Annex VIII: Product Quality Review (PQR) Requirements for Generic Pharmaceutical Products

For an established generic product a product quality review may satisfy the requirements of sections 3.2.P.2.2.1 (a), 3.2.P.2.3 (a) and 3.2.P.3.5 of the PD and QOS-PD.

A product quality review should be submitted with the objective of verifying the consistency of the quality of the FPP and its manufacturing process.

Rejected batches should not be included in the analysis but must be reported separately together with the reports of failure investigations, as indicated below.

Reviews should be conducted with not less than 10 consecutive batches manufactured over the period of the last 12 months, or, where 10 batches were not manufactured in the last 12 months, not less than 25 consecutive batches manufactured over the period of the last 36 months and should include at least:

A review of starting and primary packaging materials used in the FPP, especially those from new sources.

A tabulated review and statistical analysis of quality control and in-process control results.

A review of all batches that failed to meet established specification(s).

A review of all critical deviations or non-conformances and related investigations.

A review of all changes carried out to the processes or analytical methods.

A review of the results of the stability-monitoring programme.

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A review of all quality-related returns, complaints and recalls, including export- only medicinal products.

A review of the adequacy of previous corrective actions.

A list of validated analytical and manufacturing procedures and their revalidation dates.

Notes

Reviews must include data from all batches manufactured during the review period. Data should be presented in tabular or graphical form (i.e. charts or graphs), when applicable.