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Analysenzertifikat / Certificate of analysis

Produkt / Product	Batch No.:
5-Fluorouracil (Ph.Eur. 8 th Ed.)	20126 / 1501B198

The test parameters and the requirements follow the agreed specification unless indicated otherwise:
SPEC-Pr.-No. 20126/5 (valid Nov. 04th, 2014).

The analysis was made available by the manufacturer unless indicated otherwise.

Methode / Method	Anforderungen / Requirements	Ergebnisse / Results
Ph. Eur.		
Appearance	white or almost white crystalline powder	conforms
Identification (IR)	positive	positive
Assay (titration)	98.5 – 101.0 %	100.6 %
Appearance of solution (0.5 g / 50 ml aqueous solution)	clear, not more intensely coloured than reference solution BY ₇ or Y ₇	conforms
pH (0.5 g / 50 ml aqueous solution)	4.5 – 5.0	4.6
Heavy metals	20 ppm maximum	< 20 ppm
Loss on drying	0.5 % maximum	< 0.1 %
Sulphated ash	0.1 % maximum	< 0.1 %
Related substances (TLC)		
2-Ethoxy-5-fluorouracil	0.25 % maximum	< 0.25 %
Urea	0.1 % maximum	< 0.1 %
Related substances (HPLC)		
Barbituric acid	0.1 % maximum	< 0.1 %
5-Hydroxyuracil	0.1 % maximum	< 0.1 %
Uracil	0.1 % maximum	< 0.1 %
5-Methoxyuracil	0.1 % maximum	< 0.1 %
5-Chlorouracil	0.1 % maximum	< 0.1 %
Each unspecified impurity	0.10 % maximum	< 0.05 %
Total impurities	0.5 % maximum	< 0.1 %
Additional tests (not specified)		
Bacterial endotoxines	0.048 maximum	< 0.01 IU/mg
Microbiology		
TAMC	100 cfu/g maximum	< 100 cfu/g
TYMC	10 cfu/g maximum	< 10 cfu/g
Manufacturing date:	01 / 2015	
Release date:	03 / 2015	
Retest date:	01 / 2020	

- PELIGRO: Producto de la lista
 de Farmacovigilancia Tóxico en caso
 de sobredosis o uso inadecuado
 Los organismos reguladores deben
 adoptar medidas de emergencia. P273

FLUOROURACILO-5 GRANUL

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93946

25-05-2016

* test performed at external laboratory

Dr. Raschke / QC

Name / Department

Raschke
Signature / Unterschrift

07/04/2015

Date / Datum