Technical Report of Flexsafe® 2D Bags in Shell Qualification for Liquid Handling & Shipping

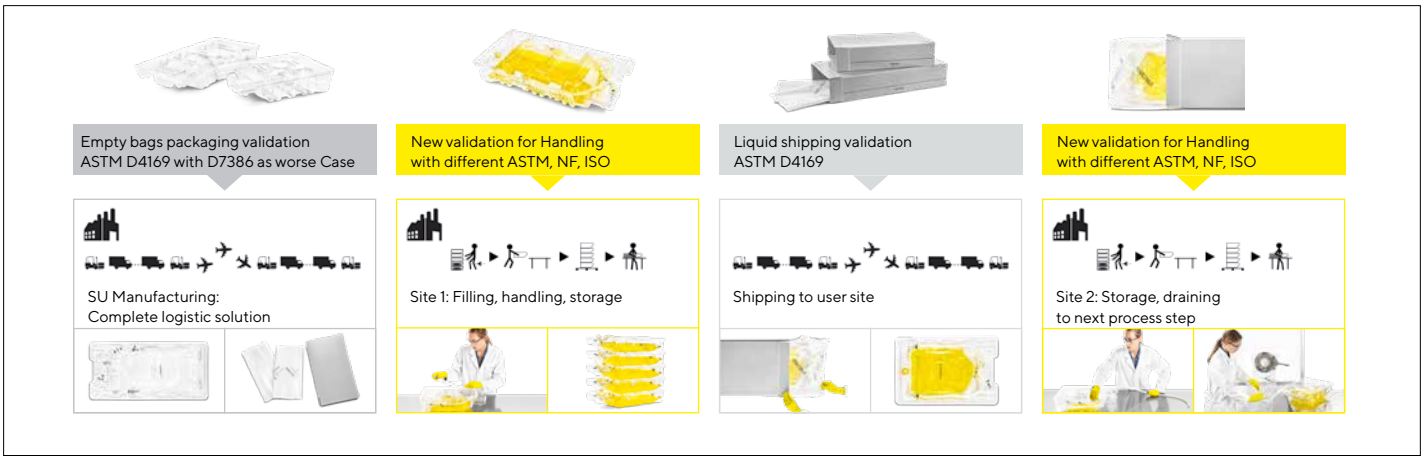
Technical Note

Scope
This technical report describes the qualification of our liquid shipping solutions for Flexsafe® 2D bags in shell 5 L, 10 L and 20 L in order to provide safe and robust liquid handling & transportation. The Flexsafe® shipping systems have been extensively tested against the most stringent international standards ASTM D4169, D7386 and a mix of ISO, EN or NF norms for a range of temperature from 4°C (39.2°F) to 40°C (104°F).

Executive Summary

Sartorius Stedim Biotech has qualified liquid handling & shipping for Flexsafe® 2D bags in shell and shippers in order to support end-users for shipping biotech fluids, like media, buffer, intermediates, drug substances and drug product. The liquid handling & shipping qualification is designed to answer the new challenges associated with the growing adoption of single-use technologies in more critical process steps of cGMP commercial productions and the increased need of transportation of valuable liquids all around the world.

Understanding the product life cycle and associated risks are pre-requisites to establish the suitable qualification testing approach. For truck or international transportation conditions and during manual handling, the shipping system must withstand various mechanical shocks and vibration levels to maintain container closure which have been evaluated during preliminary testing under real conditions and in laboratory. Flexsafe® 2D Bags have been qualified via a 4-step qualification program providing an end-to-end logistic solution for liquid handling & transportation:



Flexsafe® 2D bags offer a safe and reliable end-to-end logistic solution for handling and shipping high critical fluids like bulk drug substances extensively qualified for a range of volumes from 10% to 120% of their nominal volume for a range of temperature from 4°C (39.2°F) to 40°C (104°F).

Qualification Approach

Regulatory agencies like FDA[2], EMA[3] or EU[4] emphasize the need for end-user to ensure that their drug processes produce consistent and reproducible results which meet the quality standard of the drug product. Validation is "Establishing documented evidence that provides a high degree of assurance that a specific process" including shipping "will consistently produce a product meeting its pre-determined specifications and quality attributes" (FDA[2]).

A properly designed system will provide a high degree of assurance that every process step, including shipping has been properly evaluated before its implementation. In the biopharmaceutical industry, qualification and validation are intended to demonstrate that the manufacturing process provides the desired level of compliance of the product and specifically its activity, sterility and potency. Qualification of a shipping system and equipment is part of the process validation.

