

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 231/2012, E 235 NATAMYCIN. (See end of Document for details)

ANNEX

E 235 NATAMYCIN

Synonyms	Pimaricin
Definition	Natamycin is a fungicide of the polyene macrolide group, and is produced by strains of <i>Streptomyces natalensis</i> and other relevant species
Einecs	231-683-5
Chemical name	A stereoisomer of 22-(3-Amino-3,6-dideoxy-β-D- mannopyranosyloxy)-1,3,26-trihydroxy-12-methyl-10-oxo-6,11,28-trioxatricyclo[22.3.1.0 ^{5,7}]octacos-8,14,16,18,20-pentaene-25-carboxylic acid.
Chemical formula	C ₃₃ H ₄₇ O ₁₃ N
Molecular weight	665,74
Assay	Content not less than 95 % on the dried basis
Description	White to creamy-white crystalline powder
Identification	
Colour reactions	On adding a few crystals of natamycin on a spot plate, to a drop of: concentrated hydrochloric acid, a blue colour develops, concentrated phosphoric acid, a green colour develops, which changes into pale red after a few minutes
Spectrometry	A 0,0005 % w/v solution in 1 % methanolic acetic acid solution has absorption maxima at about 290 nm, 303 nm and 318 nm, a shoulder at about 280 nm and exhibits minima at about 250 nm, 295,5 nm and 311 nm
pH	5,5-7,5 (1 % w/v solution in previously neutralised mixture of 20 parts dimethylformamide and 80 parts of water)
Specific rotation	$[\alpha]_D^{20} + 250^\circ$ to $+ 295^\circ$ (a 1 % w/v solution in glacial acetic acid, at 20 °C and calculated with reference to the dried material)
Purity	
Loss on drying	Not more than 8 % (over P ₂ O ₅ , in vacuum at 60 °C to constant weight)
Sulphated ash	Not more than 0,5 %

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Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Microbiological criteria	
Total plate count	Not more than 100 colonies per gram

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