PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

Risk Assessment Document for IPQC Isolator	
Identification number:-	Document Number:-
Effective Date:-	Revision Number:-

Risk Assessment Document
IPQC Isolator
Equipment ID:……..

Revision index

Revision	Date	Reason for revision
00		

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1.0 Approval

This document is prepared by the validation team of ……Plans for the project '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.

PREPARED BY		
NAME	**DESIGNATION**	**SIGNATURE /DATE**

CHECKED BY		
NAME	**DESIGNATION**	**SIGNATURE /DATE**

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

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2.0 Introduction

According to the definition, given in Annex 15, 20 to the EU-GMP-Guide, a risk assessment is a method to 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	

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5.0 Equipment Description:

IPQC Isolator is designed for carrying out friability testing, weight checking and moisture analyzer of the products. The control system for isolator will effect containment and also monitor, control and alarm the pressure inside the isolator

The tablet bag containing the tablet is bought into the chamber through the 6: RTP rotate in a liner bag. Operating glove ports, the bag is opened and tablet is tested. The moisture analysis, weigh checking, friability testing of product is carried out inside the chamber using the glove port. The WIP of isolator is carried out using the spray gun provided in the chamber by washing down with purified water. The isolator is free draining. The waste water drain has ball valve recessed in the isolator is connected to catch pot.

In this GMP risk Assessment all critical components of the IPQC Isolator, based on the technical details, are listed and rated according to their influence of the product quality, EHS and operational requirements

6.0 Participants

Name (block letters)	Function	Signature

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.
  Risk identification is a systematic use of information to identify hazards referring to the risk question or problem description.
  Risk analysis is the estimation of the risk associated with the identified hazards. It is the qualitative or quantitative process of linking the likelihood of occurrence and severity of harm.
  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.

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

Identification of Risk associated with the equipment, is generally based on prior experience and the 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; records to show all steps of defined procedures have been taken; full traceability of a product through batch records and distribution records; and systems for recall and investigation of complaints.

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.
Qualitative analysis uses word form or descriptive scales to describe the magnitude of potential consequences/ impact and the likelihood that those consequences will occur.
The qualitative measures of likelihood includes descriptors like "Unlikely", "Possible" and "Likely", whereas the qualitative measures of consequence/ impact includes descriptors like "Minor", "Moderate" and "Major".

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*

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.

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Level	Descriptor	Example detail description
		• Minor effect on personnel health • Used in the initial stage of operation, however it may affect the final output but those are not used for final release of output. • Effect on environment such as clean room.
3	Major	• Features having direct impact on product quality/ outcome of equipment like contact parts MOC, Surface finish, Control system, Process air quality etc. • Failure could lead to regulatory non-compliance. • Loss/ damage to equipment or its critical sub-components • Critical instruments not calibrated or not of desired range or accuracy. • Proper supporting documentation not provided. • Major effect on personnel health

Based on the above parameters of likelihood and consequence a qualitative risk analysis matrix is prepared to identify the overall Level of Risk, as mentioned in table below.

Qualitative risk analysis matrix – level of risk*

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

The final Risk level shall thus be described using descriptors such as “Low”, “Medium” & “High”, where each descriptor implies the following meaning:

Low – Risk can be accepted or ignored. These do not affect the final quality of the equipment/ system and it can be managed by routine procedures and are unlikely to need specific application of resources.

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

High – Action plans must be developed, with clear assignments of individual responsibilities and timeframes.

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8.0 Risk Assessment:

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.

Column 1: **Serial number** of Risk assessment item

Column 2: **Process step/Component**: Identify the process step or component associated with the risk.

Column 3: **Risks**: Identify the type of risk associated with the process or component.

Column 4: Verify that whether there is **GMP risk.**

Column 5: **Justification**: Provide justification for declaring both yes/no for GMP Impact in column 3.

Column 6: For the risk **other than of GMP risk,** write what is the other type of risks e.g. EHS, Operational.