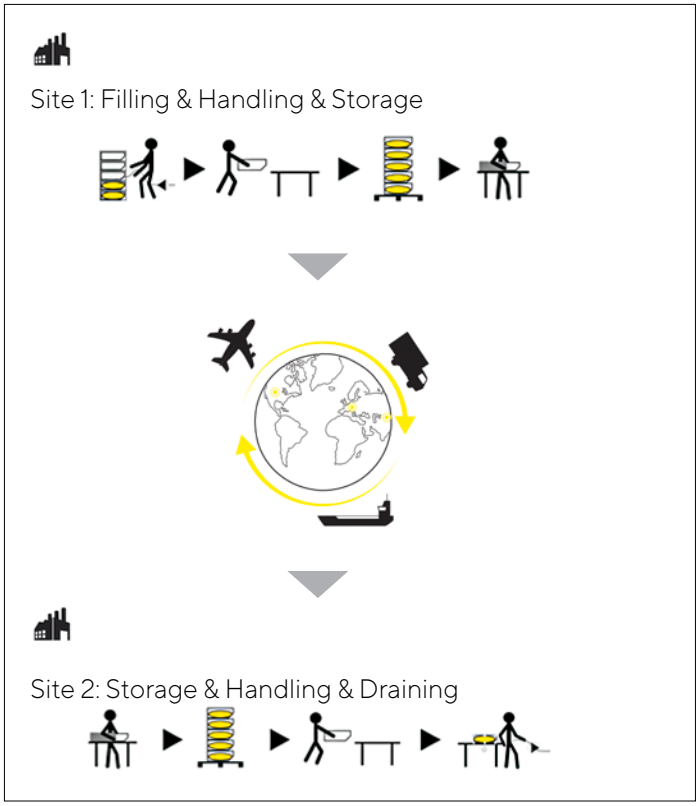
According to the PDA technical report N°665, "Shipping systems must be qualified for their intended use through proper design and testing in consultation with a packaging engineer. The transportation routes must be defined for international shipment. A risk assessment for vibration, handling, delays and seasonal variation should be established.

ASTM D4169[1] are well-known standard norms for simulating under worse case conditions hazards during transportation phases. But what about manual handling during all the filling, storage, manipulation and draining steps that are necessary during the life cycle of the single-use system?

In order to qualify the system with the more relevant testing parameters and provide safe liquid handling & shipping systems, several preliminary tests have been performed before the final qualification testing program.

Since manual handling is not obviously covered by established standards, a first step consisted in identifying the different handling sequences. Secondly, acceleration of the filled Flexsafe® 2D bags in shell during these handling sequences have been measured under normal conditions and more severe conditions. Finally, the analysis of this data in collaboration with a packaging engineer provided the sequence of tests to be performed in order to qualify the system with relevant safety margin.

For shipping qualification, ASTM D4169 testing standards are well known international methods allowing to simulate at worse case level the hazards, shocks, shakes and vibrations impacting a system during transportation. These norms have been used to qualify the packaging of empty bags in shell being shipped from Sartorius to the end-user. They have been used as well to qualify the transportation phases of filled Flexsafe® bags in shell packaged in their shippers and shipped from the filling site to the user site. This technical report provides the rational, testing program and results for filled Flexsafe® 2D bags in shell considering all steps of their life cycle, including handling phases and shipping.



5 L & 10 L shippers with double polyethylene overpouches

Flexsafe® 2D 5 L bag in shell

Dimensions of the Shells:

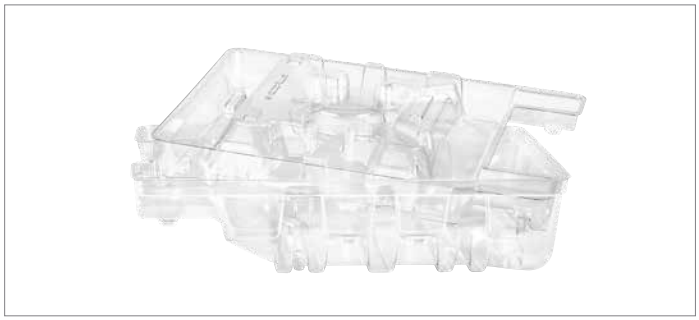
Volume	Length	Width	Height
5 L	562.5 mm	374.8 mm	143.5 mm
10 L	756 mm	375 mm	145.5 mm
20 L	766 mm	581 mm	218,5 mm

Dimensions of the Shippers:

Volume	Length	Width	Height
5 L	600 mm	391 mm	160 mm
10 L	794 mm	391 mm	160 mm
20 L	797 mm	597 mm	227 mm

Material

The solution is composed of Flexsafe® 2D bags ready-to – use in a transparent protective shell for supporting all handling steps. After filling, the bag in shell is packaged into polyethylene overpouches and plastic box providing the appropriate shipping solutions with optimized palletization.



Top & bottom 5 L shells

Test Summary

This logistic solution has been extensively qualified according to the most severe international norms in the industry for both manual handling and transportation cycle covering the entire life cycle:

Step	Specimen	Norm	T=0	T=3y
1. Transportation to customer's site	2D bag in shell	ASTM D4169 D7386	✓	NA
2. Bag in shell Filling & Storage	2D bag in shell	Internal Specification	NA	✓
3. Bag in shell a) Handling & Packaging in shipper	2D bag in shell* & shipper	ISO, NF ASTM norms	NA	✓
b) Transportation	2D bag in shell* & shipper	ASTM D4169 D7386	NA	✓
c) Handling Storage & Draining	2D in shell*	ISO, NF ASTM norms	NA	✓

* Flexsafe® 2D bags in shell samples were the same samples that have been used and have been tested successively for the handling tests, the transportation and finally the second handling tests.

