Validation Analysis of a Plastic Shrinkage Process after an Injection Molding Operation

Patricia A. Valbuena Correa
Manufacturing Competitiveness
Jose Alberto Morales, PhD
Industrial Engineering Department
Polytechnic University of Puerto Rico

Abstract *— A validation process is essential during the start up of a new mold to ensure that the product will fulfill the function for which it was created. One common problem for production is finding the right parameters to achieve product specifications and optimum functionality. As part of this validation process a Shrinkage Study were performed in order to adjust original parameters on the machine after some functionality problems came up.*

The purpose of this study is to analyze through a variance experiment how molded products are subject to change in dimensions and shapes during their first 28 days of production. The results obtained by this study were used to re-adjust some parameters on the injection molding machine in order to achieve product functions stability, and release time before going to the next point of use.

Key Terms *— Dimensional Stability, Injection Molding, Shrinkage Study, Validation Process.*

INTRODUCTION

Injection molding is a big business worldwide, and an important plastic processing method. It consumes approximately 32 wt% of plastic industry. Therefore, it is essential for injection molding manufacturers to meet dimensional specifications and functional expectations of their molded products. Running a new molded part or device can become an every day challenge for production. During the injection molding process there are three basic operations [1] from the injection unit to the clamping unit. See Figure 1 [2]:

1) Heat the plastic in the injection or plasticizing unit so that it will flow under pressure.
2) Allow the plastic melted to cold and solidify in the mold.
3) Open the mold to eject the molded product.

A validation process is recommended to ensure dimensions are within specifications, not only for drug manufacturers, which is required by regulations, but for non-medical products as well. In that way it is possible to produce high quality products to their customers and keep the competitiveness in a demanding market. It is known a company obtains economic advantages when it takes care in keeping the quality levels of its products. This not only represents savings in expensive products reworks, but also in customer complains that consequently could finish in

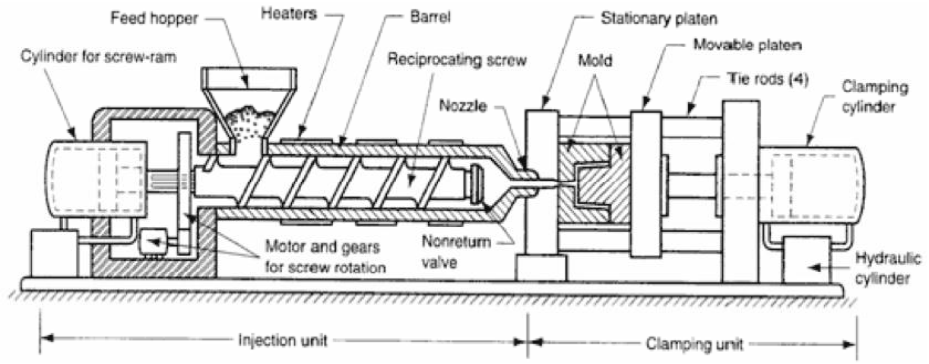

Figure 1
A Single Screw Injection Molding Machine System

business partnerships. Hence, producing quality products with the lower price should become a very important goal [3]. According to FDA Sec 490.100: "A validated manufacturing process has a high level of scientific assurance that it will reliably produce acceptable product. The proof of validation is obtained through rational experimental design and the evaluation of data, preferably beginning from the process development phase and continuing through the commercial production phase". The validation process should include an Installation Qualification, an Operational Qualification and a Performance Qualification [4].

This research emphasizes the importance of performing a shrinkage study as part of the Operational Qualification process when starting up of a new mold to produce the lid for a new candy package (Figure 2). Usually, shrinkage also causes warpage of the molded part, especially when it has thin surfaces. Mold shrinkage is observed in an injection thermoplastic molded part when it gets smaller than the cavity in which it was molded [5]. There are several factors affecting the quality of molded parts like machine parameters, molding material, part and mold design. However, shrinkage and warping are highly related to the machine parameters [6]-[7]. This Shrinkage Study performed as part of the Operational Qualification phase gave important information about how dimensions could change in a plastic device over a certain period of time, especially on thinner areas. The resin used for the lid was a Sunoco ZS-751 Polypropylene, which is a plastic polymer, (C3H6) widely used, especially for lids and caps that require a hinging mechanism [8]- [9].

