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From the Desk of Editor-in-Chief

MESSAGE

Dear Members of the Academic Community,

I am immensely pleased to extend my heartfelt congratulations on the occasion of the publication of the 10th issue of the Multidisciplinary Research Journal of GTU. This milestone is a testament to our dedication to advancing knowledge, fostering innovation, and promoting interdisciplinary collaboration.

Over the years, this journal has emerged as a beacon of scholarly excellence, showcasing the diverse range of research endeavors undertaken by our esteemed faculty, researchers, and students. Each issue has contributed to the growing body of knowledge across various domains, demonstrating the remarkable intellectual vibrancy of our institution.

I would like to extend my gratitude to the editorial team, reviewers, authors, and all those who have played a vital role in the development and success of this journal. I urge all members of our academic community to continue their valuable contributions, fostering a culture of research and innovation that pushes boundaries and drives positive change.

Congratulations once again to all those who have been a part of this remarkable journey.

Warm regards,

Dr. Rajul K. Gajjar
Hon'ble Vice Chancellor,
Gujarat Technological University, Ahmedabad

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EXPERIMENTAL INVESTIGATION ON PERFORMANCE OF P- HCCI ENGINE USING BIODIESEL MIXTURE

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Abstract

This paper presents the performance of single cylinder HCCI Engine using Biodiesel Mixture. The Homogeneous charge compression ignition (HCCI) combustion is a new trend alternative technology to current engine combustion systems. Many inventions in HCCI is being worked out to use it as a method to reduce exhaust emissions and also fuel economy. The quality of homogeneous mixture of air and fuel is the key feature of HCCI combustion. HCCI has the characteristic nearly eliminate NOx emissions while increasing efficiency as in diesel engine. HCCI adapts a pre mixture of gas-phase fuel and air being burned spontaneously and entirely by an auto ignition process. Homogeneous Charge Compression Ignition (HCCI) engines promises a high thermal efficiency combined with low levels of NOx and PM emissions. The purpose of this study is to analyze the effect of alternative fuel when used in the HCCI engine combustion process. The experiments were conducted in a modified single cylinder water-cooled diesel engine. In this experiment we use diesel and bio-diesel Mixture as the fuel at different millisecond injection.

Keywords: Homogeneous Charge Compression Ignition (HCCI), Diesel, Diesel Engine, Performance and Exhaust Emission, Biodiesel Mixture

1. INTRODUCTION

Because of the reduction of petroleum of reserves and air pollution emerged from exhaust emissions, there have been great efforts to use alternative fuels in diesel engines for substitution diesel fuel. Known petroleum reserves are limited and will eventually destroyed. Biomass energy technologies are use waste or plant matter to produce energy with a lower level of greenhouse gas emissions than fossil fuel sources. The biofuel economy will grow rapidly during the 21st century. The biofuel economy, and its related bio refineries, will be shaped by many of the same forces that shaped the development of the hydrocarbon economy and its refineries over the past century.

Biodiesel is step by step gaining acceptance in the recent market as an ecofriendly fuel and the demand is expected to increase all at once as an alternative renewable energy source in the near future. The biggest difference between biofuels and petroleum feed stocks is oxygen content. Biofuels have oxygen levels of 10 to 45% while petroleum has essentially none, making the chemical properties of biofuels very different from those of petroleum. All have very low sulfur levels and many have low nitrogen levels. Biodiesel which has combustion characteristics similar to diesel and biodiesel blends has shorter ignition delay, higher ignition temperature and pressure as well as peak heat release compare to diesel fuel. Moreover, the engine power output and brake power efficiency was found to be equivalent to diesel fuel. Biodiesel and diesel blends can reduce smoke opacity, particulate matters, un-burnt hydrocarbons, carbon dioxide and carbon monoxide emissions but nitrous monoxide emissions have slightly increased.

Biodiesel HCCI is new technology to use of both biofuels and HCCI combustion. The main aim is to use HCCI combustion mode is simultaneous reduction of NOx and soot, as well as reduction of fossil CO_2 emissions. In this mode, biodiesel combustion burns lower in-cylinder temperature, therefore it reduces NO_X emissions. Biodiesel HCCI mode also enhances the fuel efficiency because of combustion of ultra-lean mixtures.

1.1 Biodiesel Mixture as an Alternative Fuel for IC Engine

Biodiesel is an oily liquid synthesized from fatty material. It has a light yellow color and mild odor and a bitter taste, it has many advantages such as: Renewable, it can be extracted from vegetable oil, Potential for Carbon Neutral lifecycle, simple to make, Non-toxic, Biodiesel is free from sulphur (< 0,001 %), the only alternative fuel that does not require engine modification or retuning, safer for storage and handling than petroleum diesel, Can be used neat or blended in any ratio with petroleum diesel and dramatically reduced emissions. Because of high viscosity of vegetable oils and low volatility causes the atomization and spry patterns problems, leading to incomplete combustion and severe carbon deposits, injector choking and piston ring sticking.

The methods used to reduce the viscosity are:

- Emulsification,
- Pyrolysis,
- Dilution and
- Transesterification process.

Among these four methods, the transesterification is commonly used commercial process to produce clean and environment friendly Biodiesel. Methyl esters of used cooking oil, sunflower oil, rice bran oil, palm oil, soybean oil, Mahua oil, Jetropha oil,castor,karanj and coconut oil have been successfully tested on C.I. engines. In present research Biodiesel Mixture is use as an Alternative fuel. My Research I Used three vegetables Oils like Castor, Karanj and Coconut to make Biodiesel Mixture.

Table 1. Important properties of Biodiesel Mixture and diesel

Fuel Property	Biodiesel Mixture	Diesel
Density Kg/m^3	0.890	0.860
Boiling point,℃	130	188-343
Kinetic Viscosity, cst	4.204	2-4
Calorific Value,kJ/kg	37,891	42,000
Flashpoint, °C	140	55
Auto ignition Temp.°C	230	316
Cetane number	57	51

For compression ignition engines conversions to HCCI Engine are require homogeneous charge insert in to cylinder so injection system modified. We use heater to vaporize biodiesel fuel then install it in intake manifold.

1.1.1 Objectives of Research

- To modify of a single cylinder diesel engine run in to HCCI mode fuelled with Diesel and Bio-fuel.
- Tuning of fuel vaporizer with Diesel engine to run it on HCCI mode in optimized condition.
- To study effect of the bio-fuel on performance parameters like brake thermal efficiency, brake Specific fuel consumption and emission etc. with HCCI mode of working.
- To study the emission parameters mainly exhaust parameters like hydrocarbon emission, oxides of carbon (CO & CO2) and oxides of nitrogen (NOx) by running engine HCCI mode with bio-fuel.

1.1.2 Research Methodology

HCCI: Homogeneous Charge Compression Ignition

HCCI is a form of internal combustion in which the fuel and air are compressed to the point of auto ignition. HCCI engines are operated with the compression ignite on of homogeneous charge formed by premixed air and fuel mixtures through early injection on to the hot surface of a heated chamber known to be the vaporizer.

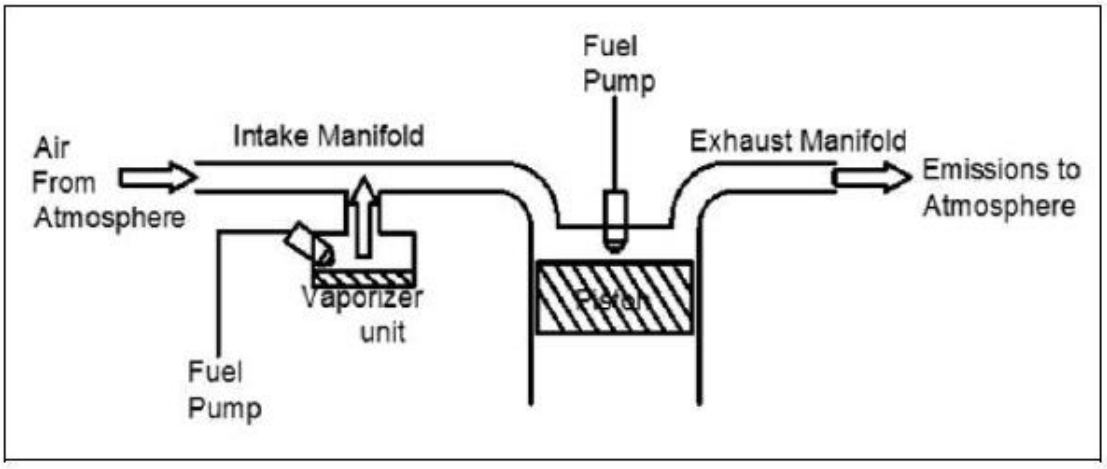
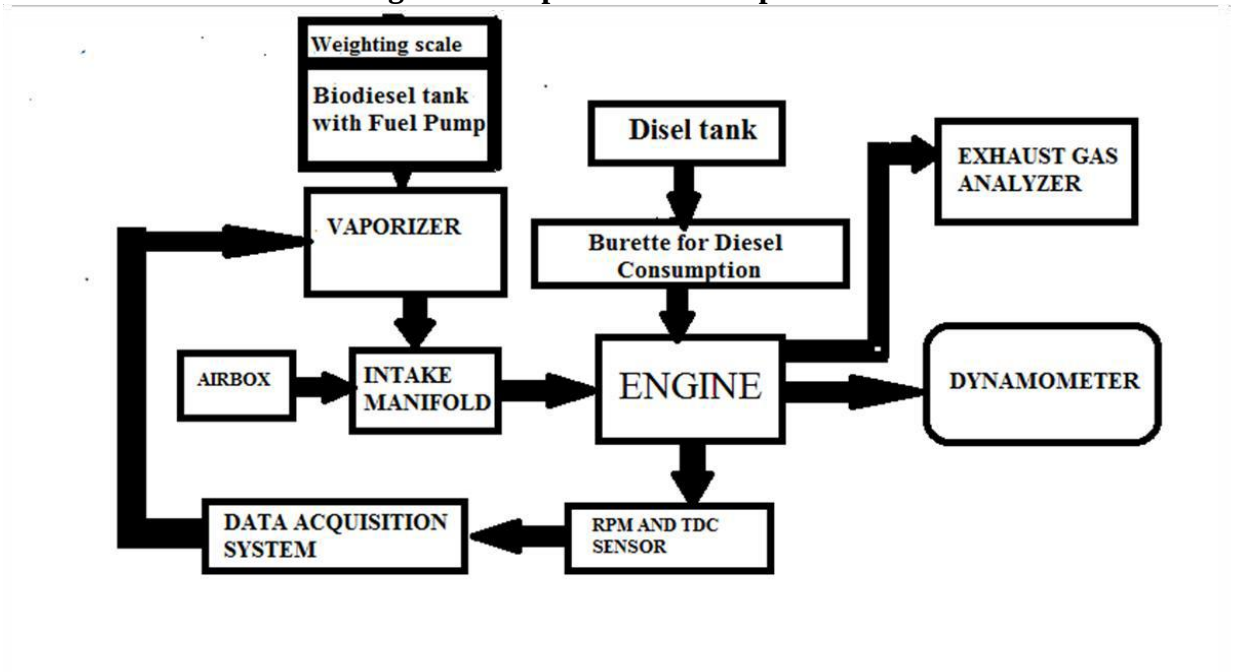


Figure 1.1-Basic HCCI concept

HCCI technology uses homogeneous charge inside the combustion chamber and this is obtained by premixing the air and vaporized fuel outside the combustion chamber.

Schematic Diagram of Experimental Setup.



- Experimental Procedure to Test Engine with Modification for HCCI
- Fuel Vaporizer system is installed in the intake manifold.
- Ensure cooling water circulation for eddy current dynamometer and engine.
- Start the set up and run the engine at no load for 4-5 minutes.
- Switch on the computer and run engine software. Reading taken with help of sensors whose sensed output is connected to the Data acquisition system.
- The engine is started by first connecting the Data acquisition system with the Computer and then followed by software initialization.
- An electronically controlled port injection system is employed to inject bio- fuel in to the inlet manifold with vaporizer system.

- Gradually increase load on the engine. And also readings are observed for various injections timings decided at each load condition.
- Wait for steady state and log the data in the engine software.
- The exhaust gas composition CO, UHC, CO2, O2 and NOx emissions were measured by gas analyzer.
- View the results and performance.

1.2 Biodiesel production

- Sodium hydroxide was added to methanol in a mixer and stirred for 10 to 15 minutes until it is completely dissolved.
- It was then mixed with the three mix vegetables oil in a reactor equipped with a heater, magnetic stirred at 60℃. Stirring was continued and the product was placed in a separating funnel and left over night for glycerin to settle to the bottom of the funnel and then removed in a measuring cylinder.
- The impure methyl ester (biofuel) has contain moisture so biodiesel should be moisture free then I add hexane into biodiesel**.**

Fig1.2 Actual experimental set-ups for Making Biodiesel Mixture

2. LITERATURE REVIEW

[1] Gajendra Singh, Akhilendra Pratap Singh, Avinash Kumar Agarwal present on "Experimental investigations of combustion, performance and emission characterization of biodiesel fuelled HCCI engine using external mixture formation technique." From Elsevier

In this paper study of in a modified two cylinder engine, in which, one cylinder was operated in HCCI mode while other was operated in conventional CI mode. HCCI engine can be operated with a wide variety of fuels starting from mineral diesel to various blends of biodiesel (B20 and B40). The basic requirement of the HCCI engines is homogeneous mixing of fuel and air, which is done by using port fuel injection strategy in this study. An external device was used for fuel vaporization and mixture formation. For controlling HCCI combustion, different EGR conditions (0%, 15% and 30%) were also applied.