1. Transportation to customer's site

The test program is chosen in order to test the packaged bags in worst case conditions, and are relevant for pallet shipment with ASTM D4169 – Standard Practice for Performance testing of Shipping Containers and Systems- and for single parcel shipment with ASTM D7386 – Performance Testing of Packages for Single Parcel Delivery Systems. Since the single parcel tests program is more severe than the pallet tests, the Flexsafe® 2D bags in shell and the shells alone have been tested according to ASTM D7386.

After the test sequences, the boxes are visually inspected, as well as the over-pouches, the shells and the bags. A functional test was performed by checking the bag and primary overpouch integrity via the dye penetration method.

Sequence of Tests for Single Parcel Shipment (ASTM D7386, Assurance Level II)

Boxes of Flexsafe® 2D bags in shell and shells alone (5 boxes per volume) have been tested according the following test sequence:

Tropical Pre-Conditionning	ASTM D4332	40°C (104°F) | 90%humidity during 72 hours
Free fall drop test	ASTM D5276	4 drop tests 358 mm, 2 drop tests 508 mm
Vibration under compressive load	ASTM D4728	one side 60 min, two sides 30 min
Low pressure	ASTM D6653	40°C & 4°C 595.73 hPa 1 hour
Free fall drop test	ASTM D5276	4 drop tests 358 mm, 2 drop tests 508 mm
Vibration without compressive load	ASTM D4728	two times 30 min opposite side
Free fall drop test	ASTM D5276	2 drop tests 358 mm, 3 drop tests 508 mm, 3 drop tests 813 mm
Stacking – Box compression	DIN 55440	V= ±10 mm/min

Test Configurations

The tested configurations presented a complex tubing assembly, thus representing worst case conditions as described in the table below:

	Type of Finished Product	Packaging Configuration	Irradiation Dose	Quantity of Tested Products
Flexsafe® 2D bags in shell	Standard Flexsafe® 5 L (shell, MPC, LT|MPC)	Single Parcel	25 – 45 kGy	5
	Standard Flexsafe® 10 L (Shell, MPC, LT|MPC)	Single Parcel	25 – 45 kGy	5
	Standard Flexsafe® 20 L (Shell, MPC, LT|MPC)	Single Parcel	25 – 45 kGy	5
Shells alone	Standard Shell 5 L for Handling	Single Parcel	Non irradiated	5
	Standard Shell 10 L for Handling	Single Parcel	Non irradiated	5
	Standard Shell 20 L for Handling	Single Parcel	Non irradiated	5

Test Results
For each configurations, results are listed below:

Packaging of Flexsafe® 2D Bags in Shell 5 L, 10 L & 20 L – Single parcel – ASTM D7386 Assurance Level II

Inspected part	Test	Acceptance criteria	Results
Box for Flexsafe® 2D bags in shell 5 L, 10 L & 20 L	Visual Inspection	No holes, no damage on glued | taped areas, no collapsed boxes	Pass
Primary overpouches	Visual Inspection	No channel, no hole, no tear	Pass
Shells	Visual Inspection	No breakage, no cracks	Pass
Flexsafe® 2D bags and components5 L, 10 L & 20 L	Visual Inspection	No damage, no leak on bags or connections	Pass
	Functional test	No leak	Pass

Packaging of Shells Alone 5 L, 10 L & 20 L – Single Parcel – ASTM D7386 Assurance Level II

Inspected part	Test	Acceptance criteria	Results
Box for Shells 5 L, 10 L & 20 L	Visual Inspection	No holes, no damage on glued | taped areas, no collapsed boxes	Pass
Shells	Visual Inspection	No breakage, no cracks	Pass
	Functional test	Snapping possible	Pass

Conclusion:
Flexsafe® 2D bags in shell and shell alone are safely packaged and their packaging is designed to withstand the most commonly used distribution cycles on pallets or via single parcel shipments.

2. Bag in shell filling and storage

The purpose was to demonstrate the compatibility of the bag with their shell and the ability of securing the tubing all along the life cycle when used at minimum, nominal or maximum filling volumes.

A variety of designs representing the different possibilities of configurations for this product range have been tested:

- tubing lengths from 500 mm to 2,000 mm
- various connectors, e.g. Opta®, MPC, TriClamp, STCII, GammaSart® ...
- configurations with the leak test line

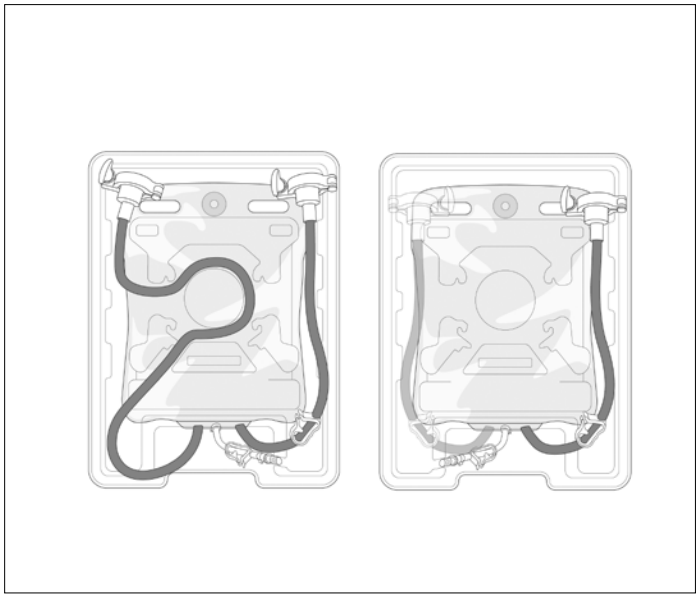
Samples were irradiated at a worse case conditions 50 kGy and were accelerated aged up to an equivalent of 3 years of shelf life.

