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Detection of the breakage of pharmaceutical tablets in pneumatic transport

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Abstract

Pneumatic transport of pharmaceutical tablets is very convenient, compact and greatly reduces contamination. A potential problem, however, is the breakage of a significant fraction of the transported tablets, causing serious product quality problems. Since the flowrate of tablets transported through a given pneumatic transport line increases with gas velocity, lines are often operated at gas velocities slightly below the velocity at which tablets break. Minor changes in operating conditions can have a large effect on the impact resistance of tablets and on the observed tablet breakage rate. Therefore, maintaining a constant gas velocity is not sufficient to keep the tablet breakage rate below an acceptable level. The objective of the present study was to develop a reliable and non-invasive on-line method for the detection of tablet breakage.

Pharmaceutical acetaminophen tablets were transported pneumatically in a 0.1 m diameter pipeline consisting of a 5 m vertical and a 4.0 m horizontal section made of either re-enforced PVC or steel. The pipeline flow regime was determined by visual observation through clear pipeline sections. Tablet breakage was quantified by screening tablet samples. Acoustic measurements were recorded at different locations along the pipeline. Analysis of the signals from microphones attached to the wall of the elbow and horizontal section provided a reliable detection of conditions leading to tablet breakage.

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Keywords: Pneumatic transport; Process monitoring; Tablet breakage; Acoustic probe; Signal analysis

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 to provide 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. Fragmentation can be so severe that the flow characteristics drastically change (Salman et al., 2002). Tablets must meet stringent specifications regarding their chemical, physical and biological properties, and damaged tablets cannot be passed on to the consumer.

The objective of this paper is to present a detection method for particle breakage in a pneumatic transport line. Only noninvasive sensors were used to avoid the practical difficulties associated with invasive probes in pharmaceutical applications.

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External microphones were selected as the non-invasive sensors and their signals were analyzed with advanced methods.

2. Background information

This section provides background information on pneumatic transport, particle attrition and breakage, acoustic emissions and their detection, and the signal analysis methods used in the present study.

2.1. Pneumatic transport

There are two types of pneumatic transport systems: dilute phase transport, where particles occupy less than 5% of the line volume, and dense phase transport where particles may occupy up to 50% of the line volume.

In dilute phase horizontal pneumatic transport, particles do not travel forward in a straight line, parallel to the pipe wall. Although gravity pulls the particles toward the bottom of the pipe, they are ideally kept in suspension by turbulent gas eddies.

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Nomenclature	
a, b, c	empirical regression parameter
В	calculated breakage index
$F_{\rm s}$	solids flux $(kg/(m^2 s))$
Κ	kurtosis
М	number of points in the signal
n _e	number of collisions per second from microphone
	signal at the elbow
$n_{\rm h1}$	number of collisions per second from microphone
	signal 1.8 m from the elbow in the horizontal sec-
	tion
U_{g}	superficial gas velocity (m/s)
x	distance of the probe from the vertical to horizon-
	tal elbow (m)
x_1, x_2	independent regression variables
у	signal value
, Ţ	signal mean
z	dependent regression variables

However, as the gas flowrate is reduced or the solids flowrate increased, particles eventually deposit on the bottom of the pipe (Fan and Zhu, 1998).

2.2. Particle attrition and breakage

Parameters which influence particle breakage and attrition in pneumatic conveying are the particle strength (particle material, size and shape), operation parameters (particle velocity, concentration and loading ratio) and the bend structure of the transport line (radius of curvature, material, type of bend and the number of bends) (Kalman, 1999).

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 (Kalman, 2000). Stresses that contribute to particle breakage include impact and friction. These stresses are present in every conveying system. However, the contribution of each depends on the type of conveying: impact and friction stresses are dominant in dense phase conveying while friction stresses are dominant in dense phase conveying (Frye and Peukert, 2002). During pneumatic conveying, particles experience impact stresses at bends, due to the change in the flow direction (Kalman, 1999).

