CHEMISCHE FABRIK BERG Gesellschaft mit beschränkter Haftung

Chemische Fabrik Berg GmbH . Mainthalstraße 3 . 06749 Bitterfeld-Wolfen . Germany

Analysenzertifikat / Certificate of analysis

Produkt / Product	Batch No.:
5-Fluorouracil (Ph.Eur. 7th Ed. & USP 34)	20126 / 1109B133 Lot: 0030612

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 %	100.5 %
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 %
USP		
Appearance	white to practically white, crystalline powder	conforms
Identification		
Infrared Absorption	conforms	conforms
Ultraviolet Absorption	conforms	conforms
Reaction with bromide	conforms	conforms
Loss on drying (vacuum, 4h, 80°C)	0.5 % maximum	0.1 %
Residue on ignition	0.1 % maximum	< 0.1 %
Heavy metals	20 ppm maximum	< 20 ppm
Content of fluorine*	13.9 – 15.0 %	14.4 %
Assay (HPLC)	98.0 – 102.0 %	98.9 %
Additional test		
Bacterial endotoxines*	report test results	< 0.01 IU/mg

Date of analysis:	10 / 2011 (Ph.Eur.) 01 / 2012 (USP, on retained sample)
Manufacturing date:	09 / 2011
Retest date:	09 / 2016

* tests performed at external laboratory

Dr. Hennig / QC — Name / Department

Signature / Unterschrift

23/01/2012 — Date / Datum

CHEMISCHE FABRIK BERG Gesellschaft mit beschränkter Haftung

Chemische Fabrik Berg GmbH . Mainthalstraße 3 . 06749 Bitterfeld-Wolfen . Germany

Certificate of Conformity

Produkt / Product	Batch No.: 20126 / 1109B133
5-Fluorouracil (Ph.Eur.)	

Name of Active Ingredient: 5-Fluorouracil
CEP No.: (if available) n.A.
ASMF Version No n.A.
Batch No.: 20126/1109B133
Manufacturing date: 09/2011
Retest/Expiry date: 09/2016

Results of analysis: see separate Certificate of Analysis dated on 21.10.2011

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 established manufacturing process and the established test methods.
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.

Above mentioned batch is released for shipping.

Name and position of person authorising the batch release: Dr. Ilse Frosch (Head of Quality Assurance)

i.A. Dr. Raschke / QC	Raschke	21/10/2011
Name / Department	Signature / Unterschrift	Date / Datum