For each type of configurations, a variety of tests have been performed for simulating the use of the bags from initial handling and filling, up to draining and discarding.

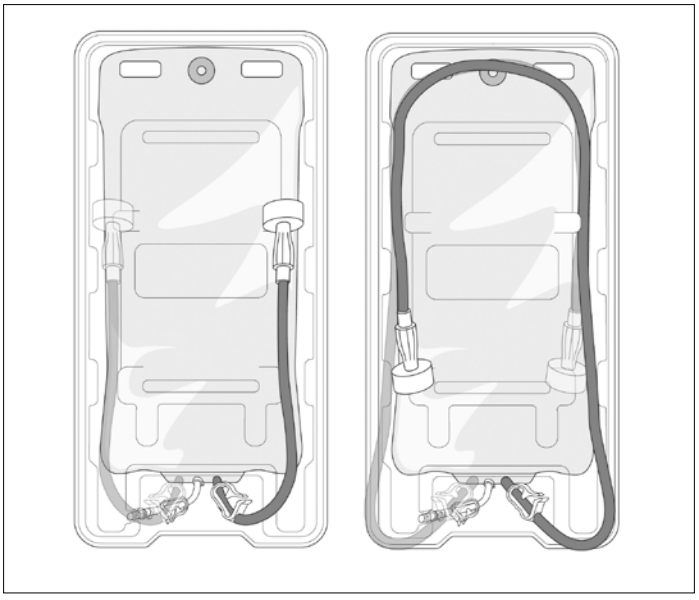
The results are summarized in the following table:

Test	Acceptance Criteria	Results
Assembly	disassembly of the bags in shell system	No plastic deformation of the shell.	Pass
	No damages	leak on the bag and tube line.	Pass
Components and tubing positioning	No contact of the connector with the bag.	Pass
	Draining and filling connector are accessible	Pass
Bags in shell filling by peristaltic pumping	No leakage of the bag nor plastic deformation of the shell	Pass
Shell transparency	Bag visible	Pass
Capability to read the label on tubing or bag	Label readable	Pass
Ensure the containment	leak proof of the liquid in case of bag leakage	The maximal liquid volume remain contained by the system	Pass
Disposal	System is dismountable	Pass
Stacking of bags in shell with up to 1.5 m tube lines	Shell design allow a tube line placement up to 1.5 m	Pass

The Flexsafe® 2D bag in shell system demonstrated its ability to secure the bags and the tubing during handling with a mix worse case configurations. The shells allows to accommodate multiple connectors and tubing lengths from 0.5 m to 2 m as described in the following drawings.



Examples: Flexsafe® 2D bags in shell for 5 L with 2 different configurations (500 mm or 1,000 mm tubing length)



Examples: Flexsafe® 2D bags in shell for 10 L with 2 different configurations (500 mm or 1,500 mm tubing length)

3. Handling, stacking & transportation qualification

The purpose of this test is to demonstrate the mechanical resistance of the shell and the integrity of the Flexsafe® 2D bags during handling, stacking and shipping operations.

The new testing protocol built for this mechanical resistance is a combination of tests elaborated with packaging engineers and R&D experts. The aim was to take into account the complete life cycle of the product:

- Handling in cleanroom when filling the Flexsafe® 2D bags in shell
- Transportation for Flexsafe® 2D bags in shell, packaged into the shipper
- Handling in cleanroom for draining the Flexsafe® 2D bags in shell

Flexsafe® 2D bags in shell for handling and in shippers for transportation have been qualified for safe and robust liquid handling & shipping applications under the most stringent standards like ISO, NF EN, several ASTM norms including ASTM D4169 via the following qualification program.

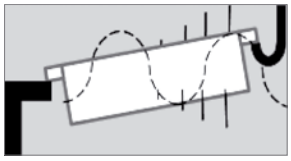
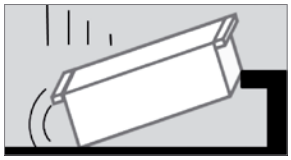
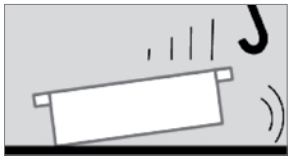
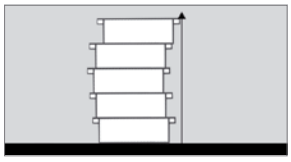
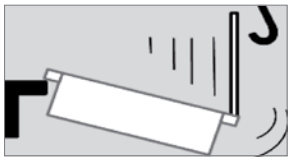
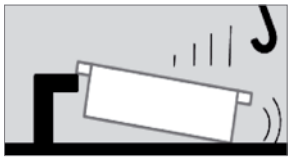
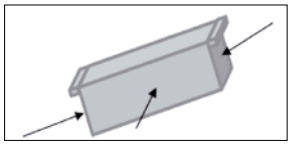
Test Definition

The tests for handling have been defined by understanding how product will be used in real condition. Based on this life cycle analysis, each test has been sorted according to worst case normal usage or accidental:

- Worst case testings simulate a normal usage of the product (ie. Normal handling, installation on table ...) but severized in order to ensure a reliable product performance,
- Accidental testings simulate use cases which normally not occurred. These testing are simulating accident or misusage of the product as bumping in front of a table corner, or an unexpected fall ... Performing this testing provides additional safety margin.