Figure 2
Photo of the Lid

The lid operation is described as follow (see Figure 3): Immediately after the lid is molded, an additional operation is performed with a unit robot (attached to the molding machine) to close the lids before they go to a bulk package through a conveyor. This is a mold of 8 pieces per shot.

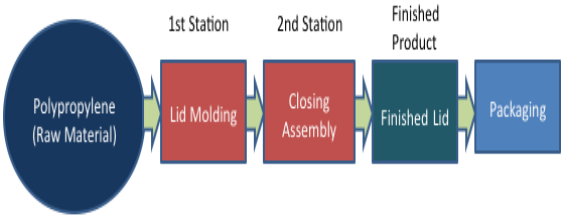

Figure 3
Lid Molding Operation

During validation some malfunctioned problems were detected on the opening system of the lid causing for some of them to open spontaneously when the container was on the filling line. Therefore, some parameters were changed after analyzing that the lid had suffered some shrinkage in the area of the opening system, which happened to be slightly thinner than the rest of the lid.

DESIGN OF EXPERIMENT

Four critical dimensions were analyzed (see figure 4): Total Outside Length (TOL), Total Outside Width (TOW), Fit Length (FL) and Fit Width (FW). Each dimension was measured using a digital caliper (in millimeters) at the following intervals: 15 minutes, 30 minutes, 60 minutes, 2 hours, 24 hours, 48 hours, 7 days and 28 days. Because this mold has 8 cavities, samples were taken from one mold shot of 8 lids. Also, samples were kept on an average room temperature of 22°C.

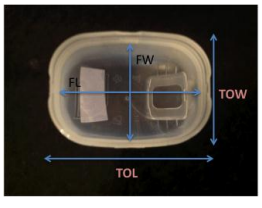

Figure 4
Lid's Dimensions

A comparison was made between two set of samples; the first set was taken immediately after the problem had arisen, and the second one approximately two weeks later. After analyzing the shrinkage of the first set, it was observed more shrinkage on the Fit Width dimensions. Therefore, holding time and holding pressure parameters were increased.

First Set of Samples

The following tables show dimensions before parameter changes.

Table 1

Total Outside Length from One Mold Shot

	at 15 min	at 60 min	at 2 hrs	at 24 hrs	at 48 hrs	at 7 days	at 28 days
1	60.38	60.40	60.22	60.38	60.33	60.39	60.37
2	60.29	60.35	60.36	60.25	60.30	60.34	60.35
3	60.39	60.41	60.35	60.38	60.38	60.40	60.48
4	60.38	60.40	60.39	60.44	60.35	60.32	60.39
5	60.34	60.45	60.42	60.44	60.32	60.52	60.53
6	60.65	60.43	60.50	60.47	60.39	60.46	60.47
7	60.32	60.50	60.44	60.33	60.39	60.39	60.39
8	60.40	60.52	60.50	60.45	60.45	60.45	60.46
Mean	**60.39**	**60.43**	**60.40**	**60.39**	**60.36**	**60.41**	**60.43**
Min	**60.29**	**60.35**	**60.22**	**60.25**	**60.30**	**60.32**	**60.35**
Max	**60.65**	**60.52**	**60.50**	**60.47**	**60.45**	**60.52**	**60.53**
SD	**0.11**	**0.06**	**0.09**	**0.07**	**0.05**	**0.07**	**0.06**
CV	**0.18**	**0.09**	**0.15**	**0.12**	**0.08**	**0.11**	**0.11**

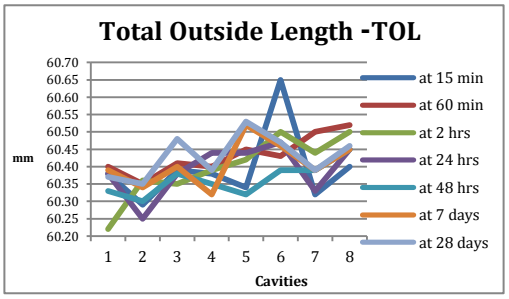

Figure 5

TOL Graph from Table 1

Table 1 and Figure 5 show not significant shrinkage on the Total Outside Length of the lids, as a contrary some expansion is observed. Standard deviation average is 0.07mm and variation average is 0.12mm, which are low.