Conclusion: Two-stage heat release was observed for HCCI combustion mode. First stage combustion was due to low temperature combustion chemistry, while the second stage combustion was dominated by high temperature combustion chemistry. Chemical kinetics of diesel HCCI was found to be faster compared to

biodiesel HCCI. Effect of EGR was investigated and it was found to be a very effective tool to control HCCI combustion. Reduction in power output and increase in ISFC were observed upon increasing biodiesel content in the test fuel, possibly because of biodiesel's lower calorific value compared to mineral diesel.

[2] Salvador M. Aceves, Daniel Flowers, Joel Martinez-Frias, Francisco Espinosa-Loza, William J. Pitz and Robert Dibble Present on, "Fuel and Additive Characterization for HCCI Combustion", SAE International, Paper - 2003- 01-1814.

In this paper study of HCCI combustion using diesel and its blends with biodiesel as test fuels in a constant speed engine. Since diesel like fuels are difficult to mix homogeneously with intake air, external mixing using a biodiesel vaporizer was done to achieve HCCI combustion. Mineral diesel has lower boiling range as compared to biodiesel therefore external mixture formation was easier for mineral diesel compared to biodiesel/blends. Two-stage heat release was observed for HCCI combustion mode. First stage combustion was due to low temperature combustion and second is high temperature combustion. This is - paper experiments were performed in a modified two cylinder diesel engine, in which, one cylinder is operated in HCCI mode while other is operated in conventional CI mode. In this experiment perform with a wide variety of fuels starting from diesel to various blends with biodiesel (B20 and B40). For varying EGR rate (0%, 15%, and 30%).

Conclusion: This study concludes t h a t N O x emissions reducing different biodiesel blends. A power output reduces and an increase in ISFC was observed upon increasing the biodiesel blend. CO, HC and smoke emissions was small increase observed with increasing biodiesel content and EGR rate.

[3] HarisankarBendu, S. Morgan (2014) present on "Mixture preparation and control strategies in HCCI engines."

In this paper study of the different strategies of controlled auto-ignition by HCCI combustion and mixture preparation method for external and in-cylinder.

Conclusion: The HCCI combustion engines have the potential to improve the thermal efficiency, while reducing the trade-off emissions in conventional diesel engines. The port fuel injection has a high degree of mixture homogeneity compared to the injection methods, but lacks start of combustion control. The emissions of NOx and smoke are low in all advanced combustion modes in comparison with conventional diesel engine, while the UHC/CO emissions are increasing in all temperature combustion concepts except in MK combustion.

[4] Francisco J. Jiménez-Espadafor, Miguel Torres, José A. Velez, Elisa Carvajal, JoséA.Becerra (2011) present on "Low temperature combustion mode in HCCI engine fuelled with diesel and biodiesel fuels."

In this paper study of HCCI combustion fuelled with diesel and biodiesel based on a high swirl ratio and EGR rate. In the experiment measure the HRR, NOx, CO, HC and soot emissions. Also evaluate the performance of early injection strategy use in the fuel wall impingement. Bowl shape piston geometry has been designed with a dedicated swirling flow model.

Conclusion: High injection delay in HCCI combustion with colza biodiesel, high swirl level and EGR rate. This condition reduces maximum engine power compared with diesel combustion mode, but significantly reduces NOx and soot emissions. Also EGR rate increase NOx emissions reduce and smoke level increase, like conventional diesel combustion. Biodiesel percentage increase small increase in NOx and soot emissions.

[5] Hyung Jun Kim , Kwan Soo Lee , Chang Sik Lee (2011) present on "Effect of narrow spray angle and advanced injection timing in HCCI combustion engine fuelled in DME."

In this paper study of the performance and emission characteristics of HCCI combustion according to the narrow spray angle and advanced injection timing fuelled with dimethyl ether (DME) in the diesel engine. The shape of the piston head are modified to bowl type to apply the narrow spray angle and advanced injection timing. The spray, combustion and emission characteristics are calculated by using numerical method of the KIVA-3 V release 2 codes coupled with chemical kinetic model of DME oxidation. Model validation was conducted by a comparison of experimental results data and accurate prediction. To evaluate combustion, performance and emission in the engine for the injection timing range BTDC 80° to BTDC 10°.

Conclusion: In the injection timing BTDC 30° the Nitrogen oxide (NOx) emission is decreased, while injection timing of BTDC 70° the hydrocarbon (HC) and carbon monoxide (CO) emissions at high levels. Also, the IMEP and ISFC have decreasing and increasing patterns respectively as the injection timing was advanced. Regarding engine performance, increasing of the injected fuel mass yield an increase of IMEP but these results in increased the fuel consumption.

Summary and Conclusion:

- As seen from above literature survey, use of bio-fuel as fuel in engine gives best performance and lower emission. So it is economical and environment Friendly, that is the reason of select bio-fuel as a fuel.
- The IMEP increases with the increase of premixed ratio at low to medium loads.
- The emissions of NOx and smoke are low in all advanced combustion modes in comparison with conventional diesel engine.
- The lower soot generation for biodiesel is hypothesized due to a lower soot formation rate and a higher soot oxidation rate.
- The HCCI combustion engines have the potential to improve the thermal efficiency, while reducing the trade-off emissions in conventional diesel engines.
- Low volatility and high viscosity of biodiesel with convectional diesel engine choke the fuel injector upon long-term usage.

2.1 Reasons To Modify Diesel Engines Conversion In To HCCI Engine

- The problem of air pollution around the globe is real and serious, diesel exhaust emissions are a major source of pollution in most urban centers around the world and a major contributor to climate change. Trucks, buses, generators and ships burn millions of gallon of diesel fuel daily. Many countries are to alternative fuels to reduce diesel exhaust emissions, especially in urban centers.
- Furthermore, as the price of crude oil continues to increase, the use of alternative fuel becomes increasingly economical and reduces the import burden of oil country like India.
- Price of diesel is low compare to petrol and has higher efficiency than petrol so people of the urban area are switched over to the diesel engine which make a serious problem in urban are to solve this problem higher efficient and economical operated Biodiesel fuelled diesel engine is required.
- Biodiesel is an alternative source if petroleum source is out of stocks
- HCCI Engine is give high power output compared to C I Engine also it used alternate fuel.

2.1.1 Modification Done To Convert Diesel Engine In To Hcci Engine.

- Cutoff System
- Data Heater Installed On Copper Pipe
- Install Heater In Intake Manifold
- Injector Acquisition Unit.
- Temperature Sensor Installation

2.1.2 Analysis Part as Experimental Set-up

A. Experimental engine test rig.

Fig 2.1 Actual experimental set-ups for modified engine (HCCI engine)

A vertical, single cylinder, water-cooled, four stroke, and high speed diesel engine has been used for the experiment. The technical specification of engine is as under:

Engine	Kirloskar AV1
Dynamometer	eddy current, water cooled
Bore (mm)	87.5
Stroke (mm)	110
Displacement (cm^3)	661
Compression ratio	17.5
RPM	1500
H.P.	5.2

3. FINDING RESULTS AND DISCUSSION

- **Engine performance parameters for conventional Diesel and Diesel-Biodiesel HCCI:**

A. Effect of Load on Specific Fuel Consumption:

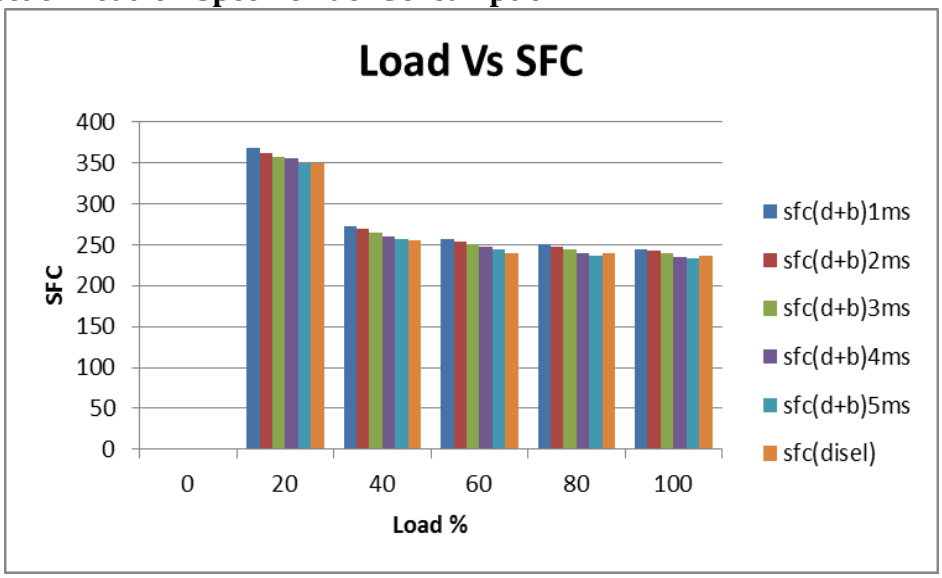


Fig 3.1 Load vs. Specific Fuel Consumption both diesel and Biodiesel.

Fig.1 shows the correlation between the load (%) and SFC consume by the engine while operating on diesel and Biodiesel. SFC consume by the engine was found decrease with increase load for the both the fuel. But compare to diesel the SFC of Biodiesel slightly increase.

B. Effect of Load on Volumetric Efficiency

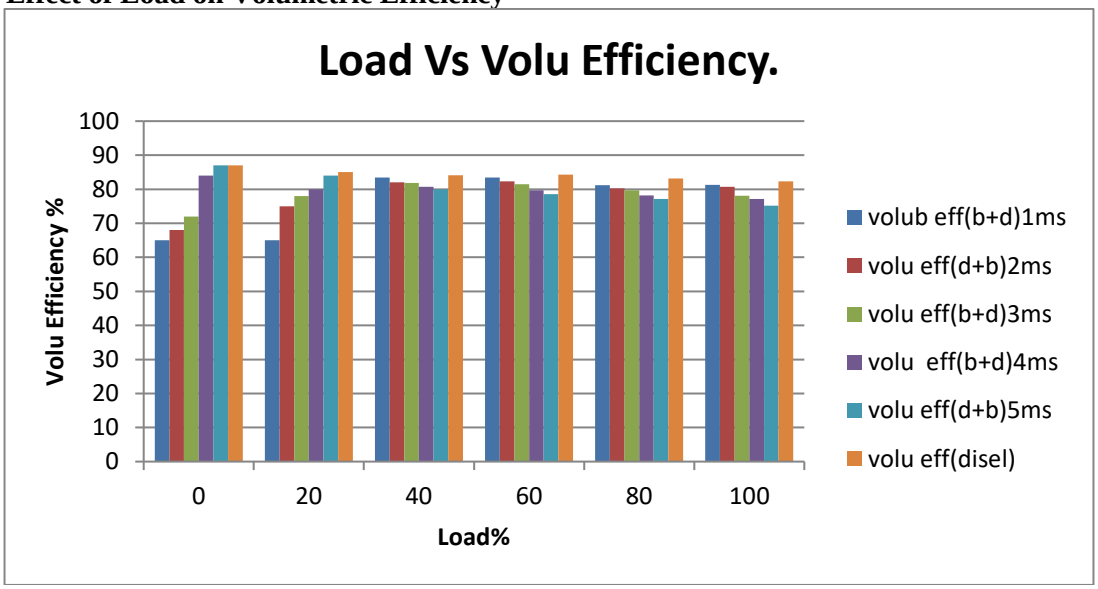


Fig 3.2 Load Vs. Volumetric Efficiency for both diesel and Biodiesel.

C. Effect of Load on Exhaust gas Temperature

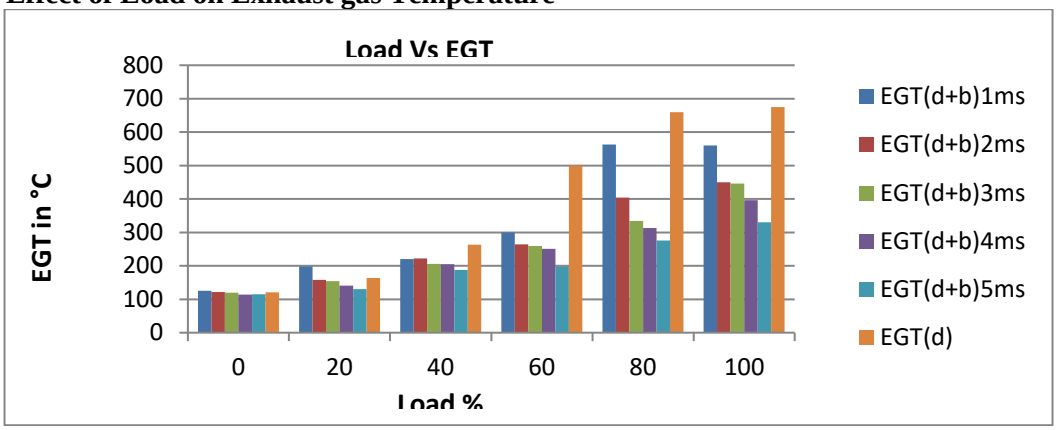


Fig 3.3 Load Vs. Exhaust Gas Temperature both diesel and Biodiesel.