There is no existing standard dedicated to simulate handling for biotech industry. Nevertheless, they are some we can use coming from other industry comparable with application. These norms have been used in order to define the testing method.

Test definition rational, sorting in worst case or accidental type and similar existing standard are summarized in the following table.

Description		Risk	Tests Rational		Existing Norm Close to Application
Vibration		Worst case	▪ Walk of operator carrying the bag in shell (asynchronous walk) ▪ Fatigue of the gripping system		NFH 34-010
Drop on corner		Worst case	▪ Drop of the bag in shell on a bench. Because the product is heavy, the operator tends to first place the corner of the system		ISO 7965
Rotational flat drop		Worst case	▪ Drop of the bag in shell on a bench		ISO 7965
Stacking		Worst case	▪ Vertical deflection measure to qualify stack-ability up to 5 shells		NA
Hangman		Accidental	▪ Rough gripping of the bag in shell by its handle ▪ Bag in shell in semi-free fall and held firmly by the operator's hand		NFH 34-010
Rotational edge drop		Accidental	▪ Accidental fall		ISO 7965
Impact test		Accidental	▪ Accidental shock of the bag in shell on a corner of bench		NFH 060

Tests performed on 10%, 100% and 120% filled volume

Transportation protocol has been defined using well know ASTM D4169 Standards.

Test Protocol

A detailled analysis of product usage in reality allows defining the testing protocol in terms of number and type of test to be performed during the qualification.

Samples were irradiated at a worse case conditions 50 kGy and were accelerated aged up to an equivalent of 3 years of shelf life.

The following tables summarize this rational for handling qualification:

1. First Handling from Filling to Packaging

Life Cycle Analysis				Testing Protocol	
Step for 5 L, 10 L & 20 L	Event | Risk	Type	Maximum Number of Event	Test	Quantity
Before filling, empty shell and bag in shell ▼ After filling, handling of the system to intermediate storage area ▼ From the storage to the packaging area ▼ From packaging to the cleanroom exit area	Stacking	Normal	Few hours	Worst case	24 hours
	Hangman	Accidental*	0	Accidental	1
	Vibration	Normal	Few seconds	Worst case	1 min
	Rotational edge drop	Accidental*	0	Accidental	1
	Rotational flat drop	Normal	4	Worst case	5
	Dropt test on corner	Normal	4	Worst case	5
	Impact test	Accidental*	0	Accidental	1
	Stacking	Normal	Few hours	Worst case	24 hours

* Accidental normally should not occur.
For 20 L products, accidental tests were made separately with new samples.

Measurement of acceleration on filled Flexsafe® 2D bags in shell during handling in real-world conditions with 3 different operators & on filled Flexsafe® 2D bags in shell & in their shipper during testing in laboratory according to the new defined protocol for handling.

Comparison of both measurements in order to confirm the right set up parameters of the testing program used to qualify handling conditions with a revelant safety margin:

- Worst case laboratory sollicitations for normal usage are more stringent than real testing conditions in level and number of sollicitations.
- Accidental sollicitation in laboratory exceed between 2 and 5 times real sollicitations. Real accidental event are in reality really rare. According to protocol, it has been decided to be as safe as possible to apply 2 times per product the 3 types of accidental solicications.

Therefore, applying twice worst case conditions and the 3 accidental testing conditions per product during the qualification will ensure a sufficient safety margin and so the confirmation of a robust solution