Column 7: **Justification**: Provide justification for considering any risk.

Column 8: **Risk level** Determine the Risk level as High, Medium or low based on the impact.

Column 9: **Risk Control:** It is further divided into following three sections

Column 9a: **Mitigation Method**: Write the risk mitigation strategy as considered in design.

Column 9b: **Residual risk level**: After the risk mitigation what is the residual risk level, whether it is acceptable, low or Medium

Column 9c: **Verification**: Write the test point where the risk mitigation strategy will be verified.

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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.	Charging	Charging of tablets is not possible.	Yes	Basic requirement	No	NA	High	RTP / liner bags shall ensure effective charging of tablets.	Acceptable	IQ/OQ
Process										
2.	Inlet Air	• Inlet Air is not filtered.	Yes	It will lead to product contamination	No	NA	High	• Inlet air filter assembly with Pre filter and HEPA filter will be considered in design.	Acceptable	IQ
3.	Differential pressure across the inlet HEPA filter	Differential pressure across inlet HEPA filter cannot be measured	Yes	GMP requirement	No	NA	Medium	• Differential pressure gauge shall be provisioned to monitor differential pressure across the HEPA	Acceptable	IQ
4.	Visibility in the chamber	Visibility in the chamber is poor	Yes	Readability of weight is critical to process requirement	No	NA	High	Suitable light fixtures are to be provisioned inside the isolator for visibility. Min 500 lux shall be maintained.	Acceptable	IQ/OQ
5.	Height of isolator	Isolator height is not suitable to dock the material collection bin	Yes	Design inadequate	No	NA	Medium	Working height is considered to accommodate a vessel of specified height	Acceptable	IQ

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6.	Docking not gastight	Docking not gastight	No	Does not have any impact on quality of the product	EHS	Contamination of air with high potent drug	High	• Supplier to ensure the gastight closure of isolator. • Regular leak test schedule. • Preventive maintenance to include schedule of leak test and gasket replacement.	Acceptable	OQ/ SOP
7.	Exhaust air	Exhaust air contaminated	No	Does not have any impact on quality of the product	EHS	Product exposure to environment may lead to operator health risk	High	HEPA filter with wet scrubber shall be provided at the exhaust line.	Acceptable	IQ
8.	Exhaust HEPA Filter	Exhaust HEPA filter got clogged	Yes	Exhaust will get stopped resulting in increase in pressure in chamber	EHS	The product may be leaked into the room atmosphere	High	• Differential pressure gauge should be provided for monitoring differential pressure across Exhaust HEPA filter. • Alarm provision in case of Exhaust HEPA filter choked.	Acceptable	IQ/ OQ

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								Mitigation Method	Residual risk level	Verificatio
9.	Pressure of chamber	Pressure of chamber cannot be measured	Yes	GMP requirement	No	NA	Medium	• Differential pressure gauge/ transmitter shall be provisioned for measurement of differential pressure across chamber & room. • There should be alarm in case of containment breach.	Acceptable	IQ / OQ
10.	Size of isolator and container	Docking cannot be done due t mismatched aperture diameter between isolator and container	No	Use of isolator for EHS reason	EHS	Contaminati on of external/ room with high potent drug	High	Aperture on isolator, container and split valve will be kept same for correct interfacing	Acceptable	IQ
11.	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
12.	Size of sleeve	Size of sleeve not adequate	Yes	Design adequacy	No	NA	Medium	Design considered a size of minimum 200 mm sleeve port03.	Acceptable	IQ
13.	Weighing balance	Tablets weight cannot be taken	Yes	Process requirement	No	NA	High	Weighing balance shall be installed inside the isolator	Acceptable	IQ

