

FLUOROURACILO (EUR. PH.)

PRODUCT CODE: 000978	CAS Nº: 51-21-8	ANALYSIS Nº: 029/24
MANUFACTURER BATCH: FLU2023049	CERTIFICATE ID: 41.096	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 04/05/2023	
METAPH BATCH: 0160224	RETEST DATE: 03/05/2028	

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	4.8
Impurities F and G		
Impurity F	=< 0.25 %	< 0.25 %
Impurity G	=< 0.2 %	< 0.2 %
Related substances		
Impurity A	=< 0.1 %	Not Detected
Impurity B	=< 0.1 %	Not Detected
Impurity C	=< 0.1 %	Not Detected
Impurity D	=< 0.1 %	Not Detected
Impurity E	=< 0.1 %	Not Detected
Unspecified impurities	=< 0.10 %	Not Detected
Total impurities	=< 0.5 %	Not Detected
Loss on drying	=< 0.5 %	0.1 %
Sulfated ash	=< 0.1 %	0.06 %
Assay	98.5 - 101.0 %	100.8 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Fluorouracil is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

(*) Data adapted from the manufacturer's certificate of analysis.

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.

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.

Analysis date: 12/03/2024
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

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

