

22nd April 2016

Mylan Reference: PQC-UKIE-2016-045
Creon 25,000 Capsules, Batch 52564.

On April, 11th we identified in a Twitter message a product complaint relating to Creon 25,000. This indicated that three capsules of Creon were empty.

As the marketing authorisation holder for Creon, Mylan sent the batch number (which was provided in a subsequent Tweet on April, 12th) and the details of the complaint to Abbott, the manufacturer of Creon, for expedited investigation.

The manufacturer reviewed the batch records and did an in-depth check of the associated quality system data (encapsulation, packaging and calibration). In addition a retained sample of the batch was also examined by the manufacturer. Furthermore, the manufacturer also conducted a review of the general quality control systems in the production process: It was concluded that a container with three empty capsules would have been definitely been separated by the 3-step automated control systems (filling machine check, camera system and automated weigher).

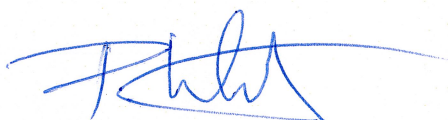
Taking everything in consideration the manufacturer concluded that the complaint description could not be confirmed.

Despite that this is the first and only complaint for the product batch, we and the manufacturer keep monitoring carefully at every level (plant, pharmacists, and patients).

Unfortunately we don't have a direct contact to the patient. If you should hear back from the patient, please ask if the container was sealed when he received it and from which pharmacy he was dispensed the product. It would be useful to have the added information in order to investigate further.

We take the upmost care and attention to provide high quality products to our patients which are not only safe and efficacious to use but also meet the highest standards for customer satisfaction.

Yours sincerely,



Patrick Weston
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Mylan EPD