

(Coat of arms)

Thüringer Ministerium
für Soziales und Gesundheit
(Thuringian Ministry for Social
Welfare and Health)

Permit for the manufacture of pharmaceutical substances

Ref.: 65232-001

In accordance with § 13 para. 1 of the Law on Pharmaceutical Products (AMG) enacted on 24th August, 1976 (German Federal Law Gazette I pp. 2445, 2448), last amended by the Seventh Law amending the AMG on 25th February, 1998 (German Federal Law Gazette I p. 374), I hereby grant the company

**Laborchemie Apolda GmbH
Utenbacher Strasse 72/74
99502 Apolda**

permission to manufacture pharmaceutical substances

in the production facility located at **99502 Apolda, Utenbacher Strasse 72/74.**

The following have been appointed as the persons responsible:

- Production manager: Mr Bartsch, Dipl.-Chem.

Deputy: Mr Trica

- Supervising manager: Dr Michaelis

Deputy: Mr Dietze

- Sales manager: Mr Köhlmann

This permit relates to the manufacture of the active substances D-penicillamin, chlorobutanol-hemihydrate, anhydrous chlorobutanol, Na-DMPS, aloxiprin, silver protein acetyl tannin, methenamin silver salt and acetyl amino-propoxybenzene as well as the packaging of dispensatory products from bulk.

The permit is based on a description of the company, a quality management manual and the drug-master files.

Under § 14 (4) AMG, the permit is also valid for the company Mikrobiologische Labor Dr. Bernhard GmbH, Berlin, in so far as microbiological tests are conducted there on the company's behalf.



This permit can be withdrawn without compensation if a reason described in § 18 para. 1 AMG is deemed to exist.

Erfurt, 27th May, 1998

p.p.

(signature)
Dr. Keiner

(Official seal) Thuringian Ministry
for Social Welfare
and Health

This is to certify that this translation into English faithfully reproduces the contents of the German original.

~~Erfurt~~ 3rd January, 2002



Jürgen Bendedikt