The gas velocity and therefore, the particle velocity before a collision, determine the momentum which becomes the impact load during the collision. By increasing the gas velocity, the impact load increases. The particle concentration also has a large effect by reducing the particle velocity at higher concentrations (Kalman, 2000).

The literature suggests that there exists a threshold velocity, below which particle breakage does not occur (Salman et al., 2002). Therefore, to avoid particle breakage it is essential that the velocity remain below this critical value. Many products cannot be conveyed in dense phase and at low velocity. Therefore, the conveying air velocity must be as close as possible to the minimum transport velocity (Salman et al., 2002).

The number of unbroken particles is very sensitive to both the impact velocity and impact angle. A particle impact in a bend consists of a tangential and normal component. The tangential component causes slide and shear loads that can damage the particle. Kalman (2000) suggests that significant damage is caused by the normal component and increasing the bend radius decreases the angle of collision. Salman et al. (2002) found that at an impact angle of 90°, no visible failure occurs at low velocities. Salman et al. (1995) determined that damage caused by oblique impacts is a maximum at an angle of approximately 40°. Below this angle damage due to both forms decreases rapdily, leading to virtually no damage for all impacts.

The flow of particles through a bend can be a sliding bed or a bouncing motion. With each impact in the bend, the velocity of the particle is reduced, so significantly that an acceleration zone is required to reaccelerate the particles exiting the bend (Klinzing et al., 1997). Kalman (2000) suggests that attrition is lowest in long radius elbows, since small particles can follow the air stream easily through the bend. However, Frye and Peukert (2005) suggest that particles with large diameters have high inertial forces and particles do not follow the gas stream through the bend, but directly impact the outer wall of the bend. Frye and Peukert (2002) also found that by changing the ratio of bend radius to pipe diameter, particle attrition is reduced since normal stresses decrease, which outweighs the increasing tangential stress.

Mason and Smith (1972) determined that the bend material affected the erosion rate and materials respond differently to angles of impact. Brittle pipe material has the maximum erosion for normal impacts, whereas ductile materials have the most erosion at 20° and little erosion at 90° . Kalman (2000) suggests that flexible walls can absorb more energy and therefore should lower attrition rates.

2.3. Breakage predictions

Methods have been proposed to predict the breakage of particles in pneumatic transport. Frye and Peukert (2002, 2005) suggest that through process functions (conveying conditions) and material functions (material properties), a model can be developed to predict the amount of attrition occurring in a pneumatic conveying system. Process functions are calculated using computational fluid dynamics whereas the material functions are determined through single particle experiments. Work continues on model development. Konami et al. (2002) determined that attrition of irregular particles was initially high until the particles became more spherical and attrition became constant. It was also determined that the rate of fine particle production was equal to one-tenth of the granule diameter, allowing for the prediction of fine particle production. Huang et al. (2003) assumed that particles break due to collisions with the inner walls and at bends, changing the dust fraction and particle size distribution and resulting in a possible change in acoustic output. The acoustic data series, sampled at 50 000 Hz, was analysed using the fast Fourier transform power spectral density (FFT PSD);

partial least squares regression was used to relate the acoustic analysis and the dust fraction. This provided a model for predicting the degree of breakage for some powders.

2.4. Acoustics

Acoustic sensors are inexpensive and can withstand a wide range of process conditions. They provide reliable, on-line and non-intrusive monitoring. There are two acoustic monitoring methods:

- active acoustics detect the effect of the process on a transmitted ultrasonic acoustic wave; and
- passive acoustics detect the acoustic emissions generated by the process.

Generally, passive acoustic methods are much easier to implement and are preferred when the process acoustic emissions are strong, as is the case with pneumatic transport.

Acoustics is defined as the study of sound. Sound is caused by pressure vibrations that can be detected by the human ear or microphones. In processes involving the movement of solid particles, acoustic emissions are caused by particles colliding with each other, vessel walls or other objects (Boyd and Varley, 2001).

