

FLUOROURACILO (EUR. PH.)			
PRODUCT CODE: 000978		CAS Nº: 51-21-8	ANALYSIS Nº: 001/22
MANUFACTURER BATCH:	FLU2021040	CERTIFICATE ID:	33.585
SUPPLIER BATCH:	0107766	MANUFACTURING DATE:	09/04/2021
METAPH BATCH:	0010122	EXPIRY DATE:	08/04/2026

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder (*)
Solubility	Sparingly soluble in water, slightly soluble in ethanol (96 per cent)	Complies
Identification	Complies	Complies (*)
Appearance of solution	Clear and not more intensely coloured than reference solution Y7 or BY7	Complies
pH	4.5 - 5.0	4.7
Impurities F and G		
Impurity F	=< 0.25 %	< 0.25 %
Impurity G	=< 0.2 %	< 0.20 %
Related substances		
Impurity A	=< 0.1 %	Not Detected
Impurity B	=< 0.1 %	Not Detected
Impurity C	=< 0.1 %	Not Detected
Impurity D	=< 0.1 %	0.06 %
Impurity E	=< 0.1 %	Not Detected
Unspecified impurities	=< 0.10 %	Not Detected
Total impurities	=< 0.5 %	0.06 %
Loss on drying	=< 0.5 %	0.02 % (*)
Sulfated ash	=< 0.1 %	0.07 % (*)
Assay	98.5 - 101.0 %	99.1 % (*)
Microbiological control		
TAMC	=< 100 CFU/g	< 10 CFU/g
Residual solvents [In-house]		(**)
Dimethylformamide	=< 0.088 %	Not Detected

COMPLIES WITH

European Pharmacopoeia 10.0

REMARKS

Product fully analyzed inside the EU.

Fluorouracil is subjected to the requirements of the ICH Q3D "Elemental Impurities".

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

(*) Data controlled by Metapharmaceutical Industrial SL.

Release date: 17/02/2022
Signature: Ferran Gonzalez de Rivera Rier
Conclusion: Complies



Manufacturer: 40000394
NANTONG JINGHUA PHARMACEUTICAL Co., Ltd.
2-02# Crossroad Between 3 Haibin Road and 2 Tonghai Road
Yanhai Economic Development Zone, Rudong
226 407 Jiangsu

Original certificate available upon request

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(**) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Keep containers tightly closed, protected from light and moisture.

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