LIST OF PHARMACEUTICAL GUIDELINE FOR VALIDATION QMS SYSTEM / EQUIPMENT / PROCESS / CSV / DATA INTEGRITY

Contact us at: pharmaguidehub@yahoo.com

Sr. No.	Category	Guideline
1.	**QMS**	**Deviation** ➢ deviation handling and quality risk management WHO,july-2013 ➢ ICH Q10 (international conference on harmonization) PQS-10) ➢ 21 CFR 211.100 (Deviation description) ➢ PICS-2013-Guid to good manufacturing practice for medical product. **Risk management ICH-Q9** ➢ ICH Q9 (Quality Risk Management- Step 4) November 9, 2005 ➢ WHO TRS no.961-2013-WHO guideline in quality risk management ➢ PICS PE-009-15 MAY-2021 **Change control** ➢ Central drugs standard control organization CDSCO/PAC1108 ➢ ICH-Q10- pharmaceutical quality system ➢ WHO TRS NO-992,2015 annex-3-guideline on good manufacturing practice ➢ Guideline for industrial-QS guide (change control and CAPA) ➢ 21 CFR 211.100 (Deviation) **OOS(out of specification)** ➢ USFDA_2022 -Investigating Out-of-Specification (OOS)Test Results forPharmaceutical Production Guidance for Industry-May 2022 **CAPA (corrective and preventive action)** ➢ FDA- investigation to determination root cause relating to product ,processes, and thequality system ➢ ICH Q10 (international conference on harmonization) PQS-10) ➢ FDA-sept-2006 pharmaceutical CGMP regulations for **change control, CAPA, riskassessments.** **Handling Of Market** ➢ Complaint-schedule-M Drug and cosmetic act-1940 & drug and cosmetic rules1945,india ➢ 21code of federal regulation ,part-211
2.	**HVAC qualification** ✓ **Air velocity** ✓ **ACPH** ✓ **Integrity** ✓ **NVPC** ✓ **Containment leak test** ✓ **Recovery test** ✓ **Viable EMP**	➢ Air velocity-WHO GMP for HVAC-2016/WHO feb-2018 ➢ WHO GMP, Annex 1 : Manufacture of Sterile Products ➢ ACPH- schedule-M grade B,C,D ACPH should not be less than 20 ACP/min ➢ Integrity (PAO)- ISO-14644-3-2005 ➢ NVPC- Annex 1 : Manufacture of Sterile Products ➢ Airflow direction test and visualization- ISO 14644-3 -2019 ➢ Recovery test- ISO 14644-3 -2019 ➢ Containment leak test- ISO 14644-3 -2019 ➢ Segregation test- ISO 14644-3 -2019 ➢ Viable- Annex 1 : Manufacture of Sterile Products **ISO-14644-1,2, ISO 14644-3 2019**
3.	**AUTOCLAVE**	➢ HTM-2010- Health Technical Memorandum-TR-48 ➢ HTM-2016- Health Technical Memorandum ➢ EN-285 2015- European standard norms ➢ PDA-Technical Monograph no. 1, 2002 revision- industrial moist heat sterilization inautoclaves

