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Pharmaceutical Technology Report

PTR-001

Validation of an Automated Data Acquisition and Analysis System for Instrumented Tablet Presses[(1)]

by
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Summary

The collection and analysis of compaction and ejection forces during tablet manufacture is valuable information to the pharmaceutical formulator. The use of an automated system for data collection and analysis affords rapid calculation and instantaneous display of the results. However, for an automated system to be useful, it must be reliable. The objective of this study was to validate an automated system.

A calibrated load cell was used with an oscillographic recorder equipped with bridge and DC amplifiers. Two instrumented tablet presses containing different types of instrumentation were calibrated with the load cell. Once calibrated, the oscillographic recorder was used to validate the operation of the automated tablet press acquisition and analysis system. The automated system consisted of both computer hardware and software. Final validation of the system consisted of manufacturing tablets and collecting data on both the automated system and oscillographic recorder.

Results indicated that there is a direct, linear relationship between the forces measured by the oscillographic recorder and those by the automated system. This relationship had a correlation of greater than 0.99, a slope approaching unity, and a negligible intercept. Thus, the automated system was proven to be reliable, resulting in time savings and increased accuracy.

Introduction

Many tablet presses used in the development of tablet formulations today are instrumented to allow the forces of compaction and ejection to be monitored. Typically, tablet presses are instrumented with either strain gauges or piezoelectric load cells, which measure the tablet compaction forces and transmit the electrical signals to oscilloscopes, or oscillographic recorders. During usual operation, the signals representing the forces from the tablet press are recorded and appear as individual peaks. These peaks are then manually measured and the average of 10 or more peaks is used to calculate the force. This is a tedious and time-consuming process resulting in potential calculation and/or transcription errors. With the proliferation of microcomputers, such as the IBM PC,[(2)] it is becoming more common to collect laboratory data directly into the computer using automated procedures.

To ensure that an automated process is accurate and precise, a validation of the system is necessary. This work describes the procedure used to validate an automated data acquisition and analysis system for two instrumented tablet presses.

[(1)]This work was performed in the AQUALON Pharmaceutical Laboratory and was presented by Jurij Holinej at the 5th Annual AAPS meeting in Las Vegas, Nevada, on November 5, 1990, as a Contributed Paper for the PT Poster Session.

[(2)]IBM Personal Computer, IBM Corp., Boca Raton, Florida.

Experimental

1. A calibrated load cell[3] was used to measure the upper and lower punch forces on a single-punch tablet press[4] instrumented with piezoelectric transducers.[5] The load cell was also used to measure the forces of precompaction, compaction, and ejection on a rotary tablet press[6] instrumented with strain gauges.[7] All signals were collected directly on an oscillographic recorder.[8]
2. The output signals from the calibrated load cell and those from each tablet press were compared and found to be linear. Regression analysis was performed on the data. The slope of the regression equation was used to generate calibration factors for each force measurable by the presses. These factors were used to convert the recorded signals from the presses into units of force.
3. The calibration factors generated above were used in the data acquisition and analysis (DAA) software.[9] Tablets were compressed over a wide range of forces. Force data from the tablet presses was collected simultaneously by the oscillographic recorder and the DAA software. Linear regression analysis was performed on the data.

Results

The correlation coefficients derived from the calibration of the tablet presses with the load cell are reported in the following table. It is evident that the responses between the tablet press force transducers and the load cell are linear.

Linear Regression Correlation Coefficients for Tablet Press Force Transducer Calibrations

Tablet Press	Force	Coefficients
Single Punch	Upper Punch	0.9935
	Lower Punch	0.9996
Rotary	Precompaction	0.9982
	Compaction	0.9982
	Ejection	0.9968

The single-punch tablet press upper and lower punch force signals measured by the DAA software were identical to those measured by the oscillographic recorder. Figures 1 and 2 display the linear relationship between the forces reported by the DAA software and compared with those measured by the oscillographic recorder. The correlation coefficients for both the upper and lower punches were greater than 0.999 over the range of 5 to 45 kN of force.

