

# Indian Pharmacopoeia Commission

## Microbiology Division

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### Addition of Bacterial Endotoxin Test in the API and Formulations Monographs of Indian Pharmacopoeia 2018

#### 1. **Aciclovir**, Page 988

Insert after **Assay**

*Aciclovir intended for use in the manufacture of parenteral preparations without a further appropriate procedure for the removal of bacterial endotoxins complies with the following additional requirement.*

**Bacterial endotoxins** (2.2.3). Not more than 0.5 Endotoxin Unit per mg of aciclovir.

#### 2. **Calcitonin (Salmon) Injection**, Page 1245

Insert before **Other tests**

**Bacterial endotoxins** (2.2.3). Not more than 0.625 Endotoxin Unit per unit of calcitonin (salmon).

#### 3. **Calcium Folate**, Page 1251

Insert after **Assay**

*Calcium Folate intended for use in the manufacture of parenteral preparations without a further appropriate procedure for the removal of bacterial endotoxins complies with the following additional requirement.*

**Bacterial endotoxins** (2.2.3). Not more than 0.5 Endotoxin Unit per mg of calcium folinate.

#### 4. **Ciprofloxacin**, Page 1399

Insert after **Assay**

*Ciprofloxacin intended for use in the manufacture of parenteral preparations without a further appropriate procedure for the removal of bacterial endotoxins complies with the following additional requirement.*

**Bacterial endotoxins** (2.2.3). Not more than 0.5 Endotoxin Unit per mg of ciprofloxacin.

#### 5. **Clindamycin Injection**, Page 1420

Insert before **Other tests**

**Bacterial endotoxins** (2.2.3). Dilute the injection in *water BET* to give a solution containing 10 mg per ml. The solution contains not more than 6.0 Endotoxin Units per ml.

#### 6. **Cyanocobalamin Injection**, Page 1475

Insert before **Other tests**

**Bacterial endotoxins** (2.2.3). Not more than 0.4 Endotoxin Unit per µg of cyanocobalamin.

#### 7. **Desoxycortone Acetate Injection**, Page 1521

Insert before **Other tests**

**Bacterial endotoxins** (2.2.3). Not more than 71.4 Endotoxin Units per mg of desoxycortone acetate.

**8. Dobutamine Hydrochloride for Injection, Page 3845**

Insert before **Assay**

**Bacterial endotoxins** (2.2.3). Not more than 5.56 Endotoxin Units per mg of dobutamine.

**9. Doxapram Injection, Page 1623**

Insert before **Other test**

**Bacterial endotoxins** (2.2.3). Not more than 3.3 Endotoxin Units per mg of doxapram hydrochloride.

**10. Docetaxel Trihydrate, Page 1608**

Insert after **Assay**

*Docetaxel Trihydrate intended for use in the manufacture of parenteral preparations without a further appropriate procedure for the removal of bacterial endotoxins complies with the following additional requirement.*

**Bacterial endotoxins** (2.2.3). Not more than 0.3 Endotoxin Unit per mg of docetaxel.

**11. Hydroxocobalmin Injection, Page 1914**

Insert before **Other test**

**Bacterial endotoxins** (2.2.3). Not more than 0.4 Endotoxin Unit per  $\mu\text{g}$  of hydroxocobalmin.

**12. Hyoscine Hydrobromide Injection, Page 1930**

Insert before **Other test**

**Bacterial endotoxins** (2.2.3). Not more than 555.0 Endotoxin Units per mg of hyoscine hydrobromide.

**13. Ifosfamide Injection, Page 3872**

Insert before **Assay**

**Bacterial endotoxins** (2.2.3). Not more than 0.125 Endotoxin Unit per mg of ifosfamide.

**14. Isoprenaline Injection, Page 2008**

Insert before **Other test**

**Bacterial endotoxins** (2.2.3). Not more than 1250.0 Endotoxin Units per mg of isoprenaline hydrochloride.

**15. Ivermectin Injection, Page 2023**

Insert before **Other test**

**Bacterial endotoxins** (2.2.3). Not more than 0.016 Endotoxin Unit per  $\mu\text{g}$  of ivermectin.

**16. Labetalol Injection, Page 2048**

Insert before **Assay**

**Bacterial endotoxins** (2.2.3). Not more than 1.2 Endotoxin Units per mg of labetalol hydrochloride.

**17. Lignocaine Hydrochloride, Page 2096**

Insert after **Assay**

*Lignocaine Hydrochloride intended for use in the manufacture of parenteral preparations without a further appropriate procedure for the removal of bacterial endotoxins complies with the following additional requirement.*