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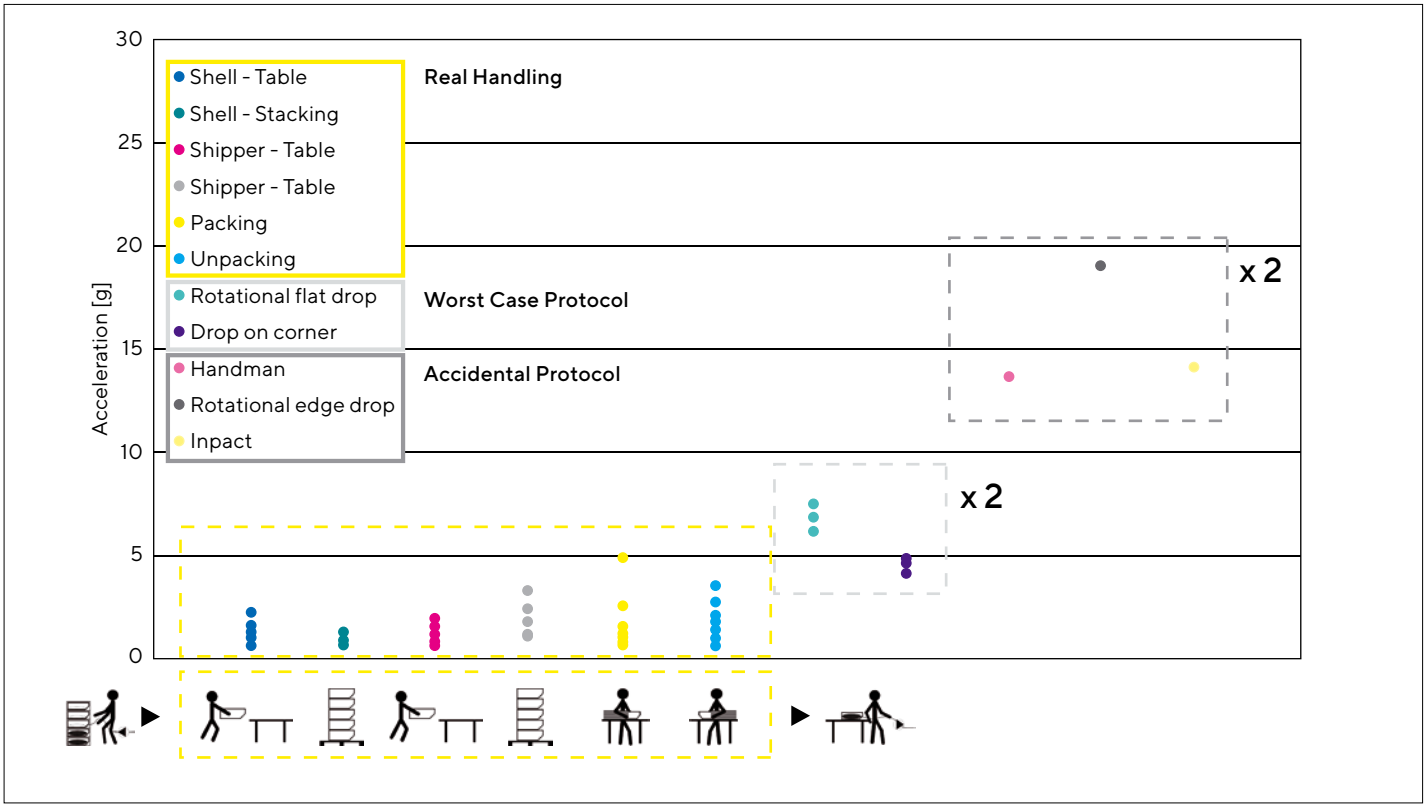
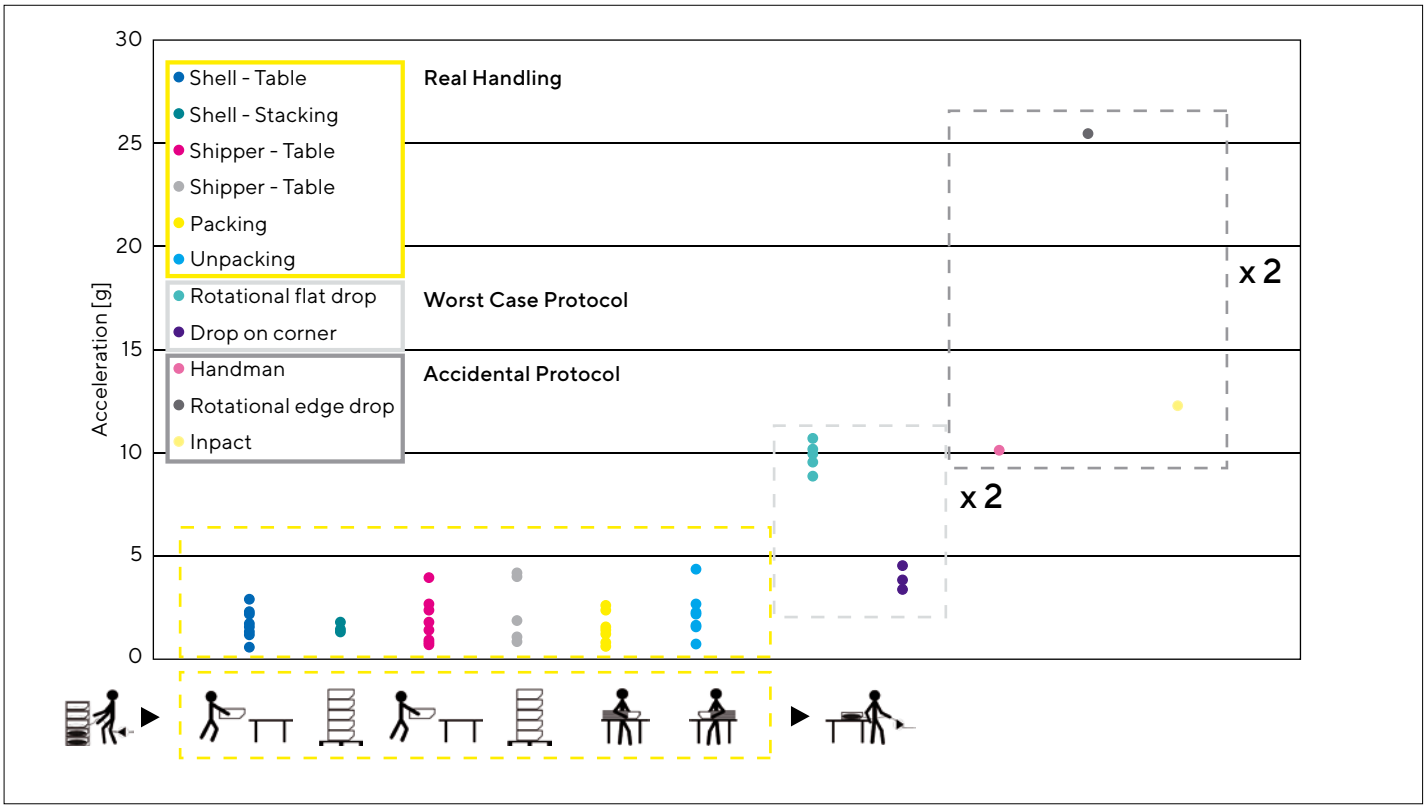
Flexsafe® 2D bags in laboratory shell validation according this defined and confirmed protocol for handling.