As shown from Fig.3 that at high load temperature increase but compare to diesel it is lower temperature of exhaust.

D. Effect of Load on CO2 emissions

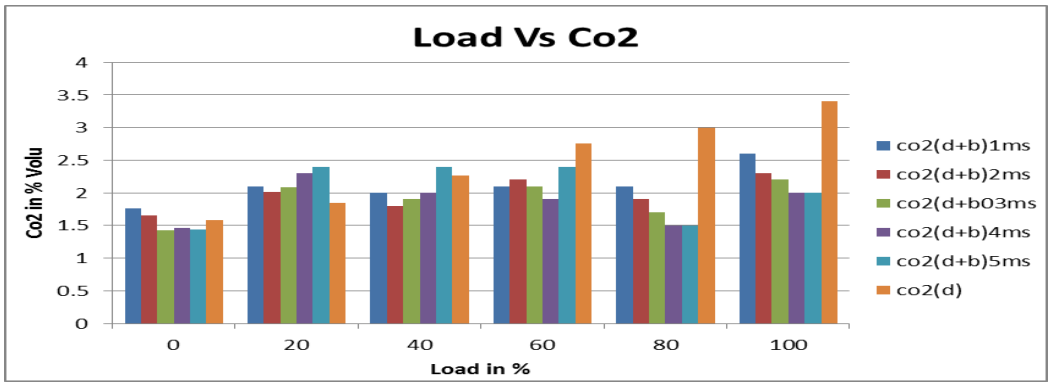


Fig 3.4 Load Vs. CO2 emission both diesel and Biodiesel.

CO_2 emission was increased as the load increased and it is decreases for the higher load for biodiesel.

E. Effect of Load on CO emissions

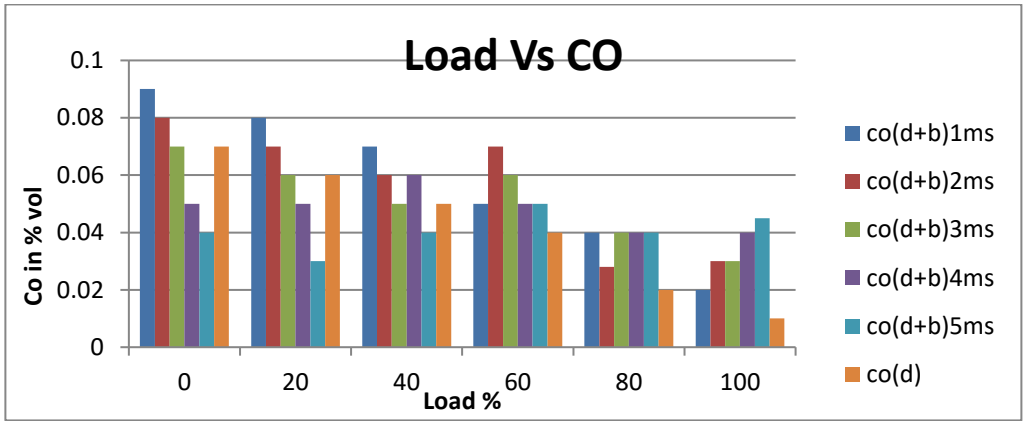


Fig 3.5 Load Vs. CO emission for both diesel and Biodiesel.

It is cleared from Fig-5 that CO emissions are very low compare to diesel while High milli second injection for Biodiesel.

F. Effect of Load on NO emissions

NO emissions were found also low in HCCI engine compare to diesel engine at Low and High Load Condition.

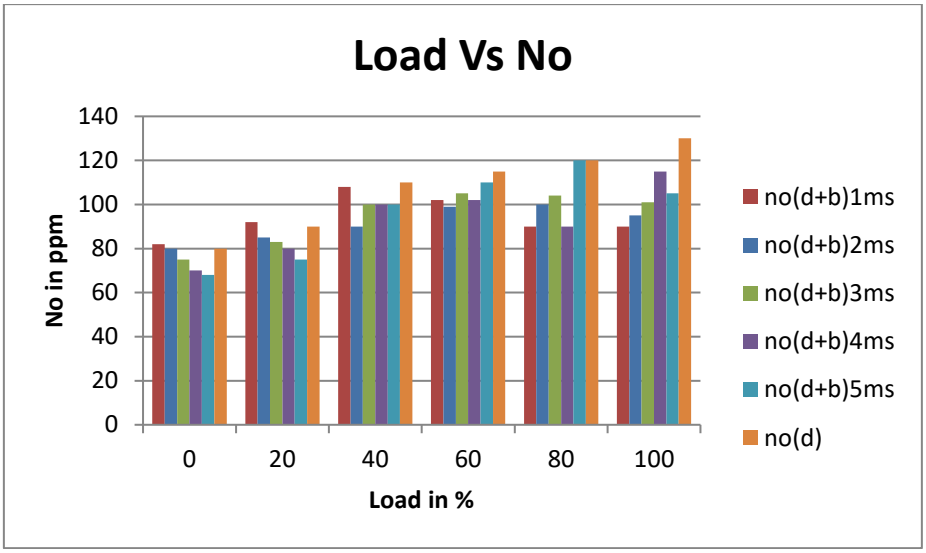


Fig 3.6 Load Vs. NO emission for both diesel and Biodiesel.

4. CONCLUDING REMARKS

- Specific fuel consumption of Biodiesel injection decrease at gradual increase load but compare to diesel engine slightly increase. With increase in milli - second injection in HCCI mode, the SFC decrease.
- Exhaust gas temperature overall decrease in all load rating.
- Volumetric efficiency decrease at 0 to 20% load but increase in high milli second.
- The volumetric efficiency decreases with increase in Load and this is due to fact that the engine cylinder temperature during suction is higher for higher load Conditions. With increase in HCCI, the volumetric efficiency decreases which is due to the displacement of the part of air by the vaporized fuel during the suction stroke.
- The brake thermal efficiency is measured at every 20% rise in load from 20% to 100% of rated load condition. The brake thermal efficiency increases with the increase in load up to 100%, then after it decreases. For HCCI, The brake thermal Efficiency of conventional diesel engine is higher than the Biodiesel HCCI at Lower loads. As the graph show at high load with high milli second injection Increase brake thermal efficiency.
- The co emissions are lower for high time in ms at 0 to 40% load and high load co maximum compare to C.I engine. The CO is observed at different load conditions. Graph represents the variation of CO emission with the increase of load from 0% to 100% at every 20% load increase. The CO emission is observed to be decreasing due to increased rate of complete conversion of C to CO2.
- The NOx emissions are lower for diesel-biodiesel HCCI compared to the conventional diesel in the low load and high load. The NOx emission is observed to be increasing with load and this is due to the rise in combustion temperature favoring the NOx formation. The NOx emission is lower for HCCI engine than the conventional engine for lower loads. At higher load conditions the Biodiesel HCCI emissions maintains its lower pace.

- The hydrocarbon emission is observed with different load conditions. Graph -represents the variation of HC emission with the increase in load from 0% to 100% at every 20% load increase but high load it is decrease. HC emission decrease with increase in load denotes a much complete combustion taking place in the engine combustion chamber.
- Biodiesel is viable alternative fuel for the diesel engine. Existing diesel engine was successfully converted into HCC engine.

These observations lead to the conclusion that up to 3ms HCCI leads to the highest performance with lower emissions and hence is most suitable when compared to the conventional diesel system.

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MITIGATING THE RISK OF NITROSAMINE IMPURITIES IN DRUG SUBSTANCES AND PRODUCTS: ANALYTICAL APPROACHES AND REGULATORY GUIDELINES

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Abstract
Nitrosamine impurities, known to be highly toxic and capable of causing cancer, can have carcinogenic effects even in small quantities when present in the body. To prevent the presence of these impurities, precautions should be taken during the manufacturing and development of drug substances and products. Regulatory authorities such as the World Health Organization (WHO) and the US Food and Drug Administration (USFDA) have provided guidelines and notifications on controlling these impurities, aiming to prevent their spread in drug substances. Validated analytical techniques like gas chromatography (GC) and liquid chromatography (LC) should be employed to detect and measure these impurities. Nitrosamine impurities can be introduced into the drug substance or product through reagents, catalysts, solvents, or raw materials used during the manufacturing process. Detecting these impurities at trace levels requires sophisticated instruments, such as LC or GC combined with mass detectors, which are commonly used for this purpose.

Keywords: Nitrosamine impurities, Impurity profiling, Side effects, Analytical methods, etc.

1. INTRODUCTION [(1) (2) (3)]
Nitrosamines, specifically N-nitrosamines, are formed when molecules containing the nitroso functional group react with nitrous acid. These impurities are a concern because they have the potential to be harmful to humans. While nitrosamines can be found in some food and beverage substances, their presence in medications is considered unacceptable.

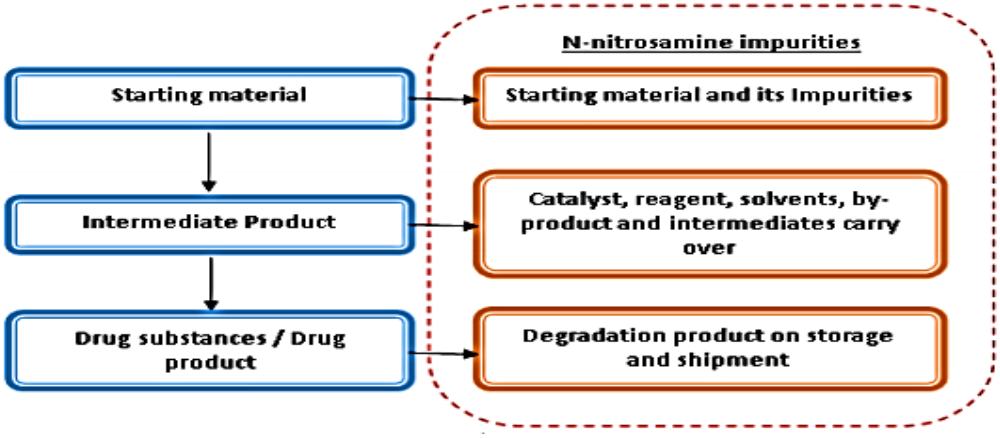
Nitrosamine formation occurs when secondary or tertiary amines react with nitrous acid, which is often generated in situ from nitrites (NO2) under acidic conditions. In the case of sartan compounds, which commonly contain a tetrazole ring, the use of sodium nitrite in the formation of this ring has been implicated. The exact source of N-nitrosodimethylamine (NDMA) in batches of ranitidine is currently unclear.

According to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), Nitrosamine impurities are classified as Class 1, indicating their potential toxicity and carcinogenicity based on data from rodent studies and mutagenicity testing.
These impurities can affect genetic material through mutations caused by chromosomal breaks, rearrangements, covalent binding, or insertion into DNA during replication. Exposure to very low levels of Nitrosamine impurities can lead to these genetic changes, potentially resulting in cancer. Therefore, it is crucial to detect Nitrosamine impurities in medications at extremely low levels to ensure public safety.

1.1 Source of Impurities [(3)]
Nitrosamine impurities can be introduced into drug substances and products through various routes, including during the manufacturing process. These impurities may be incorporated through process formation, direct introduction, degradation, or cross-contamination. The manufacturing of drug materials

involves the use of raw materials, intermediates, solvents, chemicals, and reagents. If Nitrosamine impurities are present or persist throughout these stages, they can become embedded or carried forward into the final drug product. It is important to identify and prevent the presence of these impurities at every step of the manufacturing process to ensure the safety and quality of the drug.

Figure 1: Sources



1.2 Occurrence [2] [4]:

March 2018: A risk assessment was conducted for genotoxic impurities. The issuance of the agreed document M7 (R1) helped in outlining the threat assessment.

June 2018: NDMA (N-nitrosodimethylamine) was discovered in an API (Active Pharmaceutical Ingredient) producer of valsartan. Voluntary reporting of the issue began. This incident raised concerns among regulatory authorities and ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) standards.

July 2018: Voluntary recalls of products containing valsartan were announced. Manufacturing of the API was halted, and investigations were initiated. The presence of NDMA impurity led to a significant product recall. Distribution of affected medicines was stopped, and alternative medications were recommended. Testing of valsartan for NDMA impurity was conducted, and a list of unaffected valsartan products was issued.

August 2018: Evaluation of processes to prevent the presence of unsafe impurities continued. Collaborative efforts were focused on preventing the presence of NDMA in the future. The investigation expanded to include other batches of affected products. Lists of recalled and unaffected products were issued. The manufacturing process was challenged to address the presence of genotoxic impurities specific to each product.

September 2018: The investigation into the issue continued and gained momentum. The search for NDMA impurity was intensified. FDA inspection concluded, emphasizing the responsibility of manufacturers to develop and utilize methods for detecting impurities.

