non–hemolytic. The test article extract induced 0.0% hemolysis.

CONCLUSION: The test article is considered non–hemolytic based on the methods employed.

AUTHORIZED PERSONNEL:

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TEST RESULT CERTIFICATE

Sponsor	[redacted]	**Technical Initiation**	3/4/2009
Address		**Technical Completion**	3/20/2009
Contact		**Report Date**	7/7/2009
P.O. Number	PRU12977	**Project Number**	09-0790-N3

Test Article	K-9001	**Ratio**	60 cm^2/20 ml.
Lot/Batch #	14304	**Vehicles**	USP 0.9% Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 5 in 20 Ethanol in NaCl (EtOH), and Polyethylene Glycol 400 (PEG)
Study	Class VI Test - USP	**Extraction Condition**	70 ± 2 °C for 24 ± 2 hours
Comments	None		

REFERENCES: The study was conducted based upon the following references: USP 31, NF 26, 2008, <88> Biological Reactivity Tests, *In Vivo*.

ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE: The extraction conditions were performed as stated above. The test article extracts and corresponding blanks were injected systemically and intracutaneously in mice and rabbits, respectively. The injections were in the amounts and routes set forth by USP, including the further dilution of the extracts prepared with PEG. The animals were observed for signs of toxicity and skin reactivity for up to 72 hours post treatment. In addition, the test article was implanted into the paravertebral muscles of rabbits for 7 days and observed macroscopically for signs of hemorrhage, necrosis, discoloration, encapsulation, and infection.

RESULTS: None of the mice injected with the test article extracts exhibited any signs of toxicity in the Systemic Injection Test. In addition, none of the rabbits injected intracutaneously with the test article extracts exhibited any signs of erythema, edema or clinical toxicity. In both the Systemic and Intracutaneous Tests the controls were normal through 72 hours. Also, the implant sites exhibited no significant signs of hemorrhage, necrosis, discoloration, encapsulation, or infection compared with the control sites.

CONCLUSION: The test article meets the requirements of the guidelines for the Biological Test for Plastics, Class VI - 70 °C.

AUTHORIZED PERSONNEL:

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RIM Bio, Inc.
Single Use Bio-Process Containers

Data Sheet

NxFlex T-8000 Platinum-Cured Silicone Tubing
For use in Bio-Process applications

NxFlex T-8000 is our Platinum-Cured Silicone Tubing. This material is certified to USP Class VI and meets FDA Medical and Food-grade requirements.
NxFlex T-8000 has ultra-low extractables and is recommended for use in peristaltic pumps.
NxFlex T-8000 meets the stringent requirements of the Biopharmaceutical market.

Listed below are additional characteristics:

- **Autoclavable and Gamma sterilizable**
- **Excellent Peristaltic Pump life**
- **Post-cured for improved Physical and Biocompatibility performance**
- **Superior chemical resistance**
- **Meets FDA Medical and Food-grade requirements**
- **Non-yellowing formulation**
- **Durometer range 65 ± 5**
- **Temperature range from -80° F (-62° C) to 500° F (260° C)**

Compatibility for Life Science and Medical Use – The raw material meets USP Class VI, and ISO 10993. The material has been tested and meets Cytotoxicity requirements.

Typical Physical Properties – (Method CTM0137A)

Durometer, Shore A	**65**
Tensile Strength, psi (MPa)	**1600 (11MPa)**
Elongation, 100%	**416%**
Tear Resistance, ppi (kN/m)	**160 (28 kN/m)**
Modulus at 200% elongation, psi (MPa)	**440 (13 MPa)**

Product Information
Healthcare

DOW CORNING

Dow Corning® QP1-30 Silicone Elastomer
Dow Corning® QP1-50 Silicone Elastomer
Dow Corning® QP1-60 Silicone Elastomer
Dow Corning® QP1-70 Silicone Elastomer

FEATURES

- No phthalates or latex additives
- Solventless
- Can be post-cured
- Pigmentable

BENEFITS

- United States Pharmacopeia (USP) Class VI
- Tissue Culture testing warranted

COMPOSITION

- One-part uncatalyzed silicone elastomer raw material

Translucent, Uncatalyzed Silicone Rubber Base

APPLICATIONS

Dow Corning® QP1 Silicone Elastomer Bases are an uncatalyzed material designed for compounding into elastomer used for part fabrication of medical devices and device components including those intended for implantation in humans for less than 30 days and non-implant applications.

