# MARKET ACCESSMENT OF DENTAL PRODUCTS USED IN DENTAL FLUOROSIS

Dissertation Submitted to


The IIHMR University, Jaipur

For the partial fulfilment for the award of the degree of

Masters Of Business Administration (MBA)

In

Pharmaceutical Management

By

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**IIHMR University, Jaipur**
**2021**

**DECLARATION BY STUDENT**

I hereby declare that this dissertation titled **MARKET ACCESSMENT OF DENTAL PRODUCTS USED IN DENTAL FLUOROSIS** is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

(Signature)

Name of Student

Date

**CERTIFICATE**

This is to certify that **Dr. Sahil Shaikh** in partial fulfilment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur has successfully completed his internship at Upper Yamuna River Board, Department of Water Resources, River Development and Ganga Rejuvenation, Ministry of Jal Shakti during March - June, 2021.

Place:

Date:

Preceptor/Head of the Organization

Name of the organization

CERTIFICATE

This is to certify that dissertation title **Market Accessment of Dental Products used in Dental fluorosis** is a record of the research work undertaken by **Dr. Sahil Shaikh** in partial fulfilment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur under my guidance and supervision and his/her approach to the research study has been sincere, scientific, and analytical.

Faculty Guide

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# Contents

## 1. OBJECTIVES

- To investigate market size of dental products used in Dental Fluorosis
- To know about fluorosis in India
- To discuss the sales of various Dental products used in different Defluoridation process
- To examine the fluoride level in ground water in Bhilwara district

## 2. RATIONALE

Water is a naturally occurring abundant source of nature and a gift of God to Earth, which is essential for the survival of life and ecosystem [1]. Fresh water occurs naturally in the form of surface and ground waters respectively [2]. Surface water constitutes 0.3% of the total available water resources around the globe and it is one of the preferable sources for consumption [3] and irrigational purposes especially in countries undergoing development like India. Chemical composition of water is the crucial factor determining the compatibility of consumption [4].

From the past earlier decades, due to the exponential increment in population, industrialization, urbanization and unregulated consumption of water resources [5], surface water has depleted in both quantity and quality. Contamination of various hazardous substances like fluoride, chloride, heavy metals, nitrite and nitrates, sulphates, pesticides etc. in surface water have been reported from various parts of India [6]. It is proven in many instances that consumption and utilisation of contaminated water is not only harmful for human beings but also unsafe for irrigation and industrial activities. Therefore, it is necessary to concentrate on issues arising in future, related to pressurized utilization of water resources by adequate planning and development.

Fluoride is the major inorganic pollutant in India, originated from the nature to surface water [7]. Our main intention here is to portray the available concentration of fluoride in Indian riverine streams, sources causing its contamination, to depict trends of fluoride parameter along the main rivers in India and to evaluate novel defluoridation techniques utilized in recent times with reference to drinking water.

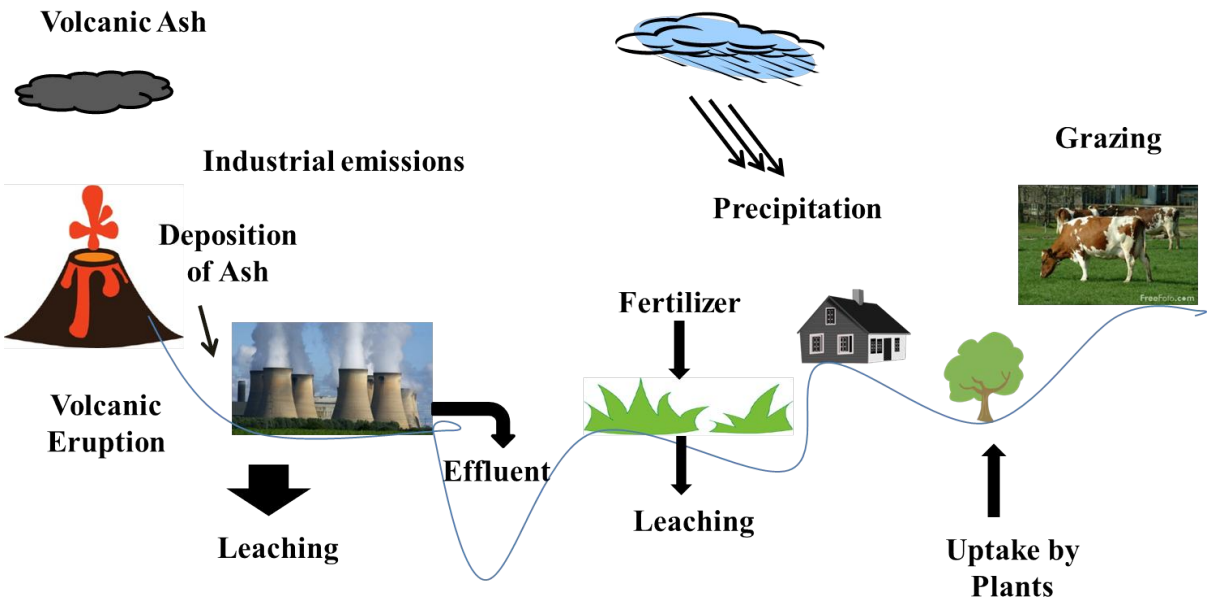



Figure 1: Sources of fluoride in environment. Reprinted with permission from Ref [8], (Copyright: M. Vithanage, P. Bhattacharya, Fluoride in the environment: sources, distribution and defluoridation, Environmental Chemistry Letters, 13 (2015) 131-147 )

## SOURCE OF FLUORIDE FOR HUMAN EXPOSURE

Fluoride exposes to Humans through sources like air, water, solid, by the intake of food and medicament, creams used as cosmetics etc.

Figure 2- Sources of fluoride contamination [25]

### Natural Occurrence

Fluorine is the 13$^{th}$ bountiful element on the surface of earth, and its abundance constitutes to be 0.06-0.09% [10]. The occurrence is recorded in the form of deposits of phosphate in the nature [15]. Calcium fluoride, fluoroapatite and cryolite are the minerals having fluorine content in abundance [14]. Calcium fluoride ($CaF_2$) in the form of fluorite or fluorspar is the most substantial source of fluorine for industrial activities having its content up to 49%. Fluorite is a commercial mineral often commonly known by the name "fluorospar", its occurrence has been recorded as a vein mineral and usually co-occur with quartz and barite.

Despite the fact that fluorides exist in the form of fluoroapatite [$Ca_5(OH, F)(PO_4)_3$], the contents of fluoride are at considerable low level ($F^-$ = 4% ) so the reason for mining of this mineral is mostly for obtaining phosphate contents.

Cryolite ($Na_3AlF_6$) has 54% fluorine content and this is rare, found only in Greenland.

Besides, calcium fluoride, cryolite and fluoroapatite, fluorides occur in small quantities with some of the minerals namely, oxides, silicates, carbonates, sellaite ($MgF_2$), topaz ($Al_2SiO_4(F, OH)_2$), etc. Likewise, some more minerals accounting for inorganic fluorides are:

- Chain silicates
- Apatite
- Tourmaline
- Clays (kaolinite, bentonite, etc.)

