



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 223943

Product:	FLUORURACIL
Lot:	223943
Expiry date:	30/01/2027
Reference:	Cumple PhEur10.8
Synonyms:	
Formula:	C ₄ H ₃ FN ₂ O ₂
Molecular weight:	130,08 g/mol

Assay	Result	Specification	
Identification	Conform	Test PhEur	
Organoleptic properties	Conform	PhEur	
Appearance of solution S (aq. 1%)	Conform	Test PhEur	=
pH of aqueous solution 1%	4,8	4,5-5,0	=
Related substances (HPLC)	Conform	Test PhEur	=
Impurities F and G (TLC)	Conform	Test PhEur	=
Heavy metals	< 20 ppm	<= 20 ppm	=
Loss on drying red. press. 80°C, 4h	0,02 %	<= 0,5%	
Sulphated ashes	< 0,1 %	<= 0,1 %	=
Assay	98,9 %	98,5-101,0%	
Impurity A	< 0,1 %	<= 0,1 %	=
Impurity B	< 0,1 %	<= 0,1 %	=
Impurity C	< 0,1 %	<= 0,1 %	=
Impurity D	< 0,1 %	<= 0,1 %	=
Impurity E	< 0,1 %	<= 0,1 %	=
Impurity F	< 0,25 %	<= 0,25 %	=
Impurity G	< 0,2 %	<= 0,2 %	=
Unspecified Impurities	< 0,10 %	<= 0,10 %	=
Total impurities	< 0,5 %	<= 0,5 %	=
Organic solvents residues	NA	NA	#

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: 21/07/2022

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00107 CHEMISCHE FABRIK BERG GmbH

Manufacturer batch: 20126-2201B361

Product	Name	Capacity	Batch
1145204	FLUOROURACILO	1 g	223943-D-1
1145204	FLUOROURACILO	1 g	223943-D-2
1145204	FLUOROURACILO	1 g	223943-D-3
1145204	FLUOROURACILO	1 g	223943-D-4
1145205	FLUOROURACILO	5 g	223943-E-3
1145205	FLUOROURACILO	5 g	223943-E-5
1145205	FLUOROURACILO	5 g	223943-E-7
1145206	FLUOROURACILO	100 g	223943-J-1
1200165	FLUOROURACILO	25 g	223943-G-1
1200165	FLUOROURACILO	25 g	223943-G-2
1200165	FLUOROURACILO	25 g	223943-G-3
1370096	FLUOROURACILO (FLB)	5 g	223943-E-1
1370096	FLUOROURACILO (FLB)	5 g	223943-E-2
1370096	FLUOROURACILO (FLB)	5 g	223943-E-4
1370096	FLUOROURACILO (FLB)	5 g	223943-E-6

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

ACOFARMA DISTRIBUCIÓN, S.A.

C/ Llobregat, 20 - 08223 Terrassa (Barcelona)

Tel./ 93-736.00.88

www.acofarma.com

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