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Design and development of microfiltration module for removal of somatic cells and bacteria from raw milk

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Abstract
This research paper details the development of an advanced microfiltration module tailored specifically for the dairy industry. The module employs larger pore size filters made of polypropylene cartridges, chosen for their availability, cost-effectiveness, and adherence to hygiene standards. The fabrication process strictly adhered to current Good Manufacturing Practices and Food and Drug Administration regulations, ensuring compliance and product safety. Material selection and thickness followed the guidelines set by the American Society of Mechanical Engineers, optimal performance and long-lasting durability. Quality testing encompassed Die Penetration testing, Moly testing, and profilometer analysis, with all results falling within the range. Microfiltration module features two filtration units one equipped with 5 µm filters and the other compatible with 3µm or 1µm filter cartridges. Detailed drawings were used as blueprint during fabrication, adhering to strict sanitary standards. The module effectively removed somatic cells and bacteria from raw milk, resulting in improved milk quality and safety.

Keywords: Design, fabrication, microfiltration, (SCC) Somatic cell count

Introduction
Milk contamination poses significant challenges throughout the milk value chain, with farm contamination being a major concern. Maintaining milk quality relies on various measures, including animal hygiene, personal hygiene, and environmental hygiene (Singh *et al*. 2020) [9]. However, unprocessed raw milk from milch animals contains harmful microorganisms and somatic cells, which can lead to milk-borne illnesses and health risks. Regulatory and public health organizations have expressed concerns about consuming raw milk due to the potential for milk-borne illnesses. Even seemingly high-quality raw milk samples can be contaminated with pathogens (Lucey, 2015) [7].

In recent years, modern on-farm milk filtration techniques have emerged, utilizing additive-free technology based on molecular size. This eco-friendly approach enables farmers to produce milk of the highest quality, meeting the stringent requirements of both governmental regulations and public expectations. Implementing a robust filtration system not only improves milk quality and value but also safeguards milking and cooling machinery from potentially harmful foreign particles. Farmers benefit from cost savings through extended milk shelf life and reduced maintenance on milking equipment, while also commanding higher market prices for their high-quality milk.

While thermal processing is the most common method for milk decontamination, it can compromise the nutritional value of milk. As an alternative, non-thermal technologies have gained popularity in the food industry. Membrane filtration, a pressure-driven separation technique, utilizes semi-permeable polymeric membranes to selectively retain or reject milk components based on pore size distribution. Microfiltration, with pore sizes ranging from 0.2 to 5 µm, has shown promise in reducing somatic cells and bacteria in raw milk. (Fernandez *et al*. 2013) [4].

The dairy industry employs various membrane technologies for different applications, including extending milk shelf life, standardizing milk constituents, improving product quality and yield, and concentrating valuable milk proteins in their natural state. Membrane filtration plays a crucial role in removing bacteria and somatic cells. By selectively permitting certain compounds to pass through while blocking others, membranes effectively concentrate or fractionate liquids.

Hydrostatic pressure differences play a vital role in membrane performance, with microfiltration membranes being particularly effective in separating fine particles in the 0.1 to 10.0 µm size range (Kumar *et al*. 2013) [5].

Somatic cells (SC) in milk comprise defense and milk-producing cells, serving as an indicator of dairy animal mammary gland health and milk quality. Environmental changes, poor management techniques, and stressful situations can significantly increase the level of somatic cells in milk. Animals suffering from mastitis, an intramammary infection, release white blood cells into the mammary gland, elevating somatic cell counts in milk. High somatic cell counts not only affect milk composition but also render it unsafe for human consumption. Several pathogens causing human illnesses, such as E. coli, Staphylococcus aureus, and Streptococcus agalactiae, can be transmitted through high somatic cell count milk. (Alhussien and Ajay, 2018) [2].

Understanding the impact of somatic cell count on milk quality and consumption is crucial, as it influences milk content and consumer behavior. Epithelial cells, macrophages, polymorphonuclear neutrophils (PMNs), lymphocytes, and epithelial cells are the five types of somatic cells present in milk. (Li *et al*. 2017) [6].

