

## AMENDMENT LIST-2 TO I.P.2010

### 2.2.3. Bacterial Endotoxins. Page 28

#### Sensitivity of the lysate. Line 4

Change **from**: 2l, 1, 0.5l and 0.25l, where l **to**: 2λ, 1λ, 0.5 λ and 0.25 λ, where λ

#### Preparation of test solutions

Change **from**:

Solution	Final concentration of added CSE in the solution	Number of replicates
A	-	4
B	2l	4
	0.5l	4
	0.25l	4
C	2l	4
	1	2
	0.5l	2
	0.25l	2
D	-	2

**to**:

Solution	Final concentration of added CSE in the solution	Number of replicates
A	-	4
B	2 λ	4
	1λ	4
	0.5λ	4
	0.25 λ	4
C	2 λ	4
	λ	2
	0.5 λ	2
	0.25λ	2
D	-	2

#### Calculation and interpretation of results. (c)

Lines 2 and 3

Change **from**: not more than 2l or not less than 0.5l **to**: not more than 2 λ or not less than 0.5 λ

### 2.4.7 Ultraviolet and Visible Absorption Spectrophotometry. Page 117

#### Resolution power. Line 3

Change **from**: minimum **to**: maximum

Line 4

Change **from**: maximum **to**: minimum

## 2.4.26 Solubility

**Temozolomide.** Page 169

Change **from:** Soluble in *water*. **to:** Sparingly soluble in *dimethylformamide* and *dimethyl sulphoxide*; slightly soluble in *water* and *acetonitrile*.

**Thiocolchicoside.** Page 169

Change **from:** Soluble in *water* and in *ethanol (95 per cent)*. **to:** Soluble in *water*; very slightly soluble in *ethanol(95 per cent)*.

**Amitriptyline Hydrochloride.** Page 804

**Assay.** Chromatographic system, line 2

Change **from:** octadecylsilane **to:** octylsilane

Line 4

Change **from:** 70 volumes **to:** 30 volumes

Line 7

Change **from:** 30 volumes **to:** 70 volumes

**Amitriptyline Tablets.** Page 805

**Dissolution.** Line 1

Change **from:** Apparatus No. 1 **to:** Apparatus No. 2

**Arginine.** Page 834

Insert the following before **Identification**

**Description.** A white or almost white crystalline powder or colourless crystals