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# An overview of Risk assessment methods in pharmaceutical industries, analysis of various risk assessment techniques & applying LOPA technique in distillation operation

**B. Sangeetha[1], A. Babu Ponnusami[2*]**
[1] Research Scholar, sangeetha.b2016@vitstudent.ac.in
[2*] Associate Professor, *ababuponnusami@vit.ac.in
School of Chemical Engg., VIT, Vellore,

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**KEYWORDS**
Layer of Protection Analysis, Risk Assessment, HAZOP, PHA, PHA survey in Pharma, Distillation operation.

***Abstract*** – The Pharmaceutical industry plays a key role in bringing new medicines to the world. While Pharma industries strive to achieve patient quality care, the operations associated with manufacturing medicines at various stages, such as research, Pilot stage, API manufacturing and Formulation, pose various hazards and risks. Therefore, it is essential to manage the risk by identifying the hazards and applying effective control measures. This paper discusses the various risk assessment tools, their suitability, and their limitations, using various case studies and an analysis of results obtained through real-time surveys. The paper also highlights the advantage of Layer of protection analysis over other tools, and its application is illustrated using distillation operation. Layer of Protection analysis is a semi-quantitative risk assessment tool to manage the risk in a better way in process Industries. LOPA provides a clear understanding of the adequacy of the safeguards suggested compared to any other qualitative risk assessment tool, such as process hazard analysis. LOPA is a systematic tool that evaluates risk by applying semi-quantitative measures to evaluate the frequency of potential incidents and the probability of failure of the protection layers. This paper will focus on various risk assessment tools available in process industries, provide a detailed overview of LOPA, and discuss the layer of protection suggested for a distillation operation in the Pharma industry.

## 1. Introduction

The Pharmaceutical industry plays a key role in bringing new medicines to the world. These state-of-the-art medicines combat deadly diseases and improve patient health. While Pharma industries strive to achieve quality patient care, the operations associated with manufacturing medicines at various stages, such as research, pilot stage, API manufacturing, and formulation, pose various hazards and risks [1-3].These hazards are due to the properties of various chemicals, such as explosivity, inflammability, corrosivity, toxicity, etc. Therefore, it is essential that managers in the drug and pharmaceutical industry put in their best efforts to identify the hazards involved in their industrial units and take necessary steps to control them efficiently. Though there are various risk assessment techniques are available and being used, the incidents keep happening.

## 2. Risk Assessment Methods

Process Hazard Analysis (PHA) is the umbrella term for a number of methods used to assess and manage risks and hazards related to process operations[4]. These methodologies are employed to assess the appropriateness and efficacy of extant safety barriers and to ascertain the necessity of supplementary barriers or risk mitigation strategies in order to avert an occurrence inside an industry [1]. Table 2.1 provides a list of the many risk assessment methods that are employed during PHA.If the proper safeguards are not in place, then the PHA will make recommendations to improve the process. PHAs are only effective if they are done properly and the potential hazards are identified. Consequently,ineffectual solicitation or deficiency of PHAmay enhance the level of risk[5].It has been identified that several major recent loss events happened due to a lack of rigorous PHA program[1, 2]

***Table 1: Various types of risk assessment techniques are used in process industries***

| S.No | PHA Technique | Suitability analysis |
|---|---|---|
| **1** | HAZID (HazardIdentification) | Identify hazards and recommend control measures. It can be used once the basic process engineering design of the project or |

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| | | |
|---|---|---|
| | | modification is known |
| **2** | HAZOP (Hazard and Operability) | A rigorous line-by-line reviewrequires piping and instrumentation diagrams with a good understanding of the barriers. These barriers need to be adopted as part of the project or studying the existing barriers as part of the operating plant |
| **3** | Safety Integrity Analysis | An assurance assessment study is conducted to ensure that all the safety instrumented functions provide the required safety performance and integrity. It is carried out in parallel with HAZOP for the critical instrument barriers |
| **4** | Bow-Tie Analysis | Bow-tie diagrams depict the relationship between Sources of risk, Controls, Escalation Factors, Events, and Consequences |
| **5** | Failure Mode Effect Analysis | A systematic qualitative technique for evaluating and documenting the cause and effects of component failures |
| **6** | What-If analysis | A simple but effective brainstorming technique for identifying hazards and determining consequences |
| **7** | Layer of Protection Analysis (LOPA) | A semi-quantitative tool for analysing hazard and risk |

