



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 214596

Product:	FLUORURACIL
Lot:	214596
Expiry date:	01/03/2026
Reference:	Cumple PhEur10.5
Synonyms:	
Formula:	C ₄ H ₃ FN ₂ O ₂
Molecular weight:	130,08 g/mol

Assay	Result	Specification	
Impurities F and G (TLC)	Conform	Test PhEur	
Total impurities	<= 0,05 %	<= 0,5 %	
Heavy metals	<= 20 ppm	<= 20 ppm	
Organic solvents residues	NA	NA	#
pH of aqueous solution 1%	5,0	4,5-5,0	
Impurity G	<= 0,2 %	<= 0,2 %	
Related substances (HPLC)	Conform	Test PhEur	
Unspecified Impurities	<= 0,05 %	<= 0,10 %	
Assay	99,3 %	98,5-101,0%	
Loss on drying red. press. 80°C, 4h	0,14 %	<= 0,5%	
Sulphated ashes	0,00 %	<= 0,1 %	
Impurity A	NDT	<= 0,1 %	
Impurity B	NDT	<= 0,1 %	
Organoleptic properties	Conform	PhEur	
Impurity E	<= 0,05 %	<= 0,1 %	
Appearance of solution S (aq. 1%)	Conform	Test PhEur	
Impurity F	<= 0,25 %	<= 0,25 %	
Impurity C	NDT	<= 0,1 %	
Identification	Conform	Test PhEur	
Impurity D	<= 0,05 %	<= 0,1 %	

Organoleptic characteristics: White or almost white, crystalline powder. Sparingly soluble in water, slightly soluble in ethanol (96 per cent).

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 30/08/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00107 CHEMISCHE FABRIK BERG GmbH

Manufacturer batch: 20126-2103B341

Product	Name	Capacity	Batch
1145204	FLUOROURACILO	1 g	214596-D-1
1145204	FLUOROURACILO	1 g	214596-D-2
1145204	FLUOROURACILO	1 g	214596-D-3
1145205	FLUOROURACILO	5 g	214596-E-1
1145205	FLUOROURACILO	5 g	214596-E-10
1145205	FLUOROURACILO	5 g	214596-E-2
1145205	FLUOROURACILO	5 g	214596-E-5
1145205	FLUOROURACILO	5 g	214596-E-8
1145206	FLUOROURACILO	100 g	214596-J-1
1145206	FLUOROURACILO	100 g	214596-J-2
1145210	FLUOROURACILO (INACTIVO)	500 g	214596-O-1
1200165	FLUOROURACILO	25 g	214596-G-1
1200165	FLUOROURACILO	25 g	214596-G-2
1200165	FLUOROURACILO	25 g	214596-G-3
1370096	FLUOROURACILO (FLB)	5 g	214596-E-3
1370096	FLUOROURACILO (FLB)	5 g	214596-E-4
1370096	FLUOROURACILO (FLB)	5 g	214596-E-6
1370096	FLUOROURACILO (FLB)	5 g	214596-E-7
1370096	FLUOROURACILO (FLB)	5 g	214596-E-9

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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