

Determination of Punches' Lubrication Parameters for a Tablet Press Machine Using Single Tip Tooling Configuration to Compress an Analgesic Consumer Healthcare Product

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Abstract — *The main goal of this engineering study is to determine a proper set of values for the lubrication interval parameters used for the punches of a tablet press machine. The values obtained will be referred as the starting point values during the tablet press machine setting up process. The scope considered in this engineering study is a tablet press machine assembled with single tip tooling to compress an over the counter analgesic product. A protocol document will be executed, which is a formal documentation practice used widely in the regulated industry. Finally, obtaining these parameter values will enhance the tablet press machine set up time, and assuring both; machine functionality and safety, and to avoid a product impact by over lubrication.*

Key Terms — *Lubrication, Parameter, Tablet Compression Process, Temperature.*

INTRODUCTION

Proper punches' lubrication in a tablet press machine is a key aspect for the assurance of the tooling and turret useful life, and the quality of the product being compressed. In order to fulfill both important characteristics, a correct determination of the intervals for the punches' lubrication parameters should be addressed. Thus, if poor lubrication is obtained in the tablet press machine, then the tooling and its turret will be damaged compromising the compressing machine functionality and usefulness of its tooling parts. In the other hand, if excess lubrication is obtained, then the product might be affected by the over lubrication effect on the tablet press machine, resulting in stained tablets, such as black spots.

RESEARCH OBJECTIVES

The objectives pursued through this engineering study are categorized in the following areas:

- Improvement of the set up process:
The determination of the punches' lubrication parameters values will provide the starting set point to the tablet press operator. This represents a time reduction during the machine set up process and eliminates the process variability generated by the machine operators during the selection of the lubrication parameters based on the operators' experience or criteria.
- Improvement on product quality:
Part of the acceptance criteria during the determination of the punches' lubrication parameter values is that they cannot produce excess lubrication, in such a way that the product may be impacted by been mixed up with the punches' lubricant, creating stained tablets.
- Improve in equipment reliability:
By acquiring a correct set of punches' lubrication parameter values, it will assure that the tablet press' tooling components, such as the punches' set, the die table or turret and its cam parts will be better protected against wear and fatigue effects. This will improve the tablet press' reliability and performance, and will extend its useful life, increasing machine uptime and providing a consistent production process. Proper lubrication over the machine's punches will reduce machine downtime due to stuck punch events. Moreover, it also reduces

compliance events by avoiding product quality impact due to stained tablets.

RESEARCH CONTRIBUTIONS

The execution of this engineering study will contribute in several aspects to the manufacturing operations of a consumer healthcare provider company located in Guayama, Puerto Rico. Through this experimental exercise a formal procedure can be established to perform similar studies to determine key equipment parameters used for manufacturing purposes for existent or new presentations as needed. As part of the tools and practices pursued in the manufacturing environment, a culture of standardization can be introduced in the set up processes by providing machines' specific parameter values for the product presentations to be compressed. This avoid that the setting up of the lubrication parameters to be an operator dependent activity at the beginning of the tablet press machine initial compression process. Moreover, establishing these lubrication parameters also contribute to improve the tablet press machine reliability by extending its tooling parts useful life.

BACKGROUND INFORMATION

The process where a mixture of granules or powder is compacted to form a tablet is called the tablet compression process. In modern days, the tablet compression process is performed by high speed rotary press machines, which are capable to monitor and control key process parameters for the tablets being produced, reducing the process variability [1].

This proposed engineering study is for the determination of lubrication parameters for a rotary press machine used for tablet compression process. The tablet compression process can be divided in three major phases: die filling, tablet compression and tablet ejection [2].

The Die Filling Phase

The die filling phase is the process where the granulation is served into the dies' orifice for the

lower and upper punches to compress it and form the tablet.

The first step in this phase is known as the over dosing (Figure 1). During this step the lower punches are lowered, one by one, inside the filling cam. Then, the granulation is introduced to the dies' orifices by means of the feeder assemblies. The over filling will be based on the size of the fill cam. Excess granulation is provided in this step to ensure proper tablet target characteristics during tablet compression.

