Status: Currently Official on 13-Feb-2025
Official Date: Official as of 01-Jun-2023
Document Type: USP Monographs
DocId: GUID-836A46DC-3D22-4F43-A483-570C812FD5A6_4_en-US
DOI: https://doi.org/10.31003/USPNF_M2355_04_01
DOI Ref: fb7ig

Aluminum Zirconium Octachlorohydrate

$Al_yZr(OH)_{3y+4-x}Cl_x \cdot nH_2O$

» Aluminum Zirconium Octachlorohydrate is a polymeric, loosely hydrated complex of basic aluminum zirconium chloride that encompasses a range of aluminum-to-zirconium atomic ratios between 6.0:1 and 10.0:1, and a range of (aluminum plus zirconium)-to-chloride atomic ratios between 1.5:1 and 0.9:1. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of anhydrous aluminum zirconium octachlorohydrate.

Packaging and storage—Preserve in well-closed containers.

Labeling—The label states the content of anhydrous aluminum zirconium octachlorohydrate.

Identification—A solution (1 in 10) responds to the test for *Chloride* ⟨191⟩.

pH ⟨791⟩: between 3.0 and 5.0, in a solution [15 in 100 (w/w)].

Change to read:

▲**Arsenic** ⟨211⟩, *Procedures, Procedure 1*▲ (CN 1-Jun-2023): 2 µg per g.

Change to read:

Limit of iron—

Standard preparation—Transfer 2.0 mL of *Standard Iron Solution*, prepared as directed under ▲*Iron* ⟨241⟩, *Procedures, Procedure 1*▲ (CN 1-Jun-2023), to a 50-mL beaker.

Test preparation—Transfer 2.7 g of Aluminum Zirconium Octachlorohydrate to a 100-mL volumetric flask, dilute with water to volume, and mix. Transfer 5.0 mL of this solution to a 50-mL beaker.

Procedure—To each of the beakers containing the *Standard preparation* and the *Test preparation* add 5 mL of 6 N nitric acid, cover with a watch glass, and boil on a hot plate for 3 to 5 minutes. Allow to cool, add 5 mL of *Ammonium Thiocyanate Solution*, prepared as directed under *Iron* ⟨241⟩, transfer to separate 50-mL color comparison tubes, dilute with water to volume, and mix: the color of the solution from the *Test preparation* is not darker than that of the solution from the *Standard preparation* (150 µg per g).

Content of aluminum—Transfer about 0.15 g of Aluminum Zirconium Octachlorohydrate, accurately weighed, to a 150-mL beaker, and add 5 mL of water and 15 mL of hydrochloric acid. Heat this solution to boiling, and continue boiling for 5 minutes. Add 40 mL of water and 15.0 mL of 0.1 *M* edetate disodium VS. Heat the solution to boiling, and continue boiling for 5 minutes. Allow the solution to cool, add 10 to 15 mL of acetic acid–ammonium acetate buffer TS, and adjust with ammonium hydroxide to a pH of 4.5 ± 0.1. Add 20 mL of alcohol, and adjust with ammonium hydroxide to a pH of 4.6 ± 0.1. Add 5 to 10 drops of dithizone TS, and titrate with 0.1 *M* zinc sulfate VS until the first permanent purple-pink color appears. Perform a blank determination, and make any necessary correction. Calculate the percentage of aluminum (Al) in the Aluminum Zirconium Octachlorohydrate by the formula:

$$2.698[15.0M_e - (zM_z + Z_e)]/W$$

in which M_e is the molarity of the edetate disodium VS; z is the volume, in mL, of zinc sulfate VS consumed; M_z is the molarity of the zinc sulfate VS; W is the quantity, in g, of Aluminum Zirconium Octachlorohydrate taken; Z_e is the equivalent volume, in mL, of edetate disodium VS consumed by the zirconium moiety, calculated as follows:

$$(Zr/M_e)(W/92.97)$$

in which *Zr* is the percentage of zirconium as determined in the test for *Content of zirconium*, 92.97 is the atomic weight of zirconium corrected for 2% hafnium content, and the other terms are as defined above. Use the result obtained to calculate the *Aluminum/zirconium atomic ratio* and the (*Aluminum plus zirconium*)/*chloride atomic ratio*.

