

Content of the annual product quality review report

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