

## Dantrolene Sodium USP43

Batch no

20241001

Mf date Retest date

Oct 09 2024 Oct 08 2028

Molecular Structure

Molecular Formula  $C_{14}H_9N_4NaO_5 \cdot 3\frac{1}{2}H_2O$ 

Molecular Weight

399.29

CAS Registry Number

24868-20-0

Oct 11 2024

| <u>Tests</u>       | Specifications  | <u>Results</u>            |
|--------------------|---|---------------------------|
| Appearance         | Yellowish-orange to orange crystalline<br>powder, no visible evidence of<br>contamination by foreign matter | Orange crystalline powder |
| Identification     | IR, RRT, sodium flame test, test D  | Positive                  |
| Water              | 14. 5 ~ 17. 0%  | 14.8%                     |
| Residual solvents  | Ethanol ≤ 2000 ppm  | 753 ppm                   |
|                    | Methanol ≤ 2000 ppm   | ND                        |
|                    | Acetone ≤ 2000 ppm  | ND                        |
|                    | DMF ≤ 620 ppm   | ND                        |
| Related substances | Related compound A ≤ 0.15%  | ND                        |
| 4                  | Related compound B $\leq$ 0.5%  | 0. 19%                    |
|                    | Related compound $C \le 0.3\%$  | 0. 05%                    |
| Assay (oab)        | 90.0 $^{\sim}$ 96.0% of $C_{14}H_{10}N_4O_5$  | 94. 8%                    |
|                    |   |                           |

| Packaging & storage | Preserve in tight, light-resistant containers. Store at room temperature |
|---------------------|--|
| Conclusion          | Material complies with USP43   |
| isi g               |  |

