Pharmaceutical Glass Interactions: A Review of Possibilities

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Abstract

Glass is used as packaging material for parenteral formulation from years. Various untoward occurrences have observed over the period of time with glass containers which leads to therapeutic failures or even toxicity to the patients. Glass has been the primary choice for packaging of parenteral formulations, unexpected degradation or product losses during stability have forced many researchers to evaluate the underlying mechanisms leading to a larger understanding of some of the untoward properties of glass. Oxides of various metal ions viz. aluminium, arsenic, barium, iron etc. are added in glass to modify its physico-chemical properties based on specific requirements. Metal ions could leach from the glass structure due to several reasons and could lead to generation of particulate matter, could cause metal ion toxicity or act as catalyst to hasten drug degradation. Delamination or formation of glass flakes is one of the major problems currently under high scrutiny by the regulators. Similarly, some molecules have an affinity to adsorb to glass leading to a low potency in the administered drug. Interaction between glass and drug product depends upon composition/type of glass, processing of glass and formulation variables such as pH, buffer, properties of drug, sterilization cycles, storage conditions etc. This review describes several possible means of interaction of glass and drug product encountered by researchers under a gamut of conditions.

Keywords: Glass, delamination, leachables and extractables, particulate matter.

Abbreviations:

Al (aluminium), As (arsenic), Ba (barium), Fe (iron), Ca (calcium), Mg (magnesium), Mn (manganese), Si (silica), SiO_2 (silicon dioxide), B_2O_3 (boron oxide), P_2O_5 (phosphorus oxide), GeO_2 (germanium oxide), Fe_2O_3 (Ferric oxide), Ti_2O_3 (titanium oxide), MnO (manganese oxide), NaCl (sodium chloride), KCl (Potassium chloride), $MgCl_2$ (magnesium chloride), $ZnSO_4$ (zinc sulphate), ETAAS (electrothermal atomic absorption spectroscopy), AAS (atomic absorption spectroscopy), SEM (scanning electron microscopy), SEM/EDX (scanning electron microscopy with energy dispersive X-ray spectroscopy), EDX (energy dispersing X-ray analysis), FDA (Food and Drug Administration), ICP-OES (inductively coupled plasma optical emission spectrometry).

INTRODUCTION

Wide ranges of packaging material are being used for different types of dosage forms. Selection of packaging material mainly depends on:

- Type of dosage form
- Mode of application
- Physico-chemical properties of formulation being packed into
- Physico-chemical properties of material being used for packaging

Regulatory requirements also vary with the intended application of the drug product like for e.g., packaging for parenteral products poses stringent regulatory requirements since sterility is a major concern there [1]. FDA also recommends specific quality controls and requirements of packaging components based on intended use of dosage forms. Glass containers have been widely used for packing of parenteral preparations since many years.

Glass containers are widely used in pharmaceutical industry but cannot be considered completely inert. Various interactions could arise when products come in contact with glass surfaces including leaching, ion exchange, precipitation, glass dissolution, surface layer exfoliation, and corrosion [2].

Various authors have reported different potential leachables from glass containers and effect of formulation and process factors on total leachables. The purpose of this article is to present a consolidated review of such reported interactions of glass with the drug product leading to a stability challenge and/or a potential or obvious toxicity to the patient.

Glass: As pharmaceutical packaging component

Commercial glasses are an inorganic material (mostly silicates) or mixture of materials that have been heated to a molten liquid state then cooled without crystallization to a solid state. Several metallic oxides have the property to cool without crystallization, e.g. SiO_2, B_2O_3, P_2O_5 and GeO_2. These oxides are used as backbone in glass. SiO_2 is the most commonly used oxide including containers for sterile dosage forms [3].

Mechanism of glass formation

Silicate glasses are made up of SiO_4 (tetrahedral form of Si), in which each Si atom attached with four oxygen atoms and each oxygen has bonding with two Si atoms via covalent bonds. Due to this type of 3-D arrangement and spatial interactions, viscosity of the melted silicates increase rapidly during cooling phase which do not allow the transition from random structure of liquid state to ordered crystalline structure [3, 4].

