Draft Amendments

Date: 15.01.2020

The following proposed amendments are placed for stakeholders comments, if any. The
comments may be sent to Indian Pharmacopoeia Commission through email id lab.ipc@gov.in

1. The proposed limit of Bacterial Endotoxin in Monographs of IP 2018 for amendment list
is given below:

**Bupivacaine Injection. Page 1422**

**Bacterial endotoxins**

Change **from**: Not more than 2.5 Endotoxin Units per mg of bupivacaine.

**to**: Not more than 2.5 Endotoxin Units per mg of bupivacaine hydrochloride.

**Methadone Injection. Page 2550**

**Bacterial endotoxins**

Change **from**: Not more than 8.8 Endotoxin Units per mg of methadone.

**to**: Not more than 8.8 Endotoxin Units per mg of methadone hydrochloride.

**Phenobarbitone Injection. Page 2902**

**Bacterial endotoxins**

Change **from**: Not more than 0.3 Endotoxin Unit per mg of phenobarbitone.

**to**: Not more than 0.3 Endotoxin Unit per mg of phenobarbitone sodium.

**Phentolamine Injection. Page 2908**

**Bacterial endotoxins**

Change **from**: Not more than 5.8 Endotoxin Units per mg of phentolamine.

**to**: Not more than 5.8 Endotoxin Units per mg of phentolamine mesylate.

**Promethazine Injection. Page 3015**

**Bacterial endotoxins**

Change **from**: Not more than 5.0 Endotoxin Units per mg of promethazine.

**to**: Not more than 5.0 Endotoxin Units per mg of promethazine hydrochloride.

**Propranolol Injection. Page 3024**

**Bacterial endotoxins**

Change **from**: Not more than 55.6 Endotoxin Units per mg of propranolol.

**to**: Not more than 55.6 Endotoxin Units per mg of propranolol hydrochloride.

**Ritodrine Injection. Page 3130**

**Bacterial endotoxins**

Change **from**: Not more than 0.5 Endotoxin Unit per mg of ritodrine.

**to**: Not more than 0.5 Endotoxin Unit per mg of ritodrine hydrochloride.

**Vinorelbine Injection. Page 3496**

**Bacterial endotoxins**

Change **from**: Not more than 3.0 Endotoxin Units per mg of vinorelbine tartrate.

**to**: Not more than 3.0 Endotoxin Units per mg of vinorelbine.
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2. The proposed monographs for replacement of Pyrogen test with Bacterial Endotoxin for amendment list is given below:

Amiodarone Intravenous Infusion. Page 1212
Insert before Other tests

Bacterial endotoxins (2.2.3). Not more than 8.33 Endotoxin Units per mg of amiodarone hydrochloride.

Colistimethate Sodium. Page 1693

Pyrogens

Change from: Colistimethate sodium intended for use in the manufacture of parenteral preparation without a further appropriate procedure for the removal of pyrogens complies with the following additional requirement.

Pyrogens (2.2.8). Complies with the test for pyrogens, using per kg of the rabbit’s weight, 1.0 ml of a solution in water for injections containing 2.5 mg of the substance under examination per milliliter.

to: Colistimethate sodium intended for use in the manufacture of parenteral preparation 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 2.0 Endotoxin Units per mg of colistin.

Cloprostenol Injection. Page 4215

Insert before Other tests

Bacterial endotoxins (2.2.3). Not more than 2500 Endotoxin Units per mg of cloprostenol.

Docetaxel Injection. Page 1874

Insert before Other tests

Bacterial endotoxins (2.2.3). Not more than 1.94 Endotoxin Units per mg of docetaxel (anhydrous).

Insulin Zinc Suspension. Page 2294

Insert before Other tests

Bacterial endotoxins (2.2.3). Not more than 80 Endotoxin Units per 100 Units of insulin.

Insulin Zinc Suspension (Amorphous). Page 2296

Insert before Other tests

Bacterial endotoxins (2.2.3). Not more than 80 Endotoxin Units per 100 Units of insulin.
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Insulin zinc Suspension (Crystalline). Page 2297
Insert before Other tests
Bacterial endotoxins (2.2.3). Not more than 80 Endotoxin Units per 100 Units of insulin.

Procainamide Injection. Page 2999
Insert before Other tests
Bacterial endotoxins (2.2.3). Not more than 0.35 Endotoxin Unit per mg of procainamide hydrochloride.

Tylosin Injection. Page 4299
Insert before Other tests
Bacterial endotoxins (2.2.3). Not more than 0.28 Endotoxin Unit per mg of tylosin.

3. Proposed monograph to change for amendment list is given below:

Erythromycin Stearate. Page 1973
Change from: Erythromycin Stearate has a potency not less than 600 Units per mg, calculated on anhydrous basis.
  to: Erythromycin Stearate has a potency not less than 600 Units of erythromycin per mg, calculated on anhydrous basis