PRESS RELEASE
Botevgrad (BG), 11 March 2016

A new plant of GE PHARMACEUTICALS LTD started production: Two of the six lines with serialization and Tamper Evidence

From the beginning of 2016 a production of medicines was developed in accordance with the EU Directive for control of falsified medical products.

After the official opening of its second plant in September 2015 GE Pharmaceuticals Ltd started production in the new building in Botevgrad/Bulgaria. The Austrian-Bulgarian packaging specialist runs six production lines that have been certified for good manufacturing practice (GMP) and will continue to expand the capacities. Upon two of the six production lines GE introduces, from the beginning of 2016, a serialization of the pharmaceutical packages by 2D-Matrix code in connection with tamper evidence. According to EU Directive 2011/62/EU these two protecting features are to become obligatory from 2019 onwards. On 19 February 2016 a delegated act of the EU Directive was published, known as "Falsified Medicines Directive" (FMD). "By this a beginning of transformation was launched" said Dr. Günter Datz, the General Manager of GE Pharmaceuticals Ltd. "Exactly for the starting stage of transformation with our products corresponding to FMD we offer an adequate technical decision to the European Pharmaceutical Industry". Along with the two lines functioning in accordance with FMD in the new Plant 2 there function another four production lines which were transferred from the existing Plant 1. The change control procedures were finalized at the end of last year. "The new Plant 2 will be thoroughly equipped for automated production – with its maximum of 14 production lines in its final stage of development" Dr. Günter Datz explained. "On the other hand Plant 1 will be used for production of small batches up to 1 000 packages, for secondary repacking as well as filling of tablets and gelatin capsules in bottles. By re-grouping of production lines the necessary space capacity was achieved."

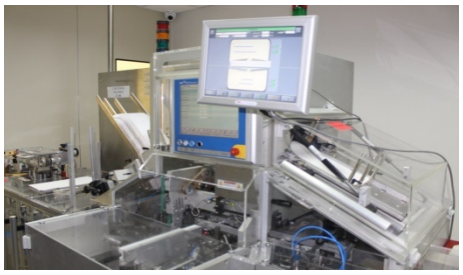
Before moving the existing production lines an extensive change control procedure was carried out. It was realized parallel to the current production from September to December 2015. After audits by the clients of GE till the end of last year a green light was given to all production lines in the new Plant 2. Along with dislocation of the existing four production lines another two lines with machines for blisters and carton packages were installed and they provided production in accordance with the FMD. In connection to a GMP certified warehouse in Plant 2 GE can manufacture on four production lines from the beginning of the year – for the time being on one of the two existing levels. On all production lines packing the blistering can be carried out under the control of relative air humidity and on two of the lines values under 40% of the relative air humidity are achievable.

GE Pharmaceuticals offers in its site in Botevgrad since 2006 a variety of services in the field of packing of tablets and hard gelatin capsules. The portfolio ranges from customs processing, trough EU-retests to performance of primary and secondary packing as well as manual re-packing. Through its Qualified Persons GE Pharmaceuticals offers of course all necessary laboratory analyses, stability tests and release of the packed products. For the first time the GMP-qualified production facility was certified by the Austrian inspection institute AGES in 2006. In the last years a number of audits and re-audits by clients took place as well as by the Bulgarian health authority BDA (Bulgarian Drug Agency). The last re-qualification by the BDA was carried out in June 2015. In addition to production GE Pharmaceuticals keeps in Botevgrad chemical and microbiological laboratories and offers respective laboratory services to external partners as well. GE Pharmaceuticals is specialized basically in production of small batches. For the last year the share of batches under 5 000 packages constituted 54% of the whole production and the batches under 1 000 packages constituted 25%.

Images:

Blister machine in the production site of GE

Plant 2 in Botevgrad – Beginning of production in 2016



Cartoning machine in the production site

The analytical laboratory of GE Pharmaceuticals

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GE Pharmaceuticals Ltd.

With currently 150 employees GE Pharmaceuticals Ltd in Botevgrad (Bulgaria) produces annually about 60 million blisters and 20 million packages of drugs. With the commissioning of the second manufacturing site in September 2015 the number of production lines increased to six - with the option to launch in future another twelve lines additionally. The Austrian-Bulgarian company was founded in 2005 as a joint venture with 31 employees. It is owned respectively to 50 percent by Ecopharm Ltd. and by Genericon Pharma Ltd, one of Austria's largest manufacturers of generics.