

Temperature and Speed Analysis of Skinetta Banding Machine and Heat Tunnel Conveyor at Chocolate Packaging Line

*Marielly Rodríguez Román
Master of Engineering in Manufacturing Engineering
Rafael Nieves, PharmD
Industrial Engineering Department
Polytechnic University of Puerto Rico*

Abstract — Food and Drug Administration (FDA) regulates pharmaceutical industries. With this regulations industries are forced to maintain a high quality standard for their product. Novartis manufactures OTC products as well as Animal health products. Periodical Audits are performed to assure that the manufacturing and packaging process are in compliance with established standards and regulations. Based on an audit performed to the chocolate packaging area, an opportunity was found to improve the banding process of chocolate tablets. Lean/Six-Sigma concepts were used to complete a detailed study of the packaging process, performed on the Skinetta Banding Machine. This study increased packaging quality and open a window to further investigate if the chocolate tablets packaging line performs efficiently. Based on the results obtained, it can be concluded that 24's chocolate tablets can be exposed to a maximum temperature of 335°F without affecting the product quality. Skinetta Heat Tunnel operational temperature range is 300°F-335°F.

Key Terms — DMAIC, Improve, Lean, Packaging Order.

INTRODUCTION

Chocolate Laxative cakes are used for the relief of occasional constipation. The product is a scored chocolate bar which contain extract of senna which works gently overnight to help the body return to regularity. The active pharmaceutical ingredient for Chocolate Laxative Tablets is Sennosides, USP. Figure 1 shows a twelve (12) tablets Ex-Lax chocolate cake.



Figure 1
Ex-Lax Chocolate 12 Tablets Cake

After the Manufacturing process of the chocolate laxative cakes is completed, the cakes are transported to the packaging area and further to the warehouse.

Chocolate Packaging Line consists of equipment for foiling, cartoning, weighing, wrapping and sealing. The equipment shown in Table 1 are used to efficiently produce high-quality chocolate tablets. [2]

Table 1
Chocolated Packaging Line Equipments

Description	Manufacturer	Model	Process Step
Foil Wrapper	Westinghouse	XSA-H04713	Wraps chocolate cakes in aluminum foil.
RA Jones Cartoner	R. A. Jones	Legacy	Consumer box filling
Ink Jet printer	Wolke	M600	Print Lot No., Price and Exp. Date on aluminum foil and consumer boxes.
Glue Station	Nordson	Series 3400V	Consumer boxes flap gluing.
Check Weigher	Sartorius Aachen GmbH & Co. KG	SYNUS 15/WS1kg	Consumer box weigh verification.
Tray Loader	Farason	Carton Stacker	Semi-automatic tray loader.
Film Wrapper	Delta Systems	Harrier	Wraps consumer boxes or tray dispenser with shrink film.
Shrink Oven	Lantech	ST-900	Consumer box film over wrap shrinkage.
Bundler Machine	Skinetta	ASK 300b	Consumer boxes are bundled and wrapped in plastic film
Corrugate Case Sealer	Little Davis	LD-19A	Shipping boxes sealing
Ink Jet Printer	Marsh	Unicorn	Corrugated boxes printing

Packaging Banding Machine Temperature ranges has to be evaluated due to melting of chocolate cakes. This range has to be evaluated to be able to apply the banding plastic as required without melting the chocolate cakes. Actually, temperature ranges fluctuate from 270°C-300°C. An analysis and testing must be made to determine if the established temperature ranges are appropriate and don't cause melting of the chocolate. Figure 2 show an Ex-Lax 24's consumer unit.



Figure 2
Ex-Lax 24's Consumer Unit

Objectives and Contributions

The objective of this project is to establish banding machine operational temperature ranges without affecting the chocolate laxative product quality.

The main contributions when the temperature analysis is completed are to assure an excellent high quality product and convenient packaging not only for the consumer but for the product conservation. This also means waste reduction and increase in the line consumer unit output by avoiding constant interventions with the banding machine.

LITERATURE REVIEW

Packaging Chocolated Line includes a primary packaging area and a secondary packaging area. Primary packaging is the term used to designate the layer of packaging in immediate contact with the product; this means that is the first packaging layer in which the product is contained. The properties

of the product (form, dimensions and consistency) dictate the importance of the primary packaging area.

Primary packaging can have various applications and functions, depending on the product, transit and storage variables. [2] The most important aspect is to protect and preserve the product from external conditions or contamination. It also serves to protect the product when being stored for long periods. In case of chocolate cakes the first packaging layer is the foil wrapper which is used to wrap the chocolate cakes with aluminum foil.