October 2018: FDA issued an analytical document regarding various products and materials. A new GCMS (Gas Chromatography Mass Spectrometry) technique was introduced, offering a more reliable method for detecting impurities. The GC-MS/MS (Gas Chromatography-Tandem Mass Spectrometry) method was also issued. NDEA (N-nitrosodiethylamine) was identified in irbesartan in FDA laboratories.

December 2018: The list of affected and unaffected products continued to be updated. Focus remained on nitrosamine impurities. Testing methods were uploaded. The scope of the methods covered API, finished products, and other ARBs (Angiotensin Receptor Blockers). Daily acceptable intake levels were established.

August 2019: Proposed method adjustments were evaluated. Facility inspections and sample testing were conducted. Compliance was assessed, and investigations were carried out to address any arising issues.

1.3 Root causes formation & infection of Nitrosamine [(5)]:

Nitrosamine impurities can be formed during the processing of APIs (Active Pharmaceutical Ingredients) under specific processing conditions and when certain raw materials, starting substances, and intermediates are present. This means that the formation of nitrosamines is not inherent to all processing methods or materials but depends on specific circumstances.

The use of sodium nitrate or other nitrates, in the presence of secondary or tertiary amines, can contribute to the formation of nitrosamines. Secondary amines, which are compounds containing an amino group bonded to two carbon atoms, can commonly be found in common bases used in the manufacturing process. Inflamed raw materials, such as recycled solvents, reagents, and catalysts, can pose a risk due to the presence of amines in waste streams. If these materials contain amines, which are organic compounds containing a nitrogen atom, there is a potential for nitrosamine formation during the production process.

The use of third-party suppliers to obtain higher-quality materials, including solvents, reagents, and catalysts, can introduce a risk if these suppliers do not provide sufficient information on the content of the substances. Additionally, if the recovery techniques used for these materials are not specifically dedicated to preventing contamination, it can increase the chances of nitrosamine impurities being present.

The use of contaminated starting materials, including intermediates supplied by companies that use processes resulting in nitrosamine formation, can lead to the presence of nitrosamine impurities. If the starting materials or intermediates used in the manufacturing process contain substances or undergo processes that generate nitrosamines, it can contribute to the overall contamination.

1.4 Types of drug affect [(3)]

As per the latest update, the European Medicines Agency's (EMA) human medicine committee (CHMP) is conducting a review to investigate the presence of a nitrosamine called NDMA in certain batches of ranitidine. The purpose of this review is to gather evidence and understand how NDMA was detected in these ranitidine batches. Furthermore, the EMA, along with national authorities, is also assessing the implications of recent tests that have identified the presence of NDMA in some batches of metformin medications used to treat diabetes. This assessment aims to evaluate the extent and potential risks associated with the presence of NDMA in these metformin batches. The objective of these ongoing reviews and assessments is to gather all relevant information, investigate the origin of NDMA contamination in ranitidine and metformin, and determine the potential impact on patient safety. The EMA and national authorities are working to ensure that appropriate measures are taken to address any identified risks and protect the health and well-being of patients.

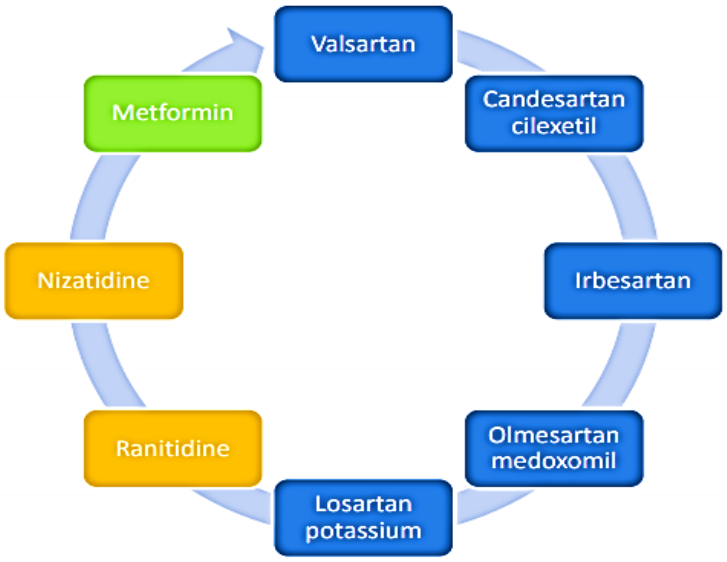
1.4.1 Drug category:

Table 1:Data category [3]

Medication name	Indication
ARB (Angiotensin Receptor Blocker) s (Sartans): Valsartan, Candesartan, Losartan and Olmesartan	High blood pressure
Ranitidine	Over the counter: • Heart burn • Sour stomach • Acid indigestion Prescription: • Heartburn • Ulcers of the stomach and intestine • Gastroesophageal reflux disease
Metformin	Type 2 diabetes (diabetes mellitus)
Nizatidine	Ulcers of stomach and intestines Gastroesophageal reflux disease
Pioglitazone hydrochloride	Type 2 diabetes (diabetes mellitus)

1.4.2 Impacted molecules [6–8]:

Figure 2: Impacted molecules



Ranitidine:

Ranitidine is a medication classified as an acidity inhibitor, primarily used for short-term treatment. It was commercially introduced in 1981 and has since become available in over 120 countries worldwide. The World Health Organization (WHO) recognizes the importance of ranitidine and includes it on the List of Essential Medicines. The inclusion of ranitidine on this list signifies its relevance in addressing essential healthcare needs and its importance in public health systems globally.

Sartans:
Certain sartan medications have been found to contain nitrosamine impurities, specifically NDMA (N-nitrosodimethylamine) and NDEA (N-nitrosodiethylamine). The presence of these nitrosamine impurities in sartans has raised concerns regarding the safety and quality of these medications. Nitrosamines are classified as potentially carcinogenic substances, meaning they have the potential to cause cancer in humans.

The detection of nitrosamine impurities in sartans originated in 2018 when NDMA was identified in valsartan, an angiotensin II receptor blocker (ARB) used to treat high blood pressure and heart failure. Subsequently, investigations expanded to other sartan medications, including losartan, irbesartan, and candesartan, where varying levels of nitrosamine impurities were also detected. The presence of nitrosamine impurities in sartans is believed to be linked to specific manufacturing processes and the use of certain raw materials. Regulatory authorities worldwide, such as the FDA (U.S. Food and Drug Administration), EMA (European Medicines Agency), and other national agencies, have issued recalls, warnings, and guidelines to address the issue. Manufacturers have been instructed to implement measures to prevent or minimize the presence of nitrosamine impurities in sartan medications, ensuring their safety for patients.

Ongoing efforts are focused on enhancing manufacturing processes, conducting rigorous testing, and implementing strict quality control measures to ensure that sartans are free from nitrosamine impurities and meet the required safety standards.

Figure 3: Data of Sartans:

	NDMA		NDEA	
Active substance (max daily dose)	**Maximum daily intake (ng)**	**Limit (ppm)**	**Maximum daily intake (ng)**	**Limit (ppm)**
Candesartan (32 mg)	96.0	3.000	26.5	0.820
Irbesartan (300 mg)	96.0	0.320	26.5	0.088
Losartan (150 mg)	96.0	0.640	26.5	0.177
Olmesartan (40 mg)	96.0	2.400	26.5	0.663
Valsartan (320 mg)	96.0	0.300	26.5	0.082

Nizatidine and metformin:
According to literature review the drug cutoff in September 2021, there have been no reports or recalls specifically related to nitrosamine impurities in nizatidine or metformin. Nizatidine is another medication used to reduce stomach acid, similar to ranitidine, but it has not been widely associated with nitrosamine impurities.

However, it's important to note that the presence of nitrosamine impurities in medications can evolve over time, and new information may have emerged since my knowledge cutoff. It is always advisable to stay updated with the latest information from regulatory authorities and consult healthcare professionals for the most current guidance on specific medications.

1.5 Limits and acceptable intake

To determine the acceptable levels of nitrosamine impurities in APIs (Active Pharmaceutical Ingredients) and drug products, the median toxic dose (TD50) is used as a basis for calculation. The TD50 is a well-established international standard recommended by the ICH M7 (R1) guidelines for assessing the acceptable extra risk associated with mutagenic and carcinogenic impurities.

For NDMA, the TD50 value is reported as 0.096 mg/kg/day for the most sensitive species, which is the rat. This translates to a dose of 1.92 ng/kg/day for NDEA. Based on these values, the acceptable intake (AI) levels for an individual with a body weight of 50 kg would be 96 mg/day for NDMA (50 kg x 1.92 mg) and 26.5 mg/day for NDEA.

The FDA (U.S. Food and Drug Administration) has provided recommendations for AI limits for various nitrosamine impurities, including NDMA, NDEA, NMBA, NMPA, NIPEA, and NDIPA. Manufacturers are advised to use these Acceptable Intakes when determining limits for nitrosamine impurities in APIs and drug products. These recommendations serve as guidelines to ensure the safety of medications with respect to nitrosamine contamination.

Figure 4: AI for various types of Nitrosamines

Nitrosamine	AI Limit (ng/day)[1,2]
NDMA	96
NDEA	26.5
NMBA	96
NMPA	26.5
NIPEA	26.5
NDIPA	26.5

1.6 Side effect of overdose [1,2,4]

1.6.1 Toxicity Profiling:

NDMA and NDEA are classified as part of a group of potent mutagenic cancer-causing agents known as the "cohort of concern." These substances have been identified by the International Agency for Research on Cancer (IARC) of the WHO as likely human carcinogens. There is limited available data on the specific toxicity of NDMA and NDEA. Based on this information, interim acceptable intakes for these impurities have been established by major regulatory bodies. NDIPA, NEIPA, and NMBA are structurally similar to NDMA and NDEA, and therefore, international regulators consider them to have a toxicological profile similar to these two impurities.

Contamination:
Contamination of nitrosamine content can occur from external sources. Recycled materials and solvents that already contain nitrosamine levels can contribute to contamination. For instance, the use of recycled DMF (Dimethyl formamide), which is treated with sodium nitrite to remove residual azide during the recovery process, serves as an example. If equipment is not adequately cleaned between uses, materials and solvents can become cross-contaminated with nitrosamines or with impurities that have the potential to react and form nitrosamines downstream.

1.6.2 Elimination of impurities (How can get rid from the impurities) [3]*:*

1. The presence of nitrosamine impurities in drug substances or products is primarily associated with the use of nitrosating agents and amines. To minimize these impurities, it is recommended to avoid the use of such reagents during the manufacturing process.
2. Nitrosamine impurities can be eliminated through the solvent used. However, if these solvents are recovered and reused, there is a risk of reintroducing the impurities. Therefore, it is advisable to refrain from using recovered solvents in the manufacturing process.
3. Contaminated raw materials, intermediates, and reagents used in drug substance production can contribute to nitrosamine impurities. Storage of these materials in the presence of trace amounts of nitrites may lead to impurity formation. It is important to properly store and test these materials for nitrosamine impurities.
4. Equipment used in drug substance manufacturing may be cross-contaminated with nitrosamine impurities from previous products. Thorough cleaning and contamination checks of the equipment are necessary.
5. Manufacturers should test and monitor the presence of nitrosamine impurities in various intermediate stages and establish appropriate limits if detected.
6. Manufacturers should adjust their processes to minimize the presence of amines, nitrites, and nitrosamine impurities at different stages.

In conclusion, the formation of nitrosamine impurities in finished products can be effectively managed by selecting synthesis routes that minimize their formation, adhering to strict good manufacturing practices (GMP) including equipment cleaning, and controlling the recovery process for solvents. API and drug product manufacturers should assess the risk, conduct confirmatory testing, and report any changes made to prevent or reduce nitrosamine impurities to regulatory authorities.

2. ANALYTICAL METHODS:

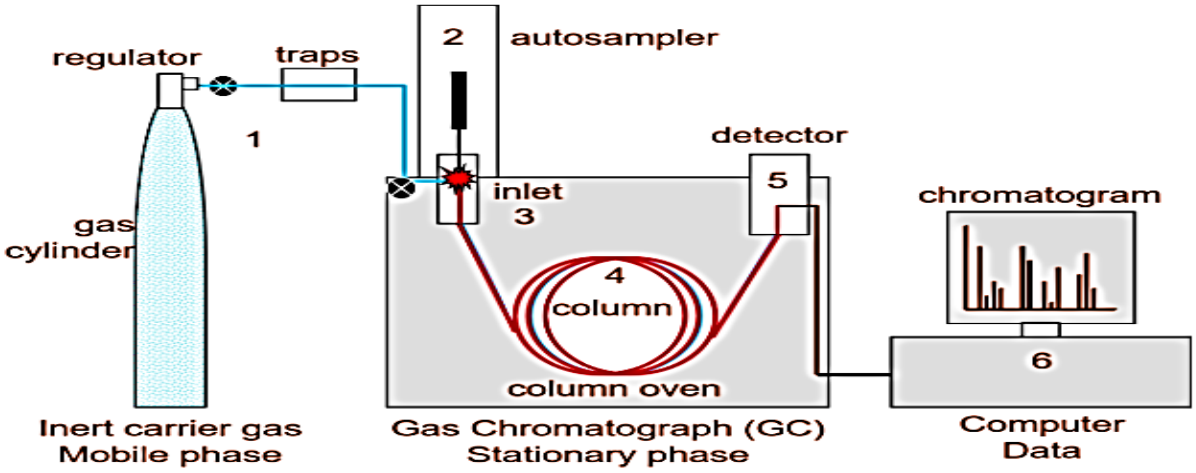
2.1 By USFDA [3,10]:

Developing analytical methods for detecting nitrosamine impurities is indeed a challenging task, primarily because these impurities exist in very low concentrations within complex matrices. The methods developed for this purpose also need to undergo validation to ensure they meet the requirements of good manufacturing practices (GMP). The FDA has published several methods to detect NDMA and NDEA in various 'sartans', addressing the specific concern at the time. The EMA has expressed the need to expand these measures to include additional nitrosamines, indicating a broader approach to addressing the issue of nitrosamine impurities.