Table 2

Shrinkage of TOL from Table 1

CAV	at 15 min	at 28 days	Dif	Shink %
1	60.38	60.37	-0.01	0.02%
2	60.29	60.35	0.06	-0.10%
3	60.39	60.48	0.09	-0.15%
4	60.38	60.39	0.01	-0.02%
5	60.34	60.53	0.19	-0.31%
6	60.65	60.47	-0.18	0.30%
7	60.32	60.39	0.07	-0.12%
8	60.40	60.46	0.06	-0.10%

Table 2 confirms observation on Figure 5 as negative shrinkage percentages are seen along the lids.

Table 3

Total Outside Width from One Mold Shot

	at 15 min	at 60 min	at 2 hrs	at 24 hrs	at 48 hrs	at 7 days	at 28 days
1	44.11	44.12	44.40	44.16	44.09	44.18	44.19
2	44.30	44.22	44.15	44.10	44.18	44.38	44.51
3	44.13	44.18	43.02	43.98	43.86	43.90	43.91
4	44.19	44.30	44.33	44.01	44.23	44.18	44.21
5	43.88	43.72	43.72	43.75	43.97	43.78	43.62
6	43.40	43.83	43.70	43.72	44.10	43.71	43.63
7	44.06	44.03	43.94	44.00	43.94	44.12	44.04
8	43.80	43.82	43.71	43.68	43.98	43.67	43.65
Mean	**43.98**	**44.03**	**43.87**	**43.93**	**44.04**	**43.99**	**43.97**
Min	**43.40**	**43.72**	**43.02**	**43.68**	**43.86**	**43.67**	**43.62**
Max	**44.30**	**44.30**	**44.40**	**44.16**	**44.23**	**44.38**	**44.51**
SD	**0.29**	**0.21**	**0.44**	**0.18**	**0.13**	**0.26**	**0.33**
CV	**0.65**	**0.49**	**1.01**	**0.42**	**0.29**	**0.59**	**0.74**

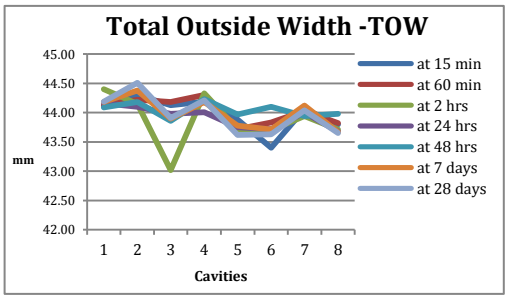

Figure 6

TOW Graph from Table 2

Table 3 and Figure 6 show some shrinkage tendency on the Total Outside Width of the lids along cavities during the 28 days of experiment. Standard deviation average is 0.26mm and variation average is 0.60mm. The higher variations are at 2hrs and at 28 days.

Table 4

Shrinkage of TOW from Table 3

CAV	at 15 min	at 28 days	Dif	Shink %
1	44.11	44.19	0.08	-0.18%
2	44.30	44.51	0.21	-0.47%
3	44.13	43.91	-0.22	0.50%
4	44.19	44.21	0.02	-0.05%
5	43.88	43.62	-0.26	0.59%
6	43.40	43.63	0.23	-0.53%
7	44.06	44.04	-0.02	0.05%
8	43.80	43.65	-0.15	0.34%

In Table 4 less consistency is seen on dimensions and some shrinkage on cavities 3 and 5.

Table 6

Shrinkage in FL from Table 5

CAV	at 15 min	at 28 days	Dif	Shink %
1	55.41	55.26	-0.15	0.27%
2	55.37	55.02	-0.35	0.63%
3	55.40	55.14	-0.26	0.47%
4	55.48	55.17	-0.31	0.56%
5	55.41	54.86	-0.55	0.99%
6	55.43	55.27	-0.16	0.29%
7	55.54	55.15	-0.39	0.70%
8	55.49	55.08	-0.41	0.74%

Table 6 shows some shrinkage along all cavities, especially on cavities 5, 7 and 8.