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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.	Moisture analyzer	Moisture of tablet cannot be tested	Yes	Process requirement	No	NA	High	Moisture analyzer shall be installed inside the isolator	Acceptable	IQ
15.	Friability testing	Friability testing could not be carried out	Yes	Process requirement	No	NA	High	Friability tester should be installed inside the Isolator	Acceptable	IQ
Discharge										
16.	Discharge of dispensed material	Discharge of dispensed material in closed condition not possible	No	NA	EHS	Staff protection	High	• The waste material shall be taken out through RTP.	Acceptable	IQ/OQ
Control system										
17.	Control system	Controlling of air handling system not possible	Yes	Equipment cannot start	No	NA	High	Control panel shall be installed to control Air handling system.	Acceptable	IQ
18.	Control System	Control system does not detect failures and generate alarms	Yes	Process optimization and validation is not possible	No	NA	High	Failure of set parameters gets indicated as alarms and machine stops.	Acceptable	OQ
Cleaning and Material of construction										

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19.	Cleaning	Improper cleaning	Yes	Accumulation of particles leading to Inefficient cleaning process	No	NA	High	▪ Proper cleaning (WIP/ process) method has to be provisioned. ▪ All gaskets provided to avoid leakage should be amenable for easy removal & re- fixing for cleaning. ▪ All bolts, nuts on the exterior part of the equipment shall be provided with cap head or cap nut.	Acceptable	IQ/ OQ
20.	Cleaning	Difficulty in cleaning	Yes	Parts need to be dissembled for proper cleaning	No	NA	Medium	▪ The design shall ensure adequate clean ability (smooth, crevice free surface, MOC SS316 or better surface). ▪ Parts that cannot be cleaned in mounted position e.g. hopper, feeder etc. to be made suitable to dissemble and clean.	Acceptable	IQ / OQ

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21.	Material of Construction	▪ Surface and construction of the machine is not compatible to product. ▪ Material reacts with cleaning media like PW, IPA etc.	Yes	It will lead to product contamination due to corrosion	No	NA	High	▪ All product contact metallic surfaces should be of SS 316 or better. ▪ 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.	Acceptable	IQ
22.	Welding	Welding quality not sufficient (Piping)	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 be available	Acceptable	IQ
23.	Gaskets, seals and O rings MOC	Gasket MOC not compatible with material handled in isolator or decontaminating agents	Yes	▪ Product contamination possible	No	NA	High	▪ MOC should be food grade (Silicon/PTFE).	Acceptable	IQ

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24.	Hand gloves	• Hand glove material is not compatible with material. • Material reacts with cleaning media like PW, IPA etc.	Yes	Material contamination	No	NA	Medium	• Hand gloves MOC should be Delrin/ Nitrile. • Material should be inert to product and cleaning media.	Acceptable	IQ
25.	Surface Finishing	Surface Finishing of Internal & external surface insufficient	Yes	▪ GMP requirement; cleaning problems. ▪ Micro-organisms may accumulate on metallic surfaces	No	NA	High	▪ Surface roughness, Ra ≤ 0.4 µm, proven by certificates for internal surface. ▪ Crevice free smooth, rounded corners & smooth surface.	Acceptable	IQ
26.	Draining of water	During cleaning, water is not drained from the surface	Yes	Chances of microbial growth if water is not drained completely	No	NA	High	A suitable slope towards drain port is considered	Acceptable	IQ
27.	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

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28.	Opening of Isolator doors	The opening of isolator doors is not warned	No	Does not have any impact on quality of the product	EHS	Product exposure to the operator	Medium	The opening of isolator door should be warned with alarm. The equipment should come to rest with exhaust on.	Acceptable	OQ
29.	Connection of utility to chamber	Chamber cannot be connected with clean media (potable water, purified water, compressed air) for cleaning	Yes	Contamination	No	NA	Medium	Nozzle and hose for connecting clean media shall be provided	Acceptable	IQ
Maintenance										
30.	Maintenance	Chamber is not accessible during breakdown maintenance o malfunction due to worn out parts	Yes	GMP requirement	No	NA	High	▪ Equipment shall be easy to maintain. ▪ Isolator will be provided with access door. ▪ Preventive maintenance procedure should be available.	Acceptable	IQ/ SOP
Safety										

