RISK ASSESSMENT FOR SAMPLING AND CLEANING STATION

Risk Assessment Document Sampling cum Cleaning Station Equipment ID:

RISK ASSESSMENT FOR SAMPLING AND CLEANING STATION

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RISK ASSESSMENT FOR SAMPLING AND CLEANING STATION

1.0 Approval

This document is prepared by the validation team of……..for the project‘ Sex Hormone OSD Formulations Facility’ of ……under the authority of their Project Manager. Hence, this document before being effective shall be approved by the QA team of ……, and authorized by the appropriate Project Authority.

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2.0 Introduction

According to thedefinition,giveninAnnex15,20totheEU-GMP-Guide,ariskassessmentisamethodto assess and characterize the critical parameters in the functionality of an equipment or process. Therefore, risk assessment is a key element in the qualification and validation approach.

In the project context, risk assessment is performed as basic GMP/EHS-Risk assessment, which shall help to identify important GMP/EHS-requirements.

3.0 Aim of the Risk Assessment

At the very basic stage of design the risk assessment is carried out to verify that all features are taken into consideration to avoid the risk of failure of critical GMP and EHS parameter in the equipment.

During study, all GMP, EHS and operational parameters will be identified and assessed for the risk, appropriate mitigation will be proposed and verification point will be identified and defined.

The Risk assessment report is produced to provide the documented evidence that design concepts or requirement are complete in considering all GMP, EHS and operational risks.

4.0 Reference Documents

S. No.	Document Title	Document Number
1.	Validation master plan	
2.	Project validation plan	

APPROVED BY		
NAME	**DESIGNATION**	**SIGNATURE /DATE**

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5.0 Equipment Description:

The sampling and cleaning station is used for the sampling of highly potent drugs(material)which needs high containment. The Sampling and Cleaning Station is equipped with Support Structure, Valves for WIP, Spray Ball, RTP Active with base tray, Jacking Hoist for docking, lifting the IBC, Canopy to provide containment withgas-proofzip,snaptubingforattachmenttothestructure,VentFilter,Gloves,Trashoutsleeve,Canister tointegratesleeveandtrashbag,SamplingRodforsamplingpurpose,hangerandfunnelforsamplecollection within the canopy.

Most of the possible risk concerning the handling/operation of the Sampling & Cleaning Station has been considered in this RA

6.0 Participants

Name (block letters)	Function	Signature

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7.0 Risk Management Process

A typical Risk management process consists of following steps:

- Risk Assessment:
  - Risk Identification
  - Risk Analysis
  - Risk Evaluation

- Risk Control
  - Risk Reduction
  - Risk Acceptance

- Result of Risk management processes

- Risk Review

- Risk Assessment consists of the identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards.
  Riskidentificationisasystematicuseofinformationtoidentifyhazardsreferringtotheriskquestionor problem description.
  Riskanalysisistheestimationoftheriskassociatedwiththeidentifiedhazards.Itisthequalitativeor quantitativeprocessoflinkingthelikelihoodofoccurrenceandseverityofharm.
  Risk evaluation compares the identified and analyzed risk against given risk criteria. Risk evaluation considers the strength of evidence for all three of the fundamental questions.

  The output of a risk assessment is either a quantitative estimate of risk or a qualitative description of range of risk. In case of qualitative description the risk is expressed using descriptors such as “high”, “medium” or “low”.

- Risk control includes decision making to reduce and/ or accept risks. The purpose of risk control is to reduce the risk to an acceptable level. The amount of effort used of risk control should be proportional to the significance of the risk.
  Risk reduction focuses on processes for mitigation or avoidance of quality risk when it exceeds a specified (acceptable) level. Risk reduction might include actions taken to mitigate the severity and probability of harm.
  Risk acceptance is a decision to accept risk. Risk acceptance can be a formal decision to accept the residual risk or it can be a passive decision in which residual risks are not specified.

- The output/ result of the quality risk management process should be appropriately communicated and documented.

- Risk management should be an ongoing part of the quality management process. A mechanism to review or monitor events should be implemented.
  The output/ results of the risk management process should be reviewed to take into account new knowledge and experience.

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This document applies the risk management principles to identify the risks associated with the design, construction and operational features of any equipment, which is going to be procured and installed in the facility.

