

2.3.R REGIONAL INFORMATION

The process validation is not applicable for commercial scale of each strength, because the manufacturing equipment and operational procedure used in the future commercial manufacturing will be the same as those used for the pilot batches.

Irbesartan drug substance monograph has been contained in current Ph.Eur; however, the Certificate of Suitability is not available yet. The whole submission data supplied by API manufacturer (Changjiang Pharm) are submitted together with the data for drug product and are enclosed in 3.2.S (Changjiang Pharm). The additional API information from drug product manufacturer is presented in [3.2.S.2.2](#), 3.2.S.4 and 3.2.S.5 (drug product manufacturer) in this dossier.