Materials and Methods

The fabrication process of the microfiltration module involved several steps carried out in accordance with FDA c-GMP and 3A hygienic standards. The process began with the selection of the material of construction, specifically FDA and 3A approved AISI-304 stainless steel for the product contact parts and AISI-302 stainless steel for non-contact parts. Testing was conducted using the Moly test to differentiate between SS-316 and SS-304 grades to ensure the proper grade of stainless steel was used.

The development of the conceptualized module involved drawing visible markings on selected SS-304 pipes to create the desired equipment geometry. SS pipes were shaped by cutting them precisely on contour marks using a profile pipe cutter. Tungsten Inert Gas (TIG) welding technique was employed for welding the SS joints, ensuring the use of argon gas to prevent oxidation. DP testing was conducted as a non-destructive test to identify any surface-breaking defects or air cracks in the welded joints.

Grinding and polishing were performed on all weld joints using grinding wheels and flexible shaft grinders to achieve hygiene finishes as per sanitary standards (AMI 2014) [3]. The fabrication of the filtration module involved accurate cutting, welding, and finishing of standard SS steel plates and pipes to match the dimensions of the filter cartridges. Plates with grooves were used to securely hold the cartridges in place, and gaskets were employed for a tight fit within the housing.

Preparation of fabrication drawings was done using AUTOCAD and SOLIDWORKS-2021, providing detailed instructions and specifications for manufacturing the components. The constructional features included a robust skid constructed with stainless steel rods and square pipes for support and stability. The skid dimensions were carefully chosen to meet the structural requirements. Additionally, detailed drawing and 3D views were created for the 5 µm and 3 µm or 1 µm microfiltration housing, showing the movement of the sample and filtration process.

Fabrication of microfiltration module and development of raw milk filtration system with Process and Instrumentation Diagram

3.1.1Preparation of piping and instrumentation diagram (P&ID) of proposed microfiltration module

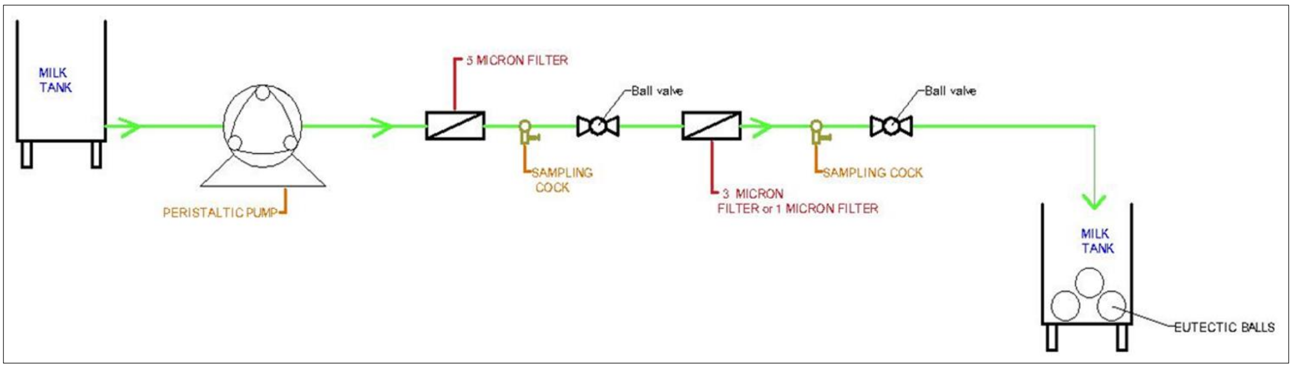

Fig 1: P & ID of the developed microfiltration module

The Process Piping and Instrumentation Diagram (P&ID) is widely used in the process industries to illustrate the integration and connection of various components in a functional system. In Figure (1), the P&ID depicts how different elements of the Microfiltration module were integrated and connected to effectively remove somatic cells and bacteria. The P&ID for the microfiltration module was created using AutoCAD-2021, adhering to industry standards and practices. This 2-D graphical representation showcases the mechanical components of the unit, including housing for 5 µm, 3 µm or 1 µm, process piping, valves, sampling lines, flow directions, and interconnections. The design features of the Microfiltration module were specifically developed to ensure the efficient removal of somatic cells and bacteria from raw milk.

