

**Certification of Substances Division**

**Certificate of suitability  
No. R1-CEP 2001-362-Rev 02**

1 *Name of the substance:*

2 **AZATHIOPRINE**

3 Code AP - Code APS

4 *Name of holder:*

5 **MICROBIOLOGICA QUIMICA E FARMACÊUTICA LTDA**

6 Rua Dr Nicanor, 238 - Inhauma

7 Brazil-20765-120 Rio De Janeiro

8 *Site(s) of production:*

9 **MICROBIOLOGICA QUIMICA E FARMACÊUTICA LTDA**

10 Rua Dr Nicanor, 238 - Inhauma

11 Brazil-20765-120 Rio De Janeiro

12 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**  
13 **R1-CEP 2001-362-REV 01**

14 After examination of the information provided on the manufacturing method and  
15 subsequent processes (including purification) for this substance on the site(s) of  
16 production mentioned above, we certify that the quality of the substance is suitably  
17 controlled by the current version of the monograph **AZATHIOPRINE** no. 369 of the  
18 European Pharmacopoeia, current edition including supplements, only if it is  
19 supplemented by the test(s) mentioned below, based on the analytical procedure(s)  
20 given in annex.

21 – Test for residual solvent by gas chromatography (Annex 1)  
22 Dimethylformamide not more than 880 ppm

23 – Test for particle size distribution by microscopy (Annex 2)

24 Material code AP:

25 Particle size not less than 90% below 25 microns

26 Bulk density not more than 0.18g/ml

27 Tapped bulk density not more than 0.23g/ml

28 Material code APS:

29 Particle size not less than 90% below 35 microns

30 Bulk density not less than 0.18g/ml

31 Tapped bulk density not less than 0.23g/ml