Secondary packaging is used to group various pre-packaged products together. Secondary packaging is not in direct contact with the actual product. The purpose of the secondary and primary packaging may be the same (to protect and preserve the product). [2] Secondary packaging can be said to have two main functions:

- Branding & Display. Secondary packaging plays a vital role in the marketing strategy surrounding the product. This is especially relevant in the case of display packaging.
- Logistics. Secondary packaging serves to group several products together for ease of handling, transport and storage. This means that secondary packaging must be able to:
 - Contain relatively large volumes of primary packaged products.
 - Transport the product safely to its retail or consumer destination.
 - Keep the primary packaging in its original condition during storage.

Secondary packaging is intended to protect not only the product, but also the primary packaging, which often is the packaging most visible to the consumer in retail displays. Materials used for secondary packaging include cardboard cartons, cardboard boxes and plastic. Figure 3 shows Chocolated cakes packaging process flow chart.

Primary Packaging

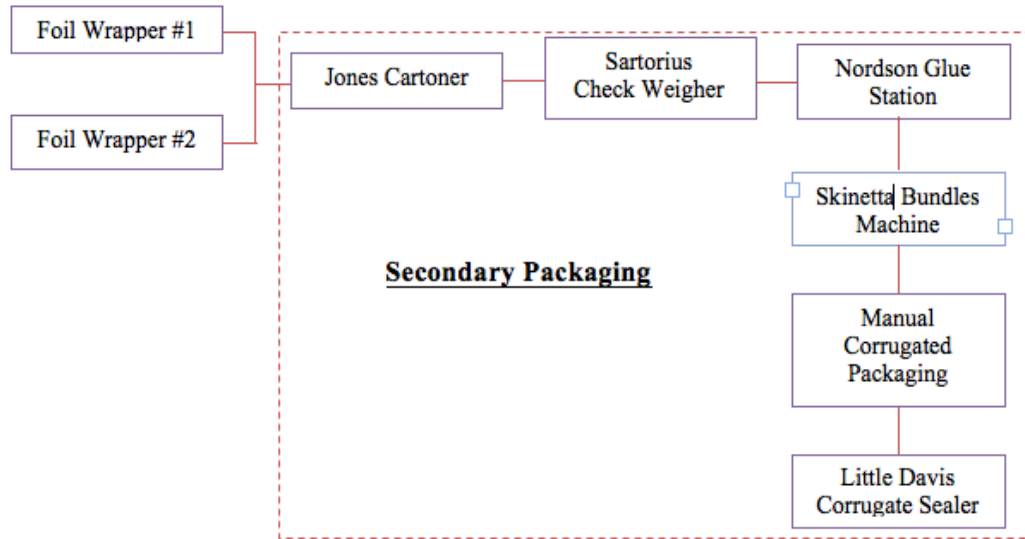


Figure 3
Chocolated Packaging Line Process Flow Chart

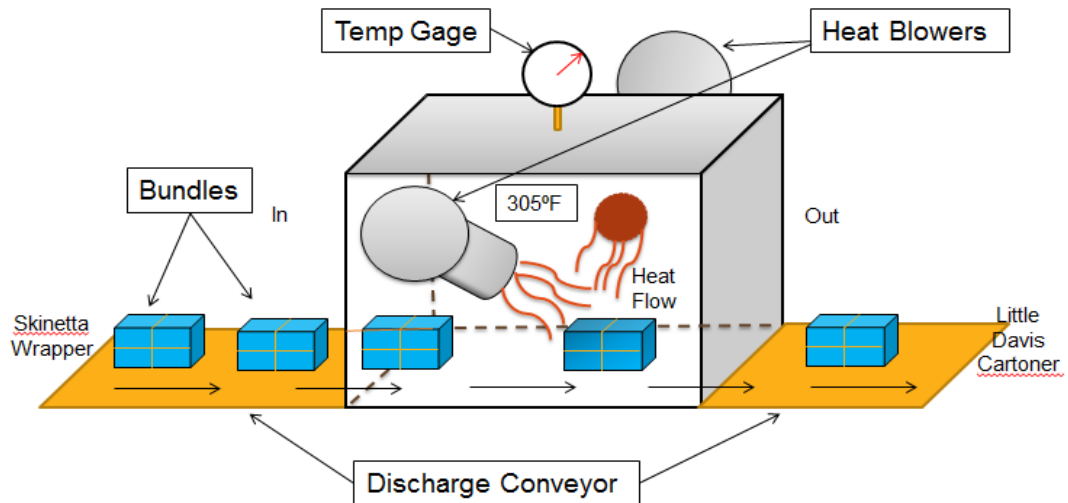


Figure 4
Skinetta Bundling Machine Heat Tunnel

METHODOLOGY

The methodology being followed during the Temperature and Speed Analysis of Skinetta Bundling Machine at Chocolate Packaging Line is DMAIC (Define, Measure, Analyze, Improve and Control).