The microphones used in this study were prepolarized electret condenser microphones, which transform sound pressure fluctuations into capacitance variations, which are further converted into an electrical voltage signal. They produce an oscillating voltage proportional to the original pressure oscillations (Valentino, 2005).

2.5. Signal analysis-kurtosis

Kurtosis is used to describe a distribution, and is a measure of the relative peakedness of the distribution. Kurtosis is calculated by

$$K = \frac{\sum_{1}^{M} (y - \bar{y})^4}{M}$$
(1)

where y is the signal value, \bar{y} the signal mean, and M is the number of points in the signal.

Kurtosis is a dimensionless value used to determine the relative height of a peak, and is classified based on the shape of the peak: leptokurtic—more peaked, mesokurtic—normally peaked, and platykurtic—less peaked. Typically, if K < 3, the distribution is platykurtic, if K > 3, the distribution is leptokurtic, and if K = 3, the distribution is mesokurtic (Flott, 1995).

2.6. Multiple regression

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. The *F*-statistic is used to indicate how well the data fits the estimated parameters. Regression can be performed based on a linear fit or a power law fit. For the linear fit involving three independent variables z, x_1 and x_2 :

$$z = a + b \times x_1 + c \times x_2 \tag{2}$$

whereas for the power law fit:

$$z = a \times x_1^{\mathsf{b}} \times x_2^{\mathsf{c}} \tag{3}$$

where a, b, c are empirical parameters.

3. Equipment and experimental methods

3.1. Pneumatic transport system

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 reenforced hose, shown in Fig. 1a. In Fig. 1b, the hose was replaced with a 0.1 m inside diameter steel pipe. Air was supplied from a compressor, controlled using a regulator, and set and monitored using a valve, calibrated pitot tube, pressure transducer and voltmeter. Air flows through a horizontal pipeline located underneath the storage silo from which powder is fed into the line with a vibrating feeder. The gas-tablet mixture flows through a 5.0 m vertical transport line, a 4.0 m horizontal pipeline and through an inclined line to a padded collection container where solids are separated from the gas stream.

The effects of elbow configurations were also studied. Three different configurations were used:

- (i) long radius PVC hose;
- (ii) 90° steel elbow;
- (iii) 90° steel elbow with the outer radius fitted with a thin foam pad.

3.2. Tablet characteristics

The tablets studied were oblong in shape with a volumeequivalent tablet diameter of 0.01 m and a sphericity of 0.72. The terminal velocity corresponding to the volume-equivalent diameter was 10.5 m/s. The tablet density was $1 400 \text{ kg/m}^3$, with an average tablet mass of 558 mg. A Bareiss hardness tester was used to determine tablet hardness; for a displacement of 2 mm, the average hardness was 15.48 N with a standard deviation of 0.1056 N.

3.3. Tablet flow properties

Tablet flow through the pipeline was controlled through the variation of the tablet feedrate and superficial gas velocities. Three superficial gas velocities were examined: 15, 17 and 19 m/s. At velocities less than 15 m/s, choking occurred in the vertical section of the pipeline. In addition, four tablet feedrates were examined: 15, 60, 105 and 185 tablets/s.



Fig. 1. (a) Schematic diagram of the pneumatic transport system using PVC hose. (b). Schematic diagram of the pneumatic transport system using steel pipe.

3.4. Acoustic sensors

Six prepolarized electret microphones model 130D10, preamplifier model 130P10, manufactured by PCB Piezotronics were used to simultaneously record acoustic signals at different locations along the pipeline. Data was acquired using a 12-bit National Instruments data acquisition card model NI PCI-6071E. Each measurement was recorded at a frequency of 40 000 Hz. Acoustic sensors were located directly on the side of the pipe, at each measurement location. Measurement locations were directly below the solids feeder, at 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. Acoustic sensors were secured to the pipeline using a shim shaped to the form of the sensor, and attached to a thin foam base. This base was held to the pipe with Velcro wrapped around the pipe circumference. It was critical that that the base of the microphone was flush with the pipe surface.