## 3. Incidents Analysis

To produce vast amounts of medications, pharmaceutical companies need vital machinery, including dryers, heat exchangers, and reactors, in addition to dangerous chemicals[2]. These pieces of machinery need to be properly constructed, used and maintained because they have the potential to malfunction and cause process problems[6]. Such malfunctions could lead to serious reactor failures brought on by violent chemical reactions, which could ultimately cause an explosion or fire with disastrous consequences, or they could result in process safety accidents, such as the discharge of a harmless gas[7, 8]. Human mistakes, other procedural and behavioural issues, and insufficiently implemented safety measures can all lead to process safety incidents[9]. Figure 1 shows the total number of fatalities connected to pharmaceuticals that were recorded between 1985 and 2019, which is a 34-year span.

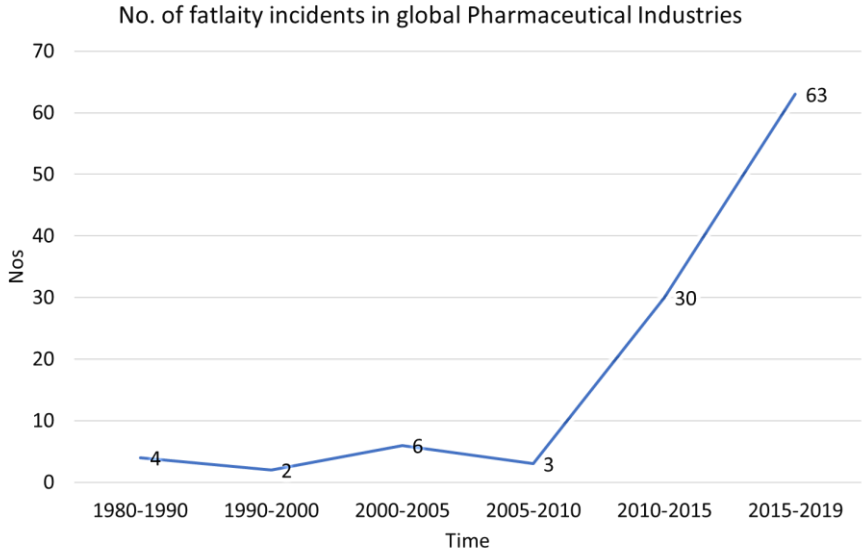


***Fig 1: No of fatality Incidents in Global Pharmaceutical industries***

Fig 1, representsanalysis of global pharmaceuticals incidents led to fatality[2, 6]. The contributing elements to occurrences are shown in Fig. 2. Hazard and risk mitigation identification (PHA) is a major influence in occurrences, outweighing all other causes. The second most frequent cause is operating procedures, which are

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followed by mechanical integrity, safety culture, training, work permits, andemergency readiness.

