

CERTIFICATE OF ANALYSIS FOR GRISEOFULIN

Items	Specifications	Results
Description	A White or yellow white microfine powder	A white microfine powder
Identification	A:IR B: Colour test	Conforms Conforms
Acidity	Not more than 1.0ml of 0.02M sodium hydroxide is required	0.6ml
Particle size	95% no more than 5 μ m	Conforms
Specific optical rotation	Calculate with reference to the dried substance +354° ~+364.	+362°
Melting point	It melts at about 220°C	220°C
Appearance of solution	The solution is clear Not more intensely coloured than reference solution Y4	Conforms Conforms
Related substances		
Dechologriseofulvin	Less than 0.60	0.30
Dechologriseofulvin	Less than 0.15	0.04
Substances soluble in light petroleum	NMT0.20%	0.09%
Loss on drying	NMT1.00%	0.11%
Sulphated ash	NMT0.20%	0.11%
Abnormal toxicity	Five mice orals, none of the mice dies within 48h	conforms
Assay(anhydrous substance	97.0%~102.0%	99.4%