CHEMISCHE FABRIK BERG Gesellschaft mit beschränkter Haftung

Chemische Fabrik Berg GmbH . Mainthalstraße 3 . 06749 Bitterfeld-Wolfen . Germany . Tel.: +49-(0)3493-78180

Analysenzertifikat / Certificate of analysis

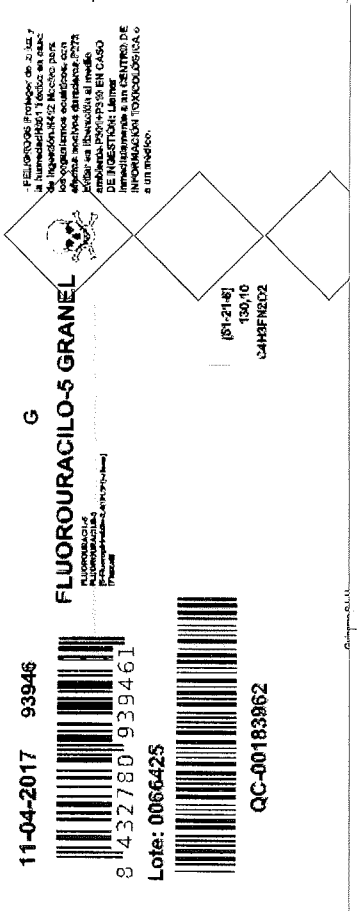
Produkt / Product	Batch No.:
5-Fluorouracil (Ph.Eur. 8th Ed.)	20126 / 1511B239

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 %	99.8 %
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	4.9
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:	11 / 2015
Release date:	01 / 2016
Retest date:	11 / 2020



* test performed at external laboratory

Dr. Raschke / QC — Name / Department

Raschke — Signature / Unterschrift

21/01/2016 — Date / Datum

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Certificate of analysis

Produkt / Product	Batch No.: 20126 / 1511B239
5-Fluorouracil (USP 38)	

The test parameters and the requirements follow the agreed specification unless indicated otherwise: **SPEC-Pr.-No. 20126/3 – USP** (valid Oct. 16th, 2014). The analysis was made available by the manufacturer unless indicated otherwise.

Method	Requirements	Results
USP		
Appearance	white to practically white, crystalline powder	conforms
Identification		
Infrared Absorption	conforms	conforms
Ultraviolet Absorption	conforms	conforms
Retention time (HPLC)	conforms	conforms
Residue on ignition	≤ 0.1 %	< 0.1 %
Heavy metals	≤ 20 ppm	< 20 ppm
Loss on drying	≤ 0.5 %	< 0.1 %
Organic impurities (HPLC)		
Related compound A (Barbituric acid)	≤ 0.15 %	< 0.05 %
Related compound B (5-Hydroxyuracil)	≤ 0.15 %	< 0.05 %
Related compound C (Uracil)	≤ 0.15 %	< 0.05 %
Related compound D (5-Methoxyuracil)	≤ 0.15 %	< 0.05 %
Related compound E (5-Chlorouracil)	≤ 0.15 %	< 0.05 %
Any individual unspecified impurity	≤ 0.10 %	< 0.05 %
Total impurities	≤ 0.5 %	< 0.1 %
Related compound F and Urea		
Related compound F (2-Ethoxy-5-fluorouracil)	≤ 0.25 %	< 0.25 %
Urea	≤ 0.2 %	< 0.1 %
Assay (calc. on dried basis)	98.0 – 102.0 %	99.8 %
Additional tests (Not specified)		
Bacterial endotoxines*	0.048 maximum	< 0.01 IU/mg
Microbiology*		
TAMC	≤ 100 cfu/g	< 100 cfu/g
TYMC	≤ 10 cfu/g	< 10 cfu/g
Manufacturing date:	11 / 2015	
Release date:	01 / 2016	
Retest date:	11 / 2020	

* test performed at external laboratory

Dr. Raschke / QC
Name / Department

Raschke
Signature / Unterschrift

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