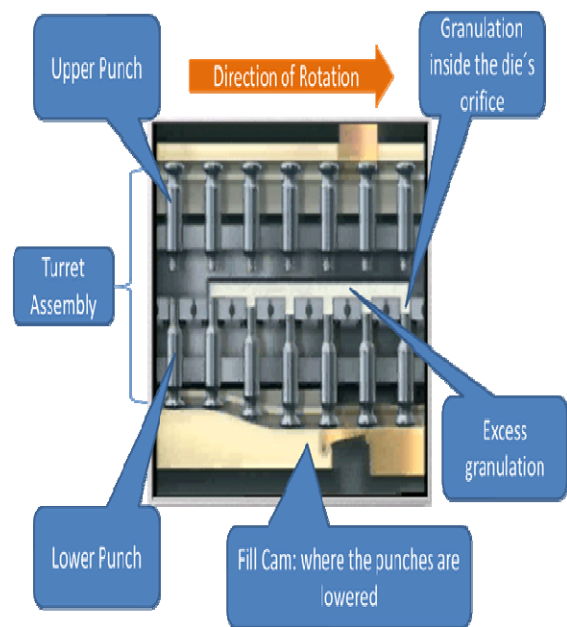


Figure 1
The Over Dosing Step

The second step in the die filling phase is known as the final filling (Figure 2). In this step the lower punches pass from the fill cam to the dosing cam. The final granulation volume inside the dies' orifice is set at the dosing cam. The control of the tablets' weight is performed automatically by adjusting the dosing cam through up and down displacements. Moreover, at the dosing cam, the lower punches are set to their final fill position, and then the excess granulation is removed by a scraper blade.

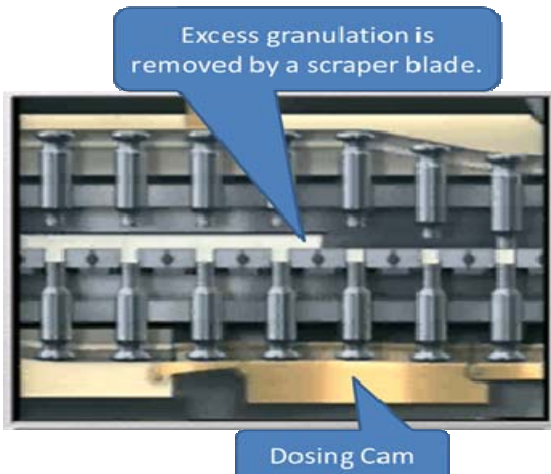


Figure 2
The Final Filling Step

The Compression Phase

The compression phase is where the granulation inside the dies' orifice is compacted by the inward movement of the lower and upper punches to form the tablet.

The first step is known as pre-compression (Figure 3). This step may be optional, depending on the compression process requirements. In this case, the pre-compression step is required as determined in the validated process where this engineering study is executed. The upper punches are moved downward through the cam assembly into the dies' orifice. During this movement the punches' heads pass under a roller, which exerts an initial compression force with the purpose to remove the air from the granulation inside the dies' orifice.

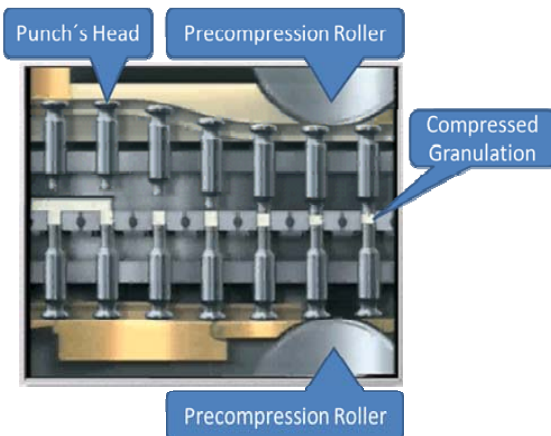


Figure 3
The Pre-compression Step

The second step is known as the main compression (Figure 4). In this step the tablet gets its final form and thickness by exposing both upper and lower punches to a second set of compression rollers, known as the main rollers. The force applied by the main compression rollers is also used to control the tablet weight.

