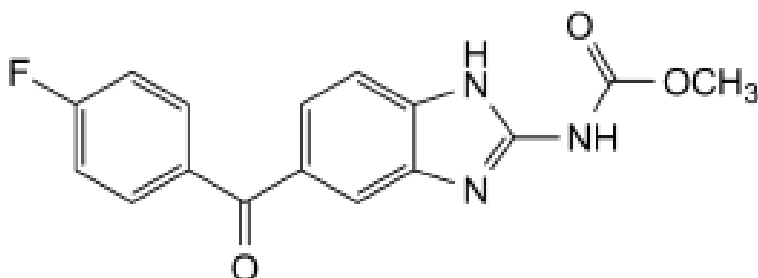


## PRODUCT      Flubendazole Ph. Eur.

CAS no.                      [31430-15-6]



CHARACTERISTICS      White or almost white powder. Practically insoluble in water, in alcohol and in methylene chloride. It shows polymorphism.

TEST	SPECIFICATION
<b>Content (Assay)</b>	99.0 to 101.0% (dried substance)
<b>Identification</b>	Conforms to Ph. Eur. tests
<b>Loss on drying</b>	Not more than 0.5%
<b>Sulphated ash</b>	Not more than 0.1%
<b>Related substances</b>	Individual impurities A, B, C, D, E, G*      Each not more than 0.25% Impurity F*    Not more than 0.50% Any other impurity with a relative retention between 1.2 and 1.3                      Not more than 0.25% Total impurities    Not more than 1.50%

### Impurities profile:

Impurity A	- methyl [5-[4-(formylamino)benzoyl]-1H-benzimidazol-2-yl]carbamate
Impurity B	- (2-amino-1H-benzimidazol-5-yl)(4-fluorophenyl)methanone
Impurity C	- (4-fluorophenyl)(2-hydroxy-1H-benzimidazol-5-yl)methanone
Impurity D	- (1H-benzimidazol-5-yl)(4-fluorophenyl)methanone
Impurity E	- methyl [5-(2-fluorobenzoyl)-1H-benzimidazol-2-yl]carbamate
Impurity F	- methyl [5-(4-fluorobenzoyl)-1-methyl-1H-benzimidazol-2-yl]carbamate
Impurity G	- methyl [5-[4-(1-methylethoxy)benzoyl]-1H-benzimidazol-2-yl]carbamate

ENQUIRY