Types Of Glass

Various minerals are added to improve the industrial feasibility and physical properties of the glass. Based upon

the minerals which are incorporated, glass families are broadly classified into two [5, 6]:

A. **Soda-lime-silicate glasses or Soda-lime glasses**

In this type of glass, soda ash (sodium carbonate) and lime stone (calcium carbonate) are added as a source of sodium oxide and calcium oxide respectively to modify the properties. These comprise of 25% by weight. Magnesium and potassium may be used as their oxides to reduce the melting point. Soda-lime glass has poor chemical resistance because of chances of leaching of mobile nature of sodium and potassium cations.

Al_2O_3 is added to improve chemical durability of the glass because Al^{+3} ions are able to form covalent bonds and hence, more resistant to leaching. Fe_2O_3 is added to provide light protection. It absorbs ultraviolet wavelengths more effectively than colourless glass [3].

B. **Borosilicate glasses**

B_2O_3 is used in replacement of some sodium and Ca ions. Borosilicate glasses have exceptional chemical durability, high heat resistance- including resistance to sudden temperature changes and thermal shock. Borosilicate glasses are most commonly used for parenteral containers due to its high resistance to thermal processes including depyrogenation, lyophilization and terminal sterilization and low alkali extractable. Fe_2O_3 and Ti_2O_3 or MnO can be added to produce amber borosilicate glasses for protection from ultraviolet light.

Mechanism Of Interaction Of Glass With Product

A. **Ion exchange**

Ion exchange is the most important mechanism of interaction between glass and product. Na+ ions which are present in glass can be replaced by the H_3O^+ ions of the solution. This reaction is dominant in neutral and acidic solutions.

B. **Attack on glass by reactive groups**

Hydroxyl groups and alkaline species present in product as well as glass itself can attack the glass leads to breaking of Si-O bonds. This reaction depends upon various factors like glass formulation, pH of product, ingredients of product etc. e.g. chelating agents are more aggressive toward glass because they are able to pull the various metal ions out of the surface. It means guidelines for selection of glass for parenteral products based on pH alone are not sufficient.

C. **Additional mechanisms**

Process involved in manufacturing of containers has effect on composition and physico-chemical parameters of the surface. e.g. during manufacturing of ampules and vials, the temperature of inner surface can exceed the boiling point of low boiling point ingredients, mainly sodium and boron. During cooling, they could condense as sodium borate. Complete removal of sodium borate from containers may not be possible during washing of containers. This alkaline residue can again affect the product by three mechanisms:

Firstly, this alkaline residue may react directly with product. Secondly, exchange of Na^+ ions with H_3O^+ ions, loss of H_3O^+ ions in the solution can increase the pH of product. Thirdly, in extreme cases, the interaction can trigger the formation of an unstable layer of silica gel which can slough off as delaminated glassy particles

Irrespective of the type, all glasses have the potential to leach alkali related components into the product upon storage which may affect the stability of that product and this varies depending on storage conditions, type of glass used for the storage, type and nature of the product being stored. There is high probability of more leachable content coming into the product at higher pH i.e., pH > 9. Most common extractables from glass includes silicon, sodium, and boron which take major part in contamination and/ or degradation of drug product [4].

Despite of the presence of various inorganic leachables viz. Al, Si, B, Ba ions etc. and interaction with different buffers viz. acetate, citrate, phosphate etc. glass is most widely used packaging material for parenteral formulations. Glasses can be modified by various techniques to better suit the formulation like amber colour glass for photo sensitive drugs. Selection of glass and the type of modification depends upon the formulation and storage.

Some researchers showed that elements of the drug and formulation variables like pH, buffers etc. causes degradation of glass, ultimately contaminating the product which leads to adverse effects in patients. Amount of various ions which could leach in the formulation varies depending upon the affinity of drug and (or) excipients for specific ions.

