Improving Performance of Tableting Process Using DMAIC and Grey Relation Analysis

Abbas Al-Refaie, Ming-Hsien Li, Issam Jalham, Nour Bata, and Kawther Al-Hmaideen

***Abstract*—This research implements the well-known six sigma approach define-measure-analyze-improve-control (DMAIC) to improve the performance of direct compression process with two quality responses; tablet's weight and hardness. At current factor settings, the $\bar{x}$ and s charts are judged in-control for both responses. However, the process was found capable for hardness but incapable for weight. Three process factors are investigated, including machine speed (S), compression force (F), and filling depth (D). The Taguchi's L_{27} array is adopted to investigate the effects of the three process factors concurrently. Then, the grey relational analysis based ranking is implemented to determine the combination of optimal factor levels, which is found as S1F3D1. Initially, the process capability values for hardness and weight are 1.5 and are 0.587, respectively. The multivariate capability index, MC_{pk}, is calculated and found 0.938. After process improvement, the process capability values are found equals to 3.31 and 0.848. The MC_{pk} is enhanced to 1.68. In conclusion, the DMAIC approach is found effective for improving the performance of direct compression process with tablet's weight and hardness.**

***Index Terms*—Direct compression, Grey analysis, Process capability, Taguchi method**

I. INTRODUCTION

The pharmaceutical industry has invested large amount of resources in improving the performance of direct compression process [1]. Tablet defects result in huge business losses due to their influence on human health. Among the key quality responses are tablet hardness and weight. Variation in these two responses leads to rejection of tremendous tablet quantities.

Among the proven approaches for improving quality and productivity is the define-measure-analyze-improve control (DMAIC) approach, which has been implemented widely to improve performance in many industrial applications [2,3].

The Taguchi method is widely applied because of its proven success in improving the quality of manufactured products in many business applications. Nevertheless, it has been only found efficient for optimizing a single quality response Nevertheless, it has been only found efficient for optimizing a single quality response [4-6]. In contrast, the grey relational analysis based on the grey system theory [7] can be utilized for solving complicated interrelationships among multiple quality responses [8, 9]. Therefore, this research utilizes DMAIC methodology to enhance the performance of the tablets' direct compression process utilizing grey relation analysis. This paper is organized as follows. Section two presents the DMAIC approach. Section three summarizes research results. Finally, section four summarizes conclusions.

II. IMPLEMENTING DMAIC APPROACH

The DMAIC approach is implemented as presented in the following subsections.

A. *Define the importance quality responses*

The direct compression of tablets is illustrated in Fig.1.

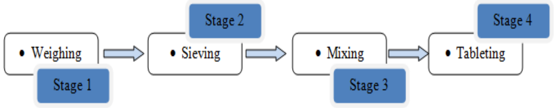

Fig.1. Process mapping.

The Tablet quality depends on two main quality responses including hardness and weight. The hardness lower and upper specifications limits of the AM-tablets are 20 and 60 measured by Newton (N), respectively. It is required that tablet hardness to be the larger the better within these specifications. The second important quality response is the tablet weight. The upper and lower specification limits of the tablet average weight are 75.0 ± 4.5 mg. The tablet hardness and weight are considered the larger-the-better (LTB) and nominal-the-best (NTB) quality types, respectively.

B. *Measuring the performance of tablet's production line*

A control chart is one of the primary techniques of statistical process control. The chart has a centre line (CL) and the upper and lower control limits represented by UCL and LCL, respectively. The CL represents where this process characteristic should fall. A widely implemented control charts for monitoring response mean and variability are the $\bar{x}$ and s charts. Twenty five samples, each sample

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with sample size of ten tablets, are taken after the process is stable. The $\bar{x}$ and s control charts for hardness are constructed then depicted in Fig. 2. The LCL, CL, and UCL for $\bar{x}$ chart are calculated 31.434, 34.497, and 37.560, respectively. While, the LCL, CL, and UCL for the s chart are estimated 0.891, 3.140, and 5.390, respectively. Similarly, the $\bar{x}$ and s control charts for the unit average weight are established as shown in Fig. 3. The LCL, CL, and UCL for $\bar{x}$ chart are found equal to 74.841, 76.476, and 78.111, respectively. While, the LCL, CL, and UCL for the s chart are of values 0.476, 1.676, and 2.877, respectively. Observing Figs. 2 and 3, nor points fall outside the control limits neither significant pattern is found. Consequently, the process is concluded operating in a statistical control state for the two measured values.