Table 5

Fit Length from One Mold Shot

	at 15 min	at 60 min	at 2 hrs	at 24 hrs	at 48 hrs	at 7 days	at 28 days
1	55.41	55.22	55.37	55.34	54.82	55.31	55.26
2	55.37	55.26	54.89	55.34	55.23	55.20	55.02
3	55.40	55.33	55.26	55.28	55.30	55.31	55.14
4	55.48	55.45	55.27	55.38	55.00	55.27	55.17
5	55.41	55.35	55.38	55.21	55.26	55.30	54.86
6	55.43	55.48	55.45	55.38	55.36	55.34	55.27
7	55.54	55.30	55.38	55.29	55.27	55.22	55.15
8	55.49	55.40	55.49	55.37	55.23	55.40	55.08
Mean	**55.44**	**55.35**	**55.31**	**55.32**	**55.18**	**55.29**	**55.12**
Min	**55.37**	**55.22**	**54.89**	**55.21**	**54.82**	**55.20**	**54.86**
Max	**55.54**	**55.48**	**55.49**	**55.38**	**55.36**	**55.40**	**55.27**
SD	**0.06**	**0.09**	**0.19**	**0.06**	**0.18**	**0.06**	**0.13**
CV	**0.10**	**0.16**	**0.34**	**0.11**	**0.33**	**0.12**	**0.24**

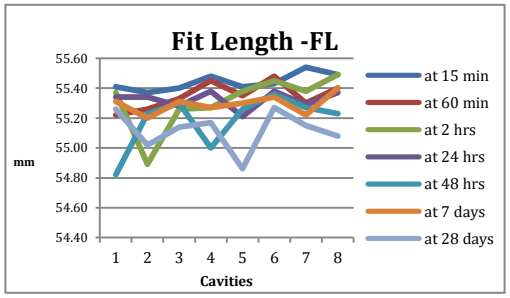

Figure 7

FL Graph from Table 5

Table 5 and Figure 7 show some shrinkage on Fit Length during the 28 days. However, standard deviation average is 0.11 and variation average is 0.20, which are low.

Table 11

Fit Width from One Mold Shot

	at 15 min	at 60 min	at 2 hrs	at 24 hrs	at 48 hrs	at 7 days	at 28 days
1	38.66	38.44	38.53	38.42	38.17	38.14	38.22
2	38.43	38.59	38.56	38.63	37.65	38.53	38.24
3	38.30	37.82	37.78	37.95	37.84	37.65	37.64
4	37.86	38.50	38.16	38.23	37.57	38.41	38.07
5	38.65	37.76	37.72	37.57	37.69	37.55	37.53
6	37.62	37.63	37.62	37.50	37.94	37.51	37.41
7	38.16	38.21	38.36	38.15	38.15	38.17	38.17
8	37.73	37.96	37.89	37.64	37.72	37.53	37.71
Mean	**38.18**	**38.11**	**38.08**	**38.01**	**37.84**	**37.94**	**37.87**
Min	**37.62**	**37.63**	**37.62**	**37.50**	**37.57**	**37.51**	**37.41**
Max	**38.66**	**38.59**	**38.56**	**38.63**	**38.17**	**38.53**	**38.24**
SD	**0.40**	**0.37**	**0.38**	**0.42**	**0.23**	**0.42**	**0.34**
CV	**1.06**	**0.97**	**0.99**	**1.10**	**0.60**	**1.11**	**0.89**

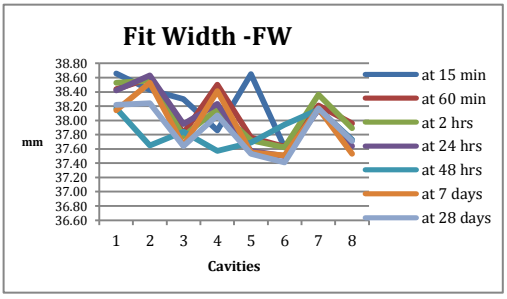

Figure 8

FW Graph from Table 7

Table 7 and Figure 8 show more movements on dimensions during the 28 days, especially on the first 24 hours. Standard deviation average is 0.36 and variation average is 0.96, being higher at 7 days. It is important to notice this is thinner dimension, so it is more susceptible to changes.