In this paper, we have broadly classified major probable mechanisms of drug product contamination by glass into 4 categories:

A. Glass delamination
B. Metal ions interaction
C. Interaction with buffers
D. Adsorption of drug(s) or formulation components on glass surfaces

A. Glass delamination or generation of glass flakes

Glass delamination or generation of glass flakes is a major concern with parenteral products that use glass vials for their storage and these glass flakes may or may not be visible for direct inspection and the products which contain these glass particles when injected directly may lead to embolic, thrombotic and other vascular events [7]. Possible reasons contributing to glass delamination is [8, 9]: (i) Differences in manufacturing process of glass vials i.e., moulding or formation from glass tubing - higher chance of delamination is associated with vials produced by tubing process due to the utilization of higher temperatures during production. (ii) Nature of formulation being stored - Alkaline and certain buffer solutions (citrate and tartrate) have higher tendency to aggravate the process of delamination (iii) terminal sterilization process (iv) Presence or absence of ammonium sulfate coating on inner surface of glass vials where the treatment with sulfur enhances the chances of delamination (iv) Storage duration and storage conditions - Storage at room temperature is believed to have higher chance of glass delamination over cold storage conditions.

Glass manufacturing process differences and the nature of product seem to be the most dominant factors that enhance glass delamination characterized by pH changes, active moiety degradation, formation of visible particles and

increased extractable levels ultimately affecting the product quality adversely.

Ronald, *et al.,* investigated the delamination/corrosion of glass by a pharmaceutical product having pH of 8.2. Authors have used three type-I borosilicate glass vials from two different vendors of which two vials (ammonium sulfate treated and the other one un-treated) were kept in contact with the product with pH of 8.2 and the remaining were used as a control. Vials were stored under 2 different temperature conditions 40°C and 30°C. Visible particulate matter was observed in vials contained product after 30 days and 8 weeks of storage at 40°C and 30°C respectively. The particulate matter was found to be glass as identified using field-emission environmental SEM equipped with X-ray analysis capabilities [9].

Richard, *et al.,* investigated the effect of formulation and process variables on the delamination process. They also studied the impact of the glass manufacturing process, supplier, and glass surface treatment on delamination process. They used Type 1 borosilicate tubing vials from 3 different suppliers (total 18 lots) and studied the effect of formulation pH and moist heat terminal sterilization on delamination. They filled glass vials with Vistide® Injection (75 mg/mL cidofovir in Water for Injection, USP) and to study the impact of pH, solutions pH were adjusted to pH 6.0, 7.0, 7.4, 8.0, and 8.5 with sodium hydroxide or hydrochloric acid. The filled vials were subjected to either one or three sterilization cycles (123°C for 19 min) following which the vials were charged on stability at 25°C, 30°C (real-time storage condition) and 40°C (accelerated testing condition). They monitored the delamination by visual inspection, particulate matter quantification, light obscuration and microscopic methods. Vials that were stored at 40°C after autoclaving showed the presence of glass particles which could be visually seen and increased amounts of the same was seen with prolonged storage time, increasing pH, sulfate treatment and higher number of sterilization cycles. At the same time, differences in the behaviour were observed between suppliers and presence or absence of sulfur coating. Real time stability data indicated that presence or absence of visible glass particles mainly depends on glass type from various suppliers due to differences in processing conditions and composition of the glass. Visible particles were found to be containing silicon dioxide and sodium which are major components of type-I glass as determined by SEM/EDX [10].

Ronald, *et al.,* investigated the factors contributing to delamination which was demonstrated using hippuric acid, glutaric acid and pemexetred and three type-I borosilicate glass vial types. The vial types studied were ammonium sulfate coated on its inner surface from one vendor, and other two vials sourced from different vendors where one vial type was uncoated and other type contained silicon dioxide coating. Empty vials were initially subjected for depyrogenation at 250°C, and 350°C followed by filling and sterilization of the filled vials by no or two terminal sterilization cycles at 122-125°C for 15min. The vials posts the treatments were stored at 5°C, 25°C, 40°C, and 60°C. pH measurements showed a decrease in pH values compared to initial high pH values (>8) and this decrease in pH was prominent at higher storage temperatures, the authors concluded that the drop in pH values was not because of degradation of test solution but because of degradation of glass itself. ICP-OES analysis revealed the presence of higher amount of Si in vials with ammonium sulfate treatment than that of silicon dioxide treated vials followed by uncoated vials. Presence of higher amount of Si in the test solutions is indicative of loss of glass durability or onset of glass delamination which may lead to formation of particulate matter or glass flakes. The authors have finally attributed the delamination to higher pH of product and anionic nature of test solutions at this higher pH [11].