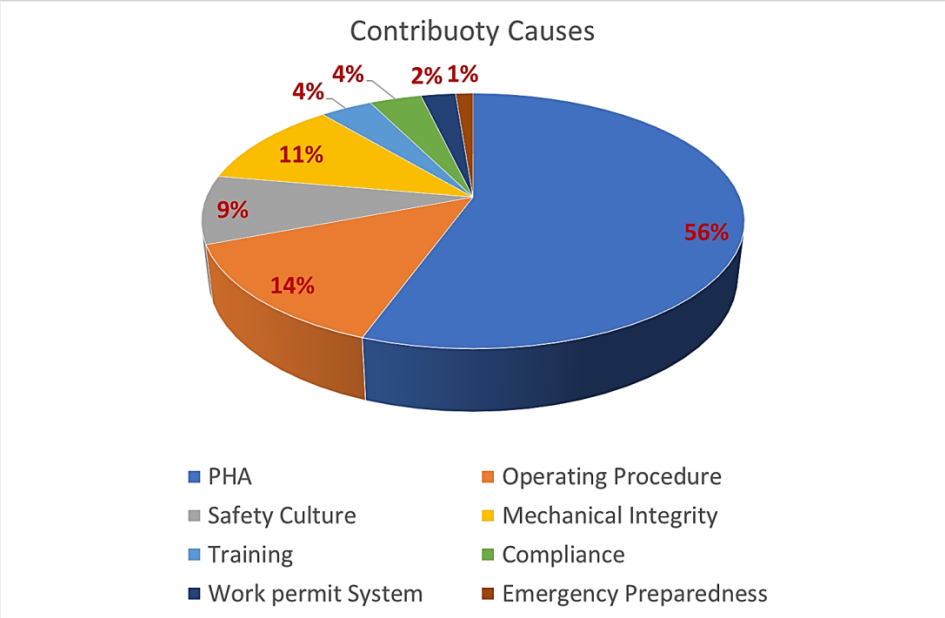


***Fig2: Contributory Causes of Incidents***

Process hazard Analysis helps identify operational risk and recommend safeguards. However, the above Analysis shows that more than 50% of incidents are caused by shortcomings in PHA, especially in ensuring effective and reliable safeguards, which are discussed in the next section.

## 4. PHA shortcomings - Safe Guards Vs. Controls

Protective mechanisms or systems known as safeguards are designed to prevent starting occurrences from leading to detrimental circumstances in the event that controls are unable to sustain a proceeding through its usual functional area. A safeguard is "any device, system, or action which would likely interrupt the chain of events preceding an initiating cause or that would mitigate loss event impacts," according to CCPS [10]. Employers are responsible for making sure PHA teams know the distinction between safeguards and controls. It's not unusual to find a "mechanical integrity program (MIP)" [11]included in a PHA as a precaution. This is an instance of claiming accountability for a control instead of a protective measure. Programs for mechanical integrity are regarded as controls rather than safeguards because their goal is to keep equipment operational[12]. PHA teams are required to evaluate the effectiveness of controls like the mechanical integrity program.Throughout the PHA process, a number of questions must be addressed, such as what happens if maintenance is delayed or the structural integrity program is inadequate. Is the control going to work? Will it be subject to compromise?

PHA teams frequently categorize operational methods, training, and designing equipment as protections in addition to MIP. Operators must only maintain a process within its regular operating range, as described in standard operating procedures and training. For this reason, rather than being safeguards, these criteria are thought of as controls. During hazard analysis, PHA teams are not supposed to point to training and standard operating procedures as precautions.

PHA teams have occasionally thought of creating equipment as a safety measure. However, the apparatus is a control rather than a safety measure if it is intended to keep the process contained within the typical range[13]. A simple process control system (BPCS) is an excellent illustration of this. Safeguards do not apply to instruments that measure natural fluctuations in process parameters and maintain the system within its customary operating range[14]. However, a distinct and autonomous alarm system combined with redundant instrumentation can be regarded as a safety measure[8]. Safeguards are devices made to function when a process is not operating within its typical parameters. Relief valves are one example of this kind of machinery. Prior to claiming ownership [12]of the relief valves, the group should confirm the following specifications:

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- A system is in place to guarantee that relief valves are designed correctly.
- A process available to guarantee that the design complies with the modifications made over time to upstream and downstream relief valve equipment
- A mechanism is in place to guarantee that the relief valve or valves cannot become dysfunctional.
- There is a system in place to guarantee that the correct relief valve is placed and
- To ensure the strength of the valves, testing and inspection are performed.

Dikes surrounding process equipment are frequently suggested by PHA teams as mitigating precautions. After a loss occurrence occurs, mitigating precautions are taken to lessen the effects. Mitigating measures only lessen the intensity of an incident if they are sufficiently protective.Hence, it is vital that the *PHA*group should corroborate and confirm the effectiveness of a dike. The following points should be considered while verifying the mitigating safeguards:

- Keeping an eye on and confirming a dike's integrity
- Steps to take to guarantee that the dike and tank drain valves are shut off while not in use
- Managing the sources of ignition near the dike and
- Sufficient foam supply for the items in the region that have been diked

As additional safety measures in PHAs, PHA teams recommend blocking valves along with emergency valves. The PHA team must decide in certain situations whether the:

- valves are placed in a position where they might be securely approached and utilized
- valves were tested as per the standard and will work effectively

Thus, when we analyse the safeguards suggested by commonly used risk assessment methods such as What-if, HAZOP, etc., most of the time, the credibility of the suggested guards could be more reliable, which can be evidenced in the following case studies.