The hydroxyl sites present in hydroxyl silicates like micas, amphiboles, and apatitie occupies by chlorine and fluorine, and the fluorine load of these minerals is particularly great when they happen in granitic rocks [26]. Occurrence of fluorine can find in hydroxyl minerals like sedimentary rocks and clays [27]. Inorganic fluoride minerals are showing more stability than chlorine containing minerals because of the approximately similar ionic radius with the hydroxyl ion, thus minimising distortion in lattice

### Air

The waste produced during the production process from phosphate fertilizers and the dust act as major cause of dispersion of Fluorides comprehensively throughout the sky[28]. The ash from the coal industries and volcanic eruptions also constitute to the fluorides [28]. The study fluoride concentration of various areas depicted that usually in the non-industrial areas the concentration was limited to 0.05-1.90 μg $m^{-3}$ on the other hand in the industrial areas the concentration went fairly high chiefly due to the coal burning and fertilizer production [29].

### Soil

Extended usage of specific drugs having fluoride contents results to toxic affects e.g. Sodium fluoride for Osteoporosis treatment and Niflumic acid (Rheumatoid arthritis).

### Toothpaste's and Rinses

Fluoride contamination is caused from the raw materials used in manufacturing of tooth paste such as calcium carbonate, talc and chalk[35]. Contamination appears in higher quantities which ranges from 800-1000 ppm. Fluoride mouth washes are extensively used to render the tooth stronger[36]. Fluoride contents are adding extensively in all the fluoridated brands, it might lies within 1000-4000 mg/l. There is a close relation observed between insertion of fluoride from toothpaste and fluorosis[37].

### Food

The concentration of fluorine found in fluorine containing plants especially in cultured plants are very low except for tea plant; it appeared 440 mg/l concentration. The lists of crops include:

- Jowar (*Sorghum julgare*)

- Wheat (*Triticum aestivam*)
- Rice (*Oryza sativa*)
- Red gram Dal *(Cajanus Cajan*) and
- Red chillies (*Capsicum annuum*)

## New Fluoridated Products in the Market

Main benefit of fluoride is in reducing the risk of dental caries. In recent years, rapid changes have occurred in the prevalence of dental caries across countries. Today countries show a decline in the prevalence in dental caries and more children are becoming caries free. Decline in dental caries may be attributed to the cariostatic efficacy of fluoride.[1] Research into the mechanisms of anticaries efficacy of fluoride is ongoing, which may lead to better prevention strategies. New and/or improved fluoride products are entering the marketplace at an increased rate; these products include toothpastes, fluoride varnishes, fluoride-containing whitening agents, and other fluoride-containing cleaning products.

### Fluoride Gels

"Fluoride Gels" are acidic, highly concentrated fluoride products that dentists topically apply to a patient's teeth about two times a year. Of all the fluoride products currently used in dentistry, fluoride gels are – without question – the most hazardous. While fluoride gels are designed to be applied "topically" (i.e., directly to teeth), very large quantities of fluoride are absorbed into the body during the treatment. Due to this large systemic exposure, many patients – particularly children – experience symptoms of acute fluoride toxicity, including nausea, gastrointestinal pain, and/or vomiting within an hour of the treatment. Gastric distress is not the only side effect. Fluoride gels produce an enormous spike in blood fluoride levels for up to 14 hours, exposing every tissue in the body to fluoride concentrations that have been can damage, in short-term exposures, the kidney, the male reproductive system, and glucose metabolism. Although the dental community has taken steps to reduce the amount of fluoride that gets into the blood from fluoride gels, the extent of fluoride exposure from these gels continues to remain excessive and toxic. Due to the conspicuous absence of safety studies, however, the public health consequences from the dental community's 40-year experiment with fluoride gels remains a disturbing mystery.

### Fluoride Varnishes

Fluoride varnishes are designed to bond fluoride to the surface of the teeth for days or weeks at a time. Most fluoride varnishes contain 5% sodium fluoride, or 22.6 milligrams of fluoride for each milliliter of varnish that is applied. While this is twice the concentration used in professionally applied fluoride gels (12.3 mg per milliliter), less varnish is used per treatment. With fluoride gels, dentists generally apply about 4 to 8 mL of gel per treatment (48 to 96 mg of fluoride). With varnishes, dentists apply about 0.5 to 1.0 mL of varnish (11.3 to 22.6 mg of fluoride). Fluoride varnishes, therefore, introduce less fluoride into the mouth than fluoride gels. Moreover, because of their slow-release quality, varnish does not cause the same severe spike in blood fluoride levels that gels create. Nevertheless, varnishes do expose a child to

significant levels of fluoride, as all of the fluoride that is introduced into the mouth with a varnish will be swallowed.

Recently, new fluoridated products have been introduced in the market, which are presented in Tables 1 and 2.

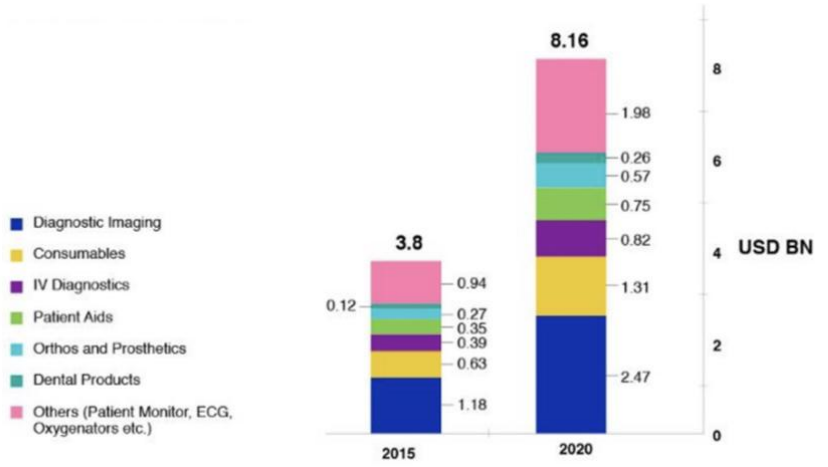
**Table 1: Recently, new fluoridated foams, gels, varnishes, rinses have been introduced in the market, which are presented in table**

**Table 2: Recently, new fluoridated prophylaxis paste and restorative materials have been introduced in the market, which are presented in table**

## Segment wise Indian market Share of Dental products:

In 2015, the Indian dental device market size by summing up the value of the market segments was evaluated to be upwards of $0.63 billion and growing at a CGAR of 10-15%. Data generated based on the product type and treatment-based devices.

