

3.2.P.8.2. POST-APPROVAL STABILITY PROTOCOL AND STABILITY COMMITMENT

3.2.P.8.2.1. Post-Approval Stability Protocol and Commitment

According to CPMP/QWP/122/02 “Note for Guidance on Stability Testing: Stability Testing of Existing Active Substances and Related Finished Products”, a post-approval stability commitment is considered unnecessary. Pfizer will continue to monitor batches on stability under long term condition to provide assurance that the product continues to meet the registered specifications through expiry.