Content of zirconium—Transfer about 250 mg of Aluminum Zirconium Octachlorohydrate, accurately weighed, to a 150-mL beaker, and add 5 mL of water and 15 mL of hydrochloric acid. Heat this solution to boiling, and continue boiling for 6 to 8 minutes. Add 30 to 40 mL of water and 5 mL of hydrochloric acid, and heat to boiling. Add 1 drop of xylenol orange TS, and, while still hot, titrate with 0.1 M edetate disodium VS until the color of the solution changes from pink to yellow. Perform a blank determination, and make any necessary correction. Each mL of 0.1 M edetate disodium is equivalent to 9.297 mg of zirconium (Zr). Use the result obtained to calculate the *Aluminum/zirconium atomic ratio* and the (*Aluminum plus zirconium*)/*chloride atomic ratio*.

Aluminum/zirconium atomic ratio—Divide the percentage of aluminum found in the test for *Content of aluminum* by the percentage of zirconium found in the test for *Content of zirconium*, and multiply by 92.97/26.98, in which 92.97 is the atomic weight of zirconium corrected for 2% hafnium content, and 26.98 is the atomic weight of aluminum: the ratio is between 6.0:1 and 10.0:1.

Content of chloride—Transfer about 250 mg of Aluminum Zirconium Octachlorohydrate, accurately weighed, to a 250-mL beaker, add 100 to 120 mL of water and 20 mL of diluted nitric acid, and swirl to dissolve. Titrate with 0.05 N silver nitrate VS using a calomel electrode and a silver billet electrode system, determining the endpoint potentiometrically. Each mL of 0.05 N silver nitrate is equivalent to 1.773 mg of chloride (Cl). Use the result obtained to calculate the (*Aluminum plus zirconium*)/*chloride atomic ratio*.

(Aluminum plus zirconium)/chloride atomic ratio—Calculate the (aluminum plus zirconium)/chloride atomic ratio by the formula:

$$[(Al/26.98) + (Zr/92.97)]/(Cl/35.453)$$

in which *Al*, *Zr*, and *Cl* are the percentages of aluminum, zirconium, and chloride as determined in the tests for *Content of aluminum*, *Content of zirconium*, and *Content of chloride*, respectively; 26.98 is the atomic weight of aluminum; 92.97 is the atomic weight of zirconium corrected for 2% hafnium content; and 35.453 is the atomic weight of chlorine: the ratio is between 1.5:1 and 0.9:1.

Assay—Calculate the percentage of anhydrous aluminum zirconium octachlorohydrate in the Aluminum Zirconium Octachlorohydrate by the formula:

$$Al(\{26.98y + 92.97 + 17.01[3y + 4 - (y + 1)/z] + 35.453(y + 1)/z\}/26.98y)$$

in which *Al* is the percentage of aluminum found in the test for *Content of aluminum*, *y* is the aluminum/zirconium atomic ratio found in the test for *Aluminum/zirconium atomic ratio*, *z* is the (aluminum plus zirconium)/chloride atomic ratio found in the test for (*Aluminum plus zirconium*)/*chloride atomic ratio*, 26.98 is the atomic weight of aluminum, 92.97 is the atomic weight of zirconium corrected for 2% hafnium content, 17.01 is the molecular weight of the hydroxide anion (OH), and 35.453 is the atomic weight of chlorine (Cl).

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
ALUMINUM ZIRCONIUM OCTACHLOROHYDRATE	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 27(4)

Current DocID: GUID-836A46DC-3D22-4F43-A483-570C812FD5A6_4_en-US
DOI: https://doi.org/10.31003/USPNF_M2355_04_01
DOI ref: fb7ig