Industry in India is presently valued at USD 5.2 billion and contributes 4-5% to the USD 96.7 billion Indian health care industry. Out of this, by projected growth rates, the Indian Dental
Medical Devices Products is estimated to be 1.31 billion USD by 2020.
Segment wise Market share of Medical devices




Segment wise Market share of Medical devices

*11*

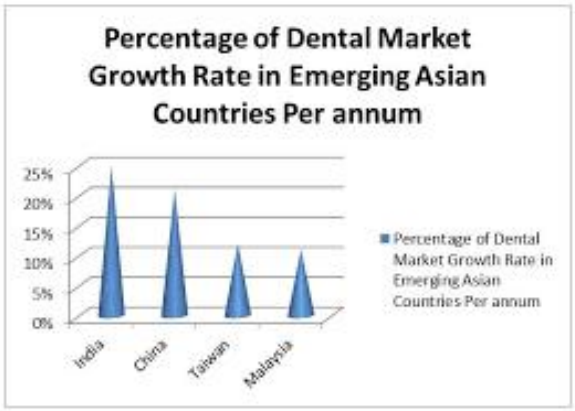
### Growth size percentage of Dental market in India:

Currently, India has about 750–800 medical device manufacturers in the country, with an average investment of Rs 170–200 million and an average turnover of Rs 450–500 million.

According to a report published by the government of India, with technological advancements such as the Medical Parks being planned in Gujarat, Andhra Pradesh and Maharashtra and continued Research and Development (R & D), the medical devices industry in India is poised to cross a market size of USD 50 billion by 2025.

Currently, India is among the top 20 global medical devices market and is the fourth largest medical devices market in Asia after Japan, China and South Korea. Equipment and Indian Dental Market Outlook 2020 – Fostering Big Growth Instruments (surgical and non-surgical) form the largest segment (53% of the Indian medical device industry), constituting about USD 2.7 Billion (2017), while the estimated market size of the consumer and durable segment is USD 1404 million.

Indian dental service industry comprises of dentists and dental ancillary. This industry has shown a phenomenal compounded annual growth rate of 12% for the period ranging from FY 2010 to FY 2018 with increased dental awareness and disposable income. In the past five years, the growth in the dental care market of India has been spurred by rising elderly population, changing lifestyles leading to oral problems, increased healthcare expenditure by the government as well as households.


Percentage of Dental Market Growth Rate in Emerging Asian Countries Per annum
25%
20%
15%
10%
5%
0%
India
China
Taiwan
Malaysia
Percentage of Dental Market Growth Rate in Emerging Asian Countries Per annum

Few investigations have been carried out in various fields related to fluoride at national and international level [38]. In this research paper a comprehensive and critical review of past researchers is carried out under different headings.

i. Distribution of Fluoride in Groundwater
ii. Fluoride in Plant
iii. Fluoride in Soil
iv. Fluoride & Health Effects
v. Fluorosis Mitigation

### Guidelines and Standards

According to WHO's guidelines for drinking water, a fluoride level of 1.5 mg/L is the desirable upper limit. India reduced the upper limit of fluoride in drinking water from 1.5 to 1.0 mg/L with a rider that "less is better" (BIS 10500, 2012). Global and Indian standard for fluoride in drinking water is given Table 1–. This is due to the extremes in climatic conditions and the diet being deficient in essential nutrients (calcium, vitamins C, E and antioxidants) in the rural communities of India. So, the Indian standard for the maximum desirable limit of fluoride in drinking water is 1.0 mg/L and the maximum permissible limit is 1.5 mg/L. As the amount of water consumed and consequently the amount of fluoride ingested is influenced primarily by air temperature, USPHS (1962) has set a range of concentrations for maximum allowable fluoride in drinking water for communities based on the climatic conditions, as shown in Table 1.

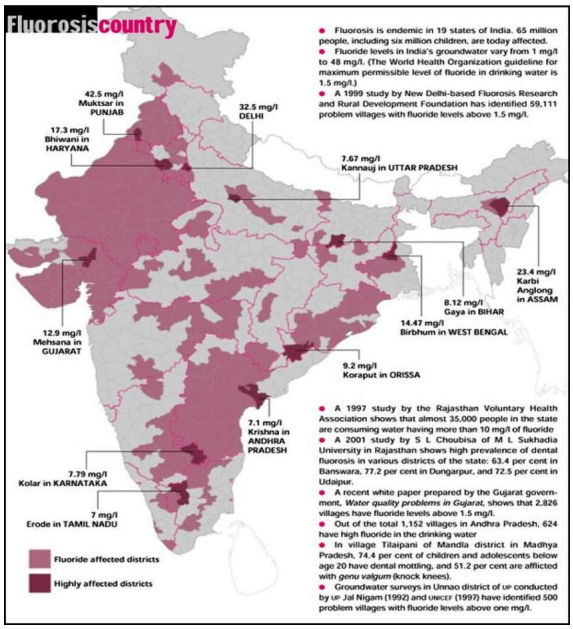
Table 1 Global and Indian standard for fluoride in drinking water

| Type of standards | Description guideline | Guideline value (mg/L) | References |
|---|---|---|---|
| Indian Standards | Allowable limit | 1.0 | BIS 10500:2012 |
| | Permissible limit in the | 1.5 | |
| WHO guideline | Guideline value | 1.5 | WHO, 2006 |
| US EPA | Desired limit | 0.7 | NRC, 2006 |
| | Permissible limit | 1.2 | |
| | Max. Contaminant level | 4 | |
| Canadian guideline | Max. acceptable (MAC) | 1.5 | MHGC, 2010 |
| South Korea | Max. permissible limit | 0.8 | ECOREA, 2013 |
| Japan | Standard value | 0.7 | MHLW, 2010 |
| Singapore | Max. prescribed quantity | 1.5 | NEA of Singapore, 2008 |
| Malaysia | Permissible limit | 1.5 | ESD, 2004 |
| Ireland | Permissible limit | 1.5 | NEIA, 2018 |
| UK | Permissible limit | 1.5 | DWI, 2009 |
| Switzerland | Permissible limit | 1.5 | Bucheli et al., 2010 |
| Australia | Max. Impurity Conc. | 1.5 | NRMMC, 2011 |
| New Zealand | Max. acceptable value | 1.5 | MH, 2008 |

Table 1: USPHS recommendation for maximum allowed fluoride in drinking water.

## Fluoride & Health Effects

Fluoride pollution is causing severe threat to human life around the world. Permissible intake concentration of fluoride lies between 0.5 and 1.5 mg/L beyond this limit it is hazardous for humans [61]. Fluoride restricts tooth decay by reinforcing demineralization of under attacked enamel; in addition, preventing the generation of acid resulting by bacteria which causes impairment in dental plaque [62]. It is worth noting that enamel having fluoride as its one of the general constituent which is fused into growing tooth and protecting it from acid dissolution. Besides, Fluoride concentration greater than 1.5 mg/L (with respect WHO-1996, drinking water standards for fluoride) causes dental and skeletal fluorosis, thyroid, kidney changes and cardiovascular, gastrointestinal, endocrine, neurological, reproductive, developmental, molecular level, immunity effects, if concentration is higher than 1.5 mg/l in drinking water [18].



