[0004] Although Type IA and Type IB glass compositions are commonly used in pharmaceutical packages, they do suffer from several deficiencies, including a tendency for the inner surfaces of the pharmaceutical package to shed glass particulates or "delaminate" following exposure to pharmaceutical solutions.

[0005] In addition, use of glass in pharmaceutical packaging may also be limited by the mechanical performance of the glass. Specifically, the high processing speeds utilized in the manufacture and filling of glass pharmaceutical packages may result in mechanical damage on the surface of the package, such as abrasions, as the packages come into contact with processing equipment, handling equipment, and/or other packages. This mechanical damage significantly decreases the strength of the glass pharmaceutical package resulting in an increased likelihood that cracks will develop in the glass, potentially compromising the sterility of the pharmaceutical contained in the package or causing the complete failure of the package.

[0006] Accordingly, a need exists for alternative glass containers for use as pharmaceutical packages which exhibit a combination of at least two of improved resistance to delamination, increased strength, and/or damage tolerance.

SUMMARY

[0006a] In one aspect, there is provided a delamination resistant glass pharmaceutical package comprising:

a glass body formed from a borosilicate Type 1 Class A or B glass composition according to ASTM Standard E438-92, the glass body having a wall portion with an inner surface and an outer surface;

the glass body has at least a class A2 base resistance or better according to ISO 695, at least a Type HGB2 hydrolytic resistance or better according to ISO 719 and Type 1 chemical durability according to USP <660>;

an interior region extending from 10nm below the inner surface and having a persistent layer homogeneity; and

a surface region extending over the inner surface and having a persistent surface homogeneity such that the glass body is resistant to delamination.

[0006b] In another aspect, there is provided a delamination resistant glass pharmaceutical package comprising:

a glass body formed from an ion-exchangeable borosilicate Type 1 Class A or B glass composition according to ASTM Standard E438-92, the glass body having a wall portion with an interior surface and an exterior surface having a thickness with a mid-point therebetween;

the glass body has at least a class A2 base resistance or better according to ISO 695, at least a Type HGB2 hydrolytic resistance or better according to ISO 719 and Type 1 chemical durability according to USP <660>;

an interior region extending from 10 nm below the interior surface of the glass body into a thickness of the glass body and having a thickness T_{LR} of at least 100 nm, wherein an extrema in a layer concentration of each constituent component of the glass composition in the interior region is within ±20% of the same constituent component in the glass composition at the mid-point of the thickness the glass body when the glass body is in an as-formed condition; and

a surface region extending over the entire interior surface of the glass body to a depth of 10 nm from the interior surface of the glass body, wherein, for a discrete point on the interior surface of the glass body, an extrema of a surface concentration of each constituent component in the surface region at the discrete point is within ±30% of a same constituent component in the surface region at any second discrete point on the interior surface of the glass body when the glass body is in an as-formed condition.

[0006c] In another aspect, there is provided a method for forming a delamination resistant glass pharmaceutical package comprising:

providing stock material formed from a borosilicate Type 1 Class A or B glass composition according to ASTM Standard E438-92 having at least a class A2 base resistance or better according to ISO 695, at least a Type HGB2 hydrolytic resistance or

better according to ISO 719 and Type 1 chemical durability according to USP <660>; and

shaping the stock material into the delamination resistant glass pharmaceutical package having a glass body having a wall portion with an interior surface and an exterior surface having a thickness with a mid-point therebetween such that the glass body has an interior region extending from 10 nm below the interior surface of the glass body into the thickness of the glass body, the interior region having a persistent layer homogeneity such that the glass body is resistant to delamination.

[0006d] In another aspect, there is provided a delamination resistant glass pharmaceutical package comprising:

a glass body formed from a borosilicate Type 1 Class A or B glass composition, the glass body having a wall portion with an interior surface and an exterior surface having a thickness with a mid-point therebetween and comprising a wall portion that transitions to a floor portion through a heel portion;

the glass body has at least a class A2 base resistance or better according to ISO 695, at least a Type HGB2 hydrolytic resistance or better according to ISO 719 and Type 1 chemical durability according to USP <660>; and

a surface region comprising a heel portion and having a depth extending from the interior surface of the glass container into the thickness of the glass body, the surface region having a persistent surface homogeneity such that the surface region is resistant to delamination.

