



# Specification #078

Finished Product Specification: (packaged batches or Lot)

Date Issued: 7/13/11

Date Revised: 03/11/2026

Rev: 009

Approved by:  
Quality Control

*Roberts*

SDS Code: 1729

Product Name: Z-COTE LSA-UC (USP) / ZnO LSA

Lot # or Packaged Batch Number:

Retest Period 3 Years

Lot/Batch Size (Kg):

Retest Date:

Retain Sample Size (g):250

"#" indicates tests required for retest

| Test                                                                       | Spec.                   | Test method                                              | Result     | Analyst/Date |
|----------------------------------------------------------------------------|-------------------------|----------------------------------------------------------|------------|--------------|
| # Identification A                                                         | Passes USP              | Current USP                                              |            |              |
| # Identification B                                                         | Passes USP              | Current USP                                              |            |              |
| # Carbonate & color                                                        | Passes USP              | Current USP                                              |            |              |
| # Alkalinity                                                               | Passes USP              | Current USP                                              |            |              |
| Iron and other heavy metals                                                | Passes USP              | Current USP                                              |            |              |
| As                                                                         | ≤6 PPM                  | Current USP                                              |            |              |
| Pb                                                                         | Passes USP              | Current USP                                              |            |              |
| # Loss on Ignition                                                         | ≤1.0%                   | Current USP                                              |            |              |
| # Assay                                                                    | 98.0-102.0%             | Current USP                                              |            |              |
| #SSA (m <sup>2</sup> /g)                                                   | 4-9                     | QA-01- 522                                               |            |              |
| Bulk Density                                                               | Reference               | QA-01- 900                                               |            |              |
| Qual. Determination of Sub-Oxidized Zinc Particulates                      | Pass                    | QA-01-912                                                |            |              |
| Cd                                                                         | ≤10 ppm                 | QA-01-1520                                               |            |              |
| Pb                                                                         | ≤10 ppm                 | QA-01-1520                                               |            |              |
| Particle Size (nm) ***<br>[1] Mean (nm)<br>[2] # Particles below 0.100(μm) | [1] >200 nm<br>[2] 0.0% | QA-01-1762<br>[DLS-Malvern]<br>Distribution Base: Number | [1]<br>[2] |              |
| Particle Size<br>[1] Mean (μm)<br>[2] # Particles below 0.100(μm)          | Run & report            | QA-01-696<br>[SLS-Horiba]<br>Distribution Base: Number   | [1]<br>[2] |              |

\*\*\*Test NOT required for ZnO LSA (Internal Products).

## RECORD DATA ON TEST RECORD IGT200

USP Specification

☐Pass ☐Fail

By: \_\_\_\_\_

Approved for further processing for pharmaceutical use:

☐Yes ☐No

By: \_\_\_\_\_

Approved for non-pharmaceutical use:

☐Yes ☐No

By: \_\_\_\_\_

Completed by: \_\_\_\_\_

Date: \_\_\_\_\_

Reviewed by: \_\_\_\_\_

Date: \_\_\_\_\_



| Revision # | Date       | Reason for Change                                                                |
|------------|------------|----------------------------------------------------------------------------------|
| 009        | 03/11/2026 | Updated Logo, Changed Lot Identifier from "IB" to "IG", Removed reference to NTC |