4.	**Depyrogenation Tunnel**	➢ PDA TR-03 2013-validation of dry heat process used for depyrogenation andsterilization ➢ EU GMP Annex-I ➢ US FDA 2004
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		➢ USP CHAPTER 1228 ➢ USP Chapter <85> recommended depyrogenation temperature is 250 ºC for 30 min. ➢ European pharmacopoeia 10.3
5.	**PSG**	➢ HTM-2010- Health Technical Memorandum-TR-48 ➢ ISPE
6.	**Temperature mapping of Cold rooms, Storage area & Deep freezer**	➢ World Health Organization (2015). Technical Supplement 8 to WHO Technical Report Series, No. 961, 2011. Temperature mapping of storage area ➢ ISPE-total number of sensor place –volume bases
7.	**Media fill**	➢ PDA Technical Report No. 22 (Revised 2011) 2011 Parenteral Drug Association ➢ USFDA September 2004 Sterile Drug Products Produced by Aseptic Processing — U.S. Department of Health and Human Services Food and Drug Administration ➢ PIC/S PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME PI 007-6 1 January 2011 ➢ EU (EUROPEAN COMMISSION) Annex-1 25 November 2008 Manufacture of Sterile Medicinal Products
8.	**Process validation**	➢ FDA-guideline for industry -process validation general principles and practices -2011 ➢ EU GMP annex-15 ➢ PIC/S-PI 006-3 25 September 2007
9.	**Cleaning validation**	➢ ACTIVE PHARMACEUTICAL INGREDIENTS COMMITTEE (APIC) -guidance on aspects of cleaning validation in API plants-sept-2016 ➢ PDA-TR NO-29-2012 ➢ ISPE-cleaning validation life cycle -2020 ➢ USFDA guideline on cleaning validation (guide to inspections validation of cleaning process FDA-1993)
10.	**Visual inspection**	➢ USP- the General Chapters ⟨1790⟩ Visual Inspection of Injections. ➢ IPA-visual inspection of sterile products best practices document-2021
11.	**Compressed Air Gas Qualification**	➢ ISO: 8573 -1:2010 (International Organization for Standardization) ➢ ISPE -for Good practice guide: PROCESS GASES-2011 ➢ BP(British pharmacopoeia)-2021) ➢ EN12021(European standard norms)
12.	**Nitrogen Air Gas Qualification**	➢ USP (United States Pharmacopeia – National Formulary) ➢ ISPE -for Good practice guide: PROCESS GASES-2011 ➢ BP(British pharmacopoeia)-2021) ➢ European Pharmacopoeia (Ph. Eur.) 10th Edition

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13.	**Good Aseptic Practices**	➢ US FDA guideline for industry ,sterile drug product by aseptic processing current good manufacturing practice ,september-2004-Good aseptic practices (pharmaceutical injection) ➢ PICS GMPPE-009-16-guide to good manufacturing practices for medical product annexure
14.	**Data integrity**	➢ USFDA-Data Integrity and Compliance With Drug CGMP Questions and Answers Guidance for Industry- December 2018- ➢ MHRA-2015-data integrity definition and guidance for industry ➢ WHO-2015-guidence on good data and record management practices. ➢ PIC/S-2016-good practice for data management and integrity. ➢ Data integrity: refers to the completeness, consistency, and accuracy of data. Complete, consistent, and accurate data should be attributable, legible, contemporaneously recorded, original or a true copy, and accurate (ALCOA). ➢ metadata"- A data value is by itself meaningless without additional information about the data- FDA allowed to look at electronic records
15.	**CSV**	➢ GAMP 5- A risk based approach to compliant Gxp computerized systems.
16.	**Self-Inspection, Batch Record Review**	➢ WHO annex-2 Good Manufacturing Practices For Pharmaceutical Products
17.	**Quality Assurance Of Pharmaceuticals**	➢ WHO Volume 2, 2nd updated edition –For Quality assurance of pharmaceuticals
18.	Q1A	Stability testing of new drug substances and products
	Q1B	Stability testing: photo stability testing of new drug substances and products
	Q1C	Stability testing for new dosage forms
	Q1D	Bracketing and matrixing designs for stability testing of new drug substances and products
	Q1E	Evaluation for stability data
	Q2	Validation of analytical procedures: text and methodology
	Q3A	Impurities in new drug substances
	Q3B	Impurities in new drug products
	Q3C	Impurities: guideline for residual solvents
	Q4	Pharmacopoeias
	Q5B	Quality of biotechnological products: analysis of the expression construct in cells used for production of r-dna derived protein products
	Q5C	Quality of biotechnological products: stability testing of biotechnological / biological products

	Q5D	Derivation and characterization of cell substrates used for production of biotechnological/biological products
	Q5E	Comparability of biotechnological/biological products subject to changes in their Manufacturing process
	Q6A	Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances
	Q6B	Specifications: test procedures and acceptance criteria for biotechnological/biological products
	Q7	Good Manufacturing practice for API (GMP)
	Q8	Pharmaceutical development
	Q9	Quality Risk Management (QRM)
	Q10	Pharmaceutical Quality System (PQS)
	Q11	Development & Manufacture of Drug substance (DMDS)
	Q12	Technical & Regulatory Considerations for Pharmaceutical Product Lifecycle Management
	Q13	Continuous Manufacturing for Drug Substances and Drug Products
	Q14	Analytical Procedure Development and Revision of Q2 (R1) Analytical Validation