Bisphosphonate dosage forms, e. g. Zoledronic acid solution can be administered intravenously as an infusion. These biphosphonate dosage forms are highly sensitive to di-and polyvalent cations, especially Ca, Ba, magnesium, Al, boron, and silicon which are present in glass composition. Precipitate formation can be seen as a result of reaction between them which affect the quality of the final product and may cause severe toxicological problems. Formation of precipitation can be seen upon longer contact time of product with glass during storage or during terminal sterilization since sterilization process could enhance the leaching of metal ions from the glass containers. There are some marketed formulations which are lyophilized products of bisphosphonates that needed reconstitution before use where chances of precipitation are not absent because of presence of trace levels of metal ion impurities in saline solutions for infusion preparation.

Alexandra, *et al.,* took a step to address the current issue and invented a container that contains polymeric coating internally which is resistant towards the bisphosphonate drug solution. Moreover, the bottle itself can be terminally sterilized by which bisphosphonate drug solutions can be stored for prolonged time periods [12].

B. Metal ions interaction

Apart from delamination of glass surfaces, another important mechanism of drug product deterioration involves interaction with metal ions. Various metal oxides are added in glass during manufacturing process to impart physical and chemical properties. These metal ions including Al, As, Ba, Fe etc. have tendency to leach out and attack the product. Some important metal ion interactions are discussed here.

Aluminium

Al is the third most abundant mineral on earth and found in almost every animal and plant. It has been reported that most adults ingest between 3 and 5 mg Al daily which gets excreted in urine. However, Al is a body constituent; it is toxic if ingested in higher amount. Al toxicity was first reported in patients with chronic renal failure. Clinical manifestations include impaired bone growth in adults and delays in metal development in neonates. Parenteral nutrition is a considerable source of Al. Therefore, in July 2004, the FDA mandated manufacturers to include amount of Al in label. Limit of Al for large volume parenterals should be not more than 25 µg/L, for small volume

parenterals the label should state the potential maximum amount at expiry of the product. In cases where Al intake is more than 4–5 µg/kg/d in patients with impaired renal function, together with premature neonates, the label should include a warning that they may experience central nervous system and bone toxicity [13-15].

Al can easily get eliminated through urine however higher levels of Al pose significant risk problems to one's body like bone growth impairment in patients with renal impairment and delayed mental development in neonates since the renal system is underdeveloped in neonates [13].

Al is a compositional part of glass and added during its manufacture as aluminium oxide and sometimes this may get leached into the product which is being stored in it and can contaminate the product. Few studies report the presence of Al in parenteral nutrition due to storage in glass containers. Content of Al increases with storage time and also depends on the nature of the substance in contact like, heparin and albumin. Product pH values at extremes also adversely affect the Al release.

Bohrer, *et al.,* evaluated the amount of Al leached in parenteral nutrition containing amino acids. They used 19 amino acids and commercial nutrition formulation to check the effect of binding of amino acids from Al of glass material. They stored solutions of amino acids in type II glass flasks and Al content was measured periodically for 400 days by ETAAS. They concluded that the contamination with Al was observed with cysteine, cystine, aspartic acid and glutamic acid only. Leaching of Al from glass because of amino acids mainly depends upon stability of formed Al- amino acid complex i.e., higher the stability of complexes higher the ability of amino acids to release Al [16].