DESCRIPTION

Dow Corning QP1 Silicone Elastomers are a one-part high consistency rubber base which is supplied absent any catalyst. Once compounded with peroxide it can be used to fabricate parts by extrusion, calendaring or molding. When compounded and cured as indicated, the resulting elastomer consists of cross-linked dimethyl and methyl-vinyl siloxane copolymers and reinforcing silica.

HOW TO USE

These silicone elastomers are supplied as a one-part uncatalyzed silicone high consistency rubber that must be thoroughly mixed with a catalyst.

Typically, a two-roll mill is used for the blending process.

HANDLING PRECAUTIONS

PRODUCT SAFETY INFORMATION REQUIRED FOR SAFE USE IS NOT INCLUDED IN THIS DOCUMENT. BEFORE HANDLING, READ PRODUCT AND MATERIAL SAFETY DATA SHEETS AND CONTAINER LABELS FOR SAFE USE, PHYSICAL AND HEALTH HAZARD INFORMATION. THE MATERIAL SAFETY DATA SHEET

IS AVAILABLE ON THE DOW CORNING WEB SITE AT DOW CORNING.COM, OR FROM YOUR DOW CORNING SALES APPLICATION ENGINEER, OR DISTRIBUTOR, OR BY CALLING DOW CORNING CUSTOMER SERVICE.

USABLE LIFE AND STORAGE

When stored at or below 50˚C (122˚F) in the original unopened containers, these products have useable life of 15 months from the date of production.

PACKAGING INFORMATION

If sourced from the Americas, *Dow Corning* QP1-Silicone Elastomer is supplied in 22.6 kg (50 lb) and 453.5 kg (1000 lb) boxes.

If sourced from Europe, *Dow Corning* QP1 Silicone Elastomer is supplied in 20 kg (44 lb) and 500 kg (1102 lb) boxes.

TESTING

Dow Corning has completed testing of *Dow Corning* QP1 Silicone Elastomers according to the United States Pharmacopeia (USP) Class VI. Documentation which supports compliance can be obtained from Dow Corning.

IMPORTANT INFORMATION

THE USER'S ATTENTION IS IN PARTICULAR DRAWN TO THE FOLLOWING STATEMENT:

It is the User's responsibility to ensure the safety and efficacy of these materials for all intended uses. Dow Corning makes no representation concerning the suitability of these products for any healthcare or pharmaceutical application. Under no circumstances should these materials be considered for implantation into the human body for periods that exceed 30 days in duration.

HEALTH AND ENVIRONMENTAL INFORMATION

To support Customers in their product safety needs, Dow Corning has an extensive Product Stewardship organization and a team of Product Safety and Regulatory Compliance (PS&RC) specialists available in each area.

For further information, please see our Web site, dowcorning.com, or consult your local Dow Corning representative.

LIMITED WARRANTY INFORMATION – PLEASE READ CAREFULLY

The information contained herein is offered in good faith and is believed to be accurate. However, because conditions and methods of use of our products are beyond our control, this information should not be used in substitution for customer's tests to ensure that our products are safe, effective, and fully satisfactory for the intended end use. Suggestions of use shall not be taken as inducements to infringe any patent.

Dow Corning's sole warranty is that our products will meet the sales specifications in effect at the time of shipment.

Your exclusive remedy for breach of such warranty is limited to refund of purchase price or replacement of any product shown to be other than as warranted.

DOW CORNING SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY.

DOW CORNING DISCLAIMS LIABILITY FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.

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TYPICAL PROPERTIES

Specification Writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales office or your Global Dow Corning Connection to learn more about physical properties before writing specifications on this product.