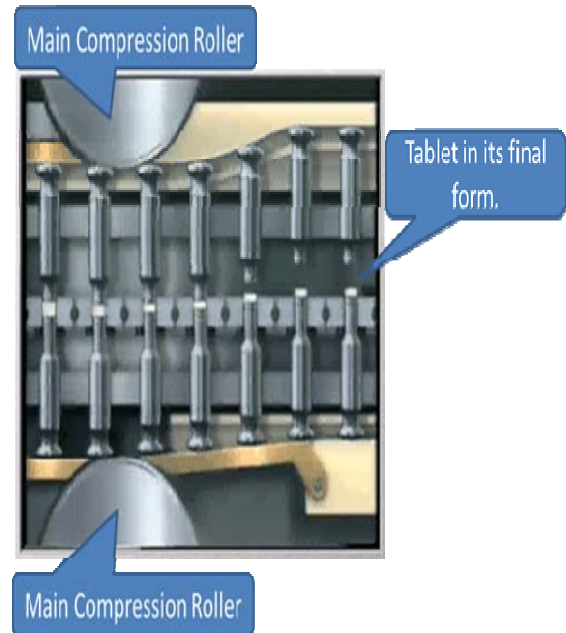


Figure 4
The Main Compression Step

The Tablet Ejection Phase

The formed tablet is ejected from the die's orifice through the take-off and the chute mechanisms (Figure 5). The lower punches are moved in an upward displacement, at the ejection cam, exposing the tablet over the die table surface. Moreover, the upper punches move in an upward displacement to leave the pathway clear of obstructions in order to expose the tablet freely. Once the tablet is exposed at the die table surface, a mechanism known as a the tablet take-off send the tablet through the chute mechanism where it can be discriminated as good or bad product.

Finally, in a rotary press machine, the tablet compression process is executed continuously, starting with the die filling phase again.

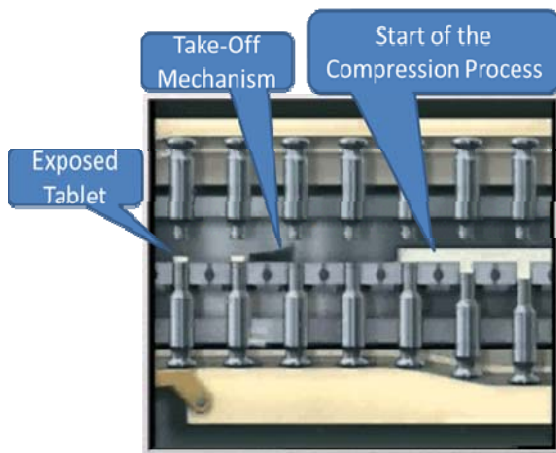


Figure 5
Tablet Ejection Step

The Importance of the Punches' Lubrication in the Tablet Compression Process

The pharmaceutical compression process of solid tablets is one of the most critical processes in drug manufacturing, because there is a high degree of consistency and accuracy that must be met at all times. Moreover, when considering compression processes using high speed equipment, the moving parts are more prone to fatigue and to heat up due to friction. The probabilities for these parts to get stuck during machine operation also increases. For example, taking into account a tablet press machine, with a turret speed of 50 to 70 revolutions per minute, which could give a production capability of 4,000 to 5,600 tablets per minute, may develop a temperature range of 100 to 120 degrees Fahrenheit at the punches' surface [2]. Such situation, if not properly addressed, may produce a catastrophic event at the tablet press parts, especially at the punches, which are the movable parts responsible for the compression of the tablet. The proper lubrication of the movable parts in this type of equipment is an essential part for the machine correct functionality and parts' useful life extension and temperature control due to friction. Thus, the engineering study proposed in this document will focus its effort in the punches' lubrication parameters of a specific tablet press machine.