## 5. Case Studies to Demonstrate Reliability, Availability and Maintainability of Safeguards

The following case studies illustrate that the failure of various safeguards resulted in major process safety events and also highlight the importance of effective safeguards.

**Case Study-1**

In one instance, in the event that the primary refrigeration system failed, the employer depended on a secondary water-based cooling to maintain the chilling mechanism for the reactor component. The employer discovered that the crisis refrigeration system was detached and ineffective in supplying vital refrigerating fluid in a timely manner when the main freezing system stopped, and the pour of cooling water halted.Four workers were killed when the reactor exploded, just minutes after the manager realized the equipment was disconnected. While the *PHA*classcould have claimed accredit for saving the contingency refrigeration procedure in this instance, it should have taken into consideration the system's failure to ensure that the precaution was operational.

**Case Study-2**

A second incident included the processing of a combustible mixture in a steam-heated mix tank. An operator will manually cut off steam and monitor the temperature of the contents of the tank during regular operations. The temperature controller will take measures to maintain the operational temperature in an emergency or if the contents exceed a critical temperature.For this reason, an instrument for detecting temperature is placed inside the tank's thermo well. Unbeknownst to both the employer and the operator, the thermo well transferring heat fluid had drained and the temperature device's reservoir bulb had been removed from its designated spot. The temperature safeguard could be more reliable as a result of these issues combined.The safety device did not work as intended on the day of the tragedy because the operator neglected to turn off the steam flow when it was necessary. The combination within the tank ignited after boiling and producing a cloud of vapor. Ultimately, one person perished in the flash fire.A PHA gave the crisis temperature cut-off mechanism a lot of credit. Despite having been installed, the temperature cut-off device was not adequately maintained, and on the day of the incident, it did not operate as needed. PHA teams have to comprehend and consider how reliable the management systems are in order to keep precautions in place.

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**Case Study-3**

A chlorine railcar unloading mechanism event affecting emergency shutoff valves was looked at by the CSB [11]. The shutoff valves were closed by operators pushing a button in the event that a chlorine hose failed. The valves failed to close due to corrosion products that had accumulated, causing a significant off-site release of chlorine. Every day, operators tested the faucets by pressing the control, but they under no circumstances made sure the spigots completely shut down. *PHA*Teams need to assess how field devices like these are tested and consider how management and operations use test results to assess how well the safeguards are working.The available protections must be properly maintained even when they are suitable. Block valve leaks, delays in testing and calibration, delays in training and exercises, poorly managed processes, and changes in procedures all contribute to safeguards' ineffectiveness and raise the possibility of a disastrous catastrophe. These examples amply demonstrate the preventive value of safeguards, but PHA demands care throughout the safeguard's lifecycle [7]. The lifecycle comprises specifications, design, setup, operation, continuing maintenance, auditing, and the current risk assessment techniques in accordance with the CSB's recommendation [9].

**Inferences**

The case examples mentioned above demonstrate how subjective PHAs may be and how this might lead to an underestimation of the risk of potentially dangerous event scenarios. Because the safeguard needs in PHAs can vary significantly depending on how event periodicity and repercussion severities are assigned. In order to adequately build hazard situations and attribute appropriate beginning event frequencies and consequent severities to them, industries must ensure that PHA teams have a strong procedure and sufficient resources in place. PHA teams must also ensure that the safety measures used in the danger scenarios are appropriate and successful in reducing the risks.

## 6. Survey on current scenario of Risk assessment methods in Indian Pharma Industries

In order to understand the challenges with respect to the risk assessment process in Indian Pharmaceutical Industries, a sample survey was carried out, and the responses from the industrial participants were analysed and shown in Fig 6.1. The survey questions were framed to understand the level of risk assessment techniques used, competency level, challenging steps in risk assessment, and knowledge about LOPA. All the responses were carefully analysed and converted into percentage levels.

