MPS PHARMA & MEDICAL

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Depyrogenation is almost always carried out via exposure to dry heat. Per USP 1228.1, dry heat depyrogenation is typically performed in oven set at a temperature somewhere between 170 degrees C and 400 degrees C for a minimum of 30 minutes. Although this process works extremely well for components made out of heat stable materials, e.g. borosilicate glass and stainless steel, it does not work on materials that have a lower melt index.

MPS products such as dropper bottles, tip, caps and tube sets are mainly made from polymeric materials such as Polypropylene (PP), Low-Density Polypropylene (LDPE), Polyvinyl Chloride (PVC) and, due to their low melt index, cannot withstand standard depyrogenation temperatures. Essentially, depyrogenation process will damage or melt the product rendering it unusable.

In general, when the components are molded, that molding temperature depyrogenates the component. If those components are packaged quickly, in non-pyrogenic containers and assembled in a fashion that doesn't contribute to an additional endotoxin load, one can maintain a low level of endotoxin on the parts.

MPS products are subjected to additional processes following the high temperature molding process which includes packaging and sterilization operations. As explained above depyrogenation process is not viable for MPS products, instead additional processes are tightly controlled and final product release includes a measurement of these pyrogens.

At MPS, final state products are sampled and tested for Bacterial Endotoxin per USP <85> and < 161> and verified to meet the endotoxin limits to ensure that they can be labeled as non-pyrogenic. All results are reported for each lot number on MPS's 'Certificate of Analysis'.

References:

FDA guidance document 1/21/2016: Submission and Review of Sterility Information in Premarket Notification (510k) Submissions for Devices Labeled as Sterile