Toru, *et al.,* studied the release of Al from borosilicate glass vials and the effect of different buffers like phosphate, citrate, acetate and histidine buffer at different pH on the release behaviour and precipitation of Al. The vials containing different buffer solutions showed the presence of Al and Si upon heating at any pH which demonstrated the ability of all buffers in extracting out the Al from glass containers and which depended upon concentration of solution, time of contact and storage temperature. Higher amounts of Al and Si were observed in glass vials with citrate buffer and in comparison to this lower amounts were observed with phosphate, acetate and histidine buffers. Upon storage particle formation was observed in phosphate and acetate buffers while no particulate matter was seen with citrate buffer which was attributed to its chelating property. This was supported by the reduction in Al content in phosphate, acetate and histidine buffer upon addition of Al ions during storage. At the end, the authors concluded that the possibility of formation of Al containing particles was much higher in phosphate buffer in comparison to other buffer solutions [17].

In an interesting study by Toru, *et al.,* authors have investigated the characteristics of inorganic particles formed in phosphate buffer filled glass vials. Upon storage of the glass vials (which are compendially recommended for injectable products) filled with phosphate buffer, visible particles were seen and authors deliberated these particles to be different from delamination of glass. The particles comprised majorly of Al, P and O, however these particles were devoid of Si. With raise in temperature of the solution, particulate formation increased, these vials upon storage showed decreased amount of Al upon storage at 5°C for 6 months indicating the presence of Al in particles formed in the solution. Upon addition of Al chelating agent i.e., citrate there was effective reduction in the formation of the particles indicated the presence of interaction between leached Al from glass vials and phosphate buffer in the vials. This was further evidenced by the formation of white particles upon addition Al ions at concentration of more than 50ppb to the phosphate buffer. Sulfur treatment of inner surface of glass bottles provides a good mean to reduce the particle formation. Thus, great care needs to be taken for the storage of dosage forms containing phosphate buffer in glass containers [18].

Bohrer, *et al.,* studied how the nature of substance can affect the Al release from glass containers. They evaluated the pharmaceutical products for parenteral use containing salts (sodium and potassium chlorides), glucose, heparin and albumin. All products were stored in glass and plastic containers. Al content was determined in glass as well as plastic containers at different storage time by AAS. They found that glass was the major contributor to Al content. Besides, Al contamination highly depended on the nature of substance which was in contact with glass surface. Table 1 shows the content of Al extracted by different substances after 60 days of storage [19].

Table 1. Al extracted by various substances after 60 days of storage

S.No.	Substance	Al content (µg/L)
1.	Salts	400
2.	Glucose	150
3.	Albumin	500
4.	Heparin	500

They found that all products stored in plastic containers contained not more than 20 µg/L of Al whereas in glass Al content reached 1000 µg/L and all of them showed an increase in Al content with age.

In another study, Bohrer, *et al.,* evaluated the interaction of container and chemicals with glass container during heat sterilization. They stored 30 commercial solutions for parenteral nutrition in glass ampoules, in contact with rubber stopper and plastic container. All containers were subjected to heat at 121 °C for 30 minutes and Al content was determined. They found Al content of 1.57% in glass, 0.05% in plastic and 4.54% in rubber. Also, total Al released depended on the interaction of chemicals and containers. Various substances showed different Al content with glass ampoules and rubber stoppers and the data was shown in Table 2 [20].

They concluded that interaction of glass with chemicals (salts, acids and alkalis) could be explained by ion exchange properties, effect of formulation pH and affinity of chemicals especially amino acids for Al [20].

Table 2. Value of Al content in different products stored in contact with glass ampoules and rubber stopper

S.No.	Substances	Container	Al content (µg/L)
1	Leucine, ornithine and lysine solutions	Glass ampoules	20
2	Solutions of basic phosphates and bicarbonate	Glass ampoules	1500
3	Cysteine, aspartic acid, glutamic acid and cystine solutions	Rubber stoppers	500

Based on available literature it is clear that glass can be a source of Al when products are being stored in glass containers but the extent of contamination may vary depending upon the type of product e.g. liquid form or powder form.