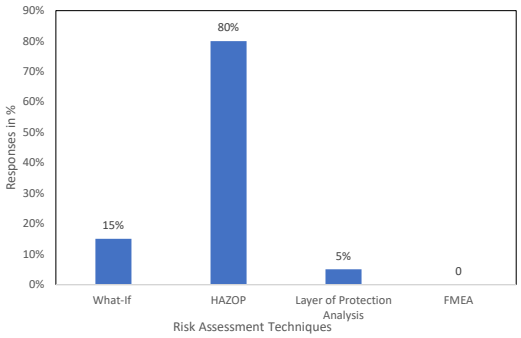


Fig.3 [a]

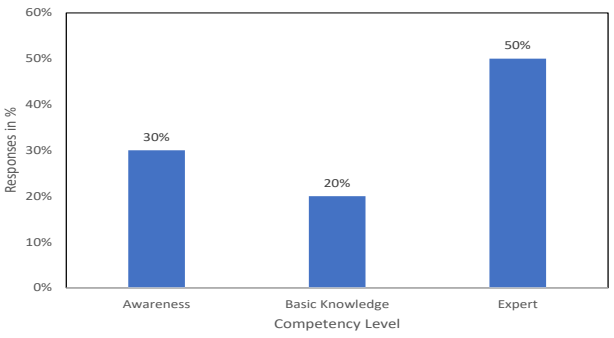


Fig.3 [b]

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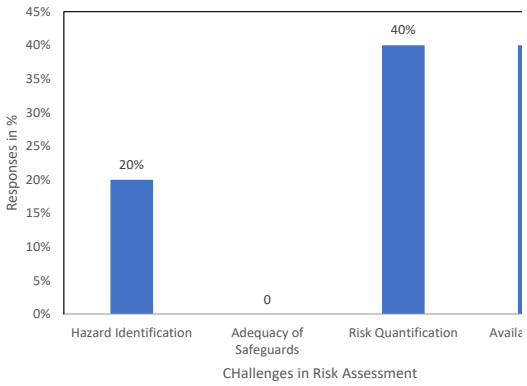


Fig 3[c]

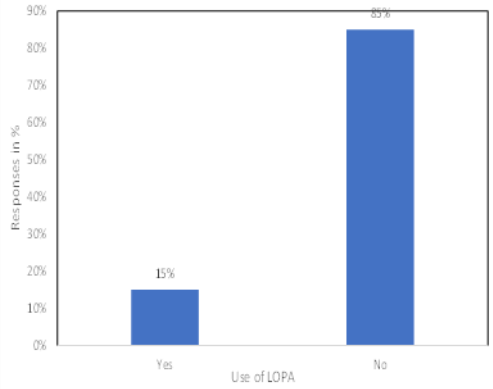


Fig.3 [d]

***Figure 3: Results of survey on Risk Assessment Scenario in Indian Pharmaceutical Industries***

(Survey Questions: a)Most Widely Used Risk Assessment Technique. b)Competency level while carrying out selected risk assessment techniques. c)Identify the most challenging step in the risk assessment procedure. d) Are you using LOPA?)

The results shows that HAZOP is most widely used technique in Pharma Industries where as LOPA is a least used tool as shown in Fig.3 [a]. Only 15% of the respondents are exposed to LOPA tool as shown in Fig.3 [d]and they had a basic awareness in LOPA as shown in Fig.3 [b].Also, it was also clearly stated that Availability of PSI and Risk quantification are the most challenging step in Risk assessment process as shown in Fig.3[c].Also, the respondents were expressed some of the challenges faced while carrying out What-If and HAZOP studies are competency, availability of PSI and time required.

From the above case study discussions and the survey results, it is clear that the risk assessment technique that is predominantly used in Pharma Industries is HAZOP. Also, from the survey results, it was evident that it has limitations in many ways, which can be overcome by using the Layer of Protection Analysis (LOPA) technique. This paper discusses LOPA and its application in solvent recovery for the separation of butyl acetate/phenol systems in the Pharma industries.

## 7. Layers of Protection Analysis (LOPA)

A semi-quantitative technique called LOPA [15] is used to calculate the risks connected to an undesirable situation or event. It examines if there are enough safeguards in place to reduce or manage the risk. The layers of defense that stop the cause from leading to the undesirable consequence are found when a cause-consequence pair is chosen.To find out if the protection is sufficient to lower risk to a manageable level, an order of magnitude assessment is performed. Reviewing the levels of defense that stand between a risk or causative event and a final result can be done qualitatively with it.Also, It provides a basis for the specification of independent protection layers (IPLs) and safety integrity levels (SIL levels) for instrumented systems, as described in the IEC 61508 series and in

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IEC 61511[15]. LOPA can be used to help allocate risk reduction resources effectively by analysing the risk reduction produced by each layer of protection.

