



Therapeutic
Goods
Administration

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COMMONWEALTH
DEPARTMENT OF
HEALTH, HOUSING AND
COMMUNITY SERVICES

File No: 86/0910

Co-ordination No: 91.156.2

The Director
TGA Laboratories

Attention: [REDACTED]

APPLICATION FOR REGISTRATION

PRODUCT: TEICOPLANIN (TARGOCID) POWDER FOR INJECTION
PLUS SOLVENT
100, 200 and 400 mg plus WFI ampoule

MANUFACTURER: GRUPPO DOW PHARMACEUTICALS PTY LTD, ITALY

APPLICANT: MERRELL DOW PHARMACEUTICALS PTY LTD
Locked Mail Bag 30
FRENCHS FOREST NSW 2086

EVALUATION OF RESPONSES TO SAFETY QUESTIONS

The Company has responded to the letter dated 12 February 1993 (f198-203).
(Numbering of question is equivalent to the letter).

Question 13 - Safety

The Company has provided a method and results for the Bacterial Endotoxin Test on the Water for Injection supplied with the TARGOCID powder (B1 App 4). No Endotoxin limit is given (the FDA Guidelines 1990 list a 0.25EU/ml limit); the method does not comply with the USP XXII 1990 <85> Bacterial Endotoxins Test and the proposed revisions in the Pharmacopial Forum Sept-Oct 1992 Vol 18, No 5. This is unsatisfactory.

The method needs to include the following:

- Calibration of a CSE with the RSE;
- Confirmation of the labeled LAL reagent sensitivity;
- Inhibition/Enhancement test with CSE standard curves in water and product;
- Maximum Valid Dilution;
- Test procedure with a CSE standard curve in water; and
- Confirmation that the supplier of reagents is approved by the FDA.

RECOMMENDATIONS

The Company is to be asked the following questions for:

TEICOPLANIN (TARGOCID) POWDER FOR INJECTION PLUS SOLVENT
100, 200 and 400 mg plus WFI ampoule

(Numbering of question is equivalent to the original letter)

Question 13 - Safety

- Please provide a general method for the Bacterial Endotoxin Test which complies with the USP XXII 1990 <85> Bacterial Endotoxins Test and the proposed revisions in the Pharmacopial Forum Sept-Oct 1992 Vol 18, No 5.
- Please provide results that show that the general method is being followed for the Water for Injection samples.
- Please confirm that an Endotoxin limit of 0.25EU/ml is used.

18/5
[REDACTED]
Molecular Biology
TGAL
18 May 1993