7.1 Identifying GMP risk

IdentificationofRiskassociatedwiththeequipment,isgenerallybasedonpriorexperienceandthe concerns of the participants of risk assessment document.
The risks identified are categorized as “GMP risk” or “Non-GMP risk”.
GMP is defined as “the practices which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.”
Thus, GMP covers all aspects of the manufacturing process: defined manufacturing process; validated critical manufacturing steps; suitable premises, storage, transport; qualified and trained production and quality control personnel; adequate laboratory facilities; approved written procedures and instructions; recordstoshowallstepsofdefinedprocedureshavebeentaken;fulltraceabilityofaproductthroughbatch recordsanddistributionrecords;andsystemsforrecallandinvestigationofcomplaints.

Thus those risks which might have a direct or indirect impact on the quality of the product are classified as “GMP risk”. Also, those risks which might result in regulatory guidelines non-compliance are also classified as “GMP risk”.
For example: The MOC of the product contact part has a direct impact on the quality of the product. Thus, it is classified as GMP risk.
The “Non GMP” risks include risks related to EHS, operational and other non-critical hazards.

Following types of risks are mainly identified during risk assessment process:

- Risk related to product contact materials for equipment and containers (eg. Selection of SS grade, gaskets, lubricants etc.)
- Risks related to appropriate utilities and their control (eg. Steam, gases, power source, compressed air etc.)
- Risks related to calibration/ preventive maintenance
- Risks related to protection the environment and health & safety of personnel.
- Risks related to cleaning &sterilization
- Risks related to control system of the equipment
- Risks related to product loss

7.2 Risk Analysis &Evaluation

The risk analysis is performed using a qualitative basis of approach.
Qualitativeanalysisuseswordformordescriptivescalestodescribethemagnitudeofpotential consequences/ impact and the likelihood that those consequences willoccur.
The qualitative measures of likelihood includes descriptors like “Unlikely”, “Possible” and “Likely”, whereasthequalitativemeasuresofconsequence/impactincludesdescriptorslike“Minor”,“Moderate” and“ Major”.

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Qualitative measures of likelihood

Level	Descriptor	Example detail description
1	Unlikely	May occur at some time
2	Possible	Might occur at some time
3	Likely	Will probably occur in most circumstances

Qualitative measures of consequence/ impact*

Basedontheaboveparametersoflikelihoodandconsequenceaqualitativeriskanalysismatrixisprepared to identify the overall Level of Risk, as mentioned in table below.

Qualitative risk analysis matrix – level of risk*

Level	Descriptor	Example detail description
1	Minor	• No impact on the product quality or outcome of the equipment. • Features required for easing equipment operation.
2	Moderate	• No direct impact on product quality/outcome of equipment. however may indirectly affect the product quality. • Minor effect on personnel health • Used in the initial stage of operation, however it may affect the final output but those aren ot used for final release of output. • Effect on environment such as clean room.
3	Major	• Featureshavingdirectimpactonproductquality/outcomeof equipment like contact parts MOC, Surface finish, Control system, Process air qualityetc. • Failure could lead to regulatorynon-compliance. • Loss/ damage to equipment or its criticalsub-components • Criticalinstrumentsnotcalibratedornotofdesiredrangeor accuracy.

ThefinalRisklevelshallthusbedescribedusingdescriptorssuchas“Low”,“Medium”&“High”,where each descriptor implies the followingmeaning:

Low–Riskcanbeacceptedorignored.Thesedonotaffectthefinalqualityoftheequipment/systemandit canbemanagedbyroutineproceduresandareunlikelytoneedspecificapplicationofresources.

Likelihood	Consequences/ Impact		
	1 – Minor	2 – Moderate	3 – Major
1 (Unlikely)	Low	Medium	High
2 (Possible)	Low	Medium	High
3 (Likely)	Medium	High	High

Medium – Risk required ongoing monitoring and review, to ensure level of risk does not increase. Otherwise managed by routine procedures.

High–Actionplansmustbedeveloped,withclearassignmentsofindividualresponsibilitiesand timeframes.

8.0 RiskAssessment

In the following section a table is produced for the risk assessment. The significance or instruction for each column is described in the following paragraph.

Column1: **Serial number** of Risk assessmentitem

Column2: **Processstep/Component**:Identifytheprocessstepor component associated with therisk.

Column3: **Risks**:Identifythetypeofriskassociatedwiththeprocessorcomponent.

Column4: Verify that whether there is **GMPrisk.**

Column5: **Justification**:Providejustificationfordeclaringbothyes/noforGMP Impact in column3.

Column6: Fortherisk**otherthanofGMPrisk,**writewhatistheothertypeofrisks e.g. EHS, Operational.

Column7: **Justification**: Provide justification for considering anyrisk.

Column8: **Risklevel**DeterminetheRisklevelasHigh,Mediumorlowbasedonthe impact.

