



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 260807**

Product:	FLUORURACIL
Lot:	260807
Expiry date:	11/01/2031
Reference:	Cumple PhEur12.2
Synonyms:	5-Fluorouracilo
Formula:	C <sub>4</sub> H <sub>3</sub> FN <sub>2</sub> O <sub>2</sub>
Molecular weight:	130,1 g/mol

Assay	Result	Specification	
Identification	Conform	Test PhEur	
Organoleptic properties	Conform	PhEur	
Appearance of solution	Conform		
pH	4,6	4,5 - 5,0	
Related substances (HPLC)	Conform	Test PhEur	
Impurities F and G (TLC)	Conform	Test PhEur	
Loss on drying	0,1 %	<= 0,5 %	
Sulphated ashes	0,01 %	<= 0,1 %	
Assay	99,3 %	98,5-101,0%	
Impurity A	ND	<= 0,1 %	
Impurity B	ND	<= 0,1 %	
Impurity C	ND	<= 0,1 %	
Impurity D	< 0,05 %	<= 0,1 %	
Impurity E	< 0,05 %	<= 0,1 %	
Impurity F	< 0,25 %	<= 0,25 %	
Impurity G	< 0,2 %	<= 0,2 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	< 0,5 %	<= 0,5 %	
Residual solvent: Dimethylformamide	< 800 ppm	<= 880 ppm	#
Elemental impurities	Conform		#
Nitrosamine impurities	Conform		#

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: 28/05/2026

Responsible: B. Chia

Technical director: Montserrat Enrique

Judgement:  
APPROVED

Manufacturer: F00037 NANTONG JINGHUA PHARMACEUTICAL, CO. LTD.

Manufacturer batch: FLU2026018

Product	Name	Capacity	Batch
1370096	FLUOROURACILO (FLB)	5 g	260807-E-1

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

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