

PRODUCT: EZETIMIBE

ITEMS	SPECIFICATIONS
APPEARANCE	A white to off-white powder
MELTING RANGE	160°C ~ 167°C
SPECIFIC ROTATION	-25.0° ~ -29.0°
IDENTIFICATION a) HPLC b) IR	RRT test solution is similar to RRT reference solution Similar to reference substance
CHLORIDE	NMT 0.01%
LOSS ON DRYING	NMT 0.5%
SULPHATED ASH	NMT 0.1%
HEAVY METALS	NMT 0.001%
RELATED SUBSTANCES ➤ Any unknown impurity ➤ Total impurities	NMT 0.10% NMT 1.0%
ENANTIOMER	NMT 0.5%
DIASTEREOMER	NMT 0.5%
RESIDUAL SOLVENTS a) Methanol b) Isopropyl alcohol c) Chlorobenzene	NMT 3000 ppm NMT 5000 ppm NMT 360 ppm
ASSAY	98.0%~102.0% (on the dried basis)
PARTICLE SIZE ➤ d(0.1) ➤ d(0.5) ➤ d(0.9)	NMT 2 µm 2.3 ~ 7.3 µm NMT 15 µm