A vital part of an overall quality-improvement program is process capability analysis by which the capability of a manufacturing process can be measured and assessed. In practice, the process standard deviation, σ, is unknown and frequently estimated by:

$$\hat{\sigma} = \frac{\bar{s}}{c_4} \tag{1}$$

where c_4 is a constant related to sample size, while $\bar{s}$ is the *CL* value in *s* chart. The estimator of C_{pk}, $\hat{C}_{pk}$, is expressed mathematically by:

$$\hat{C}_{pk} = min\left\{\frac{USL-\hat{\mu}}{3\hat{\sigma}}, \frac{\hat{\mu}-LSL}{3\hat{\sigma}}\right\} \tag{2}$$

For larger-the-better response, the $\hat{C}_{pk}$ is calculated as:

$$\hat{C}_{pk} = \frac{\hat{\mu}-LSL}{3\hat{\sigma}} \tag{3}$$

where $\hat{\mu}$ is the estimated mean, which is the equals to $\bar{\bar{x}}$; the *CL* value of $\bar{x}$ chart. In this research, the recommended minimum value of the process capability ratio is 1.45, due to safety, strength, or critical parameter for an existing process [10]. In this research, the minimal required process capability values for hardness and weight are 1.45 and 1.00, respectively. From Fig. 2, the $\bar{s}$ value for average hardness is calculated 3.140 and the *c* value for a sample size of 10 is 0.9727. Substituting $\bar{s}$ and c_4 values in Eq. (1), the $\hat{\sigma}$ is equal to 3.2281. Introducing $\bar{\bar{x}}$ of 34.497 in Eq. (3), the $\hat{C}_{pk}$ is calculated and found equals 1.5. Compared with the recommended minimum value (= 1.45), it is concluded that process is almost capable for average tablet's hardness. Similarly, the process capability is estimated for average unit weight. From Fig.3, the $\bar{s}$ value is calculated 1.676. Then, $\hat{\sigma}$ is calculated and found equals 1.723. Using Eq. (2), the $\hat{C}_{pk}$ is 0.587, which is much less than the minimum value (=1.00) and hence indicates that the process is incapable.

A criterion for selecting an optimal design is developed and called *MCpk* to be used as a capability measure for a process having multiple performance measures [11]. In this research, the *MCpk* is calculated as:

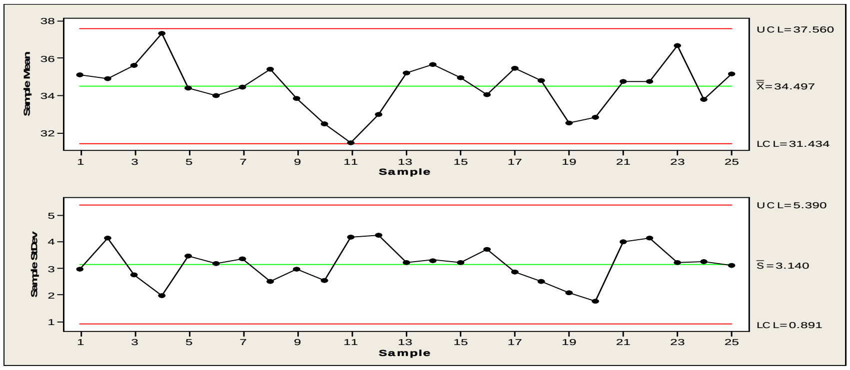

Fig. 2. The $\bar{x}$ - s control charts for hardness.