Cure conditions:
As Molded conditions (PD-50S): (5 minutes @ 116°C)
Post Cure conditions: (4 hours @ 200°C)

PERKADOX PD-50S[1]

Dow Corning® QP1 Silicone Elastomer Bases			QP1-30		QP1-50		QP1-60		QP1-70	
	Unit	Method*	As Molded	Post Cured	As Molded	Post Cured	As Molded	Post Cured	As Molded	Post Cured
Specific Gravity	NA	CTM0022	1.09	NA	1.13	NA	1.16	NA	1.20	NA
Durometer	Shore A	CTM0099	28	28	49	48	56	57	66	68
Tensile Strength	Mpa	CTM0137A	10.8	9.6	11.8	11.9	12.8	13.0	12.7	12.7
	psi	CTM0137A	1569	1394	1713	1729	1853	1891	1835	1836
Modulus at 200%	Mpa	CTM0137A	0.8	0.8	2.4	2.4	3.1	3.0	4.1	4.3
	psi	CTM0137A	120	122	348	349	447	440	601	628
Elongation	%	CTM0137A	858	798	552	547	543	539	474	472
Tear Die B	kN/m	CTM0159A	13.5	12.8	18.0	16.8	22.6	21.7	24.7	24.5
	ppi	CTM0159A	77	73	103	96	129	124	141	140
Compression Set 22HR/177°C	%	CTM0085	38.7	41.9	43	39	63	45	75	53

[1]100 parts *Dow Corning*® QP1-XX Silicone Elastomer
1.2 parts PD-50
*CTM: (Corporate Test Method) corresponds to American Standard Test Methods (ASTM) Copies of CTMs are available upon request.
NA: Not Applicable

- C0013178

DOW CORNING

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交货号	项目	交货日期
8611106567	000010	2016/01/07
销售订单号	项目	销售订单日期
7134789	000030	2015/08/26
采购订单号		采购订单日期
D03260804SC		2015/08/26

交货地址: 1140309
质保部
昆山名达贸易有限公司
江苏省昆山市
玉山镇创科路28号8号厂房
邮编: 215316

物料号 4110301
DOW CORNING(R) QP1-50 有机硅弹性体 ,500 KG 盒

客户物料号

批号	有效期
0008333585	2016/09/16
交货数量	生产日期
1 盒	2015/06/24

性质	数值	计量单位	下限	上限
外观	确定			
VISCOSITY - MOONEY R.T.	33.1	门尼单位	27.0	40.0
SPECIFIC GRAVITY	1.132		1.120	1.160
DUROMETER - SHORE A	50	肖氏A	46	54
TENSILE STRENGTH	9.6	兆帕斯卡	8.0	
ELONGATION	489	%	400	
TEAR DIE B	18.8	千牛顿/米	18.0	
担保测试	1			
	2			
	3			
TISSUE CULTURE, NO CPE	确定			

本质保书证明在原始包装中的以上原料已被测试并符合标准（除非另有所列）该物料以Dow Corning的发现所列条款为准。以上为文件副本。该规改数据可供检验。本质保书无需签字即为有效。.

内部参考号 4110301

外部参考号 000s000000

- C0013178

DOW CORNING

道康宁（张家港）投资有限公司
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分析报告

收货方传真: 1140309
512-55196105

日期
2015/11/11

交货号	项目	交货日期
8611002436	000020	2015/11/12
销售订单号	项目	销售订单日期
7134790	000010	2015/08/26
采购订单号		采购订单日期
D03260804SC		2015/08/26

交货地址 1140309
质保部
昆山名达贸易有限公司
江苏省昆山市
玉山镇创科路28号8号厂房
邮编: 215316

物料号 4110269
DOW CORNING(R) QP1-70 有机硅弹性体 ,500 KG 盒

客户物料号

批号	有效期
0008322617	2016/09/05
交货数量	生产日期
1 盒	2015/06/13

性质	数值	计量单位	下限	上限
外观	确定			
VISCOSITY - MOONEY R.T.	68.3	门尼单位	50.0	85.0
SPECIFIC GRAVITY	1.203		1.190	1.230
DUROMETER - SHORE A	71	肖氏A	66	74
TENSILE STRENGTH	11.1	兆帕斯卡	9.0	
ELONGATION	416	%	300	
TEAR DIE B	28.0	千牛顿/米	19.0	
担保测试	1			
	2			
	3			
TISSUE CULTURE, NO CPE	确定			

本质保书证明在原始包装中的以上原料已被测试并符合标准（除非另有所列）该物料以Dow Corning的发票所列条款为准。以上为文件副本。该批次数据可供检验。本质保书无需签字即为有效。.

