**FIGURE 5** Laser-etched ampoules showing pump head used and order of dispensing.

*Monitoring of the Dispensing Process*

Ampoules on the AFV 5090 are laser-etched with the unique batch code (Fig. 5) as part of the filling process. This enables them to be identified at all stages of subsequent processing prior to application of the final label, and also allows the pump head used and the sequence within the filling process to be identified.

The Bausch and Strobel vial-filling machine FVF5060 weighs each vial before and after filling and records the net weight. Vials that are out of range cause an alarm and are automatically rejected. The fill weight is adjusted manually to maintain an optimum weight.

The ampoule-filling machine AVF5090 uses three pumps and weighs a set of three ampoules before and after filling. During setup mode it automatically weighs all the ampoules and adjusts each pump to bring the weights in range. Once acceptable weights are achieved, dispensing is allowed to proceed and 3 in every 90 ampoules are checked routinely throughout the rest of the fill. Small variations will prompt the machine to self-adjust to optimize the fill weights. A weight that is out of range stops the machine and reverts it to setup mode.

The older Paxal Schubert filling machine uses a peristaltic pumping mechanism and relies on manual check weighing and adjustment. Typically 1% to 2% of the batch is checked manually.

The CV of the filling process is calculated across a number of ampoules/vials in the filling operation and the data is used to assess the accuracy of fill across the run (Fig. 6)