2.1.1 Gas Chromatography

Gas chromatography coupled with mass spectrometry (GC-MS) is widely used for the analysis of nitrosamine impurities with lower molecular weights. It is a frequently employed technique due to its high selectivity and sensitivity. The FDA has developed and validated a combined GC-MS/MS method specifically for the simultaneous determination of four nitrosamine impurities (NDMA, NDEA, NDIPA, and NEIPA) in Valsartan drug substance and drug products. This method meets all the necessary requirements, including sensitivity, repeatability, and surpasses the expected control limits. Many recent publications also utilize GC-MS or GC-MS/MS techniques, which offer excellent selectivity and low detection limits, making them suitable for nitrosamine analysis and complying with modern regulatory standards.

Figure 5: Gas Chromatography



The use of Thermal Energy Analysis (TEA) provides excellent selectivity for nitrosamines. However, when it comes to high molecular weight nitrosamines, these molecules are relatively unstable and cannot be effectively detected using gas chromatography (GC) alone.

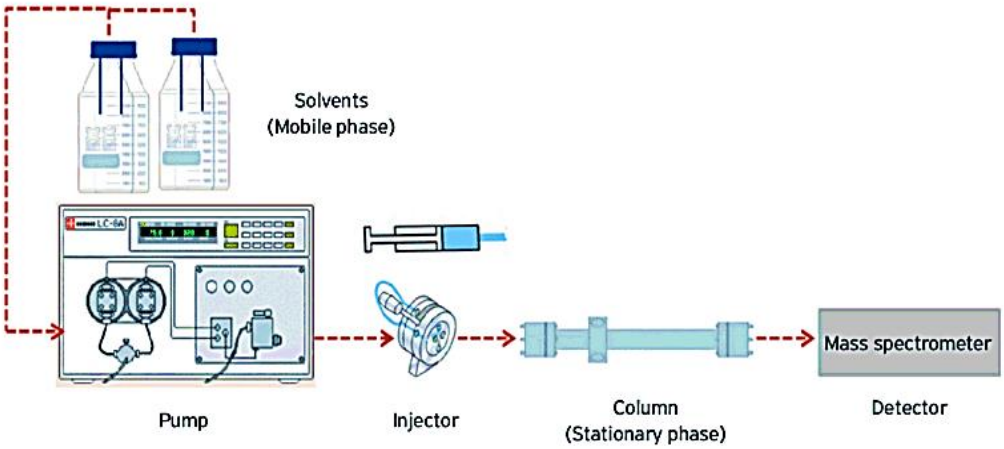
2.1.2 Liquid Chromatography

The utilization of liquid chromatography (LC) methods provides a faster alternative to traditional GC-MS techniques. By employing high-resolution accurate mass spectrometry, these methods offer good selectivity for detecting both GC-detectable and GC-undetectable compounds, including thermally stable and unstable nitrosamines.

The FDA has recognized that the GC-MS method commonly used for testing nitrosamine impurities in angiotensin II receptor blockers (ARBs) may not be suitable for analyzing ranitidine due to the generation of NDMA during sample heating. As a result, an LC-HRMS method was developed by the FDA to accurately measure NDMA levels in ranitidine drug substance and drug products in accordance with ICH Q2 (R1) guidelines.

The method has a limit of detection (LOD) of 0.011 ppm, a limit of quantitation (LOQ) of 0.033 ppm, and a range of 0.033-3.33 ppm. Furthermore, various scientific literature reports have described multiple methods utilizing liquid chromatography-mass spectrometry (LC-MS) or LC-MS/MS.

Figure 6: Liquid Chromatography[(11)]



Although limited, a few studies have documented the analysis of NDMA in drugs using conventional high-performance liquid chromatography (HPLC).
HPLC is widely employed for routine analysis and quality control of active pharmaceutical ingredients (APIs) and products. It is advantageous to have the capability of detecting NDMA impurities alongside drug substances in a single HPLC analysis. Therefore, it is crucial to develop a rapid and straightforward analytical method for the determination of NDMA in drugs using HPLC.

2.2 By Various Companies [10]:

2.2.1 International Agency for Research on Cancer (IARC):

Nitrosamine compounds are potent genotoxic agents that are known to cause cancer in various non-human species. They have been classified as probable human carcinogens by the International Agency for Research on Cancer (IARC).

Starting from June 2018, the presence of N-nitrosamines has been detected in multiple batches of drug substances, primarily in Sartans. However, the focus of health authorities has now expanded to encompass all drug substances and drug products.

Initially, N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA) were identified, but subsequently, other N-nitrosamines were discovered in addition to these two.

Health agencies have mandated pharmaceutical companies to conduct a risk assessment to determine the potential presence of N-nitrosamines in their products. Companies are required to experimentally demonstrate the absence of these impurities based on the risk assessment. The specific list of N-nitrosamines to be tested should be obtained from the risk assessment.

The IARC has established general methods for analyzing N-nitrosamines in API and drug products using techniques such as HS-GC-MS and LC-MS/MS. These methods can be adjusted with minor modifications to suit the client's specific API or drug product.

Kymos offers a proposal to meet the regulatory agencies' requirements while optimizing costs and time. The proposal consists of two steps:

- Screening of the target nitrosamines requested by the client from the provided list. A default limit of 0.03 ppm is set for this screening, which aligns with the future limit established by health agencies. Higher limits can be established based on the product or client's requirements.
- If one or more nitrosamines are found to be at or above the established limits, the development and validation of a quantitative method will be necessary and agreed upon with the client.

2.2.2 Agilent [12]:

Sample preparation:

- The analysis involved testing APIs and drug products such as valsartan, olmesartan, irbesartan, and losartan. A 500 mg portion of the API was accurately weighed into a disposable 15 mL glass centrifuge tube. Then, 5 mL of the internal standard solution was added using a volumetric pipette.
- After vortexing the samples for one minute, they were placed in a centrifuge and spun at 4,000 rpm for 2.5 minutes. Subsequently, approximately 2 mL of the dichloromethane layer was filtered through

a 0.45 µm nylon filter using a disposable pipette. The filtered solution was then transferred to a GC vial for further analysis.

Standard preparation:

Paraphrased:

- The standard stock solution was appropriately diluted to create calibration solutions with the following concentrations: 100, 80, 40, 20, 10, 5, and 2.5 ng/mL. Each calibration solution was prepared in dichloromethane and included NDMA: C13-d6 as an internal standard.
- The GC system utilized a 7697A headspace sampler connected to a multimode inlet (MMI). From the inlet, a GC capillary column, specifically an Agilent J&W VF WAXms column with dimensions of 30 m × 0.25 mm and 1.0 µm particle size, was connected to the mass spectrometer (MS). Tables 2 and 3 display the GC and MS parameters.

Figure 7: GC parameters.

Parameter	Value
MMI Injection Mode	Pulsed splitless: 12.285 psi until 0.5 min
Inlet Temperature	250 °C
Oven Temperature Program	40 °C (0.5 min) 20 °C/min to 200 °C (0 min) 60 °C/min to 250 °C (3 min)
Total Run Time	12.33 min
MS Transfer Line Temperature	250 °C
Injection Volume	2 µL
Carrier Gas	Helium, 1 mL/min

Figure 8: Mass Parameters

Parameter	Value	
Mode Source	Electron ionization, 40 eV	
Temperature	250 °C	
Quadrupole Temperature	Q1 and Q2 = 150 °C	
MRM Mode Conditions		
MS1 Resolution	All compounds Unit	
MS2 Resolution	All compounds Unit	
Collision Gas Flow	Nitrogen at 1.5 mL/mi	
Quenching Gas Flow	Helium at 4 mL/min	
Detector Gain	1	
Quant./Qual. Transitions (FDA method)	Start time: 6.5 min	NDMA 74 → 44, CE 15, dwell 150 ms 74 → 42, CE 20, dwell 50 ms NDMA:C13-d6 82 →48, CE 20, dwell 100 ms
	Start time: 7.60 min	NDEA 102 →85, CE 10 V, dwell 150 ms 102 →56, CE 18 V, dwell 150 ms
	Start time: 8.03 min	NEIPA 116 →99, CE 10 V, dwell 150 ms 71 →56, CE 10 V, dwell 150 ms
	Start time: 8.25 min	NDIPA 130 →88, CE 10 V, dwell 150 ms 130 →42, CE 10 V, dwell 150 ms
	Start time: 8.70 min	NDBA 158 →99, CE 10 V, dwell 150 ms 84 →56, CE 22 V, dwell 150 ms

2.3 Results and Discussion:

In the analysis, the compounds were effectively separated from each other, and the peaks of interest were clearly distinguished from other components such as the solvent and matrix species. The retention times of all five compounds aligned with the values specified in the FDA regulations, ensuring accurate identification and quantification.

To establish the concentration levels of the impurities, calibration curves were constructed using a linear regression model. The FDA mandates that the correlation coefficient, R^2, should be equal to or greater than 0.998 to ensure the reliability and precision of the calibration curve. In this study, the obtained calibration curves demonstrated excellent linearity, with R^2 values exceeding 0.999 for all five impurities. This high degree of linearity indicates a strong relationship between the concentration of the impurities and their corresponding peak areas, allowing for accurate and precise quantification of the impurities in the samples.

2.4 Nitrosamine Impurity Testing and Analysis, consisting N-nitrosodimethylamine (NDMA), in drugs by LC-MS and GC-MS Methods by Intertek [(13)] :

GC/MS Headspace Chromatography Mass Spectrometry Approach
The FDA Office of Testing and Research has formulated a comprehensive method combining gas chromatography (GC) and mass spectrometry (MS) using the headspace technique. This method was specifically developed to simultaneously detect and evaluate four nitrosamine impurities in drug substances and drug products belonging to the angiotensin receptor blocker (ARB) class. The targeted impurities encompass N-nitrosodimethylamine (NDMA), N-nitrosodiethylamine (NDEA), N-nitrosodiisopropylamine (NDIPA), and N-nitrosoethylisopropylamine (NEIPA). The method's development and validation process were carried out using valsartan as the representative drug substance and drug product.

Liquid Chromatography High Resolution Mass Spectrometry (LC-HRMS) Technique for the Determination of NDMA in Ranitidine Drug Substance and Drug Product
The FDA has recognized that the existing testing method used for evaluating nitrosamine impurities in angiotensin II receptor blockers (ARBs) is not suitable for the examination of ranitidine due to the production of NDMA upon sample heating. As a result, the FDA has developed a new method using liquid chromatography-high-resolution mass spectrometry (LC-HRMS) to measure the quantities of NDMA in ranitidine drug substance and drug product, following the guidelines outlined in ICH Q2 (R1). The method's limit of detection (LOD) is 10 ng/g, with a lower limit of quantitation (LOQ) of 33 ng/g and an upper LOQ of 3333 ng/g.

Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) Method for the Determination of NDMA in Ranitidine Drug Substance and Solid Dosage Drug Product
The method employed is a liquid chromatography-tandem mass spectrometry (LC-MS/MS) technique specifically designed for the analysis of NDMA in ranitidine drug substance and drug product. This LC-MS/MS method, which utilizes a triple-quad platform, serves as an alternative or confirmatory approach to the liquid chromatography-high-resolution mass spectrometry (LC-HRMS) method.

A Rapid Detection Approach

Ultra-Performance Liquid Chromatography, Low Resolution Tandem Mass Spectrometry (UPLC-LR/MS/MS) technique for the determination of NDMA, NDEA, NMBA and NDIPA in valsartan drug substance.

Intertek has also developed an alternative method utilizing ultra-performance liquid chromatography with low-resolution mass spectrometry (UPLC-LR/MS/MS). This approach enables the swift detection and quantitation of several nitrosamine impurities, including NDMA, NDEA, NMBA, and NDIPA. The method offers a limit of detection (LOD) of 5 ng/g, lower limit of quantitation (LOQ) of 15 ng/g, and upper LOQ of 75 ng/g. This method is highly suitable for a rapid initial screening to identify common nitrosamine impurities, facilitating and expediting the risk assessment process. If required, the method can be further optimized and validated for your specific APIs or drug products.