Design of experiment process

The raw milk is introduced into the system using a peristaltic pump. A valve was employed to control the flow of milk, ensuring optimal regulation. Subsequently, the milk was passed through a 5 µm filter to eliminate foreign particles and visibly noticeable dust. This initial filtration step also aids in reducing the presence of somatic cells and bacteria. The milk then enters to the 3 µm or1 µm filter. This stage is crucial as it significantly removes the quantity of somatic cells and bacteria present in the raw milk after thorough filtration. Samples were collected from the filtered milk for further analysis. These samples were carefully stored at a chilled temperature of 4 °C to facilitate storage studies and maintain their integrity as shown in flow chart (figure 2).

Raw milk

↓

Peristaltic pump

↓

Microfilter

(5µm removal of visible dust or foreign particles)

↓ → Collecting sample

Microfilter

(3µm and 1µm removal of somatic cells and microorganisms)

↓

Filtered raw milk

↓

Cooled to 4°C using eutectic ball

↓

Quality Analysis

Fig 2: Flow chart of experimental setup

Preparation of Fabrication drawing for manufacture of various components of Microfiltration module using SOLID WORKS-2021

The manufacturing drawings for the microfiltration module were created using SOLIDWORKS-2021. These detailed drawings are presented in Figures (3,4,5,6,7), were utilized in the manufacturing process of the module's components at Raghavendra Enterprises in Bengaluru. While the overall geometry of both units remained identical, the internal components, such as the cartridges, were designed with varying dimensions according to the specific requirements of the design.

These fabrication drawings served as essential references, providing precise instructions and specifications for the manufacturing team to accurately produce the intended components of the microfiltration module.

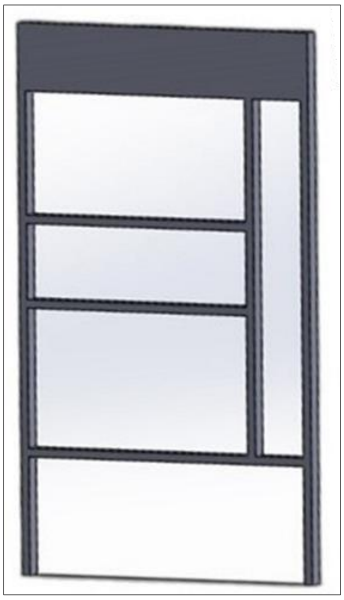

Fig 3: SS Skid (Frame)

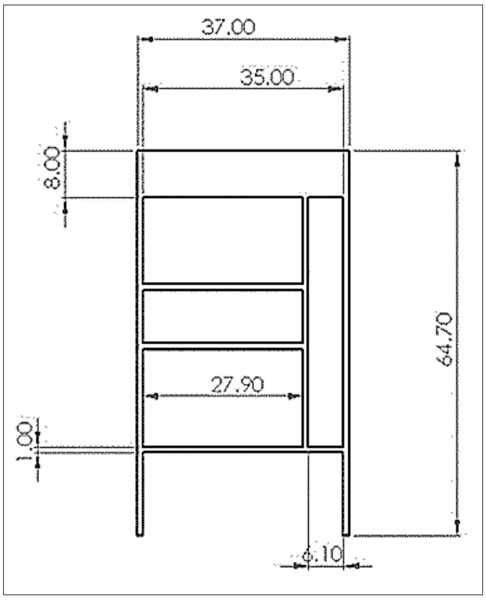

Fig 3a: Detailed sketch view of Skid(frame)

Results and Discussion

Fabrication of microfiltration module and development of raw milk filtration system with Process and instrumentation diagram.

Fabrication of 5µm filtration housing

In this research work microfiltration housing plays a crucial role in preventing leakages, preventing mixing of two streams to hold the filter cartridges firmly and in cleaning, sanitization.