5 L Handling Acquisition Real versus Protocol



10 L Handling Acquisition Real versus Protocol

2. Shipping Phase: Transportation Validation Performed According to ASTM D4169 Level I for Pallet Shipment and ASTM D7386 Level II for the Single Parcel

Pallet testing program used for the Flexsafe® 2D bags in shell packaged in their shipper within a range of temperatures: 4°C (39.2°F) and 40°C (104°F) for Flexsafe® bag in shell 5 L, 10 L & 20 L.

The validation protocol has been defined as follow:
Test Sequence Test Reference Based on ASTM D4169–16, Assurance Level I for airplane spectrum, Assurance levels I, II & II for truck spectrum – distribution cycle 12

1 Pre-conditioning 4°C (39.2°F) and 40°C (104°F) during 72 hours

2 Mechanical handling SCHEDULE A
- 2.1 Truck handling ASTM D6055 Method A | 8 cycles round trip
- 2.2 Horizontal impact ASTM D880 Method B | each side 1 shock (total 4)
- 2.3 Rotational flat drop test ASTM D6179 Method C | 2 drop tests (short and long edge)

3 Vehicle vibration SCHEDULE E
- 3.1 Vibration Truck spectrum ASTM D4169 60 minutes truck spectrum (40 min Level III, 15 min level II, 5 min level I)
- 3.2 Low pressure SCHEDULE I ASTM D6653 595.73 hPa – 60 min
- 3.3 Truck & Air spectrum ASTM D4728 Method A | 60 minutes truck spectrum (40 min Level III, 15 min level II, 5 min level I) + 120 minutes airplane spectrum Level I

4 Mechanical handling SCHEDULE A
- 4.1 Truck handling ASTM D6055 Method A | 8 cycles round trip
- 4.2 Horizontal impact ASTM D880 Method B | each side 1 shock (total 4)
- 4.3 Rotational flat drop test ASTM D6179 Method C | 2 drop tests (short and long edge)

Single parcel testing program used for the Flexsafe® 2D bags in shell packaged in their shipper within a range of temperatures: 4°C (39.2°F) and 40°C (104°F) for Flexsafe® bag in shell 5 L, 10 L & 20 L.

The validation protocol has been defined as follow:
Test Sequence Test Reference Based on ASTM D4169–16, section ASTM D7386, Assurance Level II for airplane spectrum, Assurance levels I, II & II for truck spectrum – distribution cycle 13

1 Pre-conditioning 4°C (39.2°F) and 40°C (104°F) during 72 hours
2 Handling SCHEDULE A ASTM D6179-07 | 6 drop tests (2 faces, 2 edges, 2 corners)
3 Vehicle stacking Schedule C Compression test ASTM D642
4 Loose Load vibration Schedule F ASTM D999-08 – 60 min
5 Low pressure SCHEDULE I ASTM D6653 – 595.73 hPa – 60 min
6 Vibration Truck & Air spectrum ASTM D4169-16 – 20 minutes truck spectrum (13 min, 20 s, Level III, 5 min level II, 1 min 40s level I) + 120 min airplane spectrum Level I; 3 faces

3. Final Handling from Clean Room Entry to Draining Area

Life Cycle Analysis				Testing Protocol	
Step for 5 L, 10 L & 20 L	**Event | Risk**	**Type**	**Maximum Number of Event**	**Test**	**Quantity**
From the cleanroom entry to intermediate storage area From the storage to the operational area To the draining area	Hangman	Accidental*	0	Accidental	1
	Vibration	Normal	Few seconds	Worst case	1 min
	Rotational edge drop	Accidental*	0	Accidental	1
	Rotational flat drop	Normal	4	Worst case	5
	Dropt test on corner	Normal	4	Worst case	5
	Impact test	Accidental*	0	Accidental	1
	Stacking	Normal	Few hours	Worst case	24 hours

* Accidental normally should not occur.

