

**3.2.S.2.5 Process Validation and/or Evaluation**

Three submission batches of Irbesartan drug substance were manufactured at Changjiang Pharm's facilities using the manufacturing process described in [3.2.S.2.2](#). These batches were produced in line with the current GMP requirements. The identified critical parameters have been controlled within the prescribed ranges. All the batches meet the pre-determined specifications (Refer to [3.2.S.4.4 Batch Analyses](#)). No significant deviation and process/product failures were observed (Refer to [3.2.S.2.6.3 Summary of Submission Batch Production](#) for more information about the submission batches production).

The formal performance verification of Irbesartan drug substance manufacture process will be conducted before the product is commercially distributed.