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(3)GSE Inc., Farmington Hills, Michigan.
(4)Manesty Betapress, Thomas Engineering Inc., Hoffman Estates, Illinois.
(5)PCB Piezotronics, Inc., Depew, New York.
(6)Manesty Betapress, Thomas Engineering Inc., Hoffman Estates, Illinois.
(7)Sensotec, Inc., Columbus, Ohio.
(8)Model RS 3400, Gould Electronics, Cleveland, Ohio.
(9)Tablet Press Monitor, Version 4, Metropolitan Computing Corp., West Orange, New Jersey.

Figure 1
Single-Punch Tablet Press
Upper Punch Force
Measured by DAA Software

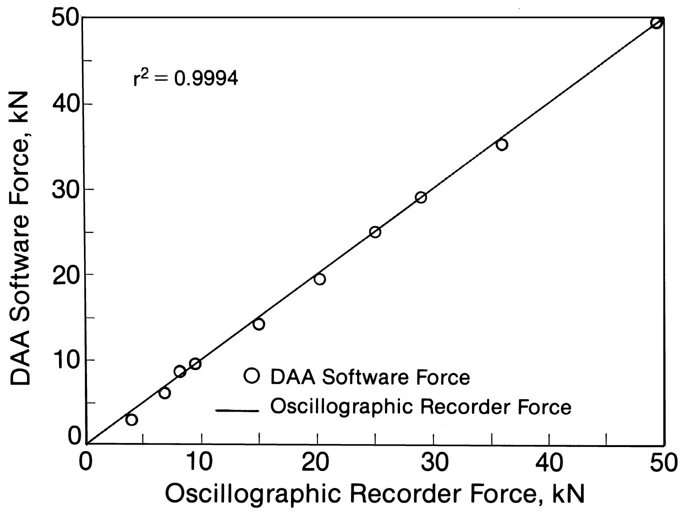
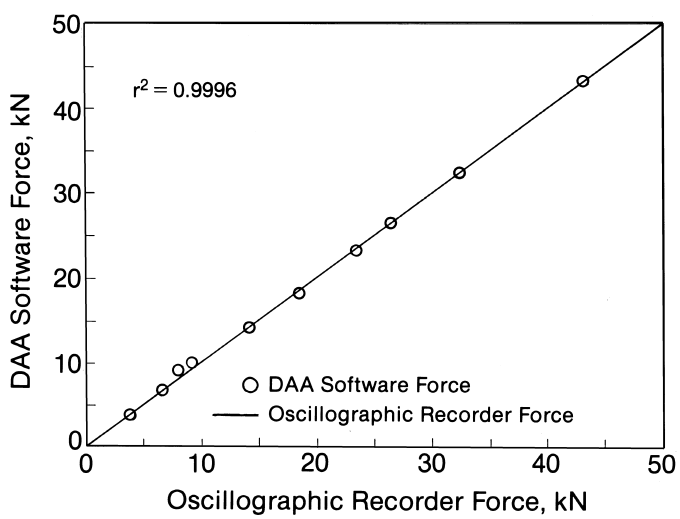
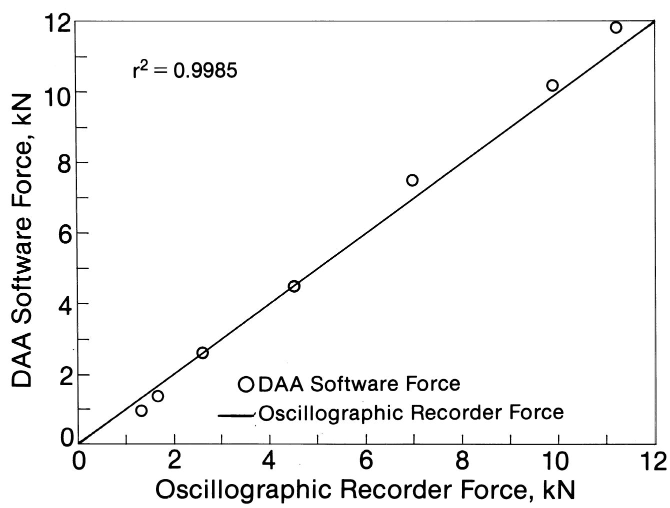