Fabrication of the housing was based on the drawing as shown in fig (4 and 4.a) the specification of the housing is depicted in table (1) The developed housing 5-µm cartridge was user-friendly design featured with easy handling, assembly and disassembly, operational friendly with selected cartridges. This feature is particularly important, as it allows for quick and easy maintenance, reducing drudgery and improving production efficiency. Additionally, the robust construction of housing using SS-304 ensures long- lasting durability without any mechanical damage making it an ideal investment for any milk production facility

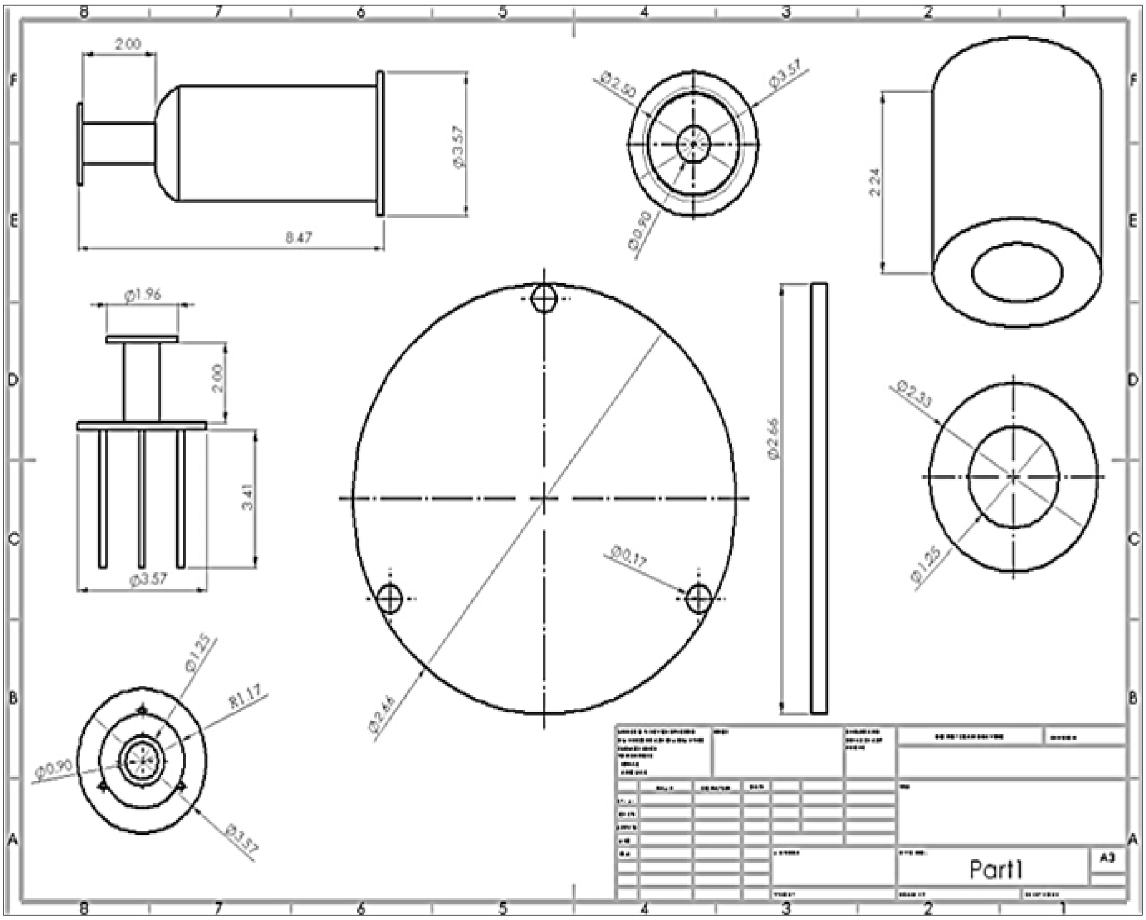

Fig 4: 2-D Design drawing of 5 µm filtration Housing

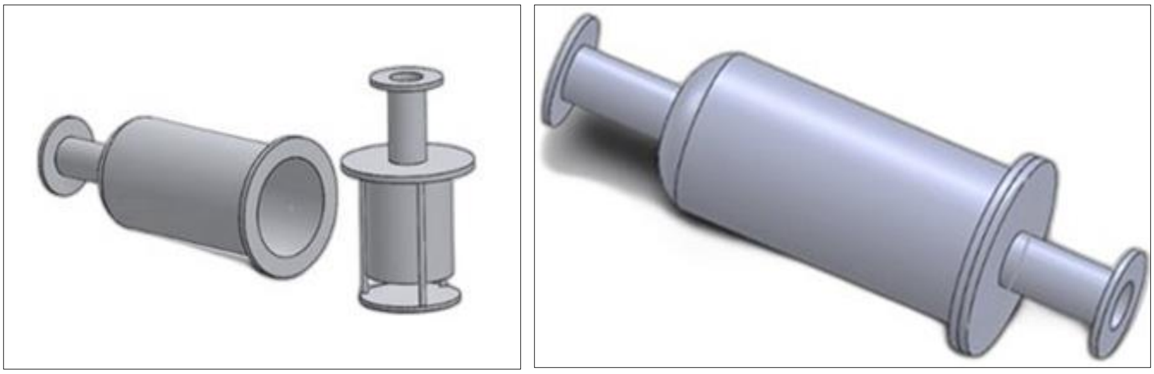

Fig 5: 3D design drawing and exploded view of 5µm filtration housing module

Table 1: Specification of 5 µm filtration housing

5 µm housing accessories	Specifications
Material of construction	AISI-304 SS
Housing Plate size	90 mm
Shell	OD –76 mm, ID – 72 mm
Housing Length	280 mm

Fabrication of 3µm filtration housing

Fabrication of the housing was based on the drawing shown in Section (3). The specification of the housing is depicted in table (2) The developed 3 µm filtration housing was user-friendly design ensures easy handling and disassembly, making it convenient to replace cartridges as needed. The 3-µm filter housing was designed to accommodate 1µm filter cartridges also as and when required to carry out experiments to ascertain the effectiveness of selected filter. This feature is particularly important, as it allows for quick and easy maintenance, reducing downtime and improving production efficiency. Additionally, the robust construction of housing using SS-304 ensures long-lasting durability without any mechanical damage making it an ideal investment for any milk production facility.

