

PRODUCT: SPIRONOLACTONE

ITEMS	SPECIFICATIONS
APPEARANCE (Ph. Eur.)	A white or yellowish-white powder
SOLUBILITY (Ph. Eur.)	Practically insoluble in water, soluble in ethanol (96%)
IDENTIFICATION a) IR-spectrum (Ph. Eur.) IR-spectrum (USP) b) TLC (Ph. Eur.) UV Absorption (USP) c) Colour reaction (Ph. Eur.) Precipitate reaction (USP)	Meets the requirements Meets the requirements Meets the requirements Meets the requirements Meets the requirements Meets the requirements
SPECIFIC OPTICAL ROTATION (Ph. Eur.) (USP)	-41° ~ -46° -41° ~ -45°
LOSS ON DRYING (Ph. Eur.) (USP)	NMT 0.5% NMT 0.5%
SULPHATED ASH (Ph. Eur.)	NMT 0.1%
RELATED SUBSTANCES (Ph. Eur.) ➤ Impurity A ➤ Impurity F ➤ Impurity C ➤ Impurity D ➤ Impurity E ➤ Impurity I ➤ Any unspecified impurity ➤ Total impurities	NMT 0.2% NMT 0.3% NMT 0.2% NMT 0.15% NMT 0.3% NMT 0.5% NMT 0.10% NMT 0.7%

ORDINARY IMPURITIES (USP)	NMT 2.0%
FREE THIOL COMPOUNDS (Ph. Eur.)	NMT 0.05ml
FREE MERCAPTO COMPOUNDS (USP)	NMT 0.10ml
CHROMIUM (Ph. Eur.)	NMT 50 ppm
ASSAY ➤ HPLC (Ph. Eur.) ➤ HPLC (USP)	97.5%~102.0% 97.0%~103.0%
RESIDUAL SOLVENTS (In-house) a) Methanol b) Tetrahydrofuran c) DMF	NMT 3000 ppm NMT 720 ppm NMT 880 ppm
PARTICLE SIZE (In-house)	95% NMT 20 microns