Table 8

Shrinkage in FW from Table 7

CAV	at 15 min	at 28 days	Dif	Shink %
1	38.66	38.22	-0.44	1.14%
2	38.43	38.24	-0.19	0.49%
3	38.30	37.64	-0.66	1.72%
4	37.86	38.07	0.21	-0.55%
5	38.65	37.53	-1.12	2.90%
6	37.62	37.41	-0.21	0.56%
7	38.16	38.17	0.01	-0.03%
8	37.73	37.71	-0.02	0.05%

Table 8 shows the biggest shrinkage was seen in cavities 5 and 3. Because Fit Width dimension is critical for making the opening system to work properly, it was decided to make some parameter changes in order to fix the problem.

Second Set of Samples

The following tables show dimensions after parameters were changed.

Table 9

Total Outside Length from one mold shot

	at 15 min	at 60 min	at 2 hrs	at 24 hrs	at 48 hrs	at 7 days	at 28 days
1	60.41	60.41	60.45	60.37	60.40	60.47	60.35
2	60.35	60.38	60.38	60.38	60.39	60.40	60.31
3	60.46	60.59	60.46	60.57	60.46	60.45	60.45
4	60.44	60.46	60.41	60.51	60.45	60.45	60.35
5	60.45	60.43	60.52	60.37	60.35	60.38	60.35
6	60.51	60.47	60.45	60.51	60.44	60.45	60.43
7	60.43	60.47	60.40	60.43	60.43	60.37	60.36
8	60.44	60.42	60.40	60.38	60.40	60.43	60.32
Mean	**60.44**	**60.45**	**60.43**	**60.44**	**60.42**	**60.43**	**60.37**
Min	**60.35**	**60.38**	**60.38**	**60.37**	**60.35**	**60.37**	**60.31**
Max	**60.51**	**60.59**	**60.52**	**60.57**	**60.46**	**60.47**	**60.45**
SD	**0.05**	**0.06**	**0.05**	**0.08**	**0.04**	**0.04**	**0.05**
Coef. Var	**0.08**	**0.10**	**0.08**	**0.13**	**0.06**	**0.06**	**0.08**

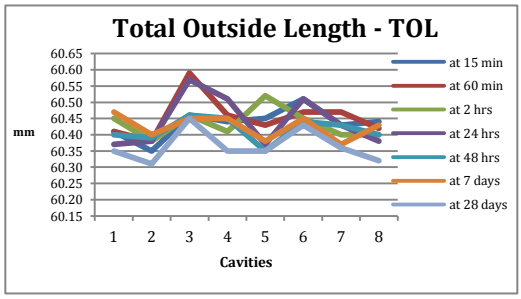

Figure 9

TOL Graph from Table 5

Table 9 and Figure 9 show similar stability when it is compared with the Total Outside Length form the first set of samples. Standard deviation average is 0.05 and variation average is 0.08, which is still low.

Table 10

Shrinkage in TOL from Table 9

CAV	at 15 min	at 28 days	Dif	Shink %
1	60.41	60.35	-0.06	0.10%
2	60.35	60.31	-0.04	0.07%
3	60.46	60.45	-0.01	0.02%
4	60.44	60.35	-0.09	0.15%
5	60.45	60.35	-0.10	0.17%
6	60.51	60.43	-0.08	0.13%
7	60.43	60.36	-0.07	0.12%
8	60.44	60.32	-0.12	0.20%

Table 10 shows shrinkage percentages are relativity low and not presenting problems on production line.