Column9: **Risk Control:** It is further divided into following threesections

Column9a: **MitigationMethod**:Writetheriskmitigationstrategyasconsideredindesign.

Column9b: **Residualrisklevel**:Aftertheriskmitigationwhatistheresidualrisklevel, whether it is acceptable, low or Medium

Column9c: **Verification**:Writethetestpointwheretheriskmitigationstrategywillbe verified.

S. No	Process steps/component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
Charging										
1.	Blended material in IBC is docked to Sampling & cleaning station	Docking not gas tight	No	Does not have any impact on product quality	EHS	Contamination of air with high potent drug posing a risk to operator's health	High	• Split valves are usedas interface between IBC and sampling & cleaningstation. • Supplier to ensurethe gastight closure split valves.	Acceptable	IQ / O Q
2.	Size of sampling & cleaning station and IBC attachment	Docking cannot be done due to mismatched aperture diameter between sampling & cleaning station and IBC.	Yes	Basic requirement	EHS	Contamination of external/ room with high potent drug	High	Aperture on sampling & cleaning station, IBC and split valve will be kept same for correct interfacing.	Acceptable	IQ
Discharging										
3.	Removal of sampled material from sampling & cleaning station	Removing of sampled material in closed condition not possible.	No	Does not have any impact on product quality	EHS	Contamination of air with high potent drug posing a risk to operator's health.	High	• Trash in and trash out sleeve shall be provided for removing ofsampled material inbags.	Acceptable	IQ
Process										

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S. No	Process steps/component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
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4.	Sampling	Sampling is not possible from the IBC	Yes	Sampling is required for validation study and routine assessmentsample .	No	NA	High	▪ Provision for glove ports should be provided to assistsampling. ▪ Sampling rod is tobe provided inside the isolator.	Acceptable	IQ / OQ
5.	Inlet/ Exhaust air	Air is not filtered / contaminated	Yes	Cross contamination possible , product may get contaminated	Yes	Unfiltered exhaust air may cause product exposure to the environmen t	High	In the supply and exhaust air, HEPA shall be provisioned to ensure pure air	Acceptable	IQ / OQ
6.	Coarse filter	Inlet air not filtered from coarse particle	No	Final air quality shall be maintained by HEPA filter	Operational	HEPA get checked frequently	High	Coarse filter shall be installed before the HEPA filter	Acceptable	IQ / OQ

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7.	Exhaust air	Exhaust air contaminate	No	Does not have any impact on product quality	EHS	Product exposure	Low	A dust extraction port shall be provided inside the isolator. HEPA filter with wet scrubber line connection shall be provided at the dust extraction line.	Acceptable	IQ
8.	Height of isolator	Isolator height is not suitable to dock the IBC.	Yes	Design inadequate	No	NA	Medium	▪ Working height is considered to accommodate a vesselof specified height beneath isolator. ▪ Jacking hoist shall be provided to supporteasy lifting of IBC.	Acceptable	IQ/ OQ
9.	Height of Glove port	Glove port height is not suitable for operation	Yes	Design inadequate	No	NA	medium	▪ The glove port height shall be approx. 1350± 50 mm from the floor level to ensuresmooth operation.	Acceptable	IQ
10.	Chamber space of isolator	Isolator chamber space is not suitable to keep the material container.	Yes	Design adequacy	No	NA	Medium	Design considered with all operational requirements.	Acceptable	IQ

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11.	Size of sleeve	Sleeve port size is not suitable to transfer minimum 5 kg powder materials and waste material.	Yes	Design adequacy	No	NA	Medium	Design considered a size of minimum 200 mm sleeve port.	Acceptable	IQ
12.	Pressure of chamber	Pressure of chamber cannot be measured	Yes	GMP requirement	No	NA	Medium	▪ Magnehelic gauge shall be installed to monitor the pressure ofchamber.	Acceptable	IQ / OQ
13.	Hand gloves	Uncomforted operation with hand gloves, chances of material spillage.	No	No impact on weighed quantity	Operational	Loss of material	High	▪ SOP: Sampling ofactive ingredient in Isolator (Sampling & cleaning Station). ▪ Training of operatorsfor the operations inisolator	Acceptable	SOP
Cleaning and material of construction										

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S. No	Process steps/component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
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14.	Cleaning	Difficulty in cleaning	Yes	Accumulation of particles, contamination of clean room possible.	No	NA	High	▪ The design shallensure adequate clean ability (smooth, SSsurface). ▪ Parts which are required for cleaning should be provided with quickfixing arrangement. ▪ Spray guns with flexible piping should beprovided for cleaning ofchamber. ▪ Spray ball with coverplate shall be provided for cleaning of IBC bin.	Acceptable	IQ