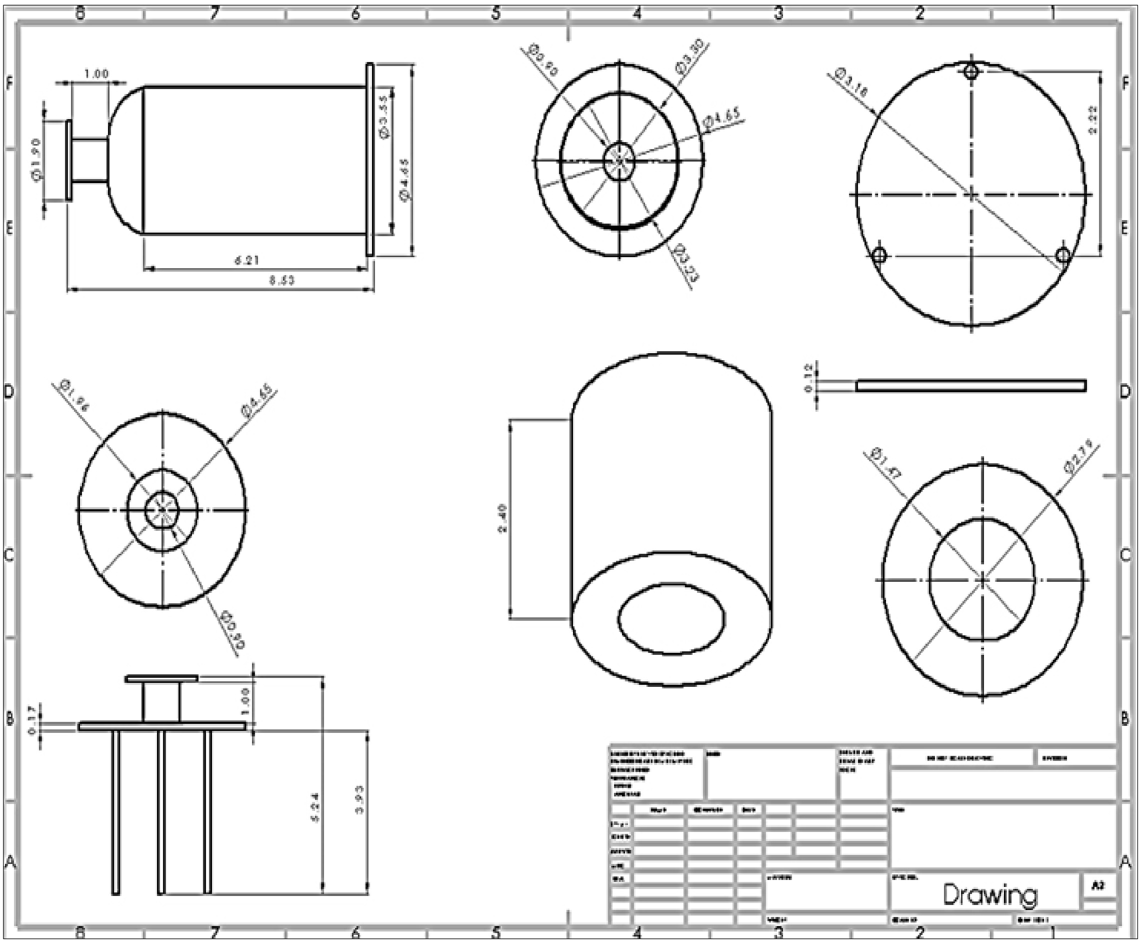

Fig 6: 2-D design drawing of 3 µm filtration Housing

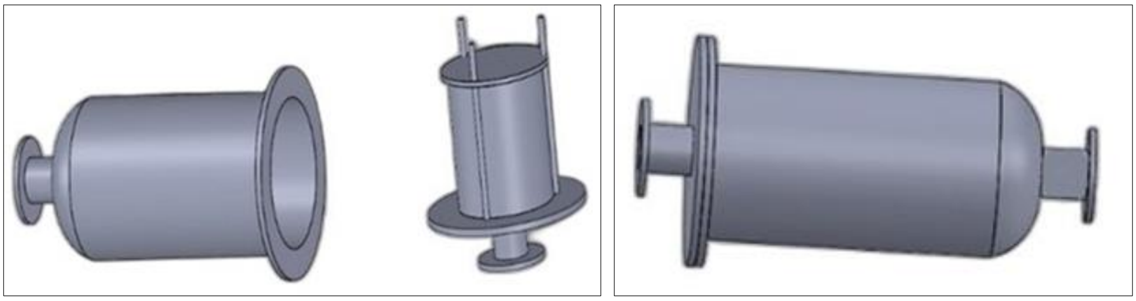

Fig 7: 3D design drawing and exploded view of 3 µm filtration housing module

Table 2: Specification of 3 µm filtration housing

3 µm housing accessories	Specifications
Material of construction	AISI-304 SS
Housing Plate size	120 mm
Shell	ID-83 mm, OD-87 mm
Housing length	290 mm

Fabricated and brought out components of Micro Filtration Module

The microfiltration module and its accessories, including the housing, frame, and pipes, were fabricated using AISI-304, a food-grade material approved by the FDA. The fabrication process followed c-GMP sanitary design standards. The assembled microfiltration module is depicted in plate (1). In microfiltration, the