Description of the Lubrication System

The lubrication system is comprised of an oil reservoir with a pressure pump, lubrication lines, a block of electro-valves and piston distributors to control the amount of oil dispensed. This lubrication system works through lubrication interval parameters that can be controlled individually via the human-man interface unit of the tablet press machine. These lubrication intervals can be adjusted from 1 to 24 minutes. The system's pump has a fixed "on" time period of 40 seconds to ensure that a constant lubrication line pressure is applied. Notwithstanding, this does not influence on the amount of oil dispensed. The amount of oil to be supplied to each point is determined by the piston distributors.

The lubrication system of this specific tablet press machines provides lubrication for the following circuits (Figure 6), which they are also the lubrication interval parameters that can be controlled:

- Upper and lower punch heads
- Upper punch shafts
- Lower punch shafts
- Ejection cam

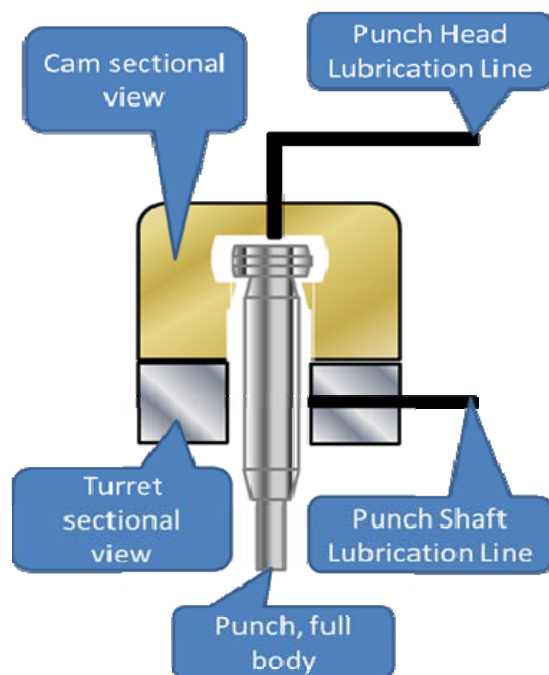


Figure 6
Lubrication Circuits

RESEARCH METHODOLOGY

To determine a proper set of parameters for the lubrication intervals of the tablet press machine's punches, the following criteria are required:

- The methodology implemented cannot impact the current validated state of the equipment. It should be simple and cannot consider modifications in the equipment programming, components or parts [3]. To meet this criteria it is proposed to perform an engineering study through the execution of a protocol, which is an official and valid documentation resource widely used in the pharmaceutical industry [3]. This protocol will be created following the current and official standard operating procedures established by the consumer healthcare provider company [4]. In this protocol we will perform the monitoring of the punches' temperature and a visual inspection over the press machine's turret and punches to determine the lubrication condition of the tablet press' parts. Changes to the current lubrication frequency parameters will be only allowed depending on the results from the monitoring process.
- The production schedule should not be impacted. With the current demand, the equipment cannot be put out of service or quarantined during the execution of this methodology. To meet these criteria, the protocol will be executed using three commercial batches. These batches are of the exact product where the engineering study needs to be performed. Due to the fact that the validated status of the machine will not be impacted by the considerations proposed to meet the criteria in the first bullet, there will be no need to quarantine the machine and the production during the protocol execution.

The Protocol Scope

The lubrication interval parameters that will be determined through the protocol execution are the following:

- Upper and lower punch heads
- Upper punch shafts
- Lower punch shafts
- Ejection cam

The acceptance criteria for the determination of the lubrication interval parameters are the following:

- Punches' shafts temperature cannot exceed 104 degrees Fahrenheit. This will be confirmed by temperature measuring tests.
- Punches' heads and shaft must show presence of lubricant all over. This will be confirmed by visual inspection.
- The turret cannot show excess of lubricant over its surface, which could lead to product contamination. This will be confirmed by visual inspection.

