

	Material Storage and Shipping Temperature Statement	Doc. No.: WF10-11
		Rev:02
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		Effective date: Feb. 8, 2019

Name of Product	sucralfate
Name of Manufacturer	ZHEJIANG HAISEN PHARMACEUTICAL CO., LTD.

Reference: Good Distribution Practice (GDP) Guidelines ICH Q7
 Guidelines of 7 March 2013 on Good Distribution Practice of Medicinal Products
 for Human Use (2013/C 68/01), Official Journal of the European Union
 <1079> Good Storage and Distribution Practices for Drug Products, USP.
 SOP50-01

Material Storage conditions (definition): tight containers, USP controlled room temperature

Material Storage temperature range: From till °C

Storage Humidity requirements (if applicable): dry

Material Shipment temperature range: From till °C

Allowable excursion temperature range: From till °C

Allowable duration of excursion hours / days / weeks / months (circle as appropriate)

- Stability studies to support shipping conditions are available?

Yes No Not Applicable

- If yes, please provide the relevant stability data. Attached:

Yes No Not Applicable

We herewith certify that this statement is valid and true for each lot supplied to LGM Pharma.

LGM Pharma will be notified in written form of any change concerning the parameters outlined above.

Signatures	
Date	2019/09/20
Name	HU CHENG
Function	QA 质管部
Signature	

