DETECTION OF CONDITIONS LEADING TO BREAKAGE OF PHARMACEUTICAL TABLETS IN PNEUMATIC TRANSPORT

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1. INTRODUCTION

Pharmaceutical tablets are a popular form of drug delivery due to their convenient and safe means of drug administration, ease of handling, and mass production using quality-controlled procedures for consistent high quality. In pneumatic conveying, the size distribution and appearance of tablets can change significantly and the product may no longer meet the required product specifications. Tablets must meet stringent specifications and broken tablets cannot be passed on to the consumer.

The objective of this research was to develop a detection method for particle breakage in a pneumatic transport line. External microphones were selected as the non-invasive sensors and their signals were analyzed with advanced methods.

1.1 Pneumatic Transport and Particle Breakage

Parameters which influence particle breakage and chipping in pneumatic conveying include air velocity, solids loading ratio, bend configuration and particle properties [1]. Particles may undergo different attrition mechanisms, such as erosion, which produces dust with a slight change in the original particle size, chipping, or breakage of the particle into two or more particles of nearly identical sizes [2]. Literature suggests that there exists a threshold velocity, below which particle breakage does not occur [3]. Therefore, to avoid particle breakage it is essential that the velocity remain below this critical value.

1.2 Acoustics

Acoustic sensors are inexpensive and can withstand a wide range of process conditions. They provide reliable, on-line and non-intrusive monitoring. Passive acoustics detect the acoustic emissions generated by the process itself. In processes involving the movement of solid particles, acoustic emissions are caused by particles colliding with each other, vessel walls or other objects [4].

1.3 Signal Analysis – Kurtosis and Multiple Regression

Kurtosis is used to describe a distribution, and is a measure of the relative peakedness of the distribution. It can thus be used to detect peaks in a signal. Multiple regression is used to determine the relationship between independent variables and a dependent variable, and identifies the main contributing variables that predict this relationship based on a linear or power law fit.

2. METHOD

Two different pneumatic transport systems were examined in this study. For most of the experiments, the pneumatic transport loop consisted of a 0.1 m inside diameter, PVC re-enforced hose and, for some experiments, this hose was replaced with a 0.1 m inside diameter steel pipe. The gas-tablet mixture flows through a 5.0 m vertical upward transport line, a 4.0 m horizontal pipeline and a downward inclined line to a padded collection container. Three different elbow configurations were used: long radius PVC hose, 90° steel elbow and 90° steel elbow lined with a thin foam pad. Three superficial gas velocities were examined: 15, 17 and 19 m/s as well as four tablet feedrates of 15, 60, 105 and 185 tablets/s. Acoustic sensors were located on the side of the pipe, at measurement locations of 2.30 and 3.20 m in the vertical section from the first elbow, on the elbow at the top of the vertical section and at 1.80 and 2.20 m in the horizontal section from the elbow. Each acoustic measurement was recorded at a frequency of 40 000 Hz. A notch filter was used to filter out 60 Hz electrical noise before analysis.

3. RESULTS & DISCUSSION

Figure 1 shows peaks existed in the raw signal, which corresponded to collisions between tablets and between tablets and the pipe wall. Kurtosis of the signal was calculated; the amplitude of peaks in the raw signal corresponded to the magnitude of the peaks of kurtosis. The number of peaks in the signal was calculated based on the number of peaks above a set threshold value. This indicated the number of collisions occurring during the transport through the system.

In industrial applications, a high breakage rate of tablets is unacceptable. In this study, an acceptable proportion of broken tablets was chosen to be 0.3%. A breakage index of 1 was assigned to trials with acceptable proportions of

broken tablets and an index of 2 for trials with unacceptable proportions. The proportion of broken tablets was determined by collecting all the conveyed tablets and sorting them manually.