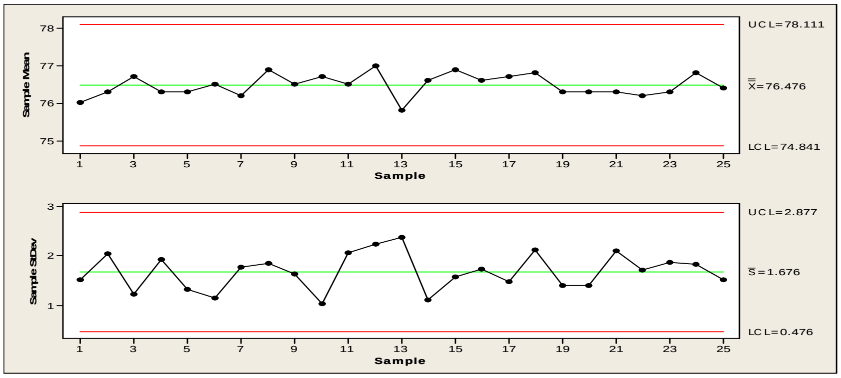

Fig. 3. The $\bar{x}$ - s control charts for weight.

$$MCpk = \left\{\prod_{i=1}^{2} \hat{C}_{pk}\right\}^{\frac{1}{2}} \qquad (4)$$

Utilizing the obtained process capabilities for averages of hardness and weight ($\hat{C}_{pk_1}$ =1.4969; $\hat{C}_{pk_2}$ = 0.587), the *MCpk* is calculated and found 0.938. Typically, the *MCpk* value larger than one indicates capable process with multiple responses. Accordingly, the tablet compression process is concluded incapable.

C. Analyzing and improving the performance of tablet's production process

C.1. Analyzing process performance

Based on previous studies [12-14] and process knowledge, the most important controllable factors are: compression force (N), filling depth (mm), and machine speed (stroke/hr). Process experts recommend that each factor is assigned three-physical value levels as shown in Table I. In this method, an orthogonal array (OA) is utilized to investigate several process factors concurrently at permissible reliability and at low cost. For compression process under study, the appropriate Taguchi's OA for investigating three factors with their corresponding two-way interactions is the L_{27} array.

Table I
Control factors settings.

Control factor	**Level**		
	1	2	3
Machine speed (S,10^3 Tab/hr)	20.00	25.00	30.00
Compression Force (N)	82.36	83.08	84.02
Filling Depth (mm)	135.00	137.05	139.01

The designed experiments were carried out on a high capacity rotary press machine of the type Manesty with the known properties of the tablet's formulation powder mixture. Two repetitions were performed for each experiment. Each repetition consists of 10 tablets. The hardness and weight tests were carried out using Unit Tester PTB 311 Pharma Test instrument and Mettler Toledo balance Model PR 503DR, respectively. The experimental results of the tablet hardness and weight of the two replicates, R_1 and R_2, respectively, are displayed in Table II.

C.2. Improving process performance

The grey relational analysis is adopted for improving the performance of tablet's direct compression process with two quality response; the averages of tablet hardness and weight, as described in the following steps:

***Step* 1**: The Taguchi method employs a signal-to-noise ratio (SNR) to measure the present variation. The definition of SNR differs according to the quality response type. Typically, larger SNR indicates better performance. The SNR for the averages of hardness and weight, η_{1i} and η_{2i}, respectively, are estimated as follows

$$\eta_{1i} = -10\log\left(\frac{1}{k}\sum_{r=1}^{k}\frac{1}{y_{ir}^2}\right) \quad , i=1,2,..., 27 \qquad (5)$$

$$\eta_{2i} = 10\log\frac{\overline{y}_i^2}{s_i^2} \quad , i=1,2,..., 27 \qquad (6)$$

where *k* represents the number of replicates. To avoid the effect of adopting different units of the two quality responses, the η_{1i} and η_{2i} are normalized. Let η_{1i}^* and η_{2i}^* denote the normalized η_{1i} and η_{2i} , respectively. Calculated respectively as:

