

## **GMP Status of Novartis Manufacturing Sites for the Novartis Access portfolio (August 2016)**

### **Novartis Pharma Stein AG, Stein, Switzerland**

Manufacturing site for [Letrozol](#)

GMP audited and approved by SwissMedic/Switzerland, US FDA, ANVISA/Brazil, Russia, CFDA/China, Turkey, MFDS/South Korea, COFEPRIS/Mexico, FDA Kenya, among others.

### **Novartis Farmacéutica S.A., Barberá del Vallés, Spain**

Manufacturing site for [Valsartan](#) and [Vildagliptin](#)

GMP audited and approved by EU (represented by Spain), US FDA, Turkey, ANVISA/Brazil, KFSA/South Korea, FDA Kenya, among others.

### **Lek S.A., Strykow, Poland**

Manufacturing site for [Bisoprolol](#), [Glimepride](#), [Metformin](#) and [Ramipril](#)

GMP audited and approved by EU (represented by Poland), Russia, FDA Kenya, NDA Uganda, among others.

### **Salutas Pharma GmbH, Barleben, Germany**

Manufacturing site for [Anastrozol](#), [HCT](#) and [Tamoxifen](#)

GMP audited and approved by EU (represented by Germany), ANVISA/Brazil, Russia, Turkey, FDA Kenya, NAFDAC/Nigeria, NDA Uganda, FDA Ghana, among others.

### **Aeropharm GmbH, Rudolstadt, Germany**

Manufacturing site for [Salbutamol Inhaler](#)

GMP audited and approved by EU (represented by Germany), Turkey, Russia, MFDS/South Korea, ANVISA/Brazil, KEMSA/Kenya, NDA Uganda, among others.

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**Sandoz Grup Saglik Urunleri Ilaclari, Gebze-Kocaeli, Turkey**

Manufacturing site for [Amlodipine and Simvastatin](#)

GMP audited and approved by Turkey, EU (represented by Germany), ANVISA/Brazil, among others.

**Sandoz Private Limited, Kalwe India**

Manufacturing site for [Furosemide](#).

GMP audited and approved by the FDA/India, EU (represented by Austria), US FDA, ANVISA/Brazil, ANMAT/Argentina, TGA/Australia, WHO/Geneva/Switzerland, PMDA/Japan, MFDS/South Korea, BFDA/Taiwan, Turkey, FDA Kenya, NAFDAC/Nigeria, MCC/South Africa, among others.

**Sandoz GmbH, Kundl, Austria**

Manufacturing site for [Amoxicillin](#)

GMP audited and approved by EU (represented by Austria), US FDA, Turkey, PMDA/Japan, MFDS/South Korea, CCD/China, ANVISA/Brazil, COFEPRIS/Mexico, Russia, MCC/South Africa, FDA Kenya, NAFDAC/Nigeria, NDA Uganda, among others.

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