housing plays a vital role in preventing leaks and the mixing of different streams. It also securely holds the filter cartridges and facilitates easy cleaning and sanitization. The housing was fabricated according to the specifications and corresponding drawing provided in fig (1, 3, 4, 5, 6).

Plate 1: micro filtration module

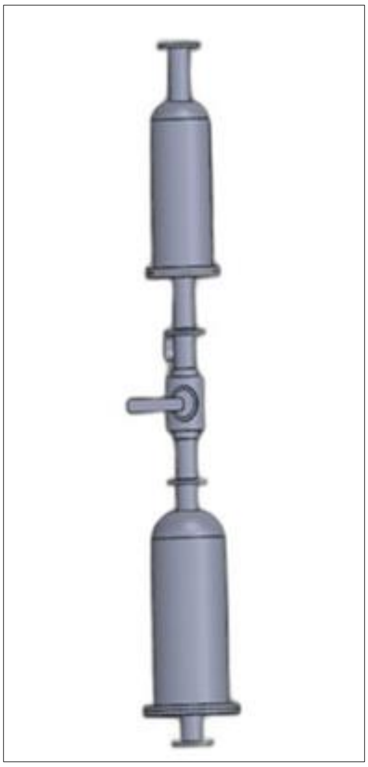

Fig 8: Top view of complete micro filtration module

Fig 9: Isom etric view of complete microfiltration Module

The current research has resulted in development of novel and unique equipment, the microfiltration module with similar two filtration housing, 5µ filtration housing and 3µ which can also hold 1µ filter cartridges, combined in a single one-line filtration module to filter Somatic Cells and Bacteria from Raw milk.