Table 6

Total Outside Width from One Mold Shot

	at 15 min	at 60 min	at 2 hrs	at 24 hrs	at 48 hrs	at 7 days	at 28 days
1	44.23	44.37	44.44	44.37	44.48	44.32	44.32
2	44.45	44.42	44.49	44.45	44.75	44.35	44.27
3	43.93	44.13	44.32	44.04	44.08	44.13	43.83
4	44.29	44.30	44.30	44.34	44.31	44.41	44.25
5	44.39	44.36	44.30	44.08	44.80	44.17	44.05
6	43.95	44.17	44.31	44.06	44.10	44.16	44.01
7	44.37	44.88	44.85	44.40	44.33	44.32	44.18
8	44.21	44.26	44.29	44.22	44.13	44.21	44.21
Mean	**44.23**	**44.36**	**44.41**	**44.25**	**44.37**	**44.26**	**44.14**
Min	**43.93**	**44.13**	**44.29**	**44.04**	**44.08**	**44.13**	**43.83**
Max	**44.45**	**44.88**	**44.85**	**44.45**	**44.80**	**44.41**	**44.32**
SD	**0.19**	**0.23**	**0.19**	**0.17**	**0.28**	**0.10**	**0.16**
Coef. Var	**0.44**	**0.52**	**0.43**	**0.38**	**0.64**	**0.23**	**0.37**

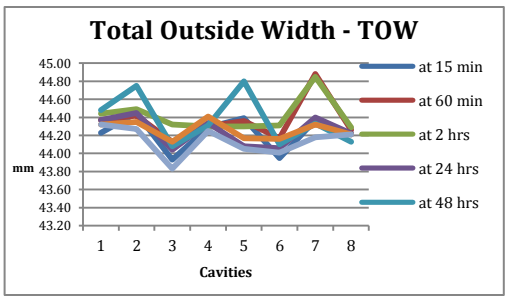

Figure 10

Total Outside Width from Table 11

Table 11 and Figure 10 show more stability in Total Outside Width if it is compared with previous set of samples. Standard deviation average is 0.19 and variation average is 0.43. Both values are lower than the previous from the first set of samples.

Table 12
Shrinkage in TOW from Table 11

CAV	at 15 min	at 28 days	Dif	Shink %
1	44.23	44.32	0.09	-0.20%
2	44.45	44.27	-0.18	0.40%
3	43.93	43.83	-0.10	0.23%
4	44.29	44.25	-0.04	0.09%
5	44.39	44.05	-0.34	0.77%
6	43.95	44.01	0.06	-0.14%
7	44.37	44.18	-0.19	0.43%
8	44.21	44.21	0.00	0.00%

Tablet 12 shows no significant shrinkage on this set of samples for Total Outside Width dimension.

Table 13
Fit Length from One Mold Shot

	at 15 min	at 60 min	at 2 hrs	at 24 hrs	at 48 hrs	at 7 days	at 28 days
1	55.37	55.35	55.29	55.27	55.35	55.33	55.34
2	55.30	55.20	55.09	55.36	55.22	55.17	55.16
3	55.37	55.36	54.88	55.46	55.35	55.32	55.33
4	55.38	55.40	55.25	55.24	55.27	55.22	55.26
5	54.99	54.89	55.22	55.29	55.22	55.14	55.18
6	55.26	54.61	54.86	55.37	55.33	55.30	55.30
7	54.80	55.21	55.18	55.25	55.15	55.24	55.11
8	55.25	55.31	55.25	55.26	55.06	55.21	55.20
Mean	**55.22**	**55.17**	**55.13**	**55.31**	**55.24**	**55.24**	**55.24**
Min	**54.80**	**54.61**	**54.86**	**55.24**	**55.06**	**55.14**	**55.11**
Max	**55.38**	**55.40**	**55.29**	**55.46**	**55.35**	**55.33**	**55.34**
SD	**0.21**	**0.28**	**0.17**	**0.08**	**0.10**	**0.07**	**0.08**
Coef. Var	**0.38**	**0.50**	**0.31**	**0.14**	**0.19**	**0.13**	**0.15**

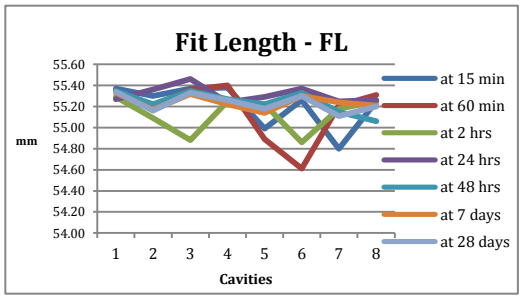

Figure 11
Fit Length from Table 13

Table 13 and Figure 11 show more stability of dimensions after the change. Standard deviation average is 0.14 with a variation average of 0.26 . This was a reduction of almost a 50% in both indicators from the set of samples before the parameter changes.