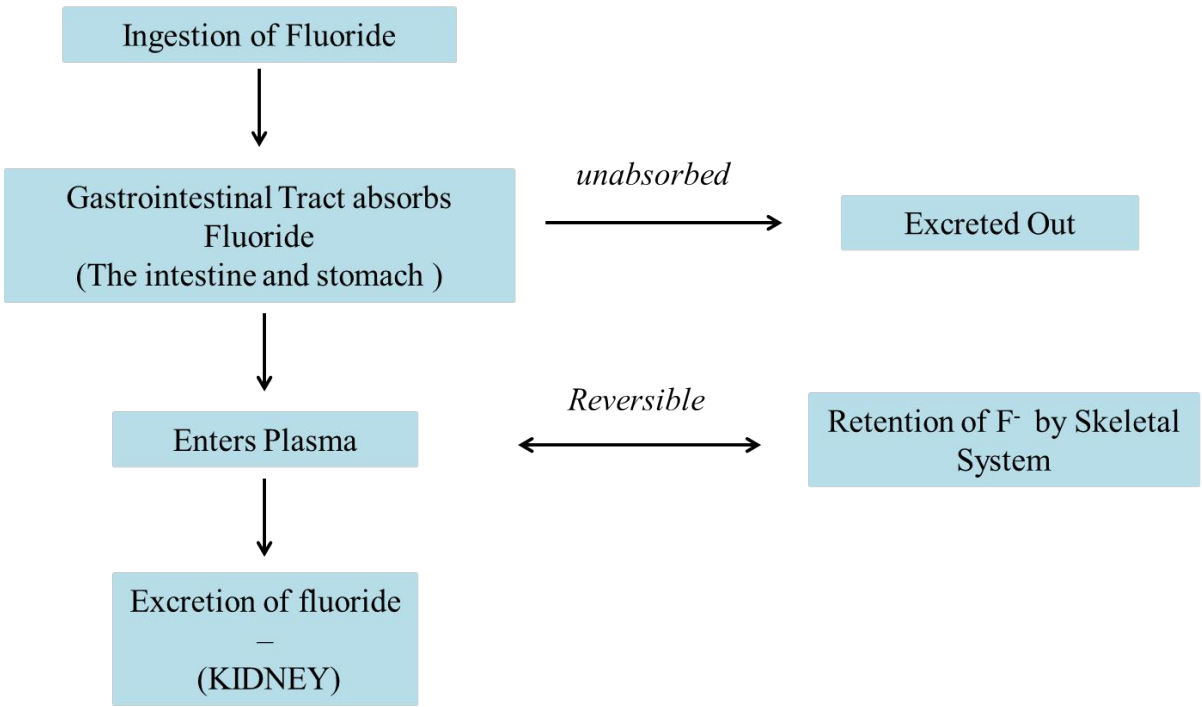
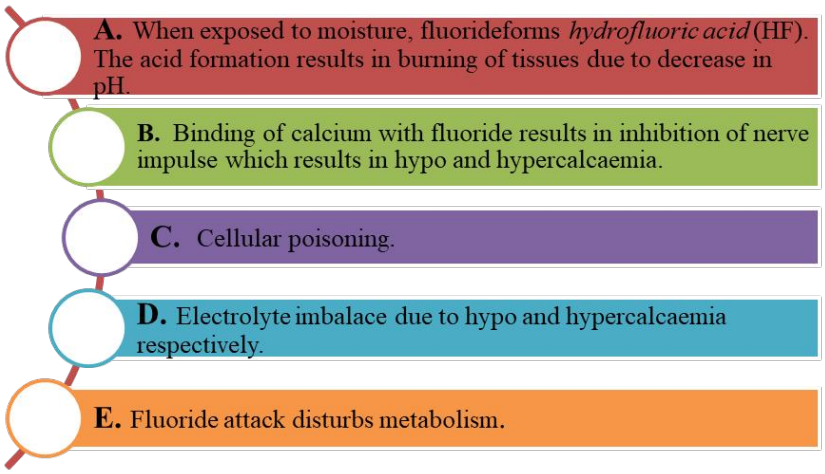



**Figure 3 – Summary of fluoride pathway through oral pathway**. Reprinted with permission from Ref [63] (Copyright : R. Ullah, M.S. Zafar, N. Shahani, Potential fluoride toxicity from oral medicaments: A review, Iranian journal of basic medical sciences, 20 (2017) 841)

## General mechanism of fluoride toxicity: [7, 63]




- **Classification of Toxicity : [63]**

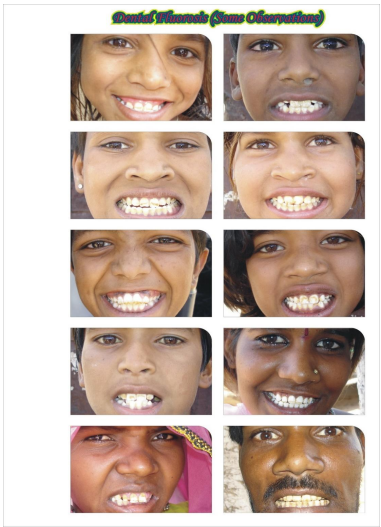
  Fluoride toxicity could be classified under two broad headings

  a) **Acute toxicity:** This kind of toxicity is more fatal. It occurs due to accidental consumption of over doses of fluoride.

  b) **Chronic Toxicity:** This one is more prevalent of the two. It occurs due to persistent exposure to the toxins or consistent time period.

### *Dental Fluorosis*

When the developing tooth is exposed to fluoride, it results in mineralisation leading to a state which is termed as fluorosis. The enamel which is affected by fluorosis has an altered structure, which degrades on further exposure to fluoride [64].



To discuss mineralisation it's essential to go through the process of bio mineralisation. Bio mineralisation could be defined as "a process through which the various living organisms undergo production of mineralised tissue." Some examples of mineralised tissue in vertebrates include tooth enamel, bone, dentin, etc. Each mineral tissue is unique in its own kind, the variation depend upon their structure and composition which are also responsible for the mechanical properties.

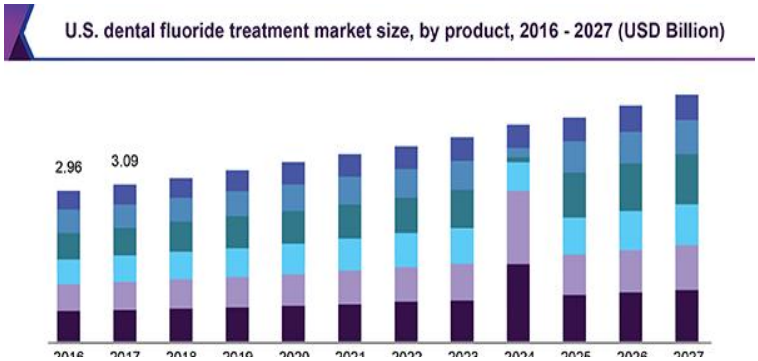
Dental fluorosis is an unalterable state raised by too much fluoride intake at the growing years and it is primary hint that infants are undergone fluoride exposure. Dental fluorosis is originated by infecting cells involved in enamel formation, known as ameloblasts. Destruction of these cells causes enamel mineralization unevenly, called hypo mineralization.