3.5. Video of horizontal flow

The transparency of the PVC hose allowed for visual observations of tablet flow. A video camera was used to visually record the tablet flow pattern at the different operating conditions in the horizontal section of the transport line. Video files were recorded at 10 frames per second. The flow pattern could easily be determined from the video files.

3.6. Experimental method

For each measurement, the superficial gas velocity was set at the desired flow rate, before solids were added to the transport line. Once the flow stabilized, acoustic measurements were recorded. After each measurement, the solids feeder was stopped and the gas flow maintained until the pipeline was completely cleared of tablets. The tablets were then collected from the collection container and sorted to separate damaged tablets from undamaged tablets.

3.7. Signal analysis methods

Raw signals were recorded using National Instruments' Labview data acquisition software in a binary format. From these raw signals, a notch filter was used to filter out 60 Hz electrical noise. Kurtosis of the signal was calculated; the amplitude of peaks in the raw signal correspond to the magnitude of the peaks of kurtosis. A threshold limit was set with a limit of 3. The number of peaks in the signal was calculated based on the number above this threshold value.

4. Results and discussion

4.1. Tablet breakage

Fig. 2a shows acetaminophen tablets before transport through the pneumatic transport system. In Fig. 2b, tablets are shown after transport through the system and separation from





Fig. 2. (a) Tablets before transport. (b) Broken tablets separated after transport.

undamaged tablets. It is shown that the tablets break in half width-wise, and tablets rarely chip or attrit.

4.2. Raw signals

Fig. 3 shows the raw acoustic signals at different locations within the pneumatic transport loop. Fig. 3a and b correspond to measurements recorded in the vertical transport line at 2.3 m and at 3.2 m from the bottom elbow respectively. The signal shown in Fig. 3c was recorded at the elbow. Signals shown in Fig. 3d and e were recorded in the horizontal section at 1.8 and 2.2 m from the top elbow respectively. The microphone locations are indicated in Fig. 1a and b.

As shown by the signals in Fig. 3, peaks exist in the signal, which correspond to collisions in the pipe between tablets, and tablets and the pipe wall. Acoustic signals of controlled tablet–tablet and tablet–wall collisions were recorded in the pipeline in the absence of air flow; the larger peaks in the signal corresponded to tablet collisions whereas smaller peaks represented collisions between the tablet and wall. As it can be seen from Fig. 3, the peaks were larger in the horizontal section compared to the peaks in the vertical section and elbow indicating that there were more tablet-tablet collisions in the horizontal section.

4.3. Kurtosis of the raw signal

Fig. 4 shows that kurtosis peaks corresponded to the peaks observed in Fig. 3. Again, Fig. 4a and b correspond to the acoustic probe at 2.3 and 3.2 m, Fig. 4c is the probe at the top elbow, while Fig. 4d and e correspond to the horizontal acoustic probes at 1.8 and 2.2 m from the top elbow. The kurtosis peaks were characterized by defining a time interval length and a threshold value of 3. Fig. 5 shows the effect of the time interval length on the calculated collision rate. A time interval length of 0.05 s, equivalent to 2000 points, was selected, as near this length the collision rate was not significantly affected by small changes in the selected time interval length. A threshold value of three was selected to distinguish a peak in the signal from the sound of the gas. A kurtosis value greater than the threshold indicated that a collision had occurred.

Comparing the signals in Fig. 3 with the kurtosis of the signals in Fig. 4, the occurrence of the peaks is the same, and the magnitudes of the peaks are similar: bigger spikes in the raw signal correspond to larger peaks of the calculated kurtosis. Comparing Fig. 4d and e with Fig. 4a–c, peaks are larger in the horizontal section, as compared to the peaks in the vertical section or elbow.

The number of peaks was used as an indicator of the number of collisions occurring during the transport through the system. After determining the number of collisions that occurred during the measurement and dividing by the residence time of the tablets in the pipeline, the number of collisions per second could be determined.

4.4. Detecting tablet breakage with the microphones

In industrial applications, a high breakage rate of tablets is unacceptable. It is important to determine that the amount of attrition or breakage is below a certain acceptable value. In this case, 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 for each trial by collecting all the conveyed tablets and sorting them manually.