Table 14
Shrinkage in FL from Table 13

CAV	at 15 min	at 28 days	Dif	Shink %
1	55.37	55.34	-0.03	0.05%
2	55.30	55.16	-0.14	0.25%
3	55.37	55.33	-0.04	0.07%
4	55.38	55.26	-0.12	0.22%
5	54.99	55.18	0.19	-0.35%
6	55.26	55.30	0.04	-0.07%
7	54.80	55.11	0.31	-0.57%
8	55.25	55.20	-0.05	0.09%

Table 14 shows less shrinkage when it is compared with the samples before the changes, especially in cavity 5 that was higher.

Table 15
Fit Width from one mold shot

	at 15 min	at 60 min	at 2 hrs	at 24 hrs	at 48 hrs	at 7 days	at 28 days
1	38.53	38.63	38.41	38.46	38.45	38.65	38.49
2	38.37	38.38	38.10	38.40	38.30	38.60	38.50
3	37.83	37.71	37.97	37.90	37.74	37.88	37.88
4	38.21	38.37	38.36	38.30	38.33	38.38	38.41
5	38.33	38.19	38.25	38.28	38.27	38.25	38.18
6	37.99	37.98	37.71	38.12	38.03	38.06	38.04
7	38.30	38.22	38.22	38.44	38.36	38.30	38.13
8	38.28	38.33	38.26	38.22	38.38	38.33	38.25
Mean	**38.23**	**38.23**	**38.16**	**38.27**	**38.23**	**38.31**	**38.24**
Min	**37.83**	**37.71**	**37.71**	**37.90**	**37.74**	**37.88**	**37.88**
Max	**38.53**	**38.63**	**38.41**	**38.46**	**38.45**	**38.65**	**38.50**
SD	**0.22**	**0.28**	**0.23**	**0.19**	**0.23**	**0.26**	**0.22**
Coef. Var	**0.58**	**0.73**	**0.60**	**0.49**	**0.61**	**0.67**	**0.58**

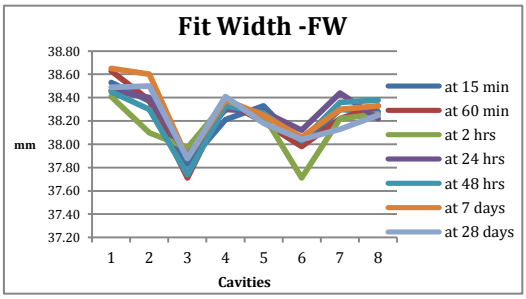

Figure 12
Fit Width from Table 8

Table 15 and Figure 12 show Fit Width have improved. More dimension stability is seen along the run. Standard deviation average is 0.23 and variation average is 0.61, which is a reduction close to the 30%.

Table 16
Shrinkage in FW from Table 15

CAV	at 15 min	at 28 days	Dif	Shink %
1	38.53	38.49	-0.04	0.10%
2	38.37	38.50	0.13	-0.34%
3	37.83	37.88	0.05	-0.13%
4	38.21	38.41	0.20	-0.52%
5	38.33	38.18	-0.15	0.39%
6	37.99	38.04	0.05	-0.13%
7	38.30	38.13	-0.17	0.44%
8	38.28	38.25	-0.03	0.08%

Table 16 shows not only a better dimension stability was obtained, but shrinkage has been reduced too along the shot.