**Bacterial endotoxins** (2.2.3). Not more than 1.1 Endotoxin Units per mg of lignocaine hydrochloride.

**18. Lignocaine and Dextrose Injection, Page 2097**

Insert before **Other test**

**Bacterial endotoxins** (2.2.3). Not more than 1.1 Endotoxin Units per mg of lignocaine hydrochloride.

**19. Lorazepam Injection, Page 2120**

Insert before **Assay**

**Bacterial endotoxins** (2.2.3). Not more than 100.0 Endotoxin Units per mg of lorazepam.

**20. Magnesium Sulphate Injection, Page 2145**

Insert before **Other test**

**Bacterial endotoxins** (2.2.3). Not more than 0.09 Endotoxin Unit per mg of magnesium sulphate.

**21. Methylethylmethazine Injection, Page 2202**

Insert before **Other test**

**Bacterial endotoxins** (2.2.3). Not more than 1.7 Endotoxin Units per µg of methylethylmethazine maleate.

**22. Metoprolol Injection, Page 2214**

Insert before **Other test**

**Bacterial endotoxins** (2.2.3). Not more than 25.0 Endotoxin Units per mg of metoprolol tartrate.

**23. Midazolam Injection, Page 2233**

Insert before **Other test**

**Bacterial endotoxins** (2.2.3). Not more than 8.33 Endotoxin Units per mg of midazolam.

**24. Nalorphine Injection, Page 2295**

Insert before **Other test**

**Bacterial endotoxins** (2.2.3). Not more than 11.6 Endotoxin Units per mg of nalorphine hydrochloride.

**25. Noradrenaline Bitartrate Injection, Page 2348**

Insert before **Other test**

**Bacterial endotoxins** (2.2.3). Not more than 83.4 Endotoxin Units per mg of noradrenaline.

**26. Physostigmine Injection, Page 2492**

Insert before **Other test**

**Bacterial endotoxins** (2.2.3). Not more than 83.4 Endotoxin Units per mg of physostigmine salicylate.

**27. Piperacillin, Page 2500**

Insert after **Assay**

*Piperacillin intended for use in the manufacture of parenteral preparations without a further appropriate procedure for the removal of bacterial endotoxins complies with the following additional requirement.*

**Bacterial endotoxins** (2.2.3). Not more than 0.07 Endotoxin Unit per mg of piperacillin.

**28. Procaine Hydrochloride, Page 2556**

Insert after **Assay**

*Procaine Hydrochloride intended for use in the manufacture of parenteral preparations without a further appropriate procedure for the removal of bacterial endotoxins complies with the following additional requirement.*

**Bacterial endotoxins** (2.2.3). Not more than 0.6 Endotoxin Unit per mg of procaine hydrochloride.

**29. Ranitidine Injection, Page 2645**

Insert before **Other test**

**Bacterial endotoxins** (2.2.3). Not more than 7.0 Endotoxin Units per mg of ranitidine.

**30. Ritodrine Injection, Page 2675**

Insert before **Other test**

**Bacterial endotoxins** (2.2.3). Not more than 0.5 Endotoxin Unit per mg of ritodrine.

**31. Sodium Chloride, Page 2740**

Insert after **Assay**

*Sodium Chloride intended for use in the manufacture of parenteral preparations without a further appropriate procedure for the removal of bacterial endotoxins complies with the following additional requirement.*

**Bacterial endotoxins** (2.2.3). Not more than 5.0 Endotoxin Unit per g of sodium chloride.

**32. Sodium Diatrizoate Injection, Page 2749**

Replace **Pyrogen** (2.2.8) with

**Bacterial endotoxins** (2.2.3). Not more than 5.6 Endotoxin Units per ml for injections containing 20.0 per cent of sodium diatrizoate; not more than 1.3 Endotoxin Units per ml for injections containing 25.0 per cent of sodium diatrizoate; and not more than 5.0 Endotoxin Units per ml for injections containing 50.0 per cent of sodium diatrizoate.

**33. Sodium Nitropruside Injection, Page 2763**

Insert before **Other test**

**Bacterial endotoxins** (2.2.3). Not more than 0.05 Endotoxin Unit per  $\mu\text{g}$  of sodium nitropruside.

**34. Thiopentone Injection, Page 2864**

Insert after **Assay**

**Bacterial endotoxins** (2.2.3). Not more than 1.0 Endotoxin Unit per mg of thiopentone sodium.

**35. Triflupromazine Injection, Page 2918**

Insert before **Other test**

**Bacterial endotoxins** (2.2.3). Not more than 5.8 Endotoxin Units per mg of triflupromazine hydrochloride.

**36. Vecuronium Bromide, Page 2962**

Insert before **Assay**

**Bacterial endotoxins** (2.2.3). Not more than 10.0 Endotoxin Units per mg of vecuronium bromide.