5.4 Content of the Product Review Report

		API for EU/ US	Bulk Formulated Product/ Drug product for US	Bulk Formulated Product/ Drug product manufactured in or for EU	Finished Product Packaging in or for EU
5.4.1	Summary	√	√	√	√
5.4.2	Batches reviewed	√	√	√	√
5.4.3	Starting / Packaging Materials			√	√
5.4.4	Analytical data	√	√	√	√**
5.4.5	Changes	√	√	√	√
5.4.6	Stability data	√	√	√	√*
5.4.7	Deviations	√	√	√	√
5.4.8	Reprocessed and reworked batches	√	√	√	
5.4.9	Rejected batches	√	√	√	√
5.4.10	Complaints	√	√	√	√
5.4.11	Recalls	√	√	√	√
5.4.12	Returned and Salvaged goods		√		
5.4.13	QA Agreements			√	√
5.4.14	Qualification status of relevant equipment and utilities			√	√
5.4.15	Market Authorization variations submitted / granted / refused			√	√
5.4.16	Post marketing commitments			√	√
5.4.17	Other	**	**	**	**
5.4.18	Comparison with previous review	√	√	√	√
5.4.19	Conclusions and recommendations	√	√	√	√