Significant signs of dental fluorosis as follows [66, 67]:

- Formation of white and yellow marks on teeth by losing its shine.
- Colour change occurs from white, yellow to brown and it covers as horizontal lines on enamel surface.
- Exposure dating can be extracted from the stage of teeth discoloration.
- Presence of brown colour spots on the centremost position of the teeth shows that a child is exposed to the higher content of fluoride from 2 to 4 years age.
- Presence of brown colour spots at the teeth tips explains that a child is exposed to the higher content of fluoride from 2 years age.
- Presence of brown colour spots at the teeth uppermost part is indicative that kid exposes to the higher content of fluoride from 4-6 years age.
- There is possibility to become total titch black, punctured in and even can be spitted off. Depending upon degree of exposure and nutritional condition of kids, this dental fluorosis can occur in numerous scales.

#### 1.1.1.1.1 Global Dental Fluoride Market:

The global dental fluoride treatment market size was valued at USD 10.8 billion in 2019 and is expected to witness significant growth in the forecast period. Increasing prevalence of dental caries and a rise in awareness regarding oral health and hygiene are some of the key factors anticipated to drive the market for dental fluoride treatment.




Moreover, a rise in the intake of sugary food and drinks, such as soft drinks, candy, flavore yogurt, cookies and fruit drinks, is anticipated to fuel market growth. Sugary food and drinks release acid when they are broken down by the bacteria present in the mouth. This acid eventually dissolves the tooth enamel, thereby causing tooth decay. According to an article published by the Wolfson Institute of Preventive Medicine, in the U.K., nearly 1 in every 3 adults and 1 in every 4 children suffer from some type of tooth decay. Tooth decay can cause tooth abscesses and eventually lead to tooth extraction.

Furthermore, dentine hypersensitivity is one of the most common dental conditions and as per the data by FDI World Dental Federation, its prevalence ranges from 3%-57%, depending on the method of investigation and population studied. Thus, high prevalence of tooth decay and dentine hypersensitivity is anticipated to increase the demand for fluoride treatments.

World Oral Health Day (WOHD), initiated by FDI World Dental Federation, aims at increasing global awareness regarding the control, prevention, and treatment of oral diseases, such as dental caries. It also aims to improve awareness, funding, and support for oral health in collaboration with governments, NGOs, national dental associations, and other entities in order to avoid preventable disorders and facilitate early detection and treatment. Such initiatives are anticipated to fuel growth of the market for dental fluoride treatment.

#### 1.1.1.1.2 Dental fluoride Product Market:

Based on product, the global market for dental fluoride treatment is segmented into toothpaste, gel, mouth rinse, dental fluoride varnish, supplements, and others. The toothpaste segment held the largest market share in 2019 due to easy and wide availability and affordability of this product. Furthermore, availability of toothpaste in various colors and flavors is contributing to high product demand.

The dental fluoride varnish segment is anticipated to witness significant growth over the forecast period. This can be attributed to relatively inexpensive treatment costs, quick and easy application of fluoride, low risk of fluoride ingestion, and good tolerance for fluoride by both infants and children. Furthermore, fluoride varnish can be applied by an oral health professional as well as a non-oral health professional, thus facilitating the adoption of the fluoride varnish treatment.

#### 1.1.1.1.3 Regional Insights:

Europe dominated the global dental fluoride treatment market and held a share of nearly 40.0% in terms of revenue in 2019. This can be attributed to favorable reimbursement framework, presence of a relatively large number of dentists, and high availability of market products for fluoride treatment. North America held the second largest market share in 2019 and is expected to maintain its position over the forecast period. Presence of advanced facilities and consumer awareness are some of the major factors driving regional growth. For instance, as of 2018, nearly 199,486 dentists practiced dentistry in the U.S., which accounts for nearly 61 dentists per 100,000 inhabitants.

Asia Pacific is anticipated to witness lucrative growth over the forecast period owing to increasing awareness about oral health and fluoride treatment in the region. In addition, high prevalence of dental caries in countries, such as India, due to high consumption of tobacco

and unhealthy lifestyle is anticipated to fuel the regional market growth for dental fluoride treatment. For instance, dental caries affects nearly 60% of the Indian population, thus facilitating the demand for dental fluoride treatment.

#### 1.1.1.1.4 Dental Fluoride Treatment Market Share Insights:

The global market for dental fluoride treatment is highly fragmented due to presence of many local as well as international players. Some of the key market players are Colgate, Philips, Dentsply Sirona, VOCO, DÜRRDENTAL, Young Dental, Ivoclar Vivadent, Ultradent Products, DMG Dental, and Church & Dwight.

Market players are actively involved in mergers & acquisitions, geographical expansion, oral health initiatives, and strategic collaborations to increase oral health awareness and boost the adoption of fluoride treatment. For instance, Colgate-Palmolive (India) Limited initiated a 'Colgate Bright Smiles, Bright Futures' program, in partnership with the Indian Dental Association (IDA), which aims at providing oral health education to children. As of 2018-19, the program reached nearly 11.5 million children across India.

#### 1.1.1.1.5 Dental Fluoride Treatment Market

**Table Dental Fluoride Treatment Market Report Scope**

| Report Attribute | Details |
|---|---|
| Market size value in 2020 | USD 11.2 billion |
| Revenue forecast in 2027 | USD 15.1 billion |
| Growth Rate | CAGR of 4.3% from 2020 to 2027 |
| Base year for estimation | 2019 |
| Historical data | 2016 - 2018 |
| Forecast period | 2020 - 2027 |
| Quantitative units | Revenue in USD million and CAGR from 2020 to 2027 |
| Report coverage | Revenue forecast, company share, competitive landscape, growth factors and trends |
| Segments covered | Product, region |
| Regional scope | North America; Europe; Asia Pacific; Latin America; Middle East & Africa |
| Country scope | U.S.; Canada; U.K.; Germany; France; Italy; Spain; China; India; Japan; South Korea; Australia; Brazil; Mexico; Argentina; South Africa; Saudi Arabia; UAE |
| Key companies profiled | Colgate; Philips; Dentsply Sirona; VOCO; DÜRRDENTAL; Young Dental; Ivoclar Vivadent; Ultradent Products; DMG Dental; Church & Dwight |
| Customization scope | Free report customization (equivalent up to 8 analysts working days) with purchase. Addition or alteration to |

| | |
|---|---|
| | country, regional & segment scope. |
| Pricing and purchase options | Avail customized purchase options to meet your exact research needs. Explore purchase options |

#### 1.1.1.2 *Skeletal Fluorosis*

Due to the excessive ingestion of fluoride, bone borne diseases like skeletal fluorosis occur [68]. The disease was first discovered in 1920's, among cattle grazing downwind of aluminium and phosphate industries. In human it was first diagnosed in 1932 among a group of Danish cryolite workers. The recommended level of fluoride consumption should be less than 1.5 mg/ml. At this concentration the consumption of fluoride won't degrade the bones and teeth. The fluoride levels are at a controversial position, for different country the levels of fluoride are different [69].


Due to increment in bone mass and density, skeletal fluorosis arises. Former researchers clearly portrayed that the mechanism involved and the development stages of skeletal.