### 7.1 Advantages of LOPA

LOPA provides many advantages in finding risk in a process that includes the following list:

- providing rational, semi-quantitative, risk-based answers,
- reducing emotionalism
- providing clarity and consistency
- documenting the basis of the decision
- Facilitating understanding among plant personnel.

### 7.2 Independent Protective Layer

An independent layer of protection (IPL)[16, 17] is a tool, system, or course of action that can stop a situation from leading to its unintended outcome, regardless of what caused it or what other protective layer is in place.

#### 7.2.1 Criteria to be an IPL

For a stratagem, system, or movement to be classified as an *independent protection layer* (*IPL*), it needs to possess the following characteristics.

**Specificity**: The IPL can identify, stop, or lessen the effects of specific, potentially dangerous event(s), including an explosion, a runaway reaction, or a loss of containment.

**Independence:**All other protective layers connected to the highlighted potential dangerous event are not dependent on an IPL. Independence necessitates that the performance be unaffected by the circumstances leading up to the failure of another layer of protection or by the failure of that layer itself. The protective surface remains separate from the initial cause, which is crucial.

**Dependability:**The assessed danger is lessened by an acknowledged and established amount, thanks to the protection offered by the IPL.

**Auditability:**The IPL is made to enable the protective function to be validated on a regular basis.

#### 7.2.2 Examples of IPL

In a process design, the following IPL can be considered to prevent the accident scenario

- The fundamentalproceeding control device
- Passive tools
- Active gadgets
- anthropic activity
- Standard operating procedures,
- Alarms with defined operator response,
- Safety instrumented systems (SIS),
- Fire and gas systems
- Deluge systems

### 7.3 Probability of Failure on Demand (PFD)

The chance that an IPL will capitulate tocarry out a given role on necessitate is known as PFD (chance of Failure on Demand), and it is used to measure an IPL's efficacy[13, 16]. Between 0 and 1, the IPL - PFD is an undefined number. For a particular originating functionprevalence, the larger the diminution in consequence frequency, the less significant the value of the$IPL - PFD$. IPL - PFD values span from 1 X 10-1), the weakest IPL, to 1 X 10-4, the greatest IPL. The values of PFDs are often stated to the nearest order of magnitude because LOPA is a simplified method[18].

**Examples of Probability of Failure on Demand**

***Table 2: Probability of Failure on Demand***

| Typical probability of PFD values (acc. IEC 61511-3) | | |
|---|---|---|
| **S.No** | **Independent Protection Layer** | **PFD** |
| 1 | Regulator | 10-1 |
| 2 | Pressure relief device | 10-2 |
| 3 | Operator response (educated, no stress) | 10-2 |
| 4 | Operator response (under high stress, average training) | 5 x 10-1 ... 10-0 |
| 5 | Operator response to alarms and procedures (low stress, recognized event) | 10-1 |
| 6 | Inherent design of vessels with pressure | 10-4 |

### 7.4 Safety Instrumented System

Safety Instrumented Functions (SIF) for processes, such as emergency shutdown (ESD), fire detection, and blow-down functions, are provided by Safety Instrumented Systems (SIS)[19]. Functional safety is governed by IEC 615008 and IEC 61511/10, 11/ international standards[15]. An arithmetical depiction of the virtue of the *SIS* in the event of a process demand is called a Safety Integrity Level, or SIL. It is employed in IEC 61508/61511 to assess SIS dependability[20]. There are four levels of safety integrity, as shown in the following table. A greater SIL indicates a more dependable or efficient SIS.

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## 8. Applying LOPA for a Solvent Recovery Operation

### 8.1 Solvent recovery

Solvent recovery is the main step in the sustainability of API. Because the Pharma industry operates with the maximum amount of Solvent, it poses a major effluent load to the industries. By revering solvents, we are not only reducing the pollution load but also taking advantage of recycling that Solvent to our process, thereby reducing the process cost[21]. This paper explains the safety protection available in the Phenol—butyl acetate recovery from a mother liquor from the API process and details various protections available to reduce the risk[22].

