PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PEOCESS VARIABLE FOR DRY POWDER INJECTION (IN GLASS VIAL)

STAGE	CRITICAL PROCESS PARAMETERS	CRITICAL QUALITY ATTRIBUTES	JUSTIFICATION
Cleaning and Sterilization of Equipment	• Cleaning Time • Sterilization Temperature • Sterilization Hold Time **(Not limited, may vary from product to product)**	• pH of rinse sample • Conductivity of rinse sample. • Absorbance of rinse sample. • Chemical & biological indicatorsF0 evaluation.	• To optimize the chemical & microbiological control into process.
Washing Process of Vials	• Speed of Washing Machine • Pressure of WFI, Purified water, Recirculated water and Compressed Air. **(Not Limited may vary from product to product)**	• Clarity test of washed vials. • LBPC **(Not limited, may vary from product to product)**	To optimize the chemical & microbiological control into process.
Washing & Sterilization of Rubber Bungs	• Numbers of washing cycles & time • Siliconization • Sterilization Temperature • Sterilization Hold Time **(Not limited, may vary from product to product)**	• Moisture Content. • Sterility Test of Sterilized rubber bungs. • Bacterial Endotoxins Test of Sterilized rubber bungs. **(Not limited, may vary from product to product)**	To optimize the chemical & microbiological control into process.
Sterilization of Aluminium Seals	• Sterilization Temperature • Sterilization Hold Time **(Not limited, may vary from product to product)**	• Sterility Test of sterilized seals. **(Not limited, may vary from product to product)**	To optimize the chemical & microbiological control into process.
Depyrogenation of Vials	• Conveyor or Speed • Depyrogenated Temperature • Pressure Differential Limit of all zones of tunnel **(Not limited, may vary from product to product)**	• Sterility Test of Depyrogenated vials. • Bacterial Endotoxins test of depyrogenated vials. **(Not limited, may vary from product to product)**	To optimize the chemical & microbiological control into process.
Filling & Sealing	• Machine Speed • Fill weight range • Pressure reading of Nitrogen & Vacuum **(Not limited, may vary from product to product)**	• As per FG specifications. • Leak test. • Clarity. **(Not limited, may vary from product to product)**	To optimize the chemical & microbiological control into process.
Visual Inspection of Filled Vials	• Visual inspector qualification • Visual Inspection Time • Light Intensity of Visual Inspection Booth • AQL • Destruction of rejection	• Physical Defects i.e. Fiber, Black Prticle, Cracked Vials, Moulding defects, Glass Particles, Dealing Defect, Particulate matters, etc. **(Not limited, may vary from**	To optimize the Effectiveness of the procedure into process.

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STAGE	CRITICAL PROCESS PARAMETERS	CRITICAL QUALITY ATTRIBUTES	JUSTIFICATION
	(Not limited, may vary from product to product)	**product to product)**	
Labeling Process	• Machine Speed • Batch Coding **(Not limited, may vary from product to product)**	• Labeling quality i.e. overprinting quality, wrinkled label etc. • Nos. of rejected Labels/Rejection percentage of labels during labeling process. **(Not limited, may vary from product to product)**	To optimize the Effectiveness of the machine
Packing	• Shrink tunnel temperature • Packing Style Weight Variation **(Not limited, may vary from product to product)**	• Overprinting quality. • Shrink quality & quantity. • Shipper labeling quality. **(Not limited, may vary from product to product)**	To optimize the Effectiveness of the Process.