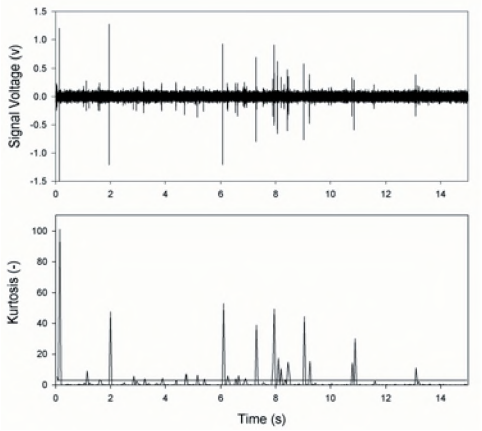

Fig. 1. Raw acoustic signal and kurtosis of signal at 2.2 m in horizontal line

Multiple regression was used to correlate the observed breakage index to the collision rate determined from the microphone signals. Figure 2 shows that there is a perfect agreement between the observed breakage index and the index obtained with the signals from the elbow and the location 1.8 m downstream of the elbow in the horizontal line. Microphone signals can, therefore, be used to monitor the breakage rate.

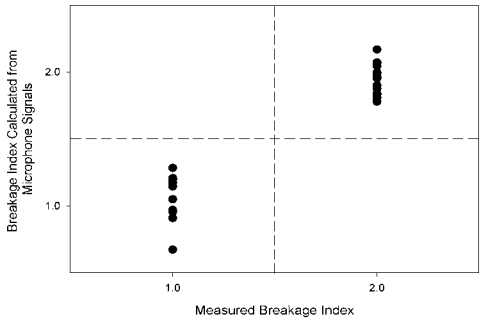

Fig. 2. Using acoustic signals to determine whether the proportion of broken tablets is acceptable (1) or unacceptable (2).

PVC hose and steel pipe were investigated to determine the effect of pipe material on tablet breakage. It was determined that the breakage rate in the steel pipe was less than in the PVC hose at high superficial gas velocities and tablet feedrates. Further investigations into elbow material and shape led to the conclusion that the higher breakage rate in the PVC hose was not due to its wall material but to the long radius of the elbow which caused the particles to significantly decelerate and affected the hydrodynamics of the horizontal section.

A boundary map which defines acceptable operating conditions was developed. Figure 3 shows that a maximum acceptable tablet feedrate of 220 tablet/s could be achieved with a conveying gas velocity of approximately 15.25 m/s in the steel pipe. With the PVC hose, the maximum acceptable tablet feedrate was lower at 160 tablet/s at a superficial gas velocity of 14.75 m/s.

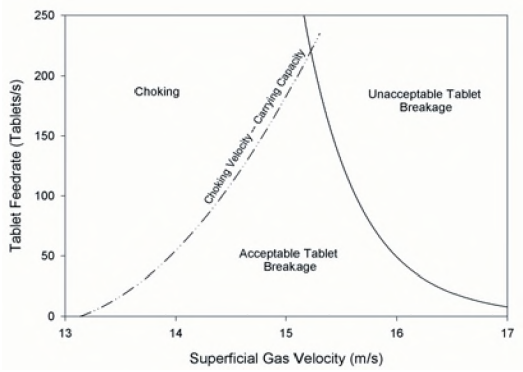

Fig. 3. Boundary conditions of acceptable and unacceptable tablet breakage based on transport conditions in steel pipe.

4. CONCLUSIONS

Unacceptable breakage rates of acetaminophen tablets in pneumatic transport could be detected with non-invasive microphones located at the elbow and horizontal sections of the pneumatic transport line.

A boundary map was developed to determine operating conditions. There was an optimum conveying gas velocity at which the tablet throughput could be maximized with acceptable breakage rates, and where tablet conveying cannot occur due to choking in the vertical section of pipe.

A steel pipe provided much lower breakage rates than a reinforced PVC hose at high superficial gas velocities and tablet feedrates. The gradual elbow associated with the PVC hose induced hydrodynamic conditions in the downstream horizontal section that promoted tablet breakage.

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