



湖北帝柏化工有限公司

HUBEI DIBO CHEMICAL INDUSTRY CO., LTD.

Certificate of Analysis

Dantrolene Sodium USP40

BATCH NUMBER	<u>20180901</u>	TEST DATE	<u>Sep. 08,2018</u>
BATCH SIZE	<u>/</u>	MANUFACTURE DATE	<u>Sep. 06,2018</u>
QUANTITY	<u>10kgs</u>	EXPIRATION DATE	<u>Sep. 05,2021</u>

<u>TEST</u>	<u>SPECIFICATION</u>	<u>RESULT</u>
Appearance	Yellowish-orange to orange crystalline powder. No visible evidence of contamination by foreign matter.	<u>Conforms</u>
Identificatio	A. The IR absorption spectrum exhibits maxima only at the same wavelengths as that of the Reference Standard<197K> B. The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay. C. Meets the requirements of the flame test for Sodium<191>	<u>Conforms</u> <u>Conforms</u> <u>Conforms</u>
Heavy Metals	Not more than 0.002% (colorimetry)	<u>Conforms</u>
Water	14.5% to 17.0%	<u>15.1%</u>
Assay	90.0-96.0% of C ₁₄ H ₁₀ N ₄ O ₅ on the anhydrous basis	<u>95.2%</u>
Residual Solvents		
Ethanol	Not more than 2000ppm	<u>760ppm</u>
Methanol	Not more than 2000ppm	<u>Not detected</u>
Acetone	Not more than 2000ppm	<u>Not detected</u>
DMF	Not more than 620ppm	<u>Not detected</u>
Related Substances		
Related Compound A	Not more than 0.15%	<u>Not detected</u>
Related Compound B	Not more than 0.50%	<u>0.14%</u>
Related Compound C	Not more than 0.30%	<u>Not detected</u>

Conclusion : The specifications conform with USP.40 standard

Quality audit:CHEN

Inspector:LI XIAO

Analyst:WANG XUEZHI