3. CONCLUSION

The significance of ensuring the quality of drug products for human health cannot be overstated. The presence of impurities in pharmaceuticals can have a direct impact on their safety and efficacy. Therefore, it is essential to detect and analyze impurities in every drug product that may be affected. In recent years, there has been an increasing emphasis on the impurity profile of pharmaceuticals, with drug safety receiving significant attention from the public and media. This article provides valuable insights into various analytical techniques employed for the determination and qualification of impurities in pharmaceuticals. It also highlights the critical factors that need to be considered during the preparation of bulk drugs.

Isolation and characterization of impurities play a crucial role in acquiring and evaluating data that establish the biological safety of drugs. This underscores the importance and scope of impurity profiling in pharmaceutical research. By identifying and understanding impurities, researchers and manufacturers can ensure the development and production of safer and more reliable drugs.

Overall, the detection and analysis of impurities in drug products are essential steps in maintaining the quality, efficacy, and safety of pharmaceuticals. The continuous advancement of analytical techniques and the focus on impurity profiling contribute to improving drug safety standards and meeting the expectations of both the scientific community and the general public.

Abbreviations

- WHO: World Health Organization
- USFDA: United states food and drug administration
- ICH: International conference of harmonization
- NDMA: Nitroso di-methyl amine
- DNA: Deoxyribose nucleic acid
- API: Active pharmaceutical ingredient
- FDA: Food and drug administration
- GCMS: Gas chromatography Mass spectroscopy
- NDEA: Nitroso di ethyl amine
- ARB: Angiotensin receptor blocker
- DMF: Dimethyl formamide
- CFR: Code of federal registration

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ANALYZING SPACE UTILIZATION IN CENTRAL STERILE SUPPLY DEPARTMENT: A BED – BASED METRIC APPROACH IN HEALTHCARE INSTITUTIONS

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Abstract

This comprehensive study conducts a meticulous examination of space utilization in Central Sterile Supply Departments (CSSD) within varied healthcare institutions, using a unique bed-based metric system. The gathered data, stemming from a diverse pool of 150 healthcare professionals in the CSSD sphere, offers insights into hospitals' adherence to ethical sterilization practices, the crucial role of CSSDs in hospital management, and the implications of effective space management concerning the number of beds.

Keywords: Central Sterile Supply Department, Space Utilization, Bed-Based Metrics, Sterilization, Healthcare Institutions.

1. INTRODUCTION

The Central Sterile Supply Department (CSSD), a pivotal cog in the machinery of any healthcare institution, plays a substantial role in maintaining patient safety, controlling infections, and ensuring the seamless functioning of the hospital ecosystem [1]. This study concentrates on understanding the space utilization in these departments concerning bed-based metrics, providing a fresh perspective into their operational efficiency.

In healthcare institutions, the efficient utilization of space within Central Sterile Supply Departments (CSSDs) plays a critical role in ensuring the seamless flow of medical supplies and maintaining optimal patient care. As healthcare facilities strive to enhance operational efficiency and cost-effectiveness, there arises a pressing need to develop innovative methods for evaluating and optimizing space utilization in CSSDs. This research publication endeavors to address this imperative by introducing a novel bed-based metric approach that enables a comprehensive analysis of space utilization in CSSDs.

2. LITERATURE REVIEW

2.1 Facility Planning & Management (G D Kunders)
The disinfection supply room plays a crucial role in ensuring patient health by providing safe and sterile medical instruments to all hospital departments. Establishing a scientific quality management mode for daily work is essential for evaluating personnel quality and controlling disinfection and sterilization processes.
2.2 Guidelines for CSSD and mechanized laundry (Ministry of Health and Family Welfare, Govt. of India)
The increasing number of Hospital Acquired Infections (HAI) in Indian hospitals emphasizes the importance of disinfection and sterilization. Using disinfectants and practices is crucial to prevent transmission of pathogens to patients. A centralized sterile supply department (CSSD) and mechanized laundry are widely accepted systems for preventing infection transmission.
2.3 Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008
2.4 Joint Commission for the Accreditation of Healthcare Organizations. Comprehensive accreditation manual for hospitals, JCAHO, Chicago, IL. 2003
2.5 Guidelines of National Accreditation Board for Hospital (NABH); 5TH Edition.

2.6 The Consortium of Accredited Health Care Institutions (CAHO) – ACE Program
2.7 William A Rutala, David J. Weber (Health Infection Control Practices Advisory Committee), Guidelines for disinfection and sterilization in healthcare facilities, 2008. www.cdc.gov/hipac/disinfectionsterilization

3. METHODOLOGY

The study utilized a survey-based research method, probing 150 healthcare professionals active in CSSD departments across a variety of hospitals [3]. The aim was to discern several parameters crucial to CSSD functioning, including the existence of a dedicated department, the number of beds, allocated space, and the appointment of a full-time officer. The questionnaire also sought information on compliance with guidelines like unidirectional flow, zoning, and restricted entry.

Objective of the Study:

1. To evaluate the Indian Central Sterilisation and Supply Department's layout and Space Utilisation of CSSD department in the Hospital.
2. To assess the distribution of space for CSSD Department based on the number of beds in the Hospital.
3. To provide recommendations of best sterilization setup with accurate procedures and working patterns based on the guidelines.

3.1 Data Collection:

Data was harvested based on a myriad of variables that encapsulate space utilization and guideline adherence. These ranged from the number of beds and allocated space for the CSSD, to the availability of dedicated officers, and the enforcement of guidelines such as unidirectional flow, zoning, and restricted entry [3].

Table 1 - Is there a dedicated department of CSSD?

	Frequency	Percent	Valid Percent	Cumulative Percent
Yes	148	98.7	98.7	98.7
No	1	.7	.7	99.3
May be	1	.7	.7	100.0
Total	**150**	**100.0**	**100.0**	

The data provided represents that there is dedicated CSSD Department facility available in the hospital.

- Frequency presents three categories, and the replies reveal that 98.7% of respondents confirm the presence of a specialized CSSD Department in the hospital, 0.7% of respondents disagree, and the other 0.7% of respondents are unaware of dedicated CSSD Department in the Hospital.

Table 2 - Number of Hospital Beds

	Frequency	Percent	Valid Percent	Cumulative Percent
1-50 beds	19	12.7	12.7	12.7
51-150 beds	89	59.3	59.3	72.0
151-300 beds	21	14.0	14.0	86.0
300 and above	21	14.0	14.0	100.0
Total	**150**	**100.0**	**100.0**	

The data provided represents the number of beds available in the hospital.

- There are four categories listed in Frequency, and the replies indicate that 12.7% of respondents have a bed capacity of 1 to 50, 59.3% have a bed capacity of 51 to 150, 14% have a bed capacity of 151 to 300 beds. 14% of the respondents' hospitals, there are more than 300 beds.

Table 3 - Approximate space allocated for the CSSD department in your hospital (in square feet)				
	Frequency	Percent	Valid Percent	Cumulative Percent
100-1000 sq. ft.	88	58.7	58.7	58.7
1001-2500 sq. ft.	55	36.7	36.7	95.3
2501-4000 sq. ft.	2	1.3	1.3	96.7
4000+ sq. ft.	5	3.3	3.3	100.0
Total	**150**	**100.0**	**100.0**	

The data provided represents approximate space allocated for the CSSD department in your hospital (in square feet)

- Frequency displays four categories, and the responses reveal that 58.7% of respondents have 100-1000 square feet allotted, 36.7% have 1001-2500 square feet allotted, 1.3% have 2501-4000 square feet allotted, and the remaining 3.3% have 4000 square feet or more allotted for the CSSD Department.

Table 4 - Is there a dedicated and full-time officer in Charge of CSSD?				
	Frequency	Percent	Valid Percent	Cumulative Percent
Yes	127	84.7	84.7	84.7
No	13	8.7	8.7	93.3
Maybe	10	6.7	6.7	100.0
Total	**150**	**100.0**	**100.0**	

The data provided represents that they have full time officer in charge of CSSD Department.

- In the three categories that Frequency displays, 84.7% of respondents confirm that a full-time officer in charge is available, 8.7% of respondents dispute this, and the remaining 8.7% of respondents are unaware of this.

Table 5 - Guidelines for Unidirectional flow without any criss-crossing or back tracking is followed?				
	Frequency	Percent	Valid Percent	Cumulative Percent
Yes	139	92.7	92.7	92.7
No	2	1.3	1.3	94.0
Maybe	9	6.0	6.0	100.0
Total	**150**	**100.0**	**100.0**	

The data provided represents whether Guidelines for Unidirectional flow without any crisscrossing or back tracking is followed or not.

- According to frequency, there are three groups in which 92.7% of respondents affirm that they adhere to all of these guidelines, 1.3% of respondents disagree that they are not following the guidelines, and the remaining 6% of respondents are unaware of the guidelines of CSSD department.

Table 6 - 'Zoning Concept' with defined and demarcated Dirty, Clean and Sterile Zone.				
	Frequency	Percent	Valid Percent	Cumulative Percent
Yes	146	97.3	97.3	97.3
No	2	1.3	1.3	98.7
Maybe	2	1.3	1.3	100.0
Total	**150**	**100.0**	**100.0**	

The data provided represents whether they have followed guidelines of Zoning in the department.

- Frequency displays three categories in which 97.3% of respondents confirm that they adhere to zoning

regulations: 1.3% of respondents said they did not obey the rules, and the remaining 1.3% said they were unaware of the Zoning concept in CSSD Department.

Table 7 - Entry to CSSD is restricted				
	Frequency	Percent	Valid Percent	Cumulative Percent
Yes	141	94.0	94.0	94.0
No	7	4.7	4.7	98.7
Maybe	2	1.3	1.3	100.0
Total	**150**	**100.0**	**100.0**	

The data provided represents whether entry to CSSD is restricted or not.

- In the three categories that Frequency presents, 94% of respondents affirm that they have restricted access to the department, 4.7% of respondents disagree that they follow the rules, and the remaining 1.3% of respondents are unaware of it.

Table 8 - Adequate space to carry out various processes of sterilization (cleaning, washing, sterilization, package, storing and dispatch) and meet the daily and emergency requirements of the facility. (7 to 10 Square feet/bed, but may vary from hospital to hospital), Rate the space allocation at your facility between 1 to 10.				
	Frequency	Percent	Valid Percent	Cumulative Percent
Excellent	87	58.0	58.0	58.0
Average	62	41.3	41.3	99.3
Poor	1	.7	.7	100.0
Total	150	100.0	100.0	

The data provided represents if there is an adequate space provided based on the number of beds and operations.

- According to three categories displayed by frequency, 58% of respondents believe they have enough space to carry out their tasks, 41.3% believe they have an average amount of space, and the remaining 7% do not like how their space has been allocated to CSSD Department.

Table 9 - Signage (internal demarcated area signages)				
	Frequency	Percent	Valid Percent	Cumulative Percent
Yes	131	87.3	87.3	87.3
No	1	.7	.7	88.0
Maybe	18	12.0	12.0	100.0
Total	150	100.0	100.0	

The data provided represents data about the signages in the department.

- Frequency displays three categories, with 87.3% of respondents confirming that they have sufficient signs that complies with quality accreditation body standards, 0.7% of respondents believing they do not have signage as per guidelines, and the remaining 12% of respondents unaware of the procedures to verify the same.
-

Table 10 - Separate receiving and dispatching window/ area				
	Frequency	Percent	Valid Percent	Cumulative Percent
Yes	145	96.7	96.7	96.7
No	2	1.3	1.3	98.0
Maybe	3	2.0	2.0	100.0
Total	**150**	**100.0**	**100.0**	

The data provided represents data about separate receiving and dispatching window.

- Frequency displays three categories in which 96.7% of respondents affirm that they have separate receiving and dispatching windows, 1.3% of respondents denied having such windows, and the other 2% of respondents are unaware of the procedures for verifying such guidelines for separate receiving and dispatching window/area in CSSD Department.

Table 11 - The facility has separate area for soiled linen and instruments.				
	Frequency	Percent	Valid Percent	Cumulative Percent
Yes	141	94.0	94.0	94.0
No	2	1.3	1.3	95.3
Maybe	7	4.7	4.7	100.0
Total	**150**	**100.0**	**100.0**	

The data provided represents that the facility has separate area for soiled linen and instruments**.**

- Frequency displays three categories in which 94% of respondents agree that they have a separate space for dirty linen and instruments, while 1.3% of respondents said they do not. Also rest 4.7% of respondents are unaware of the procedures to confirm the same.

Table 12 - Well demarcated areas for decontamination, preparation, sterilization, and storage				
	Frequency	Percent	Valid Percent	Cumulative Percent
Yes	136	90.7	90.7	90.7
No	2	1.3	1.3	92.0
Maybe	12	8.0	8.0	100.0
Total	**150**	**100.0**	**100.0**	

The data provided represents data about availability of 'Well demarcated areas for decontamination, preparation, sterilization, and storage.

- The frequency report reveals three categories, in which 90.7% of respondents confirm that they have Well demarcated areas for decontamination, preparation, sterilization, and storage, while 1.3% of respondents claimed that they do not have separate area in CSSD, rest 8% of respondents are unaware about the guidelines to verify the Well demarcated areas for decontamination, preparation, sterilization, and storage in CSSD Department.

