

吴赣药业(苏州)有限公司

Wugan Pharmaceutical (Suzhou) Co. Ltd.,

TUNCUN, TONGLI TOWN, WUJIANG DISTRICT, SUZHOU CITY, JIANGSU, 215216, CHINA

DATE: August 3, 2020

STATEMENT ON RESIDUAL SOLVENTS

PRODUCT: SULFADIAZINE SODIUM

We, Wugan Pharmaceutical (Suzhou) Co., Ltd., hereby certify that above mentioned product does not use any Class I solvents, as listed in the current USP <467>, and there is no potential for these solvents to be produced during the manufacturing process of Sulfadiazine Sodium.

Class I solvents area as follow:

Benzene

Carbon tetrachloride

1,2-Dichloroethane

1,2-Dichloroethene

1,1,1-Trichloroethane

The following solvents are used in the manufacturing process, may be generated during the manufacturing process, or otherwise have the potential to be in Sulfadiazine Sodium manufactured by Wugan Pharmaceutical (Suzhou) Co., Ltd. And are controlled below the noted limits complying with USP <467>.

Ethanol-Class III-NMT 5000ppm

Sincerely,

NAME: Xu Chuanghong

COMPANY: WUGAN PHARMACEUTICAL (SUZHOU) CO., LTD.