Define

Skinetta Bundling machine used in the chocolate packaging line to apply banding plastic to

chocolate consumer units. Consumer units are pass through a heat tunnel at established temperature ranges 270°F-300°F as shown in Figure 4. It is assumed that the temperature inside of the Heat Tunnel is equally distributed. [3] This means that heat is uniformly applied to the consumer units.

A new heat tunnel temperature range will be determined due to a FDA observation regarding an improper setting of the Skinetta Bundling Machine. It was found that the Skinetta Bundling Machine was set to a value above 300°F. This is an out of

parameter situation, a deviation was generated to investigate and propose corrective actions to resolve the situation. Based on the investigation it was determined to perform a product impact study for the Skinetta Banding Machine.

Conveyor velocity is part of the critical process parameter since the speed at which the consumer units pass through the heat tunnel, could impact the temperature range to be determinate. Conveyor speed varies between presentations as shown in Table 2.

Product impact study will be performed to Ex-Lax 12ct, 24ct and 48ct United States (US) presentations, in order to analyze and test to avoid product impact when packed chocolated tablets pass through Skinetta Heat Tunnel at established conveyor speed. Figure 5 shows the bundle configuration for Ex-Lax 12's, 24's and 48's. Red arrows demonstrate where the bundle receives the greater amount of heat from the blowers.

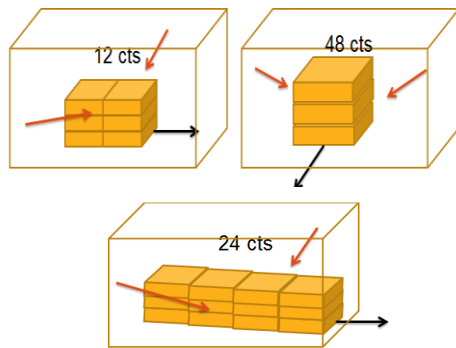


Figure 5
Ex-Lax 12's, 24's and 48's Bundles

Measure

Skinetta heat tunnel temperature and conveyor speed are the main variables of this project. During the testing phase, different conveyor speed and heat tunnel temperature parameters will be tested to evaluate the temperature impact on the chocolate tablets. New operational ranges will be established. Packaging order and Work Instructions will be updated based on this new operational range.

Analyze

Current Skinetta Operational parameters are set as established on Table 2. During a walk through,

it was found that the Skinetta Heat Tunnel was set to 306°F. A product impact study was required to determine the impact of the chocolated tablets when exposed to temperatures above the established operational range (270°F- 300°F). Figure 6 shows how the chocolate cakes are placed inside the consumer units. As part of the study, the shrinking of the plastic applied to the bundle will be also evaluated. Temperature and speed study analysis will be performed to determine new Operational ranges for Skinetta banding machine and conveyor. Analytical testing will be performed by Laboratory personnel to the samples taken.



Figure 6
Consumer Units Chocolate Cakes Configurations

Table 2
Chocolated Packaging Line Current Operational Parameters

Presentation	Current Temperature Range	Current Speed Setting
Choco Tabs 12's	270°F-300°F	70%
Choco Tabs 24's		70%
Choco Tabs 48's		60%

The first phase of the study consists of challenging each of the three chocolated presentations at its worst-case scenario without product. Table 3 shows the Skinetta Heat Tunnel temperatures to be tested. At minimum temperature conveyor speed will be set to maximum velocity (70%), at maximum Temperature conveyor speed will be set to minimum velocity (60%). By performing this test it can be determinate at what operational range the shrinking process of the Skinetta banding machine is performed correctly.

Table 3
Skinetta Banding Machine Temperature Range

Temperature (°F)														
265	270	275	280	285	290	295	300	305	310	315	320	325	330	335

Once the temperature and speed ranges are challenged without product, a chocolate temperature study will be performed to see if this new ranges do not affect the product quality (Phase 2). Using three commercial lots (one for each presentation), temperature effect on chocolate will be challenged with phase one operational ranges. Visual inspections and Analytical analysis will be made to see if the Skinetta Heat Tunnel temperature affects the product quality. Representative samples of consumer units will be taken. Hundred percent (100%) visual inspection will be performed to the samples taken at the moment of the testing. Analytical testing such as description, identification and assay will be performed to the samples taken.

Improve

Once all of the analytical testing is completed and satisfactory results are obtained. It will be concluded that the product quality and packaging process is not affected by Skinetta Heat Tunnel temperatures above 300°F. New operational range will be established.

Control

After the laboratory and visual inspection results are completed new temperature and speed ranges will be established for the Skinetta banding machine and conveyor speed. Work Instructions will be updated and personnel will be trained on the new operational ranges. Packaging Order will be also updated as part of the controls to assure that the equipment is being operated as intended.

RESULTS AND DISCUSSION

Following DMAIC strategy, the design phase consisted of determining what was the strategy to be used for the product impact study performed.