### 8.2 Properties of Butyl acetate

***Table 3: Properties of Butyl acetate***

| | | |
|---|---|---|
| **Molecular formula** | C6H12O2 | 94.11 g mol−1 |
| **IUPAC name** | Butyl ethanoate | Benzenol |
| **Molar mass** | 116.16 g/mol | 94.11 g mol−1 |
| **Appearance** | Colourless liquid with fruity odour | White Crystalline Solid |
| **Density** | 0.88 g/cm3, liquid | 81.07 g/cm³ |
| **Melting point** | -74 °C (199 K, -101°F)121112 | 40.5 °C, 314 K, 105 °F |
| **Boiling point** | 126 °C (399 K, 256°F) | 181.7 °C, 455 K, 359 °F |
| **Solubility in water** | 0.7 g/100 ml (20.0 °C) | 8.3 g/100 ml (20 °C) |
| **Flash point** | 24 °C (297 K) | 79 °C |

### 8.3Azeotropic distillation

- The characteristic of the processes involved is the presence of azeotropes. When an azeotrope (normally minimum boiling point) is present in the mixture to be treated, this will be separated before the pure components.
- A mixture of two or more liquids whose proportions cannot be modified by straightforward distillation is known as an azeotrope or constant boiling point mixture[23]. When an azeotrope is boiled, the vapor retains the same chemical proportions as the combination before boiling.
- The components of the azeotrope are not miscible from each other. Moreover, the solubility of water in the organic component must be lower than the azeotrope composition[24]. So, it is possible to send the distillate to a liquid-liquid separator, where the components are separated, taking advantage of the density difference[25]. The water phase is sent back to still and distilled again; the organic phase is collected in collection tanks. All this process is made in continuous.
- In the case of Butyl acetate/water, the distillate azeotrope is sent to the separator, where two phases are separated: one light organic phase, which contains butyl acetate plus some water, and one heavy inorganic phase, which contains water plus some butyl acetate; the light phase is collected in the collection tank, while the heavy phase is sent to back to still and distilled again[25]. In this way, butyl acetate will be gradually removed from the mixture. The same is given in Fig 7.1.
- After removing butyl acetate, distillation is carried out at reduced pressure. The vent of the condenser is connected with a vacuum pot[17]. Here, the boiling point of the solvent is reduced due to reduced pressure. Hence, distillation happens at a lower temperature[14]. Thus, the phenol solvent is distilled out and recycled to production after complies with the standard specification[26].

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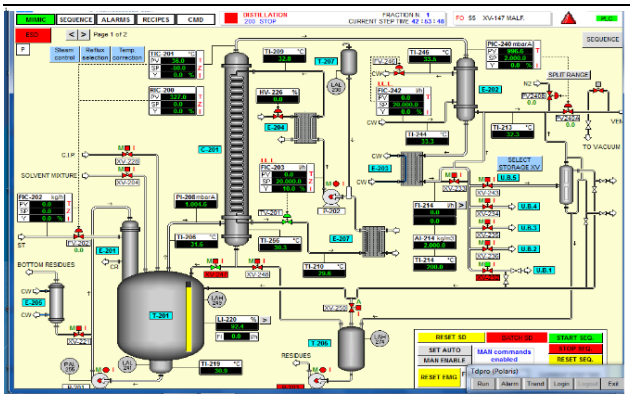

*Fig 4: Azeotropic distillation of Butyl acetate/water*

**8.4Protective SIS through Different Layers**

The following Table 4,shows the layers of protection available to protect the batch still from any untoward incident during distillation.

*Table 4: Layers of Protection in the distillation operation*

| S-NO | TRIPPING SOURCE / SET VALUES | SET PARAMETER DETAIL(CONDITIONS) | ACTION DETAIL |
|---|---|---|---|
| 1 | FI-203 – LL -5000 l/Hr. | If the Reflux water flow reaches below the Lo Low Set value of 5000 L/HR | The Main Steam Valve FV-202 Will Close by Interlock Automatically. |
| 2 | PI-208-Hi-1300 mbar. | If the Still Top Vapor Pressure reached Grater, then the High set value of 1300 mbar. | |
| 3 | TI-210-Hi-105$^0$ C. | If the Reflux water Column outlet temperature reaches Greater than the High set value of 105$^0$C. | |
| 4 | TI-213 Hi-40$^0$C. | If the primary Condenser outlet Vapor temperature reaches Greater than 40$^0$C. | |
| 5 | P-201 Not Running | If the Circulation Pump is Not Running. | |
| 6 | P-202 Not Running | If the Reflux Pump is Not Running. | |
| 7 | FV-203-Closed | If the Reflux Control Valve is Fully Closed. | |
| 8 | ESD-201 / STOP-PB | If Emergency OR Stop Push Buttons Pressed. | |

The above safeguards ensure different layers of protection available to protect the batch still due to any process upsets.

