

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