RESULTS AND DISCUSSION

After a change of parameters to reduce shrinkage, these were some of the observations made: On Total Outside Length and Total Outside Width dimensions, no big differences were observed, except for some shrinkage on the Total Outside Length from the second group; however, dimensions were more consistent amount the cavities for Total Outside Length and Total Outside Width. On Fit Length and Fit Width dimensions, it was observed that less shrinkage occurred on lids from the second group than caps from the first group. A better consistency was observed in dimensions as well. Consequently, we can say that the changes observed in order to reduce shrinkage on the lids were as expected on Fit Length and Fit Width.

Although, a small improvement on the opening system was observed, an analysis of variance with a single degree of freedom was calculated for each dimension [10]. Two hypotheses were compared with an F Test and a 95% of confidence to see how significant the change on the parameters was.

- **F Test for Total Outside Length:**
  Ho: SD Samples 1 = SD Samples 2
  H1: SD Samples 1 > SD Samples 2
  F exp=2.040405469
  F crt =3.79

With a 95% of confidence, Sample 1 is not significantly higher than the Sample 2.

- **F Test for Total Outside Width:**
  Ho: SD Samples 1 = SD Samples 2
  H1: SD Samples 1 > SD Samples 2
  F exp=1.893320534
  F crt =3.79

With a 95% of confidence, Sample 1 is not significantly higher than the Sample 2.

- **F Test for Fit Length:**
  Ho: SD Samples 1 = SD Samples 2
  H1: SD Samples 1 > SD Samples 2
  F exp=0.607484274
  F crt =3.79

With a 95% of confidence, Sample 1 is not significantly higher than the Sample 2.

- **F Test for Fit Width:**
  Ho: SD Samples 1 = SD Samples 2
  H1: SD Samples 1 > SD Samples 2
  F exp=2.459273115
  F crt =3.79

With a 95% of confidence, Sample 1 is not significantly higher than the Sample 2.

CONCLUSION

Packing step is the one for more impact during the injection molding process when controlling shrinkage of molded parts. Packing includes holding pressure and holding time parameters, which can be increased when having a shrinkage problem. This way is possible to get a better stability in dimensions, especially on thinner areas.
This information was used to determine: first, release time of the product once it has achieved its dimensional stability, and second, under what conditions it should be stored, like warehouse temperature and stoking storage instructions when is bulk packed before going to the next point of use.

REFERENCES

[1] Rosato D.V, Rosato Marlene G. *"Injection Molding Handbook"* (Third Edition) 2000 p. 26, 27, 28, 329, 330, 331, 332, 702

[2] Xcentric Molding and Engineering Inc (n.d.). "*About Injection Molding". Retrieved August 14, 2012, from* www.xcentricmold.com/aboutinjectmold.php

[3] Akbarzadeh A. and Sadeghi M. *"Parameter Study in Plastic Injection Molding Process using Statistical Methods and IWO Algorithm"* University of Mashhad, Iran. May 24, 2011.

[4] FDA. Sec 490.100 Process Validation Requeriments for Drug Products ans Active Pharmaceutical Ingredients Aubject to Pre-Market Approval CPG 7132c.08. 2004

[5] Hsien W and Huang Y. *The Influence of Cavity Deformation on the Shrinkage and Warpage of an Injection-Molded Part".* Int J Adv Manuf Technol 2007. 32: 1144-1154

[6] Chiang K. and Chang F. *"Analysis of Shrinkage and Warpage in a Injection-Molded Part with a thin shell feature using the response suface methodology"* . Int J Adv Manuf Technol 2007. 35:468-479

[7] Chang T. and Faison E. *"Shrinkage Behavior and Optimizazation of Injection Molded Parts Studied by the Taguchi Method".* Polymer Engineering and Science. May 1, 2001.

[8] De Santis F. and Pantani R. *"As-Molded Shrinkage on Industrial Polypropelene Injection Molded Parts: experiment ans Analysis".* University of Salerno-Italy.

[9] Kramschuster A. and Cavitt R. *"Quantitative Study of Shrinkage and Warpage Behavior for Microcellular and Conventional Injection Molding".* Polymer Engineering and Science 2005

[10] Breyfogle F. *"Implementing Six Sigma".* Second Edition 2003