$$\eta_{1i}^* = \frac{\eta_{1i} - min\{\eta_{1i}\}}{max\{\eta_{1i}\} - min\{\eta_{1i}\}}, \ i = 1, 2, \ ..., 27 \qquad (7)$$

$$\eta_{2i}^* = \frac{\eta_{2i} - \min\{\eta_{2i}\}}{\max\{\eta_{2i}\} - \min\{\eta_{2i}\}}, \ i = 1, 2, \ ..., 27 \qquad (8)$$

where *min*{ η_{1i} } and *max* { η_{1i} } are the smallest and the largest value of η_{1i} , respectively. Similarly, the min { η_{2i} } and max { η_{2i} } are the smallest and the largest value η_{2i} and η_{2i} , respectively, from all 27 experiments for each response.

***Step* 2**: Calculate the grey relational coefficient, $\gamma_{1i}(\eta_{o1},\eta_{1i}^*)$ and $\gamma_{2i}(\eta_{o2},\eta_{2i}^*)$, respectively as follows:

$$\gamma_{1i}(\eta_{o1},\eta_{1i}^*) = \frac{\Delta_{\min} + \zeta\Delta_{\max}}{\Delta_{o1}(i) + \zeta\Delta_{\max}}, \ i = 1,2,..., 27 \qquad (9)$$

Similarly:

$$\gamma_{2i}(\eta_{o2},\eta_{2i}^*) = \frac{\Delta_{\min} + \zeta\Delta_{\max}}{\Delta_{o2}(i) + \zeta\Delta_{\max}}, \ i = 1,2,..., 27 \qquad (10)$$

where ξ is the distinguishing coefficient, which defined in the range of zero and one and it is commonly set 0.5. The $\Delta_{o1}(i)$ and $\Delta_{o2}(i)$ are the absolute deviations of the η_{1i}^* and η_{2i}^* from the reference sequences η_{01} and η_{02} of the averages of tablet hardness and weight, calculated respectively using:

$$\Delta_{o1}(i) = \left|\eta_{o1} - \eta_{1i}^*\right|, \quad i=1,2, ..., 27 \qquad (11)$$

and

$$\Delta_{o2}(i) = \left|\eta_{o2} - \eta_{2i}^*\right|, \quad i=1,2, ..., 27 \qquad (12)$$

The $\Delta_{\min}$ and $\Delta_{\max}$ represent the smallest $\Delta_{oj}(i)$ and the largest $\Delta_{oj}(i)$ for all the 27 experiments from both quality responses, respectively.

***Step* 3**: Generate the average grey relational grade, $\overline{\gamma}_i$, using

$$\overline{\gamma}_i = \frac{1}{2}\sum_{j=1}^{2}\gamma_{ji}, \quad i=1,2,..., 27 \qquad (13)$$

***Step* 4**: Let $\overline{\overline{\gamma}}_{lf}$ denotes the average of $\overline{\gamma}_i$ values at level *l* of factor *f*. Calculate the $\overline{\overline{\gamma}}_{lf}$ values for all factor levels. Then, decide the optimal level for each factor *f* as the level that maximizes $\bar{\bar{\gamma}}_{lf}$ for this factor. In some cases, the optimal factor levels are close to each that makes level selection not be easily determined based on $\bar{\bar{\gamma}}_{lf}$. In this case, the ordinal value is to rank the $\bar{\gamma}_i$ values in an ascending order, where the lowest $\bar{\gamma}_i$ receives a rank of one. Identify the combination of optimal factor levels utilizing the ordinal values. Let SOV_{fl} be the sum of the ordinal values for level l of factor f. The higher the SOV_{fl} implies better process performance.

