Application Note

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The Importance of Accurately Measuring the Moisture Content of Plastic Resin in the Molding Process of Medical Devices

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Abstract

Moisture content is an important variable that must be monitored for and controlled during the production of plastic medical device parts. ASTM standard D6869 is the benchmark for measuring the moisture content of plastic resin, and stipulates the use of Karl Fischer (KF) titration as the applicable standard method. However, a KF titrator is expensive, and testing for moisture requires the use of toxic chemicals so that it can only be used by a trained chemist. A loss-on-drying (LOD) moisture analyzer can be an alternate method for testing moisture in plastic resin, but must be correlated to the KF titration as the measurement principles of both differ. Herein, we show that the Sartorius Mark 3 High Performance Moisture Analyzer correlates well with KF titration standards for a number of plastic resins commonly used in medical device manufacture.

The Mark 3 is a recognized ASTM 6980 standard method for testing the moisture content of plastic resin that is a good return on investment for medical device manufacturers because it is easy to use, has low maintenance costs, reduces the risk of rejected parts and customer dissatisfaction, and reduces energy consumption.

Introduction

One important variable to monitor and control for during the production of plastic medical device parts is moisture content. Resin manufacturers provide material specification sheets detailing the maximum moisture specification, or the maximum allowable ratio of water in the resin before molding or extrusion. Depending on the resin, maximum moisture specification can vary from 0.20% to as low as 0.005% moisture.

The manufacturer's data sheet also provides general guidelines on drying temperature and time for the resin before molding. For instance, a typical drying specification is drying the resin at 180 ◦F for 4 hours before molding. However, these general recommendations do not take into consideration the environment where the resin is stored, or the efficiency of the drying system being used. When following the recommendations for drying temperature and time, the result is likely to be satisfactory--if the resin is within anticipated moisture levels before loading into the dryer.

If the resin is wetter than anticipated, however, the recommended drying time may not be enough to drive off the moisture required to meet the maximum moisture specification. Molding wet resin can result in splay marks, streaking, fogging, burrs, and poor mechanical properties. Many medical device parts, such as syringes, medical tubing, and even eyeglass lenses, must be totally transparent and without visual defects. Other medical parts are molded to very precise specifications, and excess moisture can affect the flow properties of the resin, causing imperfections that make the final part useless for its intended purpose.

Over-drying a resin, on the other hand, can actually be more problematic than under-drying. An over-dried part may look perfect, yet, over-drying may burn off technically important plasticizers and additives that are critical for the durability, elasticity, and corrosion resistance of the part.

Accurate measurement of the moisture content in plastic resin

ASTM standard D6869 is the benchmark for measuring the moisture content of plastic resin, and stipulates the use of Karl Fischer (KF) titration as the applicable standard method. However, a KF titrator is both expensive to purchase and to maintain. Also, testing moisture with a KF titrator requires the use of toxic chemicals, so the test can only be performed by a trained chemist, using appropriate safety precautions. Therefore, most manufacturers prefer to use alternative methods for moisture testing.

Fortunately, ASTM 6980 states that a loss-on-drying (LOD) moisture analyzer can be an alternate method for testing moisture in plastic resin. LOD moisture analyzers measure weight loss to determine the moisture content of a sample. Because they cannot distinguish between weight loss from water and weight loss from other volatiles being driven off by heating the sample, ASTM 6980 requires that test methods on an LOD analyzer are developed to correlate to the ASTM 6869 KF titration standard.

One such LOD analyzer is the Sartorius Mark 3 High Performance Moisture Analyzer, which is recognized as an ASTM 6980 standard method for testing the moisture content of plastic resin. We undertook this study to demonstrate the calibration of the Mark 3 to the KF titration standard for a number of different resins.

Methods & Results

Our Sartorius Moisture Application labs, based in the US (Bohemia, New York) and Göttingen (Germany) offer program development for all kinds of plastic resins, including correlation to the reference method (usually KF titration). To make sure that the final program provides traceable and reproducible results for samples of different moisture content, dry and wet samples are used during program development to make sure the resulting program is sufficient in any case. Specific programs are developed for each resin to guarantee both a correlation between KF titration and the Mark 3 and to ensure ASTM 6980 requirements of are met. To date, Sartorius has developed programs for over 7,000 resins.

The table below lists some commonly used plastic resins in the molding and extruding of medical parts, along with data showing the correlation between the Mark 3 and KF titration standard. Of particular note, the standard deviation between the moisture content as determined by the KF titration standard and the Mark 3 never reaches statistical significance, indicating that the Mark 3 gives comparable results to the KF titration standard.

Generic	Specific Grade	KF Titration	Mark 3 Results	Test Times (min.)	Std. Dev.
Polypropylene	RTP 199 X 99167	0.014%	0.014%	4.0	0.001
Polystyrene	Styron 478	0.021%	0.021%	5.0	0.001
Polycarbonate	Lexan 500	0.015%	0.016%	4.0	0.002
Peek	Victrex 381G	0.015%	0.015%	4.3	0.002
ABS	Lustran LK 279	0.061%	0.060%	10	0.001
Polysulfone	Udel P-1700	0.020%	0.019%	5.0	0.001
Polyethylene	Borstar HE3490-LS	0.017%	0.016%	5.0	0.001
Polyamide	Durethan BG30X	0.071%	0.072%	5.0	0.004
PET	Rynite 530	0.020%	0.019%	3.5	0.003
Polyvinyl Choride	Apex 910-R4	0.033%	0.032%	5.0	0.002
TPC	Hytrel 8238	0.040%	0.040%	6.3	0.001
PBT	Valox 325	0.010%	0.010%	4.0	0.001

Table 1: Correlation results between Karl Fischer coulometric titration and the Mark 3 moisture analyzer.

Conclusions

Manufacturers of medical parts recognize the necessity of accurately monitoring the moisture content of their plastic resin throughout the manufacturing process. The high cost of resins used in making these parts, the stringent specification these parts must meet, and the potential liability should a part fail, all make the purchase of an LOD moisture analyzer a good investment. The Mark 3 High Performance Moisture Analyzer is a good choice for such manufacturers.

The Mark 3 can be programmed with methods for all the resins manufacturers commonly process, and is recognized as an ASTM 6980 standard method for testing the moisture content of plastic resin. The Mark 3 is easy to use and has low maintenance costs. In addition, the cost savings associated with reducing the risk of rejected parts and customer dissatisfaction as well as energy reductions by cutting drying time makes the purchase of a Mark 3 High Performance Moisture Analyzer a good return on investment.

For more information on the Mark 3, including a quote, please visit Sartorius.com

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