[0007] According to a first example, a glass container may include a body having an inner surface, an outer surface and a wall thickness extending between the outer surface and the inner surface. At least the inner surface of the body may have a delamination factor less than or equal to 10. A tenacious inorganic coating may be positioned around at least a portion of the outer surface of the body. The outer surface of the body with the tenacious inorganic coating may have a coefficient of friction less than or equal to 0.7.

[0008] In another example, a glass container may include a body having an inner surface, an outer surface and a wall thickness extending between the outer surface and the inner surface. At least the inner surface of the body may have a delamination factor less than or equal to 10. A transient coating may be positioned around at least a portion

CLAIMS

1. A delamination resistant glass pharmaceutical package comprising:

a glass body formed from a borosilicate Type 1 Class A or B glass composition according to ASTM Standard E438-92, the glass body having a wall portion with an inner surface and an outer surface;

the glass body has at least a class A2 base resistance or better according to ISO 695, at least a Type HGB2 hydrolytic resistance or better according to ISO 719 and Type 1 chemical durability according to USP <660>;

an interior region extending from 10nm below the inner surface and having a persistent layer homogeneity; and

a surface region extending over the inner surface and having a persistent surface homogeneity such that the glass body is resistant to delamination.

2. The delamination resistant glass pharmaceutical package of claim 1, wherein the interior region has a thickness T_{LR} of at least 100 nm.

3. The delamination resistant glass pharmaceutical package of claim 1, wherein a depth of the interior region is at least 10 nm.

4. The delamination resistant glass pharmaceutical package of claim 1, wherein a depth of the interior region is at least 50 nm.

5. The delamination resistant glass pharmaceutical package of claim 1, wherein the glass body is formed at a temperature greater than or equal to 1100^{o}C and less than or equal to 1650^{o}C.

6. The delamination resistant glass pharmaceutical package of claim 1, wherein the glass body is formed under processing conditions which mitigate vaporization of volatile species in the glass.

7. The delamination resistant glass pharmaceutical package of claim 1, wherein the glass body is formed under processing conditions which impart a substantially uniform temperature history to the inner surface.

8. The delamination resistant glass pharmaceutical package of claim 1, wherein the homogeneity of the glass body is determined by dynamic secondary ion mass spectroscopy.

9. The delamination resistant glass pharmaceutical package of claim 1, wherein the glass body is formed from a glass composition which is not phase separated.

10. The delamination resistant glass pharmaceutical package of claim 1, wherein the glass body is ion-exchange strengthened.

11. The delamination resistant glass pharmaceutical package of claim 1, wherein the glass body has a delamination factor less than or equal to 10.

12. The delamination resistant glass pharmaceutical package of claim 1, wherein:

the surface region extends over an interior surface of the glass body to a depth from 10 nm to 50 nm from the interior surface of the glass body; and

for a discrete point on the interior surface of the glass body, an extrema of a surface concentration of each constituent component of the glass in the surface region at the discrete point is greater than or equal to 70% and less than or equal to 130% of a same constituent component in the surface region at any second discrete point on the interior surface of the glass body when the glass body is in an as-formed condition.

13. The delamination resistant glass pharmaceutical package of claim 1, wherein:

the interior region extends from 10 nm below the interior surface of the glass body into the thickness of the glass body and having a thickness T_{LR} of at least 100 nm, wherein an extrema in a layer concentration of each constituent component of the glass composition in the interior region is greater than or equal to 80% and less than or equal to 120% of a same

constituent component in the glass composition at a mid-point of the thickness of the glass body when the glass body is in an as-formed condition.

14. The delamination resistant glass pharmaceutical package of claim 12, wherein:

the interior region extends from 10 nm below the interior surface of the glass body into the thickness of the body and having a thickness T_{LR} of at least 100 nm, wherein an extrema in a layer concentration of each constituent component of glass composition in the interior region is greater than or equal to 80% and less than or equal to 120% of a same constituent component in the glass composition at a mid-point of a thickness of the glass body when the glass body is in an as-formed condition.

