

寿光富康制药有限公司
SHOUGUANG FUKANG PHARMACEUTICAL CO., LTD

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FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

10G-07-B01

Director Técnico

BATCH CERTIFICATION

Number of the GMP certificate: J0468 and this certificate remains valid till 2013-06-22
A certificate was issued by State Drug Administration and as per Chinese gmp rules was inspected.
(Shouguang Fukang Pharmaceutical Co., Ltd.) as the manufacturer of Trimethoprim hereby certify that this batch has
been manufactured by us in full compliance with GMP requirements of the local Regulatory Authority
Date of the certificate: JAN.29.2010

PRODUCT	TRIMETHOPRIM	PHARMACOPOLeia	EP6
BATCH NO.	201001570	GROSS WEIGHT	27.5Kg/Drum
BATCH QUANTITY	500KGS	NET WEIGHT	25Kg/Drum
MANUFACTURE DATE	JAN. 27, 2010	RETEST DATE	DEC. 2014
ANALYSIS DATE	JAN. 28, 2010	RELEASE DATE	JAN. 29, 2010
TEST ITEM (Characters) Appearance Solubility Identification Melting point Infrared absorbance UV spectrum Chemical reaction Appearance of solution Related substances HPLC method A: Impurity F Any impurity single Total impurities HPLC method B: Any impurity single Total impurities Heavy metals Methanol Dimethyl sulfoxide Acetic acid Impurity K(aniline) Loss on drying Sulphated ash Assay	STANDARDS REQUIRED White or yellowish-white powder very slightly soluble in water, slightly soluble in alcohol. 199—203°C max. 287nm;240-250 Complies with reference spectrum green fluorescence at 365nm not more intensely colored than reference solution BY; ≤0.10% ≤0.1% ≤0.2% ≤0.1% ≤0.2% ≤20ppm ≤3000ppm ≤5000ppm ≤5000ppm ≤5ppm ≤1.0%(determined on 1.0g by drying in an oven at 100-105°C) ≤0.1% 98.5—101.0%	TEST RESULTS White powder Very slightly soluble in water, slightly soluble in alcohol. 201.0—201.5°C 245 Complies with reference spectrum Green fluorescence at 365nm Less intensely colored than reference solution BY; 0.04% ≤0.1% ≤0.2% ≤0.1% ≤0.2% ≤20ppm below detection limit below detection limit below detection limit below detection limit 0.1% 0.02% 99.7%	

Results: the commodity meets the standard of EP6. COS NO: R0-CEP 2005-115-Rev 00

Manager: Liu Bin

Checker: Yang Dong Run

Examiner: Liu Fang