内部参考号 4110269

外部参考号 0006000000

Cross Reference to Toxikon Test Articles

Item	Test Article Number	RIM Bio Brand Name
1	NxFlex 2000-2	NxFlex F1000 Film
2	NxFlex F1000C	NxFlex F1000C1 Film
3	NxFLM-1005	NxFlex F4000D1 Film
4	K-9001	NxFlex T9001 Tubing

Leachables Study of RIM Bio 10L Rocker Bags

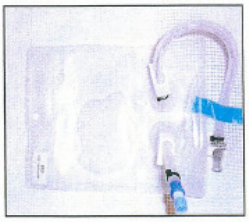
Testing performed between 2014 - 2015

Study Design

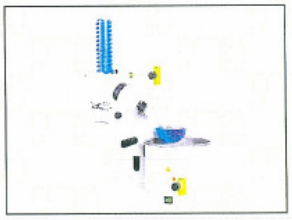
- The objective of this study was to evaluate the performance of RIM Bio's 10L Rocker Bags with EVA and PE inner Contact Layers.
- The following evaluations were performed
  - Leachable evaluation protocol
  - CHO cell sensitivity to bDtBPP
  - Leachables Study
  - UPLC Data

Leachable Testing – Objectives and Protocol

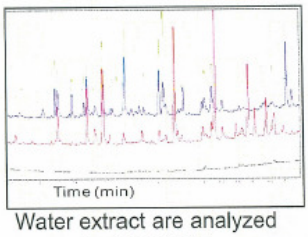
- UPLC analysis objective: detect and quantify bDtBPP in water extracts from bags
- Cell based assay objective: test effect of L/E from bags on CHO cell growth/viability



Bags are incubated with water at 50°C for 48h under agitation



Water extracts are concentrated with Rotavapor® R II



Water extract are analyzed by UPLC/MS

Water extracts are tested with Cell Based Assay (CBA)

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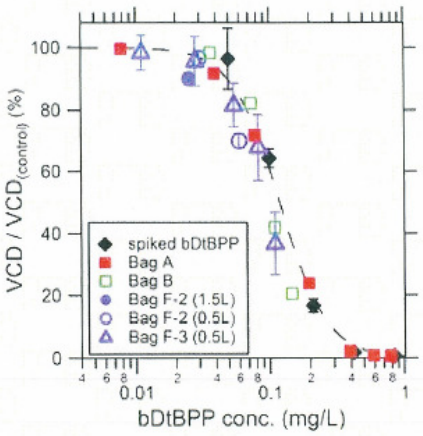
Testing RIM Bio 10L Rocker Bags for absence or presence of bDtBPP

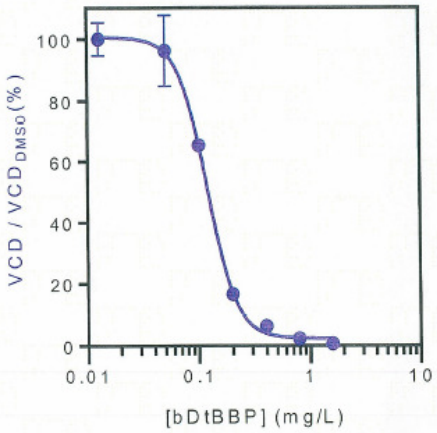
Special CHO cells were used with similar sensitivity to bDtBPP as compared to Amgen's similarly "sensitive" lines.

