

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

Analysenzertifikat / Certificate of analysis

Produkt / Product 5-Fluorouracil (Ph.Eur. 7 th Ed.)	Batch No.: 20126 / 1308B167
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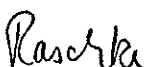
The test parameters and the requirements follow the agreed specification unless indicated otherwise:
SPEC-Pr.-No. 20126/4 (valid Nov. 24th, 2011).

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

Method / Methode	Anforderungen / Requirements	Ergebnisse / Results
Ph. Eur.		
Appearance	white or almost white crystalline powder	conforms
Identification (IR)	positive	positive
Assay (titration)	98.5 – 101.0 %	100.0 %
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	4.7
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: 08 / 2013 Release date: 10 / 2013 Retest date: 08 / 2018		

* test performed at external laboratory

Dr. Raschke / QC
 Name / Department


 Signature / Unterschrift

16/10/2013
 Date / Datum

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Certificate of Conformity

Produkt / Product 5-Fluorouracil (Ph.Eur.)	Batch No.: 20126 / 1308B167
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Name of Active Ingredient: 5-Fluorouracil
CEP No.: (if available) R1-CEP 2000-092-Rev 04
ASMF Version No n.A.
Batch No.: 20126/1308B167
Manufacturing date: 08/2013
Retest/Expiry date: 08/2018

Results of analysis: see separate Certificate of Analysis dated on 16.10.2013

Comments/remarks: none

Following relevant GMP aspects were taken into account before batch release of the API:

1. The batch of API is produced and analysed according to the validated manufacturing process and the validated test methods laid down in the valid ASMF (Active Substance Master File) and/or CEP.
2. Written procedures are established and followed for the review and approval of batch production and laboratory control records, including packaging and labeling, to determine compliance of the API with the established specification.
3. Batch production and laboratory control records of critical process steps are reviewed and approved by the quality unit(s) to be in compliance with the rules of GMP as stipulated in ICH Q7.
4. All deviations, investigations, and OOS reports are reviewed as part of the batch record review. Critical deviations or OOS results were encountered ☐ yes / ☒ no (if yes, a summary report is attached).

Above mentioned batch is released for shipping.

Name and position of person
authorising the batch release:

Dr. Ilse Frosch (Head of Quality Assurance)

Dr. Frosch / QA

Name / Department

Frosch

Signature

17/10/2013

Date