Define

Ex-Lax 24chocolated tablet United States presentation was the first to be tested as part of the exercise. The first challenge consisted of passing thirty (30) bundles every ten (10) minutes through the Skinetta Heat Tunnel for a period of thirty (30) minutes starting at a temperature of 335°F and a conveyor speed 60%.

Measure

The measure phase consisted of a visual inspection performed by the Quality Assurance personnel to the ninety (90) samples taken.[4] If any of the defects shown in Table 4 are found, the test should be performed again and the Skinetta Heat Tunnel temperature was decreased five (5) degrees until the bundles were properly packed. These results were documented on a Visual Inspection Results Form.

Table 4
QA Visual Inspection Defects

Visual inspection Defects	Acceptance Criteria (Accept 0/ Reject 1)
Plastic wrap broken or slightly affected.	0
Plastic wrap broken or slightly affected.	0

After a total of ninety (90) bundles passed through the Skinetta Heat Tunnel Banding Machine, Quality Assurance personnel inspected the samples. No defects were observed. Table 4 shows the temperatures, samples taken and Quality Assurance inspection results for Ex-Lax 24's presentation.

After the testing was completed the new operational temperature range is 300°F-335°F. This temperature operational range will be used to perform testing with chocolate tablet cakes on phase 2 of this project.

Table 4
Ex-Lax 24's Quality Assurance Inspection Results

Presentation	Temperature	Samples taken	QA Inspection	New Temp Range
24's	335	90	Pass	300°F-335°F
	325	90	Pass	
	300	90	Pass	
	295	3	Fail	
	290	3	Fail	
	285	3	Fail	
	280	3	Fail	

Analysis

The second phase (analysis phase) consists of challenging Ex-Lax 12's, 24's and 48's product quality attributes during the banding process in the Skinetta Banding machine.

For Ex-Lax 24's US presentation, Skinetta Heat Tunnel will be set at 60% conveyor speed and at a temperature range of 300°F-335°F (parameter obtain in phase 1). The first temperature to be challenged is 335°F. Eighty (80) consumer units were taken every three (3) minutes for a period of nine (9) minutes. If any defect was observed when taking the samples, Skinetta Heat Tunnel Temperature must be decreased to 5°F until no defect is observed. Once the sampling process is completed, Quality Assurance personnel must inspect the samples. The possible defects to be found are:

- Deteriorated product.
- Illegible logo caused by melted chocolate.
- Melted chocolate (not causing illegible logo)
- Chocolate cake breakage.

Improve

Once the two hundred and frothy (240) samples are taken and Quality Assurance approves the visual inspections, ten (10) samples from beginning middle and end will be taken to perform analytical testing. The analytical testing consists in: Description, Identification and Assay testing as describe on Table 5.

After the laboratory testing is completed and the results are satisfactory a new Skinetta Heat Tunnel Temperature range will be established.

Table 5
Ex-Lax 24's Quality Assurance Inspection Results

Analysis or Test	Specification
Description	A dark chocolated Tablet Embossed with "ex-lax" on one side
Identification	Correspond in color and mobility to USP Sennosides Reference Standard Solution
Assay 15mg Sennoside per tablet (formula amount)	14.25mg-15.75mg 95%-105% of formula amount

Control

A Change Control will be generated to update the packaging orders, SOP's and Work Instructions. After the documentation is updated, impacted personnel will be trained on new operational parameters.

CONCLUSIONS

DMAIC was used to provide structure to the Product Impact Study. This way the two phases of the project could be evaluated, executed and obtained satisfactory results.

The project scope established that Ex-Lax 12's, 48's and 24's presentations were to be used as worst case scenario. Due to business delay only 24's presentation was tested.

On May 2014, Ex-Lax 24's chocolate tablets presentations was challenged at 70% conveyor speed and exposed to Skinetta banding Machine Heat Tunnel at a range of 270°F to 335°F. During this exercise it was found that exposing 24's chocolate tablets to a heat tunnel temperature range of 300-320°F does not affect the banding of the consumer units or the product quality.

Additional testing was performed as part of the Temperature and Speed Analysis for the Skinetta Banding Machine, conveyor speed was set at 60% and the Skinetta Heat Tunnel Temperature was set to 335°F. Approximately three hundred consumer units were inspected as part of the product impact study. Quality Assurance inspected samples at a heat tunnel temperature of 300°F, 320°F and 335°F.

No banding defects were observed. Analytical results showed that de description, identification and assay results were satisfactory.

Based on the results obtained from this study, it can be concluded that 24's chocolate tablets can be exposed to a maximum heat tunnel temperature of 335°F without affecting the product quality. Skinetta Heat Tunnel operational temperature range is 300°F- 335°F. Standard Operational Procedure as well as the Packaging Order will be updated to include new 24's temperature range. Impacted personnel will be trained on new temperature range.

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