Alternation in body has been occurred without appearance of any symptoms in patient in first two preclinical stages. Biochemical deformities appeared in compositions of blood and bone in former stage, and in later clinical stage, histological irregularities developed like bone and joints, burning sensations, itching and tickling in the limb, proneness in muscles, continuous tiredness, and gastrointestinal disorder and reduce appetite. Paining in bones remained steady and few of the ligaments begin to calcify in second clinical stage. In the advance skeletal fluorosis, the tips turn weak and making joints movement difficult. The vertebrate moderately combined together, paralyze the patient hence this stage of fluorosis is also called as crippling skeletal fluorosis.

- **Prevention of Skeletal Fluorosis**
    1. Safe drinking water habits.
    2. Prevention of endemic fluorosis.
    3. Proper knowledge of ill effects of fluorine.

#### 1.1.1.3 *Abnormalities and crippling fluorosis*

The various consequences of the fluoride toxicity appear, when any individual is exposed to 20-80 mg of fluoride on regular basis for a time of more than 10-20 years. The above mentioned substantial exposures are linked to a level of 10mg\l in the drinking water. The state of Rajasthan, Punjab and south India are the areas where deformities and fluorosis are the widespread. The usual deformities are:

- Kyphosis
- Flexion
- Deformity of knees
- Calcification of cartilages

The quadriplegic patient bent with kyphosis and with markedly-restricted movements of his spine, with contractures of hips and knees.

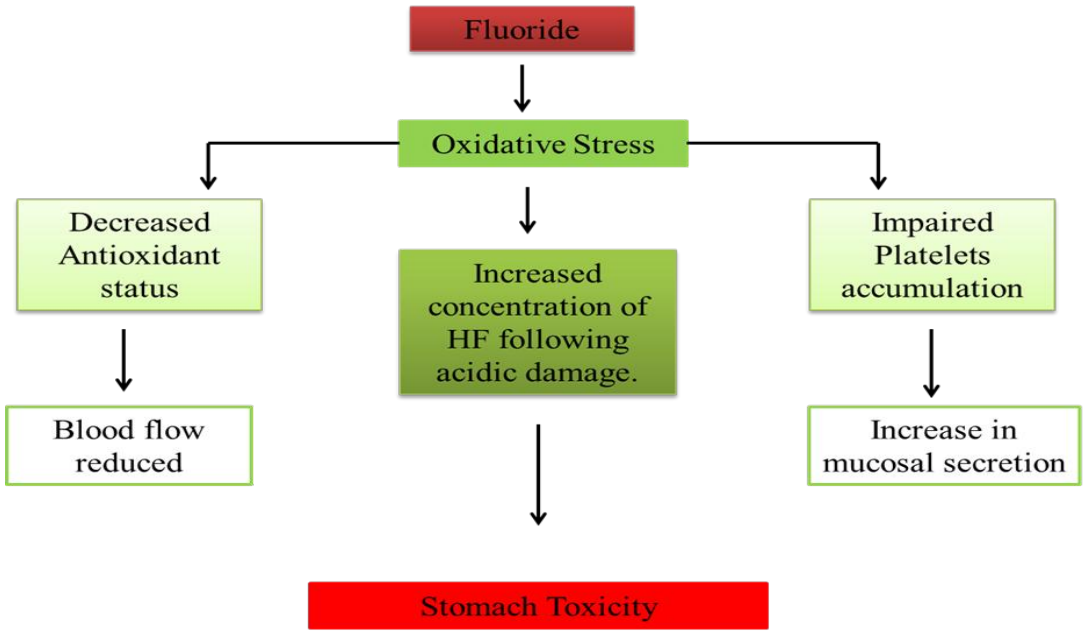



**Figure 5 – Mechanism of fluoride toxicity in stomach** Reprinted with permission from Ref [75] (Copyright: S. Thangapandiyan, S. Miltonprabu, Molecular mechanism of fluoride induced oxidative stress and its possible reversal by chelation therapy, Res Rev J Toxicol, 3 (2013) 1-11)

**FLUORIDE DISTRIBUTION IN BHILWARA TEHSIL OF BHILWARA DISTRICT:**

## Material and Methods

Groundwater samples of 121 villages located in Bhilwara tehsil of Bhilwara district were collected in pre cleaned polythene bottles with necessary precautions[21]. The samples were brought to the laboratory and fluoride concentration was determined by Ion selective electrode method[22]. All the chemicals used will be of Anal. R. Grade. A general observation was also conducted with respect to incidence of dental and skeleton fluorosis.

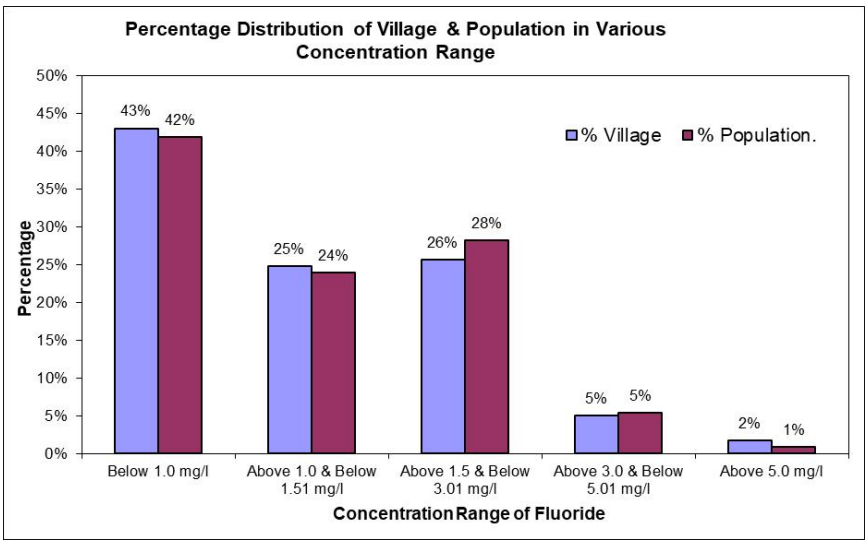
## 3. RESULT AND DISCUSSION

### Fluoride distribution

Fluoride concentration in groundwater of 121 villages of Bhilwara tehsil was examined. All the villages were categorized according to following concentration range (Table 1).

