Eurotrade World Commerce, S.L.

CERTIFICATE OF ANALYSIS

RISPERIDONE BP / Ph Eur

TEST	SPECIFICATIONS
DESCRIPTION	A WHITE OR ALMOST WHITE POWDER
SOLUBILITY	PRACTICALLY INSOLUBLE IN WATER, FREELY SOLUBLE IN METHYLENE CHLORIDE, SPARINGLY SOLUBLE IN ETHANOL (96%). IT DISSOLVES IN DILUTE ACID SOLUTIONS. IT SHOWS POLYMORPHISM
IDENTIFICATION	INFRA-RED SPECTRUM IS CONCORDANT WITH STANDARD REFRENCE SPECTRA
APPEARANCE OF SOLUTION (0.1% W/V SOLUTION IN 0.75% W/V SOLUTION OF TARTARIC ACID)	A SOLUTION IS CLEAR AND NOT MORE INTENSELY COLOURED THAN REFERENCE SOLUTION B_9
LOSS ON DRYING AT 105ºC FOR 4 HOURS	MAXIMUM 0.5% (W/W)
SULPHATED ASH	MAXIMUM 0.1% (W/W)
RELATED SUBSTANCES BY HPLC	SINGLE KNOWN AS IMPURITY NMT 0.2% (IMPURITY A, B, C, D & E) ANY OTHER IMPURITY NMT 0.10% (INCLUDING INSATURATED RISPERIDONE) TOTAL IMPURITIES NMT 0.3%
ASSAY (N)	99.0% TO 101.0% (W/W) ON DRIED BASIS

ADDITIONAL REQUIREMENT

RESIDUAL SOLVENTS	
1. METHANOL	NOT MORE THAN 100 PPM
2. ETHANOL	NOT MORE THAN 100 PPM
3. ACETONITRILE	NOT MORE THAN 200 PPM
4. DICHLOROETHANE	NOT MORE THAN 200 PPM
5. N-HEXANE	NOT MORE THAN 100 PPM
6. DICHLOROETHANE	NOT MORE THAN 5 PPM
7. BENZENE	NOT MORE THAN 2 PPM
8. TOLUENE	NOT MORE THAN 100 PPM
9. DIMETHYLFORMAMIDE	NOT MORE THAN 400 PPM

PARTICLE SIZE DISTRIBUTION (BY LASER GRANULOMETER)	100% < 60 MICRONS MINIMUM 50% < 20 MICRONS MINIMUM 10% < 10 MICRONS