Dolder AG, Immengasse 9,
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Tel: +41 61 326 66 00
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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.: 20126 / 0711B086
5-Fluorouracil (Ph.Eur.)	For commercial use

Methode / Method	Anforderungen / Requirements	Ergebnisse / Results
Appearance	white or almost white crystalline powder	conforms
Identification (IR)	positive	Positive
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
Related substances (TLC)		
2-Ethoxy-5-fluorouracil	0.25 % maximum	0.25 %
Urea	0.1 % maximum	< 0.1 %
Related substances (HPLC)		
A) Barbituric acid	0.1 % maximum	< 0.1 %
B) 5-Hydroxyuracil	0.1 % maximum	< 0.1 %
C) Uracil	0.1 % maximum	< 0.1 %
D) 5-Methoxyuracil	0.1 % maximum	< 0.1 %
E) 5-Chlorouracil	0.1 % maximum	< 0.1 %
each unspecified impurity	0.10 % maximum	< 0.05 %
Total impurities	0.5 % maximum	< 0.1 %
Heavy metals	20 ppm maximum	< 20 ppm
Loss on drying	0.5 % maximum	< 0.1 %
Sulphated ash	0.1 % maximum	< 0.1 %
Assay (titration)	98.5 – 101.0 %	100.5 %

Manufacturing date:	11/2007
Analysis date:	12/2007
Retest date:	11/2012

Dr. Raschke / QC
Name / Department

Raschke
Signature / Unterschrift

17/12/2007
Date / Datum

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Manufacturing date:	11/2007
Analysis date:	12/2007
Retest date:	11/2012

Dr. Raschke / QC	Raschke	17/12/2007
Name / Department	Signature / Unterschrift	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 / 0711B086
5-Fluorouracil (Ph.Eur.)		For commercial use

Name of Active Ingredient: 5-Fluorouracil
CEP No.: (if available) n.A.
ASMF Version No n.A.
Batch No.: 20126/0711B086
Manufacturing date: 11/2007
Retest/Expiry date: 11/2012

Results of analysis: see separate Certificate of Analysis dated on 17.12.2007

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	i. A. Raschke	17/01/2008
Name / Department	Signature / Unterschrift	Date / Datum

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