This handling step is covered by the same protocol as the point 1 since handling at user site is similar to handling at the first filling site

Test Results

Following the complete life cycle, the same samples of Flexsafe® 2D bags in shell were tested for handling, then tested for transportation (either on a pallet or for single parcel), and finally tested again for handling.

	Ageing	Irradiation Dose	Number of Samples	Norms	Acceptance Criteria	Results
Flexsafe® 2D Bags in Shell 5 L						
At 4°C (39.2°F)	3 years	50 kGy	3 batches, 8 units per batch = 24 units	Handling protocol: mix of ISO, EN NF & ASTM norms (§1, 2)	▪ No leak of the bag ▪ No break of the shell	Pass
At 40°C (104°F)	3 years	50 kGy				Pass
Flexsafe® 2D Bags in Shell & in Shipper 5 L						
Pallet At 4°C (39.2°F)	3 years	50 kGy	3 batches, 24 units per batch = 72 units	ASTM D4169-16, Assurance Level I for airplane spectrum, Assurance levels I, II & II for truck spectrum – DC 12	▪ No leak of the bag ▪ No break of the shell	Pass
Pallet At 40°C (104°F)	3 years	50 kGy				Pass
Single parcel At 4°C (39.2°F)	3 years	50 kGy	3 boxes, 1 per batch	ASTM D4169-16, section ASTM D7386, Assurance Level II for airplane spectrum, Assurance levels I, II & III for truck spectrum – DC 13		Pass
Single parcel At 40°C (104°F)	3 years	50 kGy	3 boxes, 1 per batch			Pass
Flexsafe® 2D Bags in Shell 10 L						
At 4°C (39.2°F)	3 years	50 kGy	3 batches, 8 units per batch = 24 units	Handling protocol: mix of ISO, EN NF & ASTM norms (§1, 2)	▪ No leak of the bag ▪ No break of the shell	Pass
At 40°C (104°F)	3 years	50 kGy				Pass
Flexsafe® 2D Bags in Shell & in Shipper 10 L						
Pallet At 4°C (39.2°F)	3 years	50 kGy	3 batches, 18 units per batch = 54 units	ASTM D4169-16, Assurance Level I for airplane spectrum, Assurance levels I, II & II for truck spectrum – DC 12	▪ No leak of the bag ▪ No break of the shell	Pass
Pallet At 40°C (104°F)	3 years	50 kGy				Pass
Single parcel At 4°C (39.2°F)	3 years	50 kGy	3 boxes, 1 per batch	ASTM D4169-16, section ASTM D7386, Assurance Level II for airplane spectrum, Assurance levels I, II & II for truck spectrum – DC 13	▪ No leak of the bag ▪ No break of the shell	Pass
Single parcel At 40°C (104°F)	3 years	50 kGy	3 boxes, 1 per batch			Pass

	Ageing	Irradiation Dose	Number of Samples	Norms	Acceptance Criteria	Results
Flexsafe® 2D Bags in Shell 20 L						
At 4°C (39.2°F)	3 years	50 kGy	3 batches, 8 units per batch = 24 units	Handling protocol: mix of ISO, EN NF & ASTM norms (§1, 2)	▪ No leak of the bag ▪ No break of the shell	Pass
At 40°C (104°F)	3 years	50 kGy				Pass
Flexsafe® 2D Bags in Shell & in Shipper 20 L						
Pallet At 4°C (39.2°F)	3 years	50 kGy	3 batches, 18 units per batch = 54 units	ASTM D4169-16, Assurance Level I for airplane spectrum, Assurance levels I, II & II for truck spectrum – DC 12	▪ No leak of the bag ▪ No break of the shell	Pass
Pallet At 40°C (104°F)	3 years	50 kGy				Pass
Single parcel At 4°C (39.2°F)	3 years	50 kGy	3 boxes, 1 per batch	ASTM D4169-16, section ASTM D7386, Assurance Level II for airplane spectrum, Assurance levels I, II & II for truck spectrum – DC 13	▪ No leak of the bag ▪ No break of the shell	Pass
Single parcel At 40°C (104°F)	3 years	50 kGy	3 boxes, 1 per batch			Pass

Conclusion:

Flexsafe® 2D bags in shell and in shipper have been extensively qualified for each step of its life cycle according to very severe norms (ASTM, ISO, NF EN). The result demonstrate the robustness of Flexsafe® 2D systems for safe and reliable liquid handling and shipping securing the transportation of bulk drug substances starting at 4°C for Flexsafe® bag in shell 5 L, 10 L & 20 L.

Conclusion

The selection of proven and robust single-use solutions provides end-users with safe and easy-to-use handling systems to minimize risk of product loss. Long-term product integrity and stability is maintained and safe international shipments are ensured.

Flexsafe® 2D bags in shell from Sartorius Stedim Biotech are qualified for liquid shipping at nominal volume under the international norm ASTM D4169-14 level I,II, III for cycle 12 & 13 at 4°C (39.2°F) and at 40°C (104°F) and provide safe liquid shipping for all biotech fluids.

References

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Germany
Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen
Phone +49 551 308 0

USA
Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178

For further contacts, visit
www.sartorius.com