

## Effective Methods for the Testing of Stainless Steel Passivation

Over the years, I have really enjoyed helping quality control engineers realize the full benefit of their investment in our metal testing kits. Through numerous customer interactions, I've noticed a few common challenges that arise more frequently than I could have imagined. I like to use these customer's unsolved knotty issues to help formulate the direction of next-generation product development. Why not take all our customer questions and circulate them back to our design team!

Koslow Scientific's pharmaceutical customers have provided valuable feedback and insight into their operations. Koslow Scientific has incorporated their feedback and suggestions to continually enhance the experience of quality control testing.

Last year I spoke with Julio Nazario of Florida Industrial Contractors, LLC and Borin-Chem Industrial Services Inc. (Puerto Rico.) He provides passivation services to most of the top ten of the global pharmaceutical companies. Julio shared with me some of the challenges that helped drive the development of the [Passi-Flash 3036](#). We discussed the size and shape of tanks but we also discussed the standard specs that pharmaceutical companies need to meet. "Quality is a top concern for the Pharmaceutical industry".

*The FDA (US) PART 211 -- CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS US Federal regulation 21CFR211.65(a) states:*

*Sec. 211.65 Equipment construction.*

*(a) Equipment shall be constructed so that surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.*

*"A well passivated stainless steel manufacturing plant is a baseline requirement for meeting the requirement of FDA 21CFR211.65(a). After the passivation processes have been completed, testing the passivation status is a necessary step to confirm that the passivated surfaces do not contain any free iron. Free iron could react with the pharmaceutical products being produced".*

Julio went on to share his concerns about keeping his technicians safe. "We have technicians who are typically on ladders inside pharmaceutical tanks he continued, using a single handed probe that electronically stores readings is so much better than the old fashioned methods of the past. We need to maintain a clean environment throughout the passivation testing process".

I figured that technicians would lose time if they dropped a Passi-Pad during testing. The technician would have to climb down the ladder and retrieve the pad so that no extraneous material would be left within the tank potentially contaminating or blocking the production process. So, our goals for our next generation product were:

- 1) Enable one-handed operation to perform a passivation test, and load/reload new and exhausted pads.
- 2) Enable testing the vertical walls and ceilings of tanks and pipes
- 3) Keep it simple and repeatable as possible.
- 4) Create a closed-loop for the consumable testing pads, virtually eliminating the ability to drop a pad.
- 5) Data reports export to PC/Excel/csv



The pharmaceutical tanks can be 30 meters tall.



Constant innovation is a guiding principle for Koslow Scientific. In many cases, an existing product is simply improved without a name change or price increase. Changes may not be visible to the end-user but are made to increase durability, and accuracy to ensure long term customer satisfaction. New products are typically in the planning/prototype stage for many years. Koslow Scientific aims for major leaps in performance and usability when designing a new product introduction.

Julio's clients appreciate the passivation verification of the manufacturing line Julio provides with the Passi-Flash 3036. He finds the Passi-Flash 3036 Log Reports are highly valued by his clients.

An example of a log report:

Serial No.	Log No.	Date Time	Result	Reading	Location	Notes
4314	1	2017/06/16 08:24:56	PASSV	-278	Still 16	Performed by Gary
4314	2	2017/06/16 08:24:58	PASSV	-254	Still 16	
4314	3	2017/06/16 08:25:03	PASSV	-298	Still 16	
4314	4	2017/06/16 08:25:05	PASSV	-308	Still 16	
4314	5	2017/06/16 08:25:08	NON-P	-174	Tubing 5	
4314	6	2017/06/16 08:25:10	NON-P	-128	Tubing 5	
4314	7	2017/06/16 08:25:13	NON-P	-111	Tubing 5	
4314	8	2017/06/16 08:25:16	NON-P	-81	Tubing 5	
4314	9	2017/06/16 08:25:20	PASSV	-280	Auger	
4314	10	2017/06/16 08:25:22	PASSV	-339	Auger	
4314	11	2017/06/16 08:25:23	PASSV	-252	Auger	
4314	12	2017/06/16 08:25:24	PASSV	-200	Auger	
4314	13	2017/06/16 08:25:26	PASSV	-309	Auger	
4314	14	2017/06/16 08:25:27	PASSV	-360	Auger	
4314	15	2017/06/16 08:25:30	PASSV	-329	Auger	
4314	16	2017/06/16 08:25:32	NON-P	-563	Auger	
4314	17	2017/06/16 08:25:34	PASSV	-293	Auger	
4314	18	2017/06/16 08:25:35	PASSV	-342	Auger	
4314	19	2017/06/16 08:25:37	PASSV	-301	Auger	

After numerous prototypes, we designed our industry-exclusive [Nib Cartridge System](#). Nibs are loaded by merely pressing the [Passi-Flash 3036](#) onto a Nib held in a special dispensing Tray. The tray also contains a convenient Ejection Port. This port removes spent nibs and holds them for later disposal.



I talked to multiple customers about saving time while passivation testing. Customer feedback also directed the development of the [Passi-Extension Arm \(3036 accessory\)](#). This product helps a technician to test a larger area of a tank without climbing up/down a ladder as often.

In 2020 we will be introducing the “Badger” an accessory kit for the 2026 that brings the NIB system to our existing 2026 customers and also provides the ability to test hard to reach places. The “Badger” includes the [Passi-Probe Pipe Explorer](#) which enables testing pipes with Interior Diameter (ID) of one inch or larger.

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