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15.	Cleaning	Improper cleaning	Yes	Accumulation of particles leading to contamination of product during sampling	No	NA	High	▪ Proper cleaning method has to be provisionedfor sampling & cleaning station and IBC, so as to minimize the contaminationrisk. ▪ All gaskets provided to avoid leakage should be amenable for easy removed & re- fixingfor cleaning. ▪ All bolts, nuts on the exterior part of the equipment will bewith cap head or cap nut.	Acceptable	IQ/ OQ
16.	Drain	Water is not completely drained	Yes	Water stagnation leads to micro burden.	No	NA	High	▪ Water drainage tobe considered to ensure completedrainage. ▪ A suitable slopetowards drain port isconsidered.	Acceptable	IQ

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17.	Material of Construction	▪ Surface and construction of the machine is not compatible toproduct. ▪ Material reactswith cleaning media like PW, IPAetc.	Yes	It will lead to product contamination due to corrosion	No	NA	High	▪ All product contact metallic surfaces shouldbe of SS 316 or better with a surface finish of ≤ 0.4Ra. ▪ All welds and joints shall be ground finish;metallic surface will have no crevices. ▪ Non Contact surfaces should be SS304 with external surface matt finish. ▪ The isolator surfaceshould preferably be made of polyurethane. ▪ Hand Gloves should preferably be made of nitrile rubber or delronand should be compatible to productand decontaminating agents.	Acceptable	IQ

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18.	Isolator surface	Isolator surface is not dried	Yes	Require dryness for operation. Chances of microbial growth if surface is not dried	No	NA	High	Isolator should be suitable to connect with compressed air	Acceptable	IQ
19.	Connection of utility to sampling & cleaning station	Chamber cannot be connected with clean media (potable water, purified water, compressed air) for cleaning& drying.	Yes	Contamination	No	NA	Medium	Suitable sanitary end connections shall be provided to connect utilities.	Acceptable	IQ
20.	Welding	Welding quality not sufficient	Yes	GMP requirement; Cleaning problems, surface conditions out of specification in case of bad welding quality.	No	NA	High	▪ Standard welding technique:Orbital welding. ▪ Welding verification reports shall beavailable.	Acceptable	IQ
21.	Gaskets, seals and O ringsMOC	Gasket MOC not compatible	Yes	▪ Product contamination possible	No	NA	High	▪ MOC should be offood grade(Silicon/PTFE). ▪ Should be compatiblewith decontaminatingagents.	Acceptable	IQ

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22.	Surface Finishing	Surface Finishing of Internal & external surface insufficient	Yes	▪ GMPrequirement; cleaningproblems. ▪ Micro-organisms may accumulate on metallic surfaces	No	NA	High	▪ Surface roughness, Ra≤ 0.4 µm, proven by certificates for internal surface. ▪ Crevice freesmooth, rounded corners & smooth surface.	Acceptable	IQ
23.	Labelling	Labelling of components inappropriate	Yes	Prerequisite for qualification	No	NA	High	▪ Unique identity No. /flow direction must be on components / pipelines, operator panel, etc. (e.g. according toP&ID) ▪ All labelling in English language and accordingto projectstandard.	Acceptable	IQ
Maintenance										

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24.	Maintenance	Malfunctions due to worn parts	Yes	Basic GMP requirement	No	NA	High	▪ Machine shall be easyto maintain. ▪ Preventivemaintenance procedure should be available ▪ The unit must contain necessary protection devices to ensure thatthe equipment& the article remain in a safe condition.	Acceptable	IQ/SOP
Safety:										
25.	HEPA filters	During cleaning exhaust HEPA filter is not protected from water	No	This is a special requirement for protecting HEPA from water	Operational	HEPA filter performance is not compatible with water	High	▪ SOP: Precaution tobe taken duringcleaning ▪ Dome nut should be placed on thedust extraction port during cleaning.	Acceptable	OQ/SOP
26.	Wash water	Wash water pass through the plastic sleeve port	Yes	If not detected dispensed material may get wet	No	NA	High	▪ Trash out sleeve port should be removed after every Washingprocess. ▪ SOP: Cleaning of Sampling andCleaning Station.	Acceptable	SOP

