TSC Category	Drug Compounding and Management					
TSC	Sterile Manufacturing of Pharmaceutical Products					
TSC Description	Process orders and prescriptions, assist in compounding of sterile products and review quality of finished products					
TSC Proficiency Description	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**	**Level 6**
		HCE-DRM-2007-1.1	**HCE-DRM-3007-1.1**			
		Prepare sterile products and work areas in accordance to protocols and practice standards	Inspect the quality of compounded sterile products (CSPs) including their manufacturing processes in order to identify potential areas of sterility compromise			
Knowledge		• Medication safety practices • Sterile manufacturing protocols and practice standards • Workplace Safety and Health (WSH) • Good Manufacturing Practice • Types of containers used in packaging • Labelling requirements for compounded products • Use of tools and equipment for compounding • Proper storage areas and/or conditions for compounded products • Organisational guidelines for disposing of waste • General principles in clinical pharmacology and therapeutic use of prescribed medicine • Formulas for specific products • Types of cleanrooms • Hand-washing and scrubbing techniques • Operational procedures on Laminar Air Flow Cabinets (LAFCs) • Operating principles of different types of	• Basic microbiology • Factors affecting quality and stability of sterile products • Properties of pharmaceutical products to be sterilised • Effects of bacterial contamination on products • Types of micro-organisms • Chain of infections • Cleanroom standards and operations • Environmental monitoring and validation methods • Operations and maintenance of Laminar Air Flow Cabinets (LAFCs) • Operations and maintenance of Biological Safety Cabinets (BSCs) • Consumables required for cleanroom operations • Sterility testing of products • Organisational procedures for operating and maintenance of cleanrooms • Procedures for monitoring and supervising operating			

		Biological Safety Cabinets (BSCs) • Types of tools and equipment for drug compounding • Structures, characteristics, and operational procedures for compounding equipment • Types of consumables, ingredients and amount needed for drug compounding • Methods to clean and disinfect processing areas, equipment and instruments • Organisational guidelines to reinstate and clean work areas • Basic aseptic dispensing skills	conditions of compounding processes • Sterile manufacturing validated operating procedures and process control parameters • Preventive measures to minimise risks of contamination • Factors affecting product sterility and contamination • ISO17025 guidelines			
Abilities		• Pack finished sterile products in compliance with worksheet specifications • Prepare labels according to worksheet specifications • Label finished sterile products correctly in accordance with organisational guidelines, including any auxiliary labels • Place final sterile products in appropriate storage areas and/or conditions • Dispose of waste correctly in accordance with organisational guidelines • Prepare raw ingredients required for compounding • Conduct checks on compounding inventory to ensure sufficient supply • Prepare tools and equipment required for	• Perform accurate measurements of items, ingredients and drugs needed • Perform compounding using appropriate compounding techniques and in the appropriate sequence • Perform visual inspection of Compounded Sterile Products (CSPs) for the purposes of quality control and ensuring that no impurities are present in the finished products • Obtain appropriate authorisations and checks at designated points according to worksheets • Identify and report concerns to supervisors on compromises to the sterility of products • Manage compounding records in accordance with organisational guidelines			

		compounding in accordance with organisational guidelines • Maintain work areas before and after compounding activities	• Gather patient information and laboratory values required for compounded drugs • Assess drug orders for drug compounding procedures • Calculate doses and volumes of chemotherapy, Total Parenteral Nutrition (TPN) and intravenous (IV) admixtures and infusions • Prepare worksheets according to orders including calculating and explaining doses and volume required • Document simple interventions performed in accordance to organisational procedures • Conduct regular internal audits on the quality and manufacturing processes of CSPs • Conduct environmental testing for cleanrooms and BSCs • Implement corrective actions when unacceptable standards of operation for cleanroom, LAFCs and BSCs are observed • Maintain proper documentation of audit and monitoring results • Review current sterile manufacturing processes to meet regulatory and organisational requirements and guidelines • Identify potential areas that compromise the preparation of sterile compounded drugs			