**Content of the annual product quality review report**

1. A review of starting and primary packaging materials used in the FPP, especially those from new sources;
2. A tabulated review of quality control and in-process control results;
3. A review of all batches that failed to meet established specification(s);
4. A review of all changes carried out to the processes or analytical methods;
5. A review of the results of the stability monitoring programme; and
6. A list of validated analytical and manufacturing procedures and their revalidation dates.