

Table 10 Glossary

1. Quality Risk Management: A systematic process for the assessment, control, communication and review of risks to the quality of the drug (medicinal) product across the product life cycle.
2. Validation: Action of proving that any procedure, process, equipment, material, activity or system actually leads to the expected results (see also Qualification).
3. Quality System: The sum of all aspects of a system that implements quality policy and ensures that quality objectives are met.
4. Public Service Obligations: The authorisation/licence holder shall, in respect of a medicinal product that has actually been placed on the market and within the limits of his or her responsibility, ensure appropriate and continued supplies of that product so that the needs of patients in respect of such medicinal product are covered.
5. In a refrigerator : +2 to +8 °C
6. Qualification: Action of proving that any equipment works correctly and actually leads to the expected results. The word validation is sometimes widened to incorporate the concept of qualification.
7. Due diligence: This is a term used for a number of concepts, involving either an investigation of a business or persons prior to signing a contract, or an act with a certain standard of care.
8. Cold or Cool: +8 to + 15 °C
9. Deep freeze : Below -15 °C
10. Room Temperature: +15 to + 25 °C