The protocol execution process and final outcomes from this exercise is expected to be the following:

- Tablet press machine speed will be tested at 50, 55 and 60 revolutions per minute.
- One complete lot for each machine speed setting will be evaluated.
- Final determined parameters will be saved as part of the tablet press recipes.
- Saved parameters will be considered as the starting set points during machine set up process.

RESEARCH RESULTS

After the execution of the proposed protocol for three different lots and at different tablet press machine speeds of 50, 55 and 60 rpm's, the results were recorded in the protocol's data record forms. Information on the current lubrication interval parameters' values was obtained as well as punches' temperature readings and lubrication visual inspections. For each of the tablet press machine speed settings tested; 50, 55 and 60 RPM's; refer to the following tables; Table 1, Table 2 and Table 3 respectively:

Table 1
Lubrication Interval Parameters at 50 RPM's for Lot 1

Time Interval	Punch Lubrication Visual Inspection		Temperature Reading (Degrees Fahrenheit)	Lubrication Interval Parameters (minutes)			
	Pass	Fail		Upper / Lower Head	Upper Punch Shaft	Lower Punch Shaft	Ejection Cam
Setup	X	N/A	80.0	10	2	2	6
30 Min.	X	N/A	104.5	10	2	2	6
1 Hour	X	N/A	97.0	11	2	2	6
2 Hours	X	N/A	97.6	11	2	2	6
4 Hours	X	N/A	96.8	11	2	2	6
6 Hours	X	N/A	98.2	11	2	2	6

Note: No excess lubrication over the turret was observed during the test. Punches' body lubrication was satisfactory.

Table 2
Lubrication Interval Parameters at 55 RPM's for Lot 2

Time Interval	Punch Lubrication Visual Inspection		Temperature Reading (Degrees Fahrenheit)	Lubrication Interval Parameters (minutes)			
	Pass	Fail		Upper / Lower Head	Upper Punch Shaft	Lower Punch Shaft	Ejection Cam
Setup	X	N/A	77.8	10	2	2	6
30 Min.	X	N/A	105.7	10	2	2	6
1 Hour	X	N/A	94.3	11	2	2	6
2 Hours	X	N/A	89.6	11	2	2	6
4 Hours	X	N/A	95.0	11	2	2	6

Note: No excess lubrication over the turret was observed during the test. Punches' body lubrication was satisfactory.

Table 3
Lubrication Interval Parameters at 60 RPM's for Lot 3

Time Interval	Punch Lubrication Visual Inspection		Temperature Reading (Degrees Fahrenheit)	Lubrication Interval Parameters (minutes)			
	Pass	Fail		Upper / Lower Head	Upper Punch Shaft	Lower Punch Shaft	Ejection Cam
Setup	X	N/A	81.2	10	2	2	6
30 Min.	X	N/A	106.1	10	2	2	6
1 Hour	X	N/A	92.2	11	2	2	6
2 Hours	X	N/A	94.2	11	2	2	6
4 Hours	X	N/A	98.0	11	2	2	6

Note: No excess lubrication over the turret was observed during the test. Punches' body lubrication was satisfactory.

Observations

From the data collected in the previous tables, the following could be observed:

- The punches bodies' lubrication had satisfactory results for the three speeds, because all the inspections were marked as PASS as per the visual inspections performed during the protocol execution.
- Temperatures over the 104 degrees Fahrenheit limit were observed and adjustments were required for the three speeds when using 10 minutes for the Upper / Lower Head parameter.
- During the execution of the protocol at 50, 55 and 60 RPM's it was demonstrated that, with the final interval lubrication parameters obtained, the punches' bodies temperature did not reached 104 degrees Fahrenheit, which was one of the acceptance criteria that must be met during this process monitoring.
- The final values obtained are the following:
 - Upper / Lower Head: 11 minutes
 - Upper Punch Shaft: 2 minutes
 - Lower Punch Shaft: 2 minutes
 - Ejection Cam: 6 minutes

With the parameters set to the values established above, it could be demonstrated that the punches temperatures remained under the acceptance criteria after one hour operation of the tablet press machine (Figure 7).