Marlei, *et al.,* investigated the Al contamination in liquid and lyophilized forms of Erythropoietin which were contained in glass bottles sealed with rubber closures. The authors have found that glass and rubber were the sources of Al contamination after storage of formulation in contact with glass as well as rubber at 4 ± 2°C. As determined by atomic absorption spectrometry, higher Al contamination was found in glass vials with liquid formulation as compared to glass vials containing lyophilized form of the product. When stored in liquid form citrate and phosphate buffers extracted most of the Al present as contamination. The fact that glass container is a source of Al contamination can be supported by 19-fold increase in Al contamination after reconstitution in the same vials in 12 months as compared with the contamination before reconstitution. Moreover Al contamination after one month of reconstitution of lyophilized form is more than the contamination in lyophilized form after storage for 2 years in glass vials. The authors have concluded that lyophilized form of erythropoietin is preferred over its solution form for patients with chronic kidney disease [21].

Nakamura, *et al.,* studied minodronic acid formulations having different compositions and their stability and tendency to generated particles upon storage at 60°C for 4 weeks. Upon characterization, the formed precipitate was found to be a complex between minodronic acid and Al ions apparently leached from the glass of the ampoules. The best protection in terms of stability as well as inhibition of particulate matter was afforded to formulations buffered by citric acid and tartaric acid, citrate buffer was better amongst the two particularly providing optimal results at a solution pH of 3 to 5 where no particulate generation was observed [22].

Further, the same authors demonstrated that a liquid formulation containing 0.5 mg/ml minodronic acid, 40 mM, pH 4.5, citrate, and sodium chloride stored in flint glass ampoules at 25, 40, 50, and 60 degrees C showed particulate matter generation at 25C but not at higher temperatures. Analysis of the particulate matter by SEM/EDX revealed that the particulate matter contained Al and phosphorus. Storage in plastic containers and SiO_2-treated glass ampoules did not show the rise in number of the particulate matter. A spike of minodronic acid solution with Al ions led to the particulate generation proving the interaction of minodronic acid molecules and Al ions to form a complex and resulting in particulate matter. Regular ampoules were found to be the source of leached Al [23].

Arsenic

Transparency is one of the great properties which make glass suitable for packaging and storage of many of pharmaceutical products mainly in case of parenteral dosage forms. To make glass more transparent fining agents like arsenic oxide (III) may be added. This added arsenic oxide may get released out of glass into the product which is being stored under certain conditions like sterilization temperature and nature of substance. Released As can contaminate the product and upon intravenous administration it severely induces the toxic effects like skin ulceration, skin cancer, mucosal membrane damage, keratosis etc. [24]. Allowable limit of As species in products for IV administration should be less than or equal to 0.1 mg/L.

Bohrer, *et al.,* in a study investigated the release of As (both As(V) and As(III)) from glass containers by action of intravenous nutrition formulation constituents after heating the ampoules at 121°C for 30min using hydride generation atomic absorption spectrometry (HG AAS). Before heating the ampoules containing nutrition formulation, As content of both the substances used in formulation as well as glass ampoules was determined and the results showed the presence of As (V) in higher amount in glass than As (III). This study indicated that during heating As is getting released from the glass containers and the solution composition decides the type and amount of As species getting released. Ampoules containing water for injection and solutions of NaCl, KCl, phosphates indicated the presence of As(V) only whereas ampoules containing amino acids, glucose, gluconate and vitamins showed higher concentration of As(III) since these can reduce the As(V) to As(III) due to their reducing behaviour [25].

Bohrer, *et al.,* evaluated the presence of different As species (arsenite and arsenate) in several of the commercial parenteral formulations that included solutions of amino acids, salts, vitamins, and lipids and the measurements of As species were done using hydride generation atomic absorption spectrometry and results of which showed the presence of As in both the forms in all formulations. Presence of higher As contamination with varied ratios of As(V)/As(III) was evidenced in Calcium gluconate, sodium bicarbonate, heparin, and vitamin solutions. Interestingly the vials with water for injection and salt solutions showed only the presence of As(V) species but the ones with solutions of vitamins, gluconate, and glucose showed As(III) primarily the reason being the conversion of As(V) to As(III) since these sugars are reducing in nature. Evidence of the phenomenon was demonstrated by complete absence of As (III) in pure water and sodium chloride solution upon autoclaving for 15 minutes and occurrence of the same predominantly in solutions with reducing substances upon autoclaving [26].

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