Table 13 - Availability of equipment: • Autoclave • Trolleys & drums • Autoclaving indicator tape • Storage racks and working benches				
	Frequency	Percent	Valid Percent	Cumulative Percent
Always available	105	70.0	70.0	70.0
Partly available	44	29.3	29.3	99.3
Not available	1	.7	.7	100.0
Total	**150**	**100.0**	**100.0**	

The data provided represents data about **Availability of equipment**

- Frequency displays three categories in which 70% of respondents confirm that the equipment is always available and 29.3% of respondents report that the equipment and other materials are occasionally available. And the remaining 7% of responders are unaware of the facts needed to confirm the claim of the equipment availability in CSSD Department.

Table 14 - Uninterrupted water and electricity supply 24*7 with power backup				
	Frequency	Percent	Valid Percent	Cumulative Percent
Yes	135	90.0	90.0	90.0
No	15	10.0	10.0	100.0
Total	**150**	**100.0**	**100.0**	

The data provided represents data about availability of electricity & water supply

- Frequency displays two groups where 90% of respondents confirm that they always have access to

electricity and water supplies and 10% of respondents report partial unavailability of water & electricity supply in CSSD Department.

Table 15 - Decontamination sinks of adequate size is present for soaking, cleaning, and rinsing.				
	Frequency	Percent	Valid Percent	Cumulative Percent
Yes	143	95.3	95.3	95.3
No	1	.7	.7	96.0
Not Aware	6	4.0	4.0	100.0
Total	**150**	**100.0**	**100.0**	

The data provided represents data about Decontamination sinks of adequate size is present for soaking, cleaning, and rinsing.

- Frequency shows 3 categories in which 95.3% respondents confirm availability of Decontamination sink. 0.7% respondents denied availability of the sink while only 4% respondents are not aware about the same.

4. RESULT

The gathered data was intriguing and revealed that a robust 98.7% of healthcare institutions have in house a dedicated CSSD department [TABLE 1]. However, there was a marked variance in the bed capacity and CSSD space allocation among hospitals, with larger institutions boasting up to 300+ beds and allocating 4000+ sq. ft. for CSSD [TABLE 2 and 3]. A significant 84.7% of respondents affirmed the presence of a full-time officer in the CSSD, underscoring the importance accorded to this department [TABLE 4].

SN	QUESTIONS	RESPONSES			
1	Is there a dedicated department of CSSD?	Yes **98.7%**	No **0.7%**	Maybe **0.7%**	
2	Number of Hospital Beds	1 to 50 Bed **12.7%**	51 to 150 Bed **59.3%**	151 to 300 Bed **14%**	300 and above **14%**
3	Approximate space allocated for the CSSD department in your hospital (in square feet)	100-1000 sq. ft. **58.7%**	1001-2500 sq. ft. **36.7%**	2501-4000 sq. ft. **1.3%**	4000+ sq. ft. **3.3%**
4	Is there a dedicated and full-time officer in Charge of CSSD?	Yes **84.7%**	No **8.7%**	Maybe **8.7%**	
5	Guidelines for Unidirectional flow without any criss-crossing or back tracking is followed?	Yes **92.7%**	No **1.3%**	Maybe **8.7%**	
6	'Zoning Concept' with defined and demarcated Dirty, Clean and Sterile Zone.	Yes **97.3%**	No **1.3%**	Maybe **1.3%**	
7	Entry to CSSD is restricted.	Yes **94%**	No **4.7%**	Maybe **1.3%**	
8	Adequate space to carry out various process of sterilisation (cleaning, washing, sterilization, package, storing and dispatch) and meet the daily and emergency requirements of the facility. (7 to 10 Square feet/bed, but may vary from hospital to hospital), Rate the space	Excellent **58%**	Average **41.3%**	Poor **0.7%**	

	allocation at your facility between 1 to 10.				
9	Signage (internal demarcated area signages)	Yes **87.3%**	No **0.7%**	Maybe **12%**	
10	Separate receiving and dispatching window/ area	Yes **96.7%**	No **1.3%**	Maybe **2%**	
11	The facility has separate area for soiled linen and instruments.	Yes **94%**	No **1.3%**	Maybe **4.7%**	
12	Well demarcated areas for decontamination, preparation, sterilization, and storage	Yes **90.7%**	No **1.3%**	Maybe **8%**	
13	Availability of equipment: • Autoclave • Trolleys & drums • Autoclaving indicator tape • Storage racks and working benches.	Always Available **70%**	Partly Available **29.3%**	Not Available **0.7%**	
14	Uninterrupted water and electricity supply 24*7 with power backup	Yes **90%**	No **10%**		
15	Decontamination sinks of adequate size is present for soaking, cleaning, and rinsing.	Yes **90.7%**	No **1.3%**	Maybe **8%**	

5. CONCLUSION

5.1 Adherence to Guidelines:

The results showed a respectable level of compliance with regulations, with striking adherence to unidirectional flow (92.7%), zoning (97.3%), and restricted entry to the CSSD (94%) [TABLE 5], 6, and 7, respectively. Furthermore, a sizable 87.3% of respondents stated that the proper signage requirements set forth by quality certification authorities were followed [TABLE 9]. According to the standards, 96.7% of the respondents [TABLE 10] have separate receiving and dispatching window or areas. 94% of facilities [TABLE 11] have a dedicated space for dirty equipment and linen in CSSD Department

5.2 Inferences and Recommendations:

5.2.1 The study's findings point to a promising trend of responsibility and commitment among healthcare institutions towards upholding sterilization guidelines, an essential aspect of patient safety. The study also emphasizes the strategic importance of space management in the CSSD, connecting it with bed metrics to enhance workflow and drive operational efficiency.

5.2.2 Drawing from these observations, it is recommended that institutions not only maintain but also continually update and innovate their CSSD space management strategies in line with the best global practices. These efforts can significantly contribute to enhancing patient safety, operational efficiency, and overall service quality in healthcare institutions.

5.2.3 The data brings to light the diligent practices adopted by hospitals, affirming their dedication to quality healthcare service provision. By highlighting the connection between efficient CSSD space utilization and bed count, this study prompts healthcare institutions to continually evaluate and refine their strategies, contributing to better patient care and overall institutional efficiency.

5.2.4 By examining the spatial dynamics and workflow patterns with respect to bed capacity, this study aims to provide healthcare administrators and practitioners with invaluable insights to optimize CSSD layouts, enhance resource allocation, and ultimately improve overall patient outcomes.

5.2.5 These findings indicate a high level of commitment and dedication among healthcare institutions ensuring patient safety and the highest standards of cleanliness and sterilization.

5.2.6 The study underscores the importance of proper space utilization in the CSSD department, considering the number of beds, to optimize workflow and enhance efficiency in sterilization processes.

5.2.7 Overall, the research affirms the responsible practices implemented by hospitals, highlighting their commitment to providing quality healthcare services

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A STUDY ON EXTENDED NON FUEL SERVICES OTHER THAN PETROL, DIESEL & LUBRICANTS AT PETROLPUMPS IN AHMEDABAD & SURAT

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Abstract

This research abstract presents a comprehensive overview of the extended non-fuel services available at petrol pumps in the cities of Ahmedabad and Surat. As the demand for conventional fossil fuels diminishes due to increasing environmental concerns and the shift towards alternativeenergy sources, petrol pumps have recognized the need to diversify their offerings beyond traditional petrol, diesel, and lubricants. This abstract explores the range of additional services provided by petrol pumps in these two major cities of Gujarat, India, and their impact on customer satisfaction, revenue generation, and environmental sustainability. By analyzing data from multiple sources, including consumer surveys and industry reports, this study sheds light onthe current trends and future prospects of non-fuel services, enhancing the role of petrol pumps as multi-functional centers catering to the evolving needs of consumers.

Keywords: **Non-Fuel Retailing (NFR), Extended Retail Service, Petrol Pump, Business Environment, Indian Oil**

INTRODUCTION

Petroleum retailing in India was a stodgy and depressing industry until a few years ago. Vehicles such as cars, buses, and two-wheelers arrived, were fueled, and then left after paying cash. When Shell renovated certain gas pumps as part of the economic reform process, the surroundings began to change. Soon, better signage, the acceptance of credit cards, and carwashes were standard features in petroleum retail locations. Previously, gas stations were just used to sell fuel; however, they are increasingly gradually becoming multi-facility establishments.

Although the Indian petroleum industry has been expanding steadily, margin pressure has grown.Over the past five years, from 2010 to 2015, there has been a consistent growth of 1.2%. Similar to their international competitors, Government-owned oil marketing corporations have continuedto extend their retail network all over the country despite losing more than roughly Rs 250 crore each day from selling automotive fuel. In order to increase profitability, the oil companies Indian Oil Corporation (IOC), Bharat Petroleum Corporation (BPCL), and Hindustan Petroleum Corporation (HPCL), as well as Shell Petrol Pump, are intending to grow their non-fuel operations on existing outlets and supply the same on existing outlets.

Importance of Non-Fuel Services: The non-fuel services have the following benefits, which are listed below:

Demand for Alternative Revenue Sources

The necessity for alternative sources of income is one of the biggest problems that the oil marketing firms are currently facing. This new affair in the world of petroleum retailing today is the result of numerous circumstances.
These include:

- Increasing margin pressure.
- A desire to use real estate to boost profits.

- Changing consumer demographics, such as "value-time saving propositions, qualityand environment consciousness, prestige seeker, etc."
- The need to distinguish our offerings.

Non-Fuel Services' Emergence as a Major Activity in Retail Outlets

The PSUs' right to guaranteed returns was taken away with the demise of APM, putting more pressure on their margins. It is essential to invest heavily in the services provided at the outlets if you want to compete with the wealthy private players. The non-fuel services would be the differentiating factor as the base product is the same.

One of the key justifications for providing non-fuel services at petro-retail locations is also the evolving Indian consumer. He is seeking for a one-stop shop today that can meet all of his demands, including those for groceries, cash withdrawals from his bank, utility payments, insurance coverage renewals, quick meals, receiving certification for pollution under control,and, of course, fuel for his vehicle. The highway driver, on the other hand, is looking for a spotto freshen up, relax, and service his car while also enjoying a satisfying lunch at the pump's restaurant.

Additional sources of income

Margin pressure will intensify due to the escalating competition. Retailers will therefore need to look for alternative sources of income. To succeed in this fierce competition, merchants need to create a sustainable non-fuel model that integrates with their main gasoline business. They can learn from international experiences in this regard. Strategic insight is important, but outstandingstrategy execution is what really counts.

METHODOLOGY

Research Objectives:

- To study the range of non-fuel services other than petrol, diesel & lubricants at petrol pumps
- To study consumer preferences and behavior for non-fuel services other than petrol, diesel & lubricants at petrol pumps

Research Design:

In this article author used Descriptive research method only for the Indian Oil Corporation (IOC) petrol pumps.

Sources of Data:

Primary Sources:

Methods of data collection (e.g., surveys, observations). Questionnaire construction for consumer feedback and preferences.

Secondary Sources:

Articles on non-fuel retailing in the context of petrol pumps. White papers focusing on non-fuel retailing at petrol pumps. Newspaper articles discussing non-fuel business activities at petrol pumps. Online journals publishing research on non-fuel services and retailing.

LIMITATION

The study does not include other Public & any of the Private players, in this research article included only Non-fuel retailing at petrol pumps at Indian Oil Petrol pumps only. Author has taken sample from petrol pumps at Ahmedabad and Surat only.

Data Analysis and Interpretation

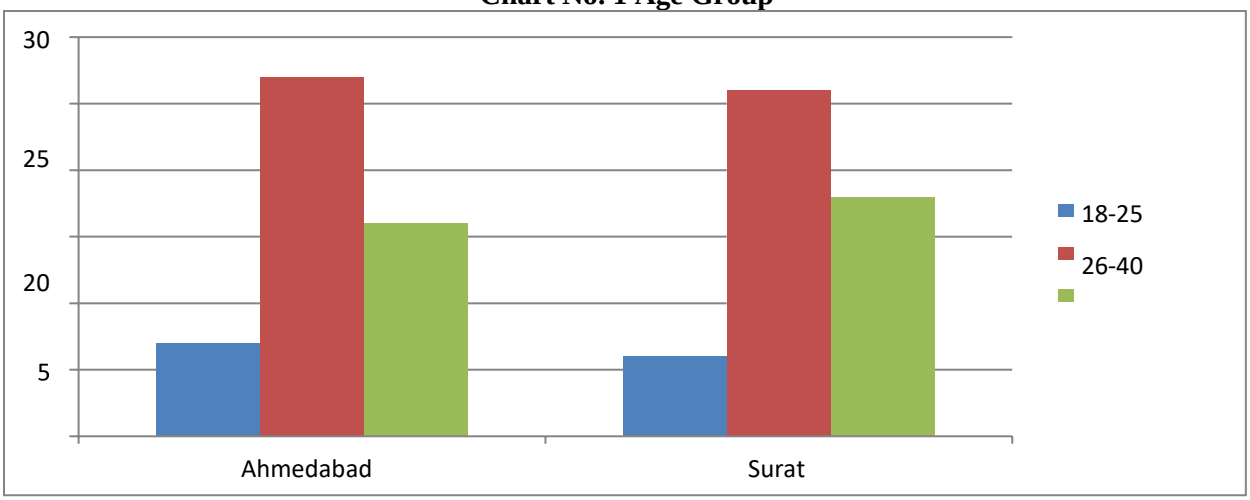
The data analysis was done from the data of filled up questionnaire from the consumers who areusing non fuel retailing at petrol pump or fuel station. Data analysis is as under.