Amgen's Data



IC_{50} for VCD range from 0.12-0.73 mg/L for different lines

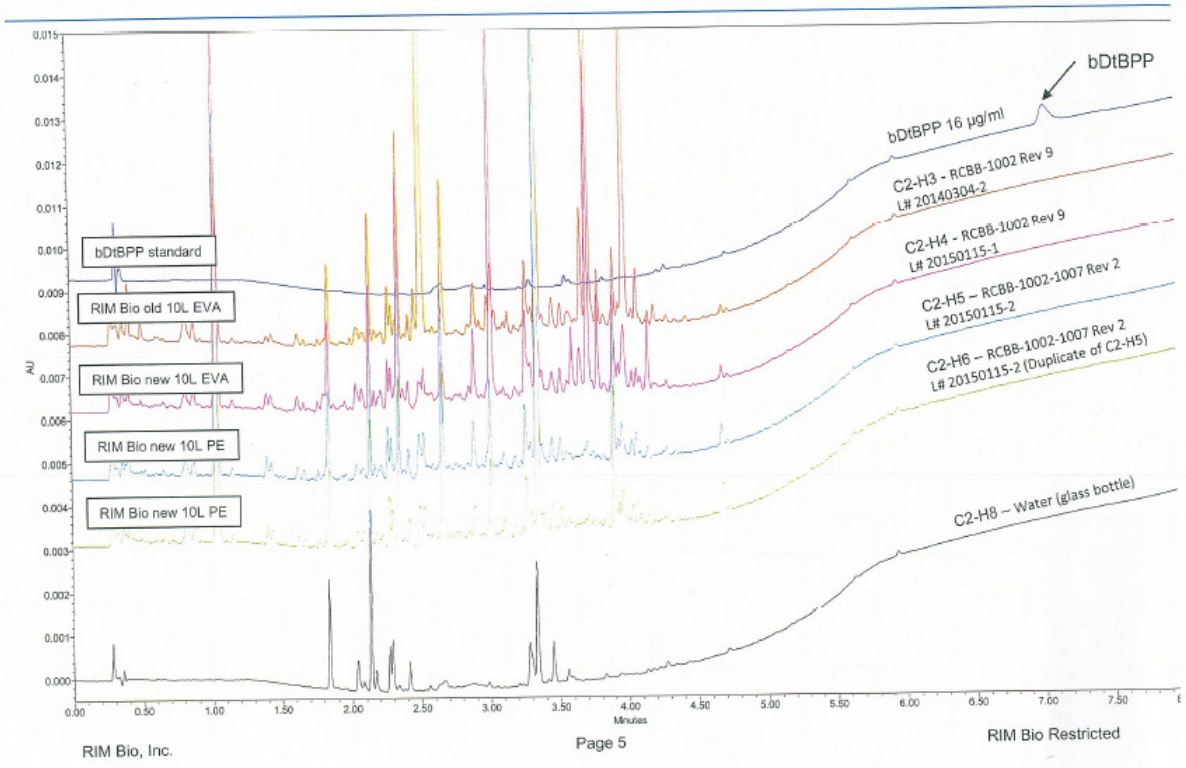
Study CHO Data



IC_{50} for VCD is 0.12 mg/L

New (2015) UPLC data

UPLC analysis of new RIM Bio 10L bags: no bDtBPP detected



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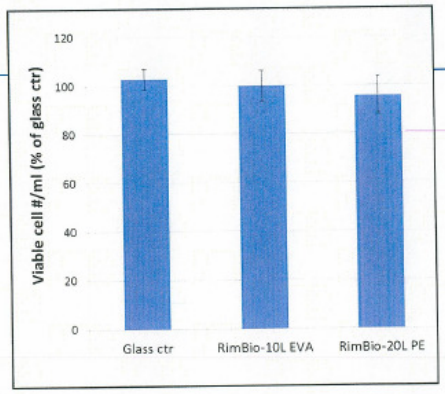
Leachable Testing of RIM Bio 10L Rocker Bags (2014)

- Leachables study
- WFI water at 37C for 3 days
- No inhibition of cell growth observed EVA and PE bags



Leachable Testing of RIM Bio 10L Rocker Bags (2015)

- Leachables study
- WFI water at 37C for 3 days
- No inhibition of cell growth observed
  EVA and PE 10L bags