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S. No	Process steps/component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
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27.	Hand gloves	Hand gloves are not replaceable	Yes	Contamination in case of damage	EHS	Product leakage	High	▪ Hand gloves should be replaceable. ▪ SOP: Preventive maintenance (for visual check in gand replacement)	Acceptable	IQ
28.	Containment	Design does not prevent leakage of powder in the environment/ System does not work properly	Yes	Chances of cross contamination	EHS	Emission of powder	High	▪ The canopy in stalled must be leak proof and exhaust should be supported with HEPA filter. ▪ Sleeve ports for material in and out, should be provided with gasp roof zips. ▪ Leak test should be conducted.	Acceptable	IQ, OQ
29.	Containment	System cannot maintain the negative pressure within the pan.	No	Does not have any impact on product quality	EHS	In case of overpressure chances of leakage into room	High	System to be designed so as to maintain negative pressure within the isolator and display of differential pressure with respect to room.	Acceptable	OQ

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30.	Waste water drainage	Rinse water drain in wrong drain	No	Does not have any impact on product quality	EHS	Will not be properly treated	Low	Isolator drain line will be directed towards the correct drain	Acceptable	Facility qualification
Measuring Instrument										
31.	Measuring Instrument	Measuring instrument is not of defined range & accuracy	Yes	Instrument is not suitable for use.	No	NA	High	Measuring instrument range & accuracy shall be defined	Acceptable	IQ / OQ
32.	Measuring Instrument	Measuring instrument could not be calibrated	Yes	Instrument is not suitable for use as it may produce false results	No	NA	High	• Must be calibrated and suitable for recalibration • Suitable calibration certificate shall be provided	Acceptable	IQ / OQ
Documentation:										
33.	Documentation	Critical surfaces are not tested for material of construction and test reports are not provided	Yes	Lack of documented evidence leads to question on the quality of MOC	No	NA	High	MOC description and certification of critical parts to be provided	Acceptable	IQ / OQ
34.	Documentation	Instrument is not provided with calibration certificate	Yes	Calibration cannot be assured due to lack of documented evidence	No	NA	High	Instrument shall be supported with calibration certificate.	Acceptable	IQ / OQ

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35.	Documentation	Equipment is not provided with design and functional specification	Yes	Design qualification is not possible	No	NA	High	Design and functional specification should be supplied as per URS	Acceptable	IQ / OQ
36.	Documentation	Equipment is not provided with Operation & maintenance manual	Yes	Correct operation is not ensured and Qualification requirement	No	NA	High	O & M manual should be supplied per URS	Acceptable	IQ / OQ
37.	Machine operation	Operator and staff is not trained	Yes	Untrained operators may not operate equipment properly	Yes	Chances of accidents	High	Proper training to be imparted with operator and staff by the vendor	Acceptable	OQ
38.	Standard Operating procedure	Standard operating procedures are not available.	Yes	Procedures critical operations cannot be carried out successfully resulting process failure.	Operational	Productivity will get decrease to unavailability of procedure.	High	SOPs for Operation, Cleaning and maintenance shall be prepared in line with operational and maintenance manual and finalized.	Acceptable	IQ / OQ

9.0 Summary and Conclusion

- Theriskassessmentisperformedtoestablishthedesignparametersoftheequipmentsoastomeetthe desired performance of the equipment i.e. Sampling and Cleaning Station.
- ThecriticalriskspertainingtoGMPandotherthanGMPwereanalyzedwithjustificationand mitigation procedures.
- For each recognized GMP-risk and other than GMP risks necessary measures are defined. Organizational measures, like SOPs ,area ls opossible measures for special GMP-risks. The availability oftheseSOPswillbecheckedatthetimeofaccomplishmentofOQofthemachine.
- Tocontroltherisk,variousmitigationmethodsshallbeverifiedthroughSOPs,operation& maintenancemanuals,andcalibrationcertificatesatrespectiveverificationpoints
- Based on Risk assessment, the URS shall beprepared.

*"It is concluded that the **Risk Assessment** performed for the equipment will mitigate the risk of failures of critical parameters during design, commissioning, installation, operation and performance of the equipment".*

10.0 Abbreviation

Acronym	Definition
cGMP	Current Good Manufacturing Practice
db	Decibel
EU-GMP	European –Good Manufacturing Practice
GA	General Arrangement
GMP	Good Manufacturing Practices
HEPA	High efficiency particulate air
HMI	Human Machine Interface
IQ	Installation Qualification
MOC	Material Of Construction
OQ	Operational Qualification
O & M	Operation and Maintenance Manual
PQ	Performance Qualification
PLC	Programmable logic controller
RH	Relative humidity
SOP	Standard Operating Procedures
SS	Stainless steel
URS	User Requirement Specification
w.r.t.	With respect to