Mahesh (2016) [8] states that in order to construct the Sub Baric Thermal Processor (SBTP), he adhered to the AMI, 2014 [3] protocols. These protocols included the selection of material, testing of stainless steel for different grades, development of geometry, cutting and rolling of stainless steel to form cylinders, TIG welding, DP testing, nozzle cutting (for doors, sight glasses, and light glass, among other things), grinding and polishing, hydraulic testing, insulation, pickling, and passivation, and the We used the identical procedures from ASI, 2014 for the construction of the microfiltration module in our current research.

The over-view of the research work for the development of micro filtration module was followed by Mahesh (2016) [8] are mentioned below.

- Preparation of detailed P&ID and manufacturing drawings of Microfiltration module
- Procuring and testing the quality of stainless steel.
- Design of equipment using Pro/E and ANSYS
- Fabrication of components strictly in accordance with fabrication drawings by adopting the international hygiene design and fabrication protocols as prescribed by AMI (2014) [3] by following standard fabrication practices.
- Design, selection and procuring of various brought out items such as pipe fittings according to the requirements.
- Assembling -interconnecting of designed and fabricated components to work as intended functional unit to perform the desired operations.
- Mounting all components on to prefabricated stainless steel mobile skid to make it a single function integrated unit to filter Raw milk.

The similar protocol was followed our research work for the development of microfiltration module. In the above mention research work they have used Pro/E and ANSYS were used for the development of the module as SBTP works under high pressure so it has to be analyzed for the pressure holding capacity for the development of SBTP we used AUTOCAD 2021 and SOLID WORK 2021 software's for the development of micro filtration module following the hygiene design and fabrication protocols as prescribed by AMI (2014) [3] complete view in plate 2.

4.2 Testing and quality assurance of fabricated components

On successful completion of design and fabrication process, several tests were carried out to ascertain strength, stability and soundness of fabrication of all components and the assembled unit of Microfiltration module. These tests were essential to ensure the design and safety requirement of process equipment as shown in Table (1) and are explained below.

- The thickness of the material was measured by Vernier micrometer which showed
  2 mm thickness which was acceptable according to ASME.
- The material MoC was checked by moly test which confirmed it was SS 304.
- The die penetration test was conducted for conforming quality of welding, the die to the other weld side was not seen, the welding was acceptable, the DP test revealed that welding was properly done
- To acertain surface finish profilometer was used and obtained a result of 0.52 Ra-µm (Roughness average), which confirmed that the surface finish met IOS standard.

Table 3: Quality control tests for components of the microfiltration module

Test	Parameter	Design requirement	Measured value	Inference
Thickness by micrometer	Wall thickness mm	2 mm	2 mm	Acceptable
Moly test for MoC	Grade of SS	Disappearance of red colour after few seconds	Disappearance of red colour after few seconds	Moc confirmed as SS-304
DP test (NDT)	Penetration of die to another weld side	No appearance of colour	No appearance of colour	Welding is satisfactory
Surface finish by Profilometer	Ra-µm (Roughness average)	0.5-0.55	0.52	Surface finish confirmed to IOS standards

According to Hivalekar (2011) [10], in their work they have provided information about the testing of various grades of stainless steel. In their work they have provided distinctions between SS 316 and SS 304 using the moly test protocol. If the colorless electrolyte turned red and the red color persisted for a prolonged period of time, it is assumed that the metal tested was SS - 316 grades. In our investigation, the electrolyte turned red during the analysis and then vanished, indicating that the substance was SS-304.