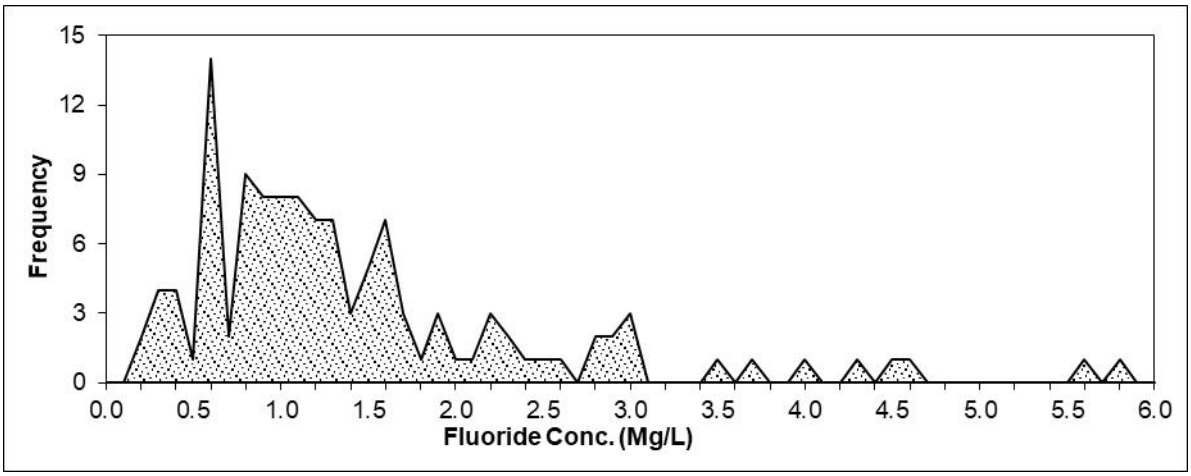
1. **Category I** : Fluoride concentration below 1.0 mg/l
2. **Category II** : Fluoride concentration between 1.0 mg/l and 1.5 mg/l
3. **Category III** : Fluoride concentration between 1.5 mg/l and 3.0 mg/l
4. **Category IV** : Fluoride concentration between 3.0 mg/l and 5.0 mg/l
5. **Category V** : Fluoride concentration above 5.0 mg/l

The distribution of fluoride in ground water of Bhilwara tehsil is shown in figure 1(A to E). Fluoride concentration ranges from 0.2 mg/l to 5.8 mg/l. The minimum concentration was recorded in two villages (Kiron ki jhopriya and Patnia) and maximum concentration was recorded from village Hurniya kheda. Figure -2 represents the frequency of fluoride concentration in the tehsil. From the figure it is clear that the frequency of fluoride concentration is high on 1.0 mg/l fluoride concentration. Maximum villages have fluoride concentration between 0.5 and 1.6 mg/l. The present survey reveals that 52 villages (43%) fall in category I



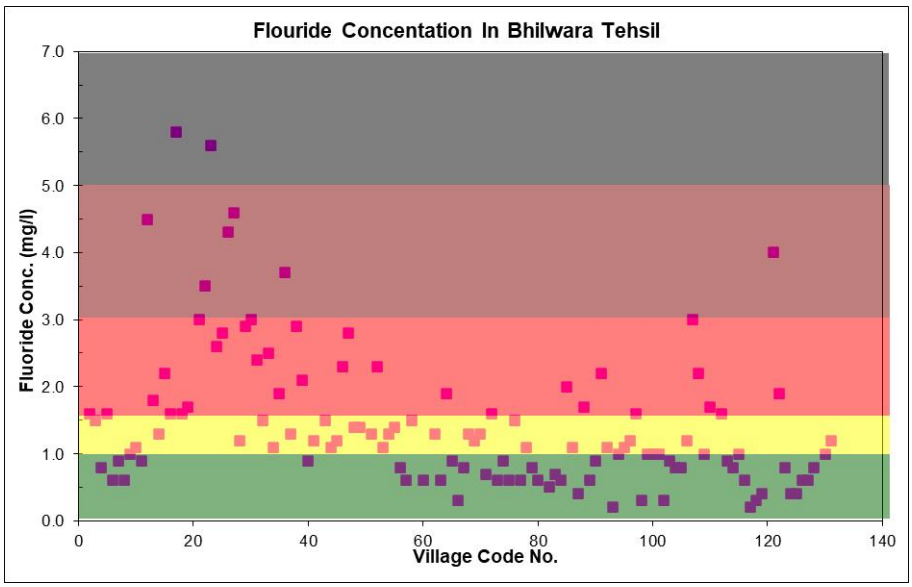
(Fig - 1A) in which fluoride concentration is below 1.0 mg/l, a maximum desirable limit of standards for drinking water recommended by Bureau of Indian Standard (BIS)[23] in IS: 10500, 1991. Therefore, no possibility of fluorosis in these villages because this concentration of fluoride is beneficial, for calcification of dental enamel especially for children below 10-year age. Once fluoride is incorporated into teeth, it reduces the solubility of the enamel under acidic conditions and thereby provides protection against dental carries.

Out of 121 villages of Bhilwara tehsil 30 villages (25%) have fluoride concentration between 1.0 – 1.5 mg/l and fall in category II( Fig – 1B). The maximum permissible limit of fluoride in standard for drinking water is 1.5 mg/l (IS: 10500; 1991). In 32% population of these villages, fluoride intake through drinking water is more than 4 mg/d in an individual. Therefore, incidence of 1st and 2nd degree dental fluorosis is possible in local residents of these villages (Fig.3).




About 28% of population of 31 villages (26%), consume water with fluoride concentration between 1.5 – 3.0 mg/l, which is above the maximum permissible limit as recommended by BIS (Fig-1C). Therefore, dental fluorosis is common in these villages. At this concentration, teeth loose their shiny appearance and chalky black, gray or white patches develop known as mottled enamel[24]. In some cases, the pre-stage of skeletal fluorosis may occur after 45-year age[10,25].

In 6 villages (5%) fluoride concentration in groundwater is above 3.0 mg/l and below 5.0 mg/l and this fall in category IV (Fig-1D). The intake of fluoride per day by an adult in these villages is very high. About 6% population of these villages may have all degree of dental fluorosis (Mild, moderately, moderately severe,



severe fluorosis) including skeletal fluorosis after 30 year of age. However, the probability of 2nd stage skeletal fluorosis age may be common after the age of 45[26].

In the entire survey the Hurniya Khere and Sankariya Khera were the village falls in category V (Fig.- 1E), which contributes 1% population of Bhilwara tehsil (Fig. 3.) In this village fluoride concentration is above 5.0 mg/l, which may result all types of fluorosis in inhabitants. The second clinical stage the affected persons may have pain in bones, which causes further calcification in ligaments. It has been reported that under such persons may suffer from stiffness in joints. At this concentration, the vertebrae partially fuse together and crippling the patient which is known as "*crippling skeletal fluorosis*". It has also been reported that high doses of fluoride is toxic to man and causes health hazards including hemorrhagic gastroenteritis acute toxic nephritis and degree of injury to the liver and heart muscles[28]. In such cases plasma epinephrine and fluoride induced hyperglycaemia is significantly increased[29]. Fluorosis is accompanied by adverse effect on the other systems and organs of the body namely liver, kidney, muscles, heart, lungs, blood and the hormonal functions[18-20;30,31]. The kidney is the principal organ through which maximum concentration of fluoride is excreted. High fluoride causes impaired kidney functions. A detailed survey of health hazards particularly fluorosis induced symptoms and empirical data on affected population in required in Bhilwara as well as other tehsil of Bhilwara district of Rajasthan.