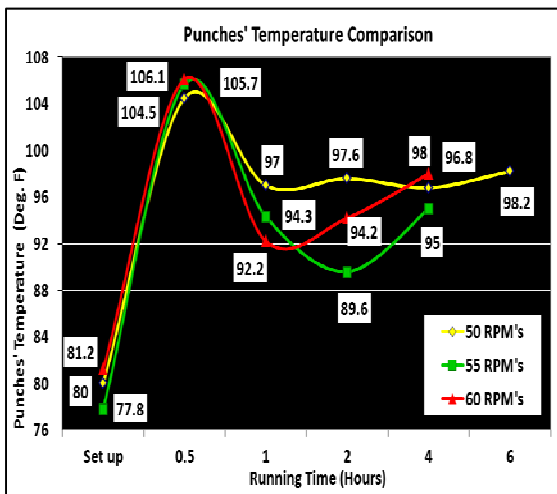


Figure 7
The Punches' Temperature Comparison

In Figure 7 it is important to note how the punches' temperature shows a converging trend between the different machine's speeds, after the fourth hour of the tablet press operation. At this point, the temperature readings were 98.0 degrees Fahrenheit for 60 RPM's, 96.8 degrees Fahrenheit for 50 RPM's and 95.0 degrees Fahrenheit for 55 RPM's.

CONCLUSIONS

Through the execution of this engineering study, the nominal values for a set of parameters related to the punches' lubrication were obtained satisfactorily. Based on the results from this process monitor, the interval lubrication parameters obtained and tested for an over the counter product using single tip tooling configuration at a tablet press machine, which assured consistent press machine operating temperature and minimized waste lubrication over the turret and over the die table, are presented in the following Table 4:

Table 4
The Obtained Lubrication Interval Parameters

Tablet Press Machine Speed (RPM's)	Upper / Lower Head	Upper Punch Shaft	Lower Punch Shaft	Ejection Cam
50	11	2	2	6
55	11	2	2	6
60	11	2	2	6

As depicted in Table 4, the values obtained for the Upper \ Lower Head was 11 minutes, for the Upper Punch Shaft was 2 minutes, for the Lower Punch Shaft was 2 minutes and for the Ejection Cam was 6 minutes. The same set of values proved to be effective in complying with the acceptance criteria established:

- Punches' shafts temperature cannot exceed 104 degrees Fahrenheit.
- Punches' heads and shafts show presence of lubricant all over.

- The turret cannot show excess of lubricant over its surface, which could lead to product contamination.

The objectives pursued in this engineering study were achieved satisfactorily:

- An improvement in the set up process was obtained by a time reduction of 30 minutes. Once an official set of nominal values for the lubrication parameters was obtained and referenced as the set up starting point, it eased the set up process to the operators. The set up process variability was also eliminated by standardizing these parameters as the starting point for set up.
- An improvement on product quality was also obtained by controlling the amount of lubrication applied to the machine during production. This contributed to the elimination of stained tablets events related to over lubrication by an incorrect set of parameters used.
- The equipment performance and reliability was improved, because there were no more events related to stuck punches during production. This increased the machine uptime up to 48 hours per month, taking into account an average downtime of 16 hours per stuck punch event and at least 3 events per month. Moreover, a reduction in the tablet press' interventions for parts replacement was noticeable due to the fact that a proper lubrication reduced the worn and fatigue effect on the table press machine parts.

Recommendations

After evaluation of the results obtained, it is recommended to consider the nominal values of these lubrication interval parameters as the starting point or reference when setting up the tablet press machine for the over the counter products using a single tip configuration tooling. Moreover, these lubrication interval parameters may need to be periodically monitored and updated as necessary, if changes to the equipment or product occur. Recipes with these settings will be saved to the tablet press

machine to be referred as the starting point when setting up the equipment.

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