After welding and fabrication, a dye penetration test was conducted to look for breaking flaws. Worman (2011) used the DP test to check boilers for any breaks or cracks. As previously indicated, the same approach was used in our research effort to test the developed module, and it was concluded that there were no breaks or cracks.

The surface quality of material was tested using a profilometer. According to Mahesh (2016) [8], there are distinct roughness average values Ra (m) for different grit sizes. The 180-grit polishing was done by using polishing wheel (Carburized silicon) the testing values were between 0.46 to 0.58 Ra (m).

Evaluation of Sanitary design and fabrication of microfiltration module

The fabrication and development of food and dairy equipment's should meet standard criteria. The findings are provided in accordance with c-GMP protocols (AMI, 2014) [3] the self-evaluation score summary consists of 10 principles, out of which points are awarded for acceptance. The equipment must meet a minimum of 90% for acceptance, and if less than 90% is achieved, the module needs more improvement. Points are awarded for satisfactory, marginal and unsatisfactory performance, respectively.

Plate 2: Developed Functional Microfiltration module

Table 4: Score summary of Sanitary design and Fabrication evaluation

Executive SCORE SUMMARY				
Score card Above 90% - Acceptable Bellow 90% - Improvement required Satisfactory – Full points Marginal – Half Unsatisfactory- no points				
Principles	**Points/Possible**			
Principle #1 – Microbiologically Cleanable	100	of	100	100%
Principle #2 – Made of Compatible Materials	90	of	90	100%
Principle #3- Accessible for inspection, Maintenance, & Cleaning/Sanitation	133	of	140	95%
Principle #4- No Liquid Collection	60	of	70	86%
Principle #5- Hollow Areas Hermetically Sealed	135	of	150	90%
Principle #6- No Niches	133	of	150	90%
Principle #7- Sanitary Operation Performance	93	of	100	93%
Principle #8-Hygienic Design of Maintenance Enclosure	50	of	50	100%
Principle #9-Hygienic Compatibility with Other Systems	45	of	50	90%
Principle #10-Validated Cleaning &Sanitizing Protocols	50	of	50	100%
Total	888	of	950	993%
The purpose of the summary worksheet is to quantify the level of continuous improvement. Acceptance is based on ability, time, resources, and cost of implementing and maintaining controls for all noted marginal and unacceptable ratings.				

In our research work the overall Score obtained for Microfiltration module for its hygiene design and fabrication was 93% which is above 90% prescribed for acceptability (AMI, 2014) [3]. Hence it was inferred that Microfiltration module has been designed and fabricated as per FDA-GMP requirements. There was a trace amount of Nitches which gave a bad score shown in table (4).
According to Mahesh (2016) [7] he has adopted Executive Sore Summary table for the self-evaluation of SBTP according to certified c-GMP protocols (AMI, 2014) [3]. The overall score obtained for SBTP for its hygiene design and fabrication was 93% which is above 90% prescribed for acceptability (AMI, 2014) [3] the same protocol was followed for awarding points for the module.

Conclusion

In conclusion, the Microfiltration module was developed according to c-GMP and ASMI protocols, ensuring high-quality standards in its design and fabrication. Solid works and Autocad 2021 were used to create accurate dimensions and provide a 3D view for fabrication purposes. The materials used in the module passed rigorous quality tests, meeting satisfactory standards. The module underwent a sanitary design fabrication evaluation, achieving a score above 90%, as deemed acceptable by AMI (2014) [3]. This confirms its compliance with FDA, c-GMP requirements. The module was conveniently mounted on a skid, facilitating easy handling.
Furthermore, the project's findings have application by exploring the use of custom-made cartridges, it becomes possible to efficiently filter honey, sugar syrup separating impurities and ensuring a cleaner final product. Additionally, the project opens up avenues for further innovation in milk filtration technology. This includes the exploration of effect of combined effect microfiltration of raw milk using 5, 3 and 1-micron filter, leveraging the benefits of different materials and pore sizes to achieve enhanced keeping quality of raw milk, and the preservation of valuable chemical constituents in raw milk. By harnessing UV technology in series, the project can be promising to contribute for reduction of bacteria in raw milk. This becomes sustainable milk filtration at farm level which will act as booster for (CMP) clean milk production.

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