**9. Results and Discussion**

If the column's pressure surpassed its design pressure, one of the consequences would be a catastrophic rupture. This catastrophic event is classed as comprehensive for the vehemence crew in the LOPA due to the potential for multiple fatalities. One x 10-8 /Yr is the greater target likelihood for extensive impact occurrences. This influence event has multiple initiating causes. The withdrawal of cooling tower water from the core condenser was one such initial cause.This could happen once every ten years. One x 10^-1 is the challenge likelihood. For this effect's event and cause, the LOPA team determined that there is only one Process Design IPL. The greatest pressure that the steam reboiler can produce after the cooling tower's water failure is less than the highestincreased workload that the purification tank and related gadgets can

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withstand. 1 x 10-2 is its PFD. A *distributed control system* (*DCS*) is the distillation column's basic process control system. When the ambient temperature or elevation in the column used for distilling rises, the DCS's logic opens a steam RCV and the hot water flowing channel[3]. The main goal of this logic is to restore the control mechanism following a trip, which will cause a controlled restart. Since it has the ability to halt the effect of an event, it is listed in the table.When a warning for high pressure or temperature appears on the DCS, the operator can be notified to use a manual valve to stop the steam supply to the distillation column[18]. Because the sensors utilized for these alarms are distinct from those used by the SIS, this outer layersatisfies the requirements for an*IPL*. The operators need to receive instruction and practice responding to these alerts.Two sensors, independent of the DCS, will be used by SIS logic integrated into a PLC to activate the steam flow regulator and a hot water RCV when the temp or stress of the column under distillation increases. The SIS is able to attain a PFD = 10-3, or SIL 3 since the PLC has enough redundancies and inspection[27].In order to provide further mitigation in the case that cooled tower liquid escapes to the condensation chamber, a pressure release valve is included in the column that undergoes distillation. The purpose of the valve is to keep the distillation column's pressure below the maximum permitted operating pressure[28].It has a PFD of 10-2. There are three different security tiers. The Diminished, This cause-and-effect relationship's occasion likelihood is computed by dividing the difficulty Probability by the IPL PFDs.

| Challenge Likelihood X Process Design X Alarms & Procedures X SIS X Relief Valve = | Mitigated event likelihood |
|---|---|

| Challenge Likelihood | Process Design | Alarms Procedures | SIS | Relief Valve | Mitigated event likelihood |
|---|---|---|---|---|---|
| 1x10-1 / Yr | 1x10-2/ Yr | 1x10-1 / Yr | 1x10-3/ Yr | 1x10-2/ Yr | 1x10-9/ Yr |

Once every impact event and its underlying causes have been examined and documented in the Layer of Safeguarding Examination form, the group will total the Reduced Incident Probabilities for each Moderate and Considerable Encounter Activity. To ensure that the column for distillation and the other production facilities do not place the impacted populations at unmanageable risk, the Risk of Fatality will be checked with the Corporate Risk Criteria.

**Conclusion**

When applied appropriately, the growing use of strict quantitative or semi-quantitative techniques (like LOPA) to assess high-hazard scenarios might reveal common-mode failure mechanisms and contribute to the effectiveness, independence, and audibility of safeguards. Therefore, Layers of Protection Analysis differs from other methods of risk assessment. This aids in determining the efficacy of suggested precautions and supports an impartial search for alternative solutions by experts. When it comes to handling layers of protection and risk assessment, LOPA is a useful tool for bringing objectivity and consistency. To support decision-making, LOPA offers a quick and affordable way to evaluate several high-consequence and high-risk situations.Greater emphasis on risk reduction is placed by LOPA on Impact Events that have a high likelihood and severity. It verifies which isolated layers of safeguarding function properly for each detected initiation prompt and makes sure that all identified Initiating Causes are taken into account. Effective resource allocation for risk reduction is possible with LOPA. LOPA outlines all that was taken into consideration and provides clarity in the reasoning process.

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