Figure 2
Single-Punch Tablet Press
Lower Punch Force
Measured by DAA Software



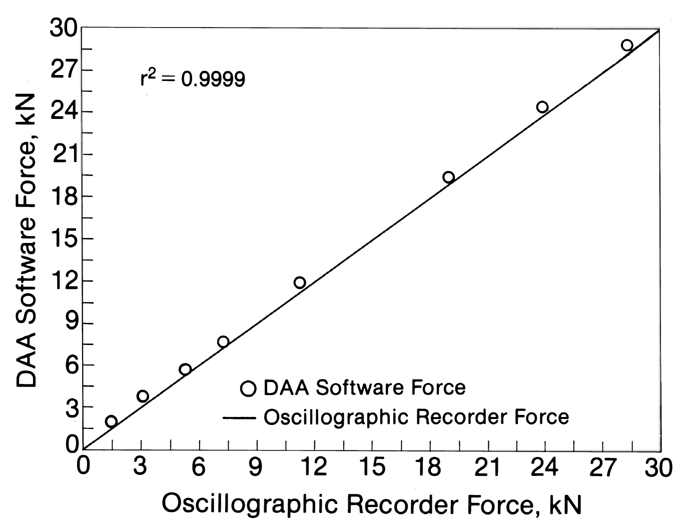
The rotary tablet press compaction signal measured by the DAA software was the same as that measured by the oscillographic recorder (Figure 3). A linear relationship was observed between the two methods of data collection with a correlation coefficient of 0.9985.

Figure 3
Rotary Tablet Press
Precompaction Force
Measured by DAA Software



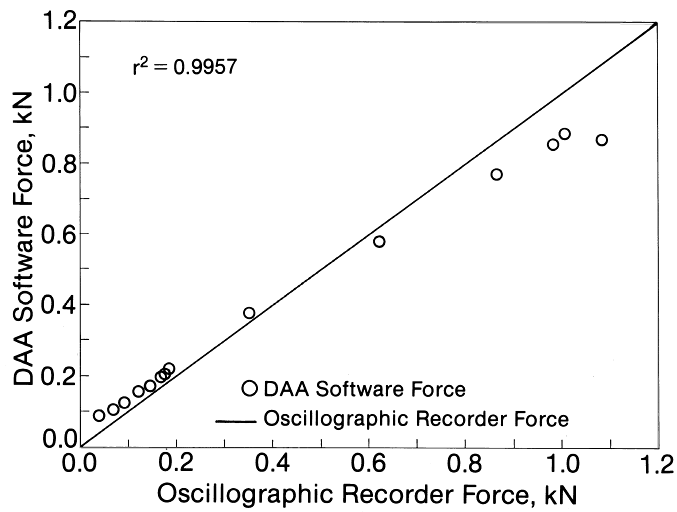
The rotary tablet press compaction signal measured by the DAA software was identical to that measured by the oscillographic recorder (Figure 4). The correlation coefficient of the linear regression between the measured signals was 0.9999. The DAA software signal was linear over a range of 1 through 29 kN of compaction force.

Figure 4
Rotary Tablet Press
Compaction Force
Measured by DAA Software



The rotary tablet press ejection signal measured by the DAA software was identical to that measured by the oscillographic recorder up to 0.8 kN of force (Figure 5). Above 0.8 kN, the signals measured by the two systems diverged. The reason for this is not clear, but it is believed that the ejection cam strain gauge generates a millivolt signal output that is in excess of that which the DAA is capable of handling. However, forces above 0.8 kN are probably much higher than would be encountered in actual practice. Despite this, the correlation coefficient for the linear regression was 0.9957 over the range of 0.1 through 1.1 kN of ejection force.

Figure 5
Rotary Tablet Press
Ejection Force
Measured by DAA Software



CONCLUSIONS

1. A single-punch and a rotary tablet press instrumented with force transducers were successfully calibrated using a standardized load cell.
2. Data acquisition and analysis software was successfully validated on a single-punch tablet press instrumented with piezoelectric load cells and on a rotary tablet press instrumented with strain gauges.