## 3.2.P.3.5 PROCESS VALIDATION AND/OR EVAUATION

The results of the process evaluation for pilot scale batches is presented below. Validation results for production scale manufacture will be added when process validation is completed.

### 3.2.P.3.5.1 Process evaluation – pilot scale batches VAL 5953

This report describes the results from the evaluation of the manufacturing process of Levetiracetam 250, 500, 750 and 1000 mg tablets according to evaluation plan doc. ref. 5950. The reason for evaluation is a new formulation of tablets. The supplier of the active material used is Neuland.

The manufacturing site was Actavis's production plant in Hafnarfjordur. The method of manufacture is wet granulation, followed by fluid bed drying and mixing with lubricant prior to tablet compression. The final step is coating of the tablets. The product is conventional tablets. The 250, 500, 750 and 1000 mg strengths are all dose proportional.

Theoretical batch size of the final blend is 108 kg corresponding to 133,333 tablets of the 750 mg strength and 100,000 tablets of the 1000 mg strength. The final blend of theoretical batch size of 108 kg is divided into two sublots. One of 39.96 kg used for compression of 148,000 tablets of the 250 mg strength and a 66.96 kg sublot used for compression of 124,000 tablets of the 500 mg strength.

In this evaluation project final blend 94428 was 103.52 kg which was divided into a sublot of 36.56 kg used for the compression of 250 mg strength and a sublot of 66.96 kg used for the compression of the 500 mg strength.
Final blend 94429 was 106.26 kg which was divided into a sublot of 39.30 kg used for the compression of the 250 mg tablet strength and a sublot of 66.96 kg used for the compression of the 500 mg strength.

Two final blends were used exclusively to compress the 750 mg strength and two final blends were used exclusively to compress 1000 mg strength.

Results of four lots of final blend instead of three lots of final blend, as stated in the evaluation plan, are reported. Referene is made to deviation chapter for further information. Total of four lots of final blend and two tablet lots of each strength were subject to evaluation.

The manufacturing process for Levetiracetam 250, 500, 750 and 1000 mg tablets has been evaluated and is considered fully evaluated.

**SAMPLING AND TESTS**

***Optimisation***

Optimisation was performed on one tablet lot of each strength.

Minimum and maximum hardness were determined to establish optimal hardness. Maximum hardness was determined from maximum stress on punches and dissolution.