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31.	HEPA filters and electrical sockets	During cleaning weighing balance, HEPA filter and electrical sockets are not protected from water	No	This is a special requirement for these components to protect from water	Operational	Components or component performance is not compatible with water	High	• SOP: Precaution to be taken during cleaning • Alarm shall be generated in case of filter blockage	Acceptable	OQ/SOP
32.	Hand gloves	Hand gloves are not replaceable	Yes	Contamination in case of damage	EHS	Product leakage	High	• Hand gloves should be replaceable type. • SOP: Preventive maintenance (for visual checking and replacement)	Acceptable	IQ/ SOP
33.	Air Handling System	System cannot maintain the negative pressure within the pan.	No	Does not have any impact on product quality	EHS	In case of over pressure chances of leakage into room.	High	System to be designed to meet the negative pressure within the pan and display of differential pressure with respect to room and alarm in case of out of limit.	Acceptable	OQ

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34.	Containment	The material charging to isolator chamber is not contained.	No	Does not have any impact on product quality	Yes	The product can effect operators health	High	• The material charging to coating pan shall be carried out through suitable containment system like split valves. • A negative pressure should be provided in the containment chamber.	Acceptable	IQ/ OQ
35.	Containment	Leakage	No	Does not have any impact on product quality	Yes	The product can effect operators health	High	• The containment should be leak proof. • Leak test should be conducted.	Acceptable	OQ
36.	Exhaust Fan	Fan motor gets overloaded	No	Does not have any impact on product quality	Operational	Air circulation may stop.	Low	Fan motor overload protection should be provided with alarm.	Acceptable	OQ
Measuring Instruments:										
37.	Measuring Instruments	Measuring instruments are not in defined range	Yes	Instruments are not suitable for use.	No	NA	High	Measuring ranges shall be defined	Acceptable	IQ / OQ

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38.	Measuring Instruments	Measuring instruments could not be calibrated	Yes	Instruments are 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:										
39.	User	Faulty operation & maintenance	Yes	SOPs are basic GMP-requirement	No	NA	High	▪ All end-users have to be trained on SOPs ▪ Training of SOPs has to be documented ▪ Training on the job of end users by vendor. ▪ Training on operation, setting parameters, trouble shooting & maintenance related activities.	Acceptable	OQ/ SOP
40.	User	Operation SOP does not contain proper information and user may operate system	Yes	User may make a wrong decision.	No	NA	High	▪ System operation SOP must be reviewed with all aspects and approved. ▪ Vendor shall provide execution support to the user to complete all stages of the qualification report.	Acceptable	OQ

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41.	Vendor	Technical documentation from vendor not adequate	Yes	Adequate technical documentation is basic GMP requirement	No	NA	High	▪ Vendor documentation (English) shall comprise: -DQ, IQ and OQ -Data sheets -Material certificates -Operating instructions -Maintenance instructions and intervals -Calibration certificates -Parts lists(sufficient detailed: part number, supplier, type) - Drawings P&I-diagrams Electrical diagram - As built GA drawing ▪ Filter certificates -As built GA drawings ▪ Running trial certificate. ▪ Certificates of bought out components.	Acceptable	IQ

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9.0 Summary and Conclusion

- The risk assessment is performed to establish the design parameters of the equipment so as to meet the desired performance of the equipment i.e. IPQC isolator.
- The critical risks pertaining to GMP and other than GMP were analyzed with justification and mitigation procedures.
- For each recognized GMP-risk and other than GMP risks necessary measures are defined. Organizational measures, like SOPs, are also possible measures for special GMP-risks. The availability of these SOPs will be checked at the time of accomplishment of OQ of the machine.
- To control the risk, various mitigation methods shall be verified through SOPs ,operation & maintenance manuals, and calibration certificates at respective verification points
- Based on Risk assessment, the URS shall be prepared.

*"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".*

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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