Then the optimal factor level, l^*, of factor f is the level that maximizes the value of SOV_{fl} , that is,

$$l^* = \left\{ l \middle| \max_l \left\{ SOV_{fl} \right\} \right\}, \ \forall f \qquad (14)$$

Applying the above procedure, the results of grey relational coefficients and grades are displayed in Table III. The $\bar{\bar{\gamma}}_{lf}$ values are calculated then summarized in Table IV. Observing the $\bar{\bar{\gamma}}_{lf}$ values of the filling depth factor, it is noted that the $\bar{\bar{\gamma}}_{1D}$ and $\bar{\bar{\gamma}}_{3D}$ values are almost equal. Hence, the SOV_{fl} values are calculated then also shown in Table III. The SOV_{fl} values are finally adopted to identify optimal factor levels. In Table IV, it is found that the combination of the optimal factor levels is $S_1P_3D_1$. Given the c_4 value for a sample size of 10 is 0.9727. The $\hat{\sigma}$ values for hardness and weight are calculated 2.901 and 1.392, respectively. The corresponding $\hat{C}_{pk}$ values are found equals to 3.31 and 0.848. The corresponding *MCpk* equals 1.68, which indicates great savings in manufacturing and quality costs.

D. Control process performance

Confirmation experiments are conducted at $S_1P_3D_1$ to check the achieved improvement. Figs. 4 and 5 depict the confirmation $\bar{x}$-s charts for the average hardness and weight, respectively. The two control charts are in statistical control and thus can be used for monitoring and controlling the future production batches. Fig. 4 also depicts the $\bar{x}$ and s control charts for average hardness from confirmation experiments. It is noted that the UCL, CL, and LCL for $\bar{x}$ chart are calculated 51.574, 48.821, and 46.068, respectively. While, the UCL, CL, and LCL for the s chart are estimated 4.844, 2.822, and 0.801, respectively. On the other hand, the $\bar{x}$ and s control charts for the weight are established as shown in Fig. 5. The UCL, CL, and LCL for $\bar{x}$ chart are found equal to 75.361, 74.04, and 72.719, respectively. While, the UCL, CL, and LCL for the s chart are of values 2.324, 1.354, and 0.384, respectively.

III. CONCLUSIONS

This research aims at improving the performance of tableting process with these two quality responses using six-sigma and grey relational analysis. Initially, the $\bar{x}$ and *s* charts are found in-control for both responses. But, the process was found capable for hardness but incapable for weight. To improve the performance of this process, this research aims at improving the performance of direct compression process by adopting DMAIC methodology. The main factors studied are machine speed (S), compression force (F), and filling depth (D) using the L_{27} array. Then, the grey relational analysis based ranking is employed to identify the combination of optimal factor levels, which is found as $S_1F_3D_1$. Initially, the $\hat{C}_{pk}$ value for hardness is improved from 1.5 to 3.31. While, the $\hat{C}_{pk}$ value for weight is enhance from 0.587 to 0.848. Further, the *MCpk* index is improved from 0.938 to 1.68. In conclusion, DMAIC approach including grey relational analysis is found effective for improving the performance of direct compression with tablet’s weight and hardness.

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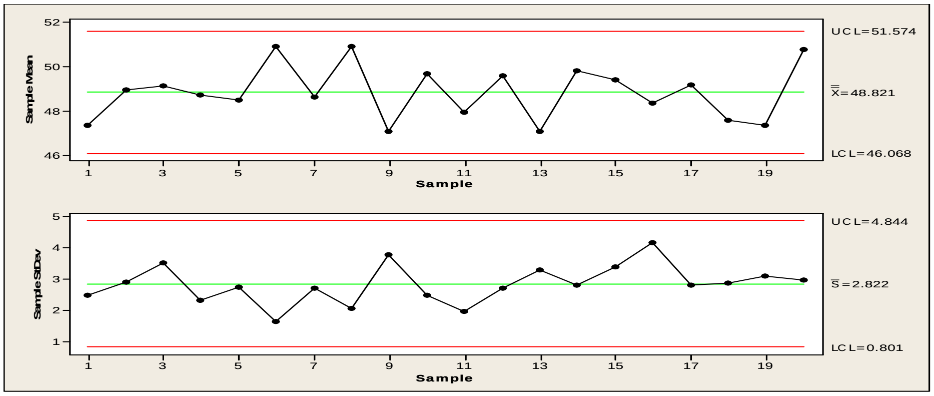

Fig. 4. The $\overline{x}$ -s charts for hardness improvement.