1. Consumer's Age group

Table No. 1 Age Group

Region	18-25		26-40		41 & Above		Total	Percentage
	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage		
Ahmedabad	7	14	27	54	16	32	50	100
Surat	6	12	26	52	18	36	50	100
Total	13	13	53	53	34	34	100	

Chart No. 1 Age Group



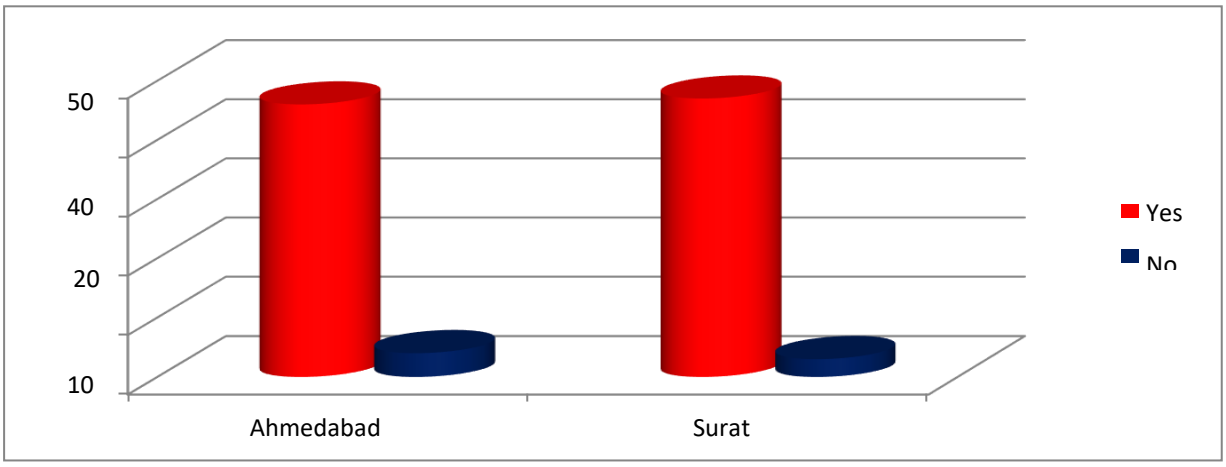
Above table and chart examined that maximum 53 (53%) customers are between 26-40 agegroup and minimum 13 (13%) consumers are 18-25 age group of Indian Oil petrol pumps.

2. Do you think the products & services other than fuels and lubricants should be madeavailable in Indian oil?

Table No. 2- Product & Service

Region	Yes		No		Total	Percentage
	Frequency	Percentage	Frequency	Percentage		
Ahmedabad	46	92	4	8	50	100
Surat	47	94	3	6	50	100
Total	93	93	7	7	100	

Chart No. 2- Product & Service



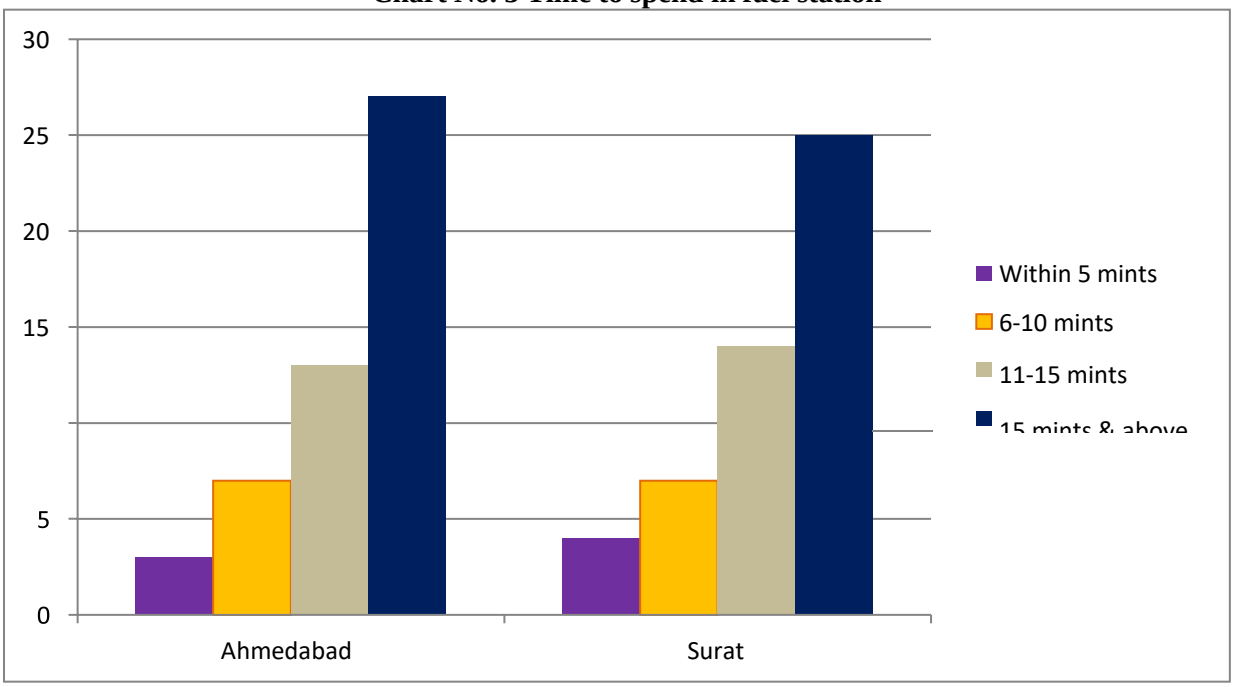
Above table No 2 and Chart No 2 shows that 93% customers are think that the products &services other than fuels and lubricants should be made available in Indian Oil petrol pumps.

3. How much time are you ready to spend in this fuel station for activities other than fueling if they are made?

Table No. 3 Time to spend in fuel station

Region	Within 5 mints		6-10 mints		11-15 mints		15 mints & above		Total	Percentage
	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage		
Ahmedabad	3	6.00	7	14.00	13	26.00	27	54	50	100
Surat	4	8.00	7	14.00	14	28.00	25	50	50	100
Total	7	7.00	14	14.00	27	27.00	52	52.00	100	

Chart No. 3 Time to spend in fuel station



Above table and chart revealed that maximum 52 (52%) customers are ready to spend 15 mintsand above time at fuel station and very least 7 (7%) customers are not ready to spend time morethan 15 mints at fuel station.

4. What other things/services do you expect from the Indian oil?

Table No. 4 Services expect from fuel Station

Region	ATM		Departmental Store		Restaurant		Garage		Car Washing		Medicine Shop		Car accessories		News stands		Coffee shop		Cyber Café		Total
	f	**%**	**f**	**%**	**f**	**%**	**f**	**%**	**f**	**%**	**f**	**%**	**f**	**%**	**f**	**%**	**f**	**%**	**f**	**%**	
Ahmedabad	17	34	9	18	6	12	4	8	3	6	3	6	3	6	1	2	3	6	1	2	50
Surat	12	24	8	16	7	14	4	8	4	8	4	8	4	8	2	4	3	6	2	4	50
Total	29	29	17	17	13	13	8	8	7	7	7	7	7	7	3	3	6	6	3	3	100

Chart No. 4 Services expect from fuel Station

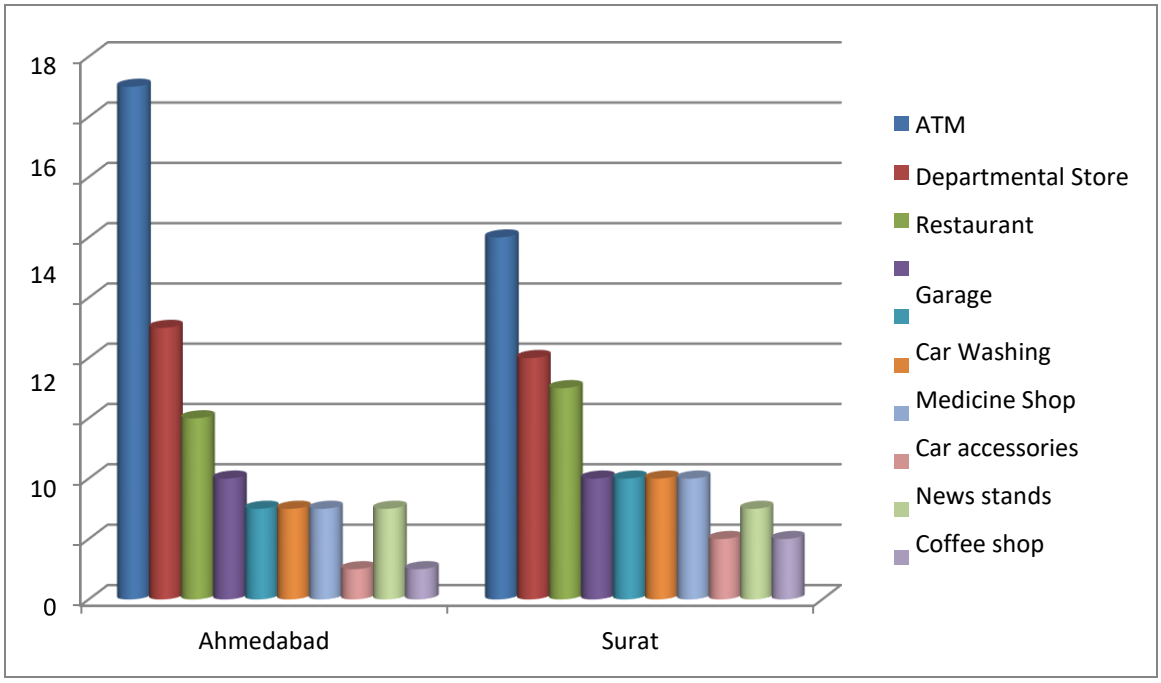


Table and chart indicates that maximum 29 (29%) customers are preferred ATM services, 17 (17%) customers are preferred Departmental stores, 13 (13%) customers are preferred Restaurant, 8 (8%) customers are preferred Garage, 7 (7%) customers are preferred car washing and Car accessories, medicine shop, 6 (6%) customers are preferred coffee shop, and 3 (3%) customers are preferred Cyber café and newsstands.

FINDINGS

There are some findings are obtained from the data analysis and interpretation

1. Age group 26-40 found that they are using non fuel services at fuel stations very highfor their routine work.
2. For the product and services the maximum customers are agree to take other thanfuels and lubricants in fuel station.
3. For the non-fuel services, maximum customers are ready to spend 15 mints and abovetime at the fuel station.
4. The analysis of the non-fuel services reflected that all the services are expecting allthe type of customers at the fuel station.

SUGGESTIONS

As Indian Market is quality interpreted as ‘no adulteration’, quality interpreted as getting the right amount of fuel, i.e. integrity and price is a very important factor.

From the primary research author have found that all most every consumer in terms of group like Age most of them preferred ATM. Apart from plastic cash, hard cash is also needed for daily basis so keeping an ATM would be the best option for all the petrol pumps to generate more profit through non fuel. Most of

the consumers of IOCL prefers departmental store to fulfill their daily needs. Medicine Shop preferred by the age group between 40 and above, and most important that maximum consumers of IOCL would like to take the non-fuel services at petrol pumps it means if oil companies will keep non-fuel services in their outlets,consumer will take those services, so in this way we can conclude that consumers preferred non-fuel services at petrol pumps if oil companies will have those services in their outlet it is obvious that they will be able to generate extra revenue.

CONCLUSION

The market and competitive pressures are changing in the IOCL, the author concludes. It is reasonable to assume that a company's ability to compete within an economy will mostly depend on how well it reflects itself through marketing and other initiatives like non-fuel commerce. It has been noted that customers frequently visit the location, use the ATM, take use of the restaurants and convenience stores, and then leave without purchasing any fuel. To ensure the success of NFR, company representatives must stay in constant contact with their current dealersor grant franchises to entice them to take advantage of other services offered at the gasoline station. At the same time, it's critical to strike a balance between providing non-fuel services and selling fuel.

This research aimed to explore the non-fuel services offered at petrol pumps and understand consumer preferences and behavior towards these services. The findings revealed that modern petrol pumps have diversified their offerings, providing services beyond traditional fuels. Common non-fuel services include convenience stores, car wash and cleaning facilities, minor vehicle repair, ATMs, restrooms, and electric vehicle charging stations.

Consumer preferences revolved around convenience, price sensitivity, service quality, and brand trust. Customers appreciated the one-stop shopping experience offered by petrol pumps but remained price-conscious and sought competitive rates. Positive service experiences led to increased customer loyalty and referrals, while established brands gained more trust from consumers.

Moreover, the research identified a growing interest in electric vehicle charging services, indicating the rising popularity of electric vehicles. To succeed in this evolving market, petrol pumps should focus on convenience, competitive pricing, service quality, and building brand trust to attract and retain customers. Embracing new trends, such as providing EV charging facilities, can position petrol pumps for continued relevance in the automotive industry.

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