To determine whether the microphone signals could be used to control the pneumatic transport system and maintain an acceptable proportion of broken tablets, a multilinear regression program was use to correlate the observed breakage index to the collision rate determined from the microphone signals. The program used the F-statistic to determine that the best statistically significant correlation could be obtained with the signals from only two of the five microphone locations: the elbow and the location 1.8 m downstream of the elbow in the horizontal line (see Fig. 1a).

Figs. 6 and 7 show that microphone signals could be used to reliably determine if operating conditions were acceptable. Figs. 6 and 7 show results obtained with linear and power-law



Fig. 3. Raw signal of tablet collisions at different locations in the PVC hose pneumatic transport system at $U_g = 15$ m/s and $F_s = 185$ tablet/s.

relationships, respectively. The actual equations are:

$$B = 1.43 + 5.71n_{\rm e} - 3.55n_{\rm h1} \tag{4}$$

and

$$B = 1.76(n_{\rm e})^{-0.575}(n_{\rm h1})^{0.563}$$
⁽⁵⁾

where *B* is the calculated breakage index and n_e and n_{h1} are the collisions per second calculated from the microphone signals at the elbow and 1.8 m downstream of the elbow, respectively.

Interestingly, the statistical correlation of the breakage index, B, with the number of hits in the horizontal line, n_{h1} , was stronger than with the number of hits at the elbow, n_e .

This shows that acoustic signals can successfully be used in determining particle breakage and attrition. The method presented uses kurtosis to predict the proportion of tablet breakage, whereas the method developed by Huang et al. (2003) uses FFT PSD to predict fines production. The rate of fine particle production was not examined, since the particles broke into large pieces and the model is based on attrition and fines production. As well, this method was only able to successfully predict fines production for half the powders tested. The prediction of Konami et al. (2002) for attrition was applied to tablet breakage; the breakage rates varied depending on the solids feedrate and superficial gas velocity, and did



Fig. 4. Kurtosis of tablet collisions at different locations in the PVC hose pneumatic transport system at $U_g = 15$ m/s and $F_s = 185$ tablet/s.

not reach a constant breakage rate proportional to the tablet diameter.

4.5. *Effects of superficial gas velocity and tablet feedrate*

Fig. 8 shows the effect of the superficial gas velocity on the number of tablets broken per second. Few tablets were broken at 15 m/s, whereas there was more breakage at 17 m/s and the most at 19 m/s. The strong effect of gas velocity on tablet breakage corresponded to results reported by other researchers (Bemrose and Bridgwater, 1987).

Fig. 9 shows that tablet breakage was greatly affected by the tablet feedrate; increasing the tablet feedrate increased the breakage rate of tablets. This suggested that breakage was primarily caused by particle–particle collisions rather than particle–wall collisions. This was confirmed by the stronger correlation of the breakage index with the signal from the horizontal line microphone, where particles collided primarily with other particles,

than with the signal from the elbow microphone, where particles collided primarily with the pipe wall.

4.6. Boundary of acceptable tablet breakage

Fig. 10 represents the boundary which separates conditions associated with acceptable breakage proportions from conditions that result in unacceptable tablet breakage. This boundary was obtained by interpolation of the experimental data. It also shows the choking velocity boundary and indicates where tablet transport is not possible. Fig. 10 shows that a maximum acceptable tablet feedrate of 160 tablets/s could be achieved with a conveying gas velocity of 14.75 m/s.

4.7. Tablet motion

The motion of tablets in the horizontal section of hose was recorded using a video camera located 1.8 m downstream of the



Fig. 5. Effect of time interval lengths on the number of collisions per second calculated by kurtosis.



