

3.2.S.2.1 Manufacturer

Irbesartan is manufactured, tested and released by Yichang Changjiang Pharmaceutical Co., Ltd (Changjiang Pharm) in accordance with Current Good Manufacturing Practice (cGMP) and ICH Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients.

Information on the manufacturer is provided in the following table:

Name and Address	Responsibility
Yichang Changjiang Pharmaceutical Co., Ltd No. 38 - 62, Binjiang Road, Yidu, Hubei Province, P.R.China Postal code: 443300 Tel: 0086 769 85315888 ext. 2539 Fax: 0086 769 85370255 E-mail: luyanlian@hecpharm.com	Manufacture, release testing, packaging, and stability studies
HEC Pharm R&D Center DongYangGuang Park, No. 368 ZhenAn Road, ShangSha Village, Chang'An Town, DongGuan City, GuangDong province, China 523871 Tel: 0086-769-85315888 ext 2539 Fax: 0086-769-85370255 E-mail: luyanlian@hecpharm.com	Contract testing of Impurity B in the finished Irbesartan drug substance

Changjiang Pharm is located at 38 to 62, Binjiang Road, Yidu, Hubei province. The location provides convenient transportation, ample water and electricity supplies and an excellent environment. The company was founded in late 2002 as a joint venture between Shenzhen HEC Industrial Co., Ltd and Hongkong North & South Brothers Investment Company, a sister company of HEC Pharm R&D Center (R&D Center).

The principal business of Changjiang Pharm is the manufacturing and marketing of active pharmaceutical ingredients (APIs) and drug products, including tablets, capsules, suspensions, granules and lyophilized powders for injection for the Chinese market.

Changjiang Pharm manufacturing site was inspected by the US FDA for Zidovudine API production and classified as acceptable in 2011.