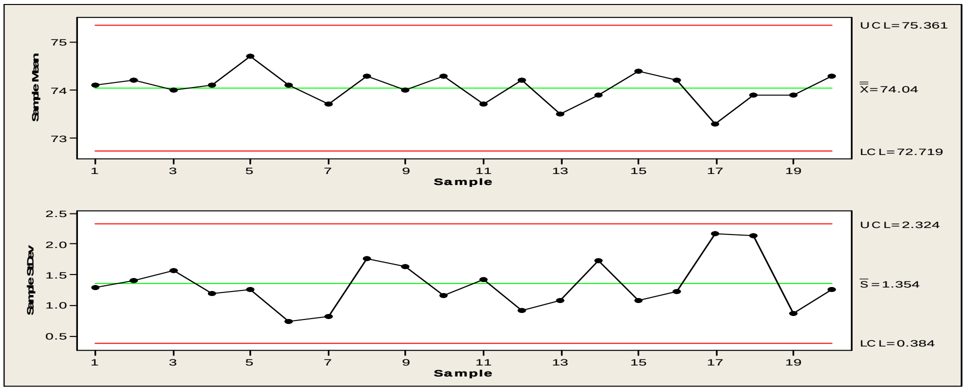

Fig. 5. The $\overline{x}$ -s chart for weight improvement.

Table II
EXPERIMENTAL RESULTS.

Sample number	**Hardness**		**S/N Ratio**	**Average**	**Weight**		**S/N Ratio**	**Average**
	***R*1**	***R*2**			***R*1**	***R*2**		
1	22.48	22.76	27.089	22.620	73.6	73.7	60.353	73.65
2	21.84	20.75	26.557	21.295	75.5	75.3	54.537	75.40
3	27.17	30.50	29.154	28.835	77.4	77.5	60.790	77.45
4	31.15	34.80	30.323	32.975	74.1	74.0	60.400	74.05
5	38.13	37.34	31.533	37.735	74.8	75.3	46.537	75.05
6	42.23	41.23	32.407	41.730	75.8	77.5	36.091	76.65
7	47.76	51.30	33.880	49.530	73.9	74.0	60.389	73.95
8	44.74	44.71	33.011	44.725	74.7	74.5	54.444	74.60
9	51.81	55.94	34.608	53.875	77.0	77.6	45.210	77.30
10	22.20	21.00	26.679	21.600	73.0	73.5	46.327	73.25
11	21.65	21.45	26.668	21.550	74.8	74.2	44.890	74.50
12	24.72	25.18	27.940	24.950	76.6	77.4	42.678	77.00
13	29.77	28.92	29.347	29.345	73.8	74.0	54.362	73.90
14	32.70	30.00	29.900	31.350	74.0	74.4	48.377	74.20
15	33.53	33.36	30.486	33.445	75.8	77.1	38.399	76.45
16	47.41	47.03	33.482	47.220	72.9	74.2	38.0631	73.55
17	54.12	53.50	34.616	53.810	74.8	74.5	50.928	74.65
18	50.15	51.39	34.110	50.770	77.3	76.8	46.766	77.05
19	22.34	21.60	26.832	21.970	74.4	74.5	60.447	74.45
20	22.98	23.92	27.397	23.450	75.2	76.6	37.692	75.90
21	26.27	27.22	28.540	26.745	77.3	77.2	60.768	77.25
22	34.07	32.48	30.434	33.275	74.8	74.5	50.928	74.65
23	32.21	30.84	29.966	31.525	73.6	74.8	38.834	74.20
24	37.48	38.91	31.635	38.195	77.0	77.4	48.721	77.20
25	42.38	43.07	32.612	42.725	74.8	75.4	44.960	75.10
26	54.93	54.47	34.759	54.700	75.2	75.6	48.516	75.40
27	47.61	48.89	33.667	48.250	77.2	77.1	60.757	77.15

