
CASE 34

LOREX PHARMACEUTICALS

Carter Blakely, manager of quality assurance for the manufacturing division of Lorex Pharmaceuticals, was pleased with the progress made so far toward the production of the company's newest product, Linatol. Linatol was a highly promising medicine for the treatment of high blood pressure developed and patented by Lorex several years ago. After eight years of thorough product testing, including clinical studies of the drug's effectiveness on humans, the Food and Drug Administration (FDA) had approved Linatol only a week ago. The manufacturing division had been able to prepare a production line during the past week and now one-shift production was scheduled to begin on Monday. The marketing division at Lorex had decided that the initial offering of Linatol would be in sealed 10-ounce bottles, packaged in cases of 12 bottles each. The wholesale price had been set at \$186 per case. The one task remaining for Blakely on this Friday afternoon was the selection of a target amount to which each of the 10-ounce bottles of Linatol would be filled.

The Manufacturing of Linatol

Linatol was blended in 5,000-liter batches using a process and formula that were kept confidential by the company. The product was then bottled on one of the company's semiautomatic filling lines. These lines consisted of an automatic filling mechanism for liquids, a capping and sealing component, and an electronic sensor capable of measuring the volume of liquid in each bottle. Bottles that were filled properly were conveyed to a packaging machine that would load and seal cartons of 12 bottles each. At top speed, the line chosen for Linatol could fill and package 1,000 bottles per hour. Because of unavoidable delays and setup requirements, the production rate was expected to average 500 cases over an eight-hour shift. These rates were slower than most of the other filling lines in use, but the relatively low production volumes of Linatol dictated that it be filled on one of the older, slower lines, which was not needed for any other product.

The entire line was operated by two employees who earned \$12.80 per hour, including fringe benefits. Every product was charged an overhead burden to cover the huge expense of maintaining an antiseptic filling room. For the line on which Linatol would be bottled, the overhead was charged at a rate of \$89.50 per hour.

The cost of the materials used by the filling line (bottles, caps, cap seals, labels, and packaging) was estimated to be \$1.10 per bottle.

Those bottles not filled to the 10-ounce requirement were identified by the electronic eye and automatically directed for special handling. A team of filling-room attendants periodically labeled these underfilled bottles as seconds and

Setting the Fill Target

It now remained for Carter Blakely to determine the fill target. The 10.2-ounce target chosen for the test was arbitrary, and certainly no economic justification existed for keeping this target. A rule often used for setting fill targets was to pick a target that was one standard deviation above the required amount. The relevant standard deviation was, of course, the standard deviation of the amounts placed in individual bottles. However, a one-standard-deviation rule, although cloaked with a certain amount of statistical justification, also seemed to ignore the peculiar economics associated with each filling situation. In fact, a one-standard-deviation rule in the past had led to several occasions when the buffer storage area for underfilled bottles had become clogged with rejected bottles, which caused a temporary stoppage of the entire filling line.

EXHIBIT 2 Filling-Line Test Results

9.89*	10.41	10.53	10.20	10.23	10.15
10.17	10.17	10.32	10.04	10.48	10.11
10.29	10.35	10.16	10.16	10.17	10.19
10.00	10.06	10.21	10.22	9.76*	10.22
10.04	10.19	10.09	10.12	10.06	10.10
10.35	10.17	10.02	10.35	10.17	9.99*
10.05	10.07	10.32	10.24	10.04	10.40
10.19	10.27	10.14	10.07	10.41	10.76
10.21	10.13	10.11	10.40	10.27	10.20
9.79*	10.24	10.20	10.29	10.00	10.31
10.53	10.14	10.35	10.21	10.23	10.16
10.47	9.84*	9.96*	10.10	10.11	10.23
10.24	10.36	10.30	10.23	10.19	10.17
10.17	10.11	10.33	10.19	9.97*	10.00
10.15	10.42	10.36	10.19	10.05	10.11
10.06	10.16	10.17	10.29	10.12	10.30
10.13	10.21	10.15	10.25	10.33	10.64
10.04	10.01	10.14	10.18	10.18	10.10
10.20	10.25	10.07	10.42	10.54	10.23
10.37	10.44	10.37	9.85*	9.91*	10.45
10.24	10.44	10.40	10.45	10.28	10.17
10.03	10.44	10.25	10.37	10.23	10.19
10.01	10.13	10.24	10.22	9.98*	9.98*
10.20	10.29	10.03	10.19	9.99*	10.13
Average	10.16	10.22	10.22	10.15	10.22
Std. dev.	0.17	0.16	0.14	0.18	0.19
Grand avg.	10.20				
Std. dev.	0.16				

*Identified by the sensor as underfilled.

EXHIBIT 1 Linatol Projected Operating Profit (5,000 liters; i.e., 169,088 ounces)

<i>Item</i>	<i>Cost</i>
Revenue:	
Commercial*	\$218,405
Seconds (15% rejects)	<u>30,834</u>
Total	<u>\$249,239</u>
Costs:	
Active ingredients	\$ 67,662
Blending direct labor	432
Blending indirect labor	170
Blending overhead	1,698
Filling materials	18,235
Filling direct labor	566
Filling overhead	1,978
Seconds packaging labor	<u>147</u>
Total	<u>\$ 90,888</u>
Gross margin	<u>\$158,351</u>

*At a 10.2-ounce target, one batch yields 1,381.44 cases. At an 85% acceptance rate, 1,174.22 of the cases are sold in the commercial market, and 207.22 are sold as seconds. This fill target and acceptance rate are for planning purposes only. The actual target and acceptance rate will be determined after the filling-line test.

hand-packaged them for sale to secondary markets (such as government hospitals) at 80 percent of the normal price of \$186 per case. Although these attendants spent most of their time hand-packaging underfilled products, a variety of other activities kept them busy. Each attendant was capable of labeling and packaging about 12 cases per hour. Attendants made \$8.50 per hour, including fringe benefits.

The initial production of Linatol had been scheduled for one 40-hour-per-week shift on the filling line for the foreseeable future. The actual batch blending of Linatol would be scheduled accordingly. An approximate operating profit statement for Linatol (prepared prior to the filling-line test) is given in Exhibit 1.

The Filling-Line Test

Prior to the start-up of production of a new product, the process capability of the filling line was tested—first with an inexpensive liquid with physical properties similar to the product and finally with the product itself. Once the filling process was “perfected,” samples of the filled bottles were individually measured. The results of 144 bottles of Linatol filled during a test are given in Exhibit 2. This exhibit also shows which of the 144 bottles were selected by the electronic sensor as underfilled. For this test, the filling mechanism was adjusted to fill to a target of 10.2 fluid ounces. The consistency of amounts in the 144 test bottles left little doubt that the fill mechanism could be set to any desired target.