15. A delamination resistant glass pharmaceutical package comprising:

a glass body formed from an ion-exchangeable borosilicate Type 1 Class A or B glass composition according to ASTM Standard E438-92, the glass body having a wall portion with an interior surface and an exterior surface having a thickness with a mid-point therebetween;

the glass body has at least a class A2 base resistance or better according to ISO 695, at least a Type HGB2 hydrolytic resistance or better according to ISO 719 and Type 1 chemical durability according to USP <660>;

an interior region extending from 10 nm below the interior surface of the glass body into a thickness of the glass body and having a thickness T_{LR} of at least 100 nm, wherein an extrema in a layer concentration of each constituent component of the glass composition in the interior region is within ±20% of the same constituent component in the glass composition at the mid-point of the thickness the glass body when the glass body is in an as-formed condition; and

a surface region extending over the entire interior surface of the glass body to a depth of 10 nm from the interior surface of the glass body, wherein, for a discrete point on the interior surface of the glass body, an extrema of a surface concentration of each constituent component in the surface region at the discrete point is within ±30% of a same constituent component in the surface region at any second discrete point on the interior surface of the glass body when the glass body is in an as-formed condition.

16. The delamination resistant glass pharmaceutical package of claim 15, wherein the extrema in the layer concentration of each constituent component in the interior region is greater than or equal to 90% and less than or equal to 110% of a bulk concentration of the same constituent component at the mid-point.

17. The delamination resistant glass pharmaceutical package of claim 15, wherein the extrema of the surface concentration of each constituent component of the glass in the surface region at the discrete point is greater than or equal to 85% and less than or equal to 115% of a same constituent component in the surface region at any second discrete point on the interior surface when the glass body is in an as-formed condition.

18. The delamination resistant glass pharmaceutical package of claim 15, wherein the glass body has a delamination factor less than or equal to 10.

19. The delamination resistant glass pharmaceutical package of claim 15, wherein the glass body is formed under processing conditions which mitigate vaporization of volatile species in the glass.

20. The delamination resistant glass pharmaceutical package of claim 15, wherein the glass body is formed under processing conditions which impart a substantially uniform temperature history to the interior surface.

21. The delamination resistant glass pharmaceutical package of claim 15, wherein the glass body is formed from a glass composition which is not phased separated.

22. A method for forming a delamination resistant glass pharmaceutical package comprising:

providing stock material formed from a borosilicate Type 1 Class A or B glass composition according to ASTM Standard E438-92 having at least a class A2 base resistance or better according to ISO 695, at least a Type HGB2 hydrolytic resistance or better according to ISO 719 and Type 1 chemical durability according to USP <660>; and

shaping the stock material into the delamination resistant glass pharmaceutical package having a glass body having a wall portion with an interior surface and an exterior surface having a thickness with a mid-point therebetween such that the glass body has an interior region extending from 10 nm below the interior surface of the glass body into the thickness of the glass body, the interior region having a persistent layer homogeneity such that the glass body is resistant to delamination.

23. The method of claim 22, wherein the stock material is shaped such that the glass body further comprises a surface region extending over an entire interior surface of the glass body to a depth of 10 nm from the interior surface of the glass body and the surface region has a persistent surface homogeneity such that the glass body is resistant to delamination.

24. The method of claim 22, wherein the stock material is shaped under processing conditions which mitigate vaporization of volatile species in the glass.

25. A delamination resistant glass pharmaceutical package comprising:

a glass body formed from a borosilicate Type 1 Class A or B glass composition, the glass body having a wall portion with an interior surface and an exterior surface having a thickness with a mid-point therebetween and comprising a wall portion that transitions to a floor portion through a heel portion;

the glass body has at least a class A2 base resistance or better according to ISO 695, at least a Type HGB2 hydrolytic resistance or better according to ISO 719 and Type 1 chemical durability according to USP <660>; and

a surface region comprising a heel portion and having a depth extending from the interior surface of the glass container into the thickness of the glass body, the surface region having a persistent surface homogeneity such that the surface region is resistant to delamination.