



PHARMA DEVILS

ENVIRONMENT HEALTH SAFETY DEPARTMENT

HAZARD IDENTIFICATION AND RISK ASSESSMENT

Department: Injection Section

Date:

HIRA Team:

Location:

S.No.	Activity	Sub-Activity	Hazard	N/A/E	Risk	Existing control Measure	Risk Considering existing control measure			Addition control measures to bring risk to (ALARP level)	Residual risk after applying additional control measures			Remarks (if Any)	
							Frequency	Severity	RPN (F*S)		Frequency	Severity	RPN (F*S)		
1.	Injection Section	Movement of persons.	Physical	A	Slip & Trip Entanglement. Struck by an object	35	3	2	6	1. Elimination 2. Substitution 3. Engg. Control 4. Administration 5. Control PPE's	345	3	1	3	-



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2.	Injection Section	Dispensing Area	Fire, Suffocation, Health Hazard, Electrical hazards, Lack of space	A	Burn injuries. Fire. Leakage Cut injuries Control valve not functioning properly Explosion / Burst Electric shock	34	4	3	12	345	3	2	6	-
3.	Injection Section	During transferring of Raw material from Polybag to SS container / Vessel.	Spillage, Fire, Health Hazard	A	Back injuries Static Charge Cut injuries Slip & trip Fall of material Entanglement Struck by an object.	34	3	2	6	345	3	1	3	-
4.	Injection Section	Manufacturing Process (Bulk Manufacturing)	Defective tools Sharp edges. Electrical hazards Physical (Eye Injury, Burn) Mechanical failure, Hot Surface Improper joints in pipeline	A	Burn injuries. Fire. Leakage Cut injuries Control valve not functioning properly Explosion / Burst Electric shock	34	4	3	12	345	3	2	6	



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5.	Injection Section	Filtration Process	Lack of space Spillage Heated pipelines Improper joints in pipe line Leakage Electrocution Gas Leakage Heated pipelines	A	Burn injuries. Fire. Leakage Cut injuries Control valve not functioning properly Explosion / Burst Electric shock	34	4	3	12	345	3	2	6	
6.	Injection Section	Decartoning of vial & Ampoules	Sharp edges Manual handling. Shifting by trolley Poor housekeeping Lack of space	A	Back injuries Cut injuries Slip & trip Fall of material Entanglement Struck by an object.	34	3	2	6	345	3	1	3	
7.	Injection Section	Washing, Sterilization & Deprogenation Process thorough Tunnel.	Defective tools Sharp edges. Electrical hazards Hot Surface Physical	A	Burn injuries. Fire. Leakage Cut injuries Control valve not functioning properly Electric shock	34	4	3	12	345	3	2	6	



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8.	Injection Section	Filling , Bunging & Sealing Process of vials & Ampoules	Sharp edges Lack of space Spillage Heated pipelines Improper joints in pipe line Leakage Electrocution Gas Leakage Heated pipelines Improper insulation.	A	Burn injuries. Fire. Leakage Cut injuries Control valve not functioning properly Explosion / Burst Electric shock	34	4	3	12	345	3	2	6	
9.	Injection Section	DHS (Dry, Heat , Sterilizer) & Leak Test (Autoclave /Leak Test Apparatus)	Lack of space Spillage Heated pipelines Improper joints in pipe line Leakage Electrocution Gas Leakage Heated pipelines Improper insulation. Poor Housekeeping Defective Tools physical	A	Burn injuries. Fire. Leakage Cut injuries Control valve not functioning properly Explosion/Burst Electric shock Slip & Trip Struck By An Object	34	3	2	6	345	3	1	3	



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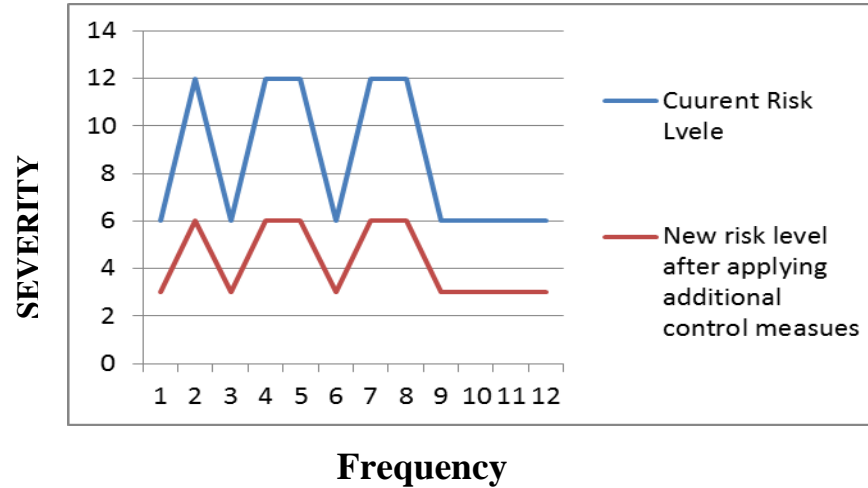
10.	Injection Section	Visual Inspection	Defective tools Sharp edges. Electrical hazards	A	Musculoskeletal disorder. Electrocution. Entanglement. Slip & trip. Struck by an object.	35	3	2	6	345	3	1	3	
11.	Injection Section	Labeling & Packing on conveyer belt	Defective tools Sharp edges. Electrical hazards	A	Musculoskeletal disorder. Electrocution. Entanglement. Slip & trip. Struck by an object. awkward body posture	35	3	2	6	345	3	1	3	
12.	Injection Section	Cleaning and maintenance of equipments & Machines	Defective tools Sharp edges. Electrical hazards	A	<ul style="list-style-type: none"> • Musculoskeletal disorder. • Electrocution. • Entanglement. • Slip & trip. • Struck by an object. 	35	3	2	6	345	3	1	3	



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MATRIX

SEVERITY	5	5	10	15	20	25
4	4	4	8	12	16	20
3	3	3	6	9	12	15
2	2	2	4	6	8	10
1	1	1	2	3	4	5
0	1	2	3	4	5	
			Frequency			

LOW
MODERATE
HIGH



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REVISION HISTORY - HIRA Register

Revision No.	Date	Reason for change	Originator (Leader)	Approval
00		New Document	Plant/Functional Manager	Plant/Functional Head

Distribution: Leader /plant/functional Head(s) /Functional Head – EHS

	Prepared By Operating Officer/Executive	Reviewed By Operating Manager	Approved By Department Head	Authorized By Head QA
Sign				
Date				
Name				