Fig. 7. Power law regression of acceptable number of broken tablets/s (1) and unacceptable number of broken tablets (2) based on signals recorded at the elbow and 1.8 m in horizontal section.

elbow. From the videos, it was apparent that the tablets rebound off the bottom pipe wall. Flow within the horizontal section was not fully suspended, but concentrated towards the bottom of the pipe. This is where the tablets would be reaccelerating upon exiting the elbow, as suggested by Klinzing et al. (1997). In this section, there is agreement between the experimental and predicted breakage rates of tablets shown in Figs. 5 and 6. The



Fig. 6. Linear regression of acceptable number of broken tablets/s (1) and unacceptable number of broken tablets (2) based on signals recorded at the elbow and 1.8 m in the horizontal section.

horizontal section showed larger peaks both from the raw signals and the corresponding kurtosis peaks (Figs. 3 and 4).

Tablet impact at different orientations was found to affect the method by which tablets fracture. Fig. 11a shows tablets impacted against a solid surface on the end become chipped at the location of the impact. Fig. 11b shows tablets impacted on their side against a solid surface break in half. This was the type of breakage encountered in this study, as shown in Fig. 2b.



Fig. 8. Effect of superficial gas velocity on number of tablets broken per second at different tablet feedrates.



Fig. 9. Effect of the tablet feedrate on tablets broken per second at different superficial gas velocities.

4.8. Effect of pipe material and elbow shape

Two different pipe materials were investigated to determine the effect of pipe material on tablet breakage: PVC hose and steel pipe. It was determined that the breakage rate in the steel



Fig. 10. Boundary for acceptable and unacceptable tablet breakage based on transport conditions in PVC hose.

pipe was less than the breakage rate in the PVC hose at high superficial gas velocities and tablet feedrates.

The effects of superficial gas velocity, tablet feedrate and elbow type are shown in Figs. 12 and 13, respectively. Fig. 12 shows the effects of the superficial gas velocity on the number





(b)





Fig. 11. (a) Tablets impacted on side. (b) Tablets impacted on end.



Fig. 12. Effect of elbow and superficial gas velocity on the number of broken tablets/s at different tablet feedrates in steel pipeline.

of tablets broken per second. Few tablets were broken at 15 m/s, with more breakage at 17 m/s. Fig. 13 shows that tablet breakage was greatly affected by the tablet feedrate: increasing the tablet feedrate increased the breakage rate of tablets.

Comparing the breakage rate of tablets in the steel pipe and the hose, it was seen that the breakage rate was significantly lower in the steel pipe. This could be attributed to the shape of the elbow. An elbow with a soft foam liner was used in the steel pipeline to determine whether the elbow material affected the breakage rate of tablets. Figs. 12 and 13 show that the breakage



Fig. 13. Effect of elbow and tablet feedrate on the number of broken tablets/s at different superficial gas velocities in steel pipeline.



Fig. 14. Boundary conditions for acceptable and unacceptable tablet breakage based on transport conditions in steel pipe.

rates in the steel and lined elbows were very similar, meaning the elbow shape had the predominant effect on the breakage rate of tablets. Although there was no significant attrition at the elbow, the gradual centrifugal action of the long-radius PVC elbow would fully decelerate the particles and thus affect the hydrodynamics of the horizontal section. This result corresponded to the work of other researchers (Frye and Peukert, 2005 and Klinzing et al., 1997) where large particles cannot follow the gas stream and bounce through the elbow. This does, however, contradict the results of Kalman (2000) since the flexible PVC hose had higher attrition rates compared to the steel pipe.

Fig. 14 represents the boundary which separates conditions associated with acceptable breakage proportions from conditions that result in unacceptable tablet breakage in the steel pipeline and choking velocities. Fig. 14 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. This was a higher feedrate than with the PVC hose.

5. 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.

This study dealt with the physical characteristics of the transport of tablets and developing a method to determine the breakage rate of the tablets. It is assumed that in industry, each system would require calibration to account for the system layout as well as the specific properties of the tablets. The correlations presented are not intended to be universal.

Increasing either the gas velocity or the tablet feedrate greatly increased the breakage rate. A boundary map was developed to determine transport conditions resulting in acceptable proportions of broken tablets. It showed that 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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