### Dental and skeletal fluorosis

Dental and skeletal fluorosis survey was carried out in Hurnia village of Bhilwara tehsil. This village was found to have fluoride concentration above 5.8 mg/l in groundwater. The entire sources present in the village were examined for fluoride concentration and found between 3.1 and 5.8 mg/l with a mean value of 4.27. Total 142 individual of different age group were examined for dental and skeletal fluorosis as per classified by Dean's 1942[24] (for dental fluorosis) and Teotia et al., in 1985[32] (for skeletal fluorosis). Data indicate that only 4 individual (2.82%) do not have dental fluorosis and 11 individual (7.75%) have questionable type of dental fluorosis. High percentage individuals are positive to dental fluorosis. The maximum individuals were found to be suffered by mild (34.51% or 49 individuals) and moderate (31.69% or 45 individuals). The severe dental fluorosis was recorded in only 16 individuals (11.27%). The dental; fluorosis characterized by light yellow to brown black horizontal lines on teeth surface edges chipped of edges.

| Parameters | Below 1.0 mg/l | Above 1.0 & Below 1.51 mg/l | Above 1.5 & Below 3.01 mg/l | Above 3.0 & Below 5.01 mg/l | Above 5.0 mg/l | Total |
|---|---|---|---|---|---|---|
| **No of Village** | 52 | 30 | 31 | 6 | 2 | 121 |
| **% Village** | 43% | 25% | 26% | 5% | 2% | 100% |
| **Population** | 46581 | 26662 | 31346 | 6008 | 901 | 111498 |
| **% Population.** | 42% | 24% | 28% | 5% | 1% | 100% |

104 individuals having age above 21 years were examined for skeletal fluorosis prevalence. From the figure it is clear that 38 individuals (36.54%) do not have skeletal fluorosis. In the skeletal fluorosis positive 66 individuals maximum 36.54% have grade I skeletal fluorosis, which is characterized by bone and joint pain. The grade II skeletal fluorosis was recorded in

28 individuals (26.92), which generalized bone and joint pain, stiffness and rigidity of dorso lumbe spine and restricted movement at spine and joints. No individual was found to have grade III type of skeletal fluorosis.

**FLUOROSIS MITIGATION**

Fluorosis couldn't be eradicated completely. The only measure to deal with it is through prevention and controlled management. Selecting alternative water sources for water consumption could be very helpful in attaining an approach for minimization of fluorosis. [90]

## 1.2 Alternative Water Sources

These include low fluoride groundwater and water harvesting

### 1.2.1 Low fluoride groundwater

The major source of water for various purposes is groundwater. There are a lot of factors affecting groundwater's suitability. One of them is presence of ions. If the concentration of ions is beyond or below the desired value respectively, then that causes adverse effects on human health. If the water is contaminated with fluoride levels more than 1.5 mg/l, then it results in chronic fluorosis [31].

Variation in the fluoride levels has been observed in the wells of locations with high levels of fluoride. Content of fluoride depends upon geological structures of aquifers. The distribution of fluoride is uneven in the groundwater, so every well needs an individual examination of the fluoride distribution in the areas which are endemic for fluorosis.

To treat high fluoridated groundwater *in-situ* and *ex-situ* methods are available which reduce down the fluoride levels and makes the water fit or consumption[31].

*In-situ Method of Treatment*- the chief aim of this method is to dilute the concentration of fluoride in groundwater. T attain this he aquifer needs a recharge which is done artificially by construction of dams. Constructions of rainwater harvesting structures are also examples of this.[91]

*Ex-situ methods of Treatment-* There are a lot of ex-situ methods available for treatment of water both at individual or at large scale. The list of processes is as follows:

i. Adsorption
   The various kinds of adsorbents used are:-
   - Activated charcoal and alumina
   - Fly ash
   - Bone char
   - Rice husk
   - Ceramic

ii. Ion Exchange process
iii. Membrane process
   - Reverse osmosis
   - Electro dialysis

#### Water harvesting

The fluoridated water is not only harmful to humans but to all living forms. It's not feasible to carry out defluoridation especially for animals, because it's costly and not feasible practicing rain water harvesting can be a major source of fresh water for both types of living forms [31].

### 1.2.2 Changing the dietary Habits

Carrying out defluoridation only on the drinking water won't attain safer limits [92]. To overcome toxic effects of fluoride it's essential to hold a control on other sources of ingestion. This could be achieved by bringing change in the dietary habits. The main objective is to reduce the use of fluoride rich food items and consume food items rich in calcium and vitamins.

## DEFLUORIDATION TECHNIQUES

Developing countries are seriously affected by the problem of high fluoride levels in the drinking water [93]. The fluoride dissolved in drinking water is odourless and completely soluble and further producing no turbidity at all. To detect the dissolved fluoride analytical grade chemicals and laboratory methods and skills are desirable. Regulation of fluorosis is a difficult task in absence of proper skill and techniques [94]. A lot of defluoridation techniques are said to exist, but only a few of them are effective and efficient simultaneously. It's essential for a technique to be cost effective and efficient in problem solving. Although a variety of procedures are available for defluoridation of water, but they remain ineffective due to absence of optimal conditions. Due to failure of defluoridation methods the primary aim has become to find out an alternate fresh source of water free from dissolved fluoride. If the fresh source of water is absent then the primary measure available is defluoridation. Various kinds of defluoridation methods are available to treat fluoridated water. The fluoride present in water combines with reagents to form an insoluble compound.

The processes of defluoridation are categorized into five main groups[95]:

1. **Adsorption methods:** some of the adsorbents showed great resemblance to the sorption media. These are clay, activated alumina, bone char, etc. the saturated columns could be regenerated.
2. **Ion exchange methods:** Expensive commercial ion exchange resins are desirable.
3. **Co-precipitation methods:** A daily amount of sludge is produced by Precipitation technique. Alum and lime resemble the co-precipitation chemicals.
4. **Contact precipitation methods:** Calcium and phosphate lies under the category of contact precipitation chemicals. In this method only the precipitate accumulates and the sludge generation is absent.
5. **Membrane processes:** These include reverse osmosis, Nano filtration and electro dialysis methods.

## 4. CONCLUSION

Dental and skeletal fluorosis survey was carried out in Hurnia village of Bhilwara tehsil. This village was found to have fluoride concentration above 5.8 mg/l in groundwater. The entire sources present in the village were examined for fluoride concentration and found between 3.1 and 5.8 mg/l with a mean value of 4.27. Total 142 individual of different age group were examined for dental and skeletal fluorosis as per classified by Dean's 1942[24] (for dental fluorosis) and Teotia et al., in 1985[32] (for skeletal fluorosis). Data indicate that only 4 individual (2.82%) do not have dental fluorosis and 11 individual (7.75%) have questionable type of dental fluorosis. High percentage individuals are positive to dental fluorosis. The maximum individuals were found to be suffered by mild (34.51% or 49 individuals) and moderate (31.69% or 45 individuals). The severe dental fluorosis was recorded in only 16 individuals (11.27%). The dental; fluorosis characterized by light yellow to brown black horizontal lines on teeth surface edges chipped of edges.

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## 5. RECOMMENDATIONS

- Analyzation Dental pharmaceutical market and focus on use of dental products
- Fluoride mitigation and using dental products based on pharmaceutical market trend of a dental products
- Using Water harvesting systems
- Change in dietary habits Of people in the sample area
- Implementing suggestive Defluoridation techniques

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