TABLE III
RESULTS OF GREY ANALYSIS

Exp.	**Normalized SNRs**		**Absolute deviations**		**Grey relational coefficients**		**Grey grade**	**Ordinal value**
i	η_{1i}^*	η_{2i}^*	$\Delta_{o2}(i)$	$\Delta_{o2}(i)$	$\gamma_{1i}(\eta_{o1}^*,\eta_{1i}^*)$	$\gamma_{2i}(\eta_{o2}^*,\eta_{2i}^*)$	$\overline{\gamma}_i$	**TOV**
1	0.06491	0.98231	0.93509	0.01769	0.34841	0.96583	0.657120	17
2	0.00000	0.74681	1.00000	0.25319	0.33333	0.66384	0.498588	9
3	0.31672	1.00000	0.68328	0.00000	0.42255	1.00000	0.711277	22
4	0.45923	0.98421	0.54077	0.01579	0.48041	0.96939	0.724903	23
5	0.60671	0.42294	0.39329	0.57706	0.55973	0.46423	0.511977	10
6	0.71321	0.00000	0.28679	1.00000	0.63549	0.33333	0.484413	8
7	0.89286	0.98374	0.10714	0.01626	0.82354	0.96850	0.896020	27
8	0.78683	0.74306	0.21317	0.25694	0.70110	0.66055	0.680826	19
9	0.98160	0.36922	0.01840	0.63078	0.96451	0.44217	0.703342	21
10	0.01487	0.41441	0.98513	0.58559	0.33667	0.46058	0.398625	4
11	0.01362	0.35624	0.98638	0.64376	0.33639	0.43715	0.386771	2
12	0.16864	0.26668	0.83136	0.73332	0.37556	0.40541	0.390483	3
13	0.34025	0.73974	0.65975	0.26026	0.43113	0.65767	0.544400	13
14	0.40763	0.49741	0.59237	0.50259	0.45772	0.49871	0.478215	7
15	0.47906	0.09342	0.52094	0.90658	0.48975	0.35547	0.422609	6
16	0.84429	0.07982	0.15571	0.92018	0.76253	0.35207	0.557301	15
17	0.98260	0.60071	0.01740	0.39929	0.96638	0.55599	0.761184	24
18	0.92084	0.43219	0.07916	0.56781	0.86332	0.46825	0.665785	18
19	0.03364	0.98611	0.96636	0.01389	0.34098	0.97297	0.656974	16
20	0.10248	0.06482	0.89752	0.93518	0.35778	0.34839	0.353083	1
21	0.24184	0.99909	0.75816	0.00091	0.39741	0.99819	0.697798	20
22	0.47277	0.60071	0.52723	0.39929	0.48675	0.55599	0.521369	11
23	0.41571	0.11106	0.58429	0.88894	0.46113	0.35999	0.410561	5
24	0.61915	0.51135	0.38085	0.48865	0.56764	0.50574	0.536687	12
25	0.73829	0.35906	0.26171	0.64094	0.65642	0.43824	0.547326	14
26	1.00000	0.74541	0.00000	0.25459	1.00000	0.66261	0.831305	25
27	0.86689	0.99864	0.13311	0.00136	0.78976	0.99728	0.893518	26

TABLE IV
OPTIMAL FACTOR LEVELS.

Control factor	**Level**[*]		
	1	2	3
Machine speed (S,10^3Tab/hr)	0.6520 (156)	0.5117 (92)	0.6054 (130)
Compression Force (N)	0.5278 (94)	0.5150 (95)	0.7262 (189)
Filling Depth (mm)	0.6116 (140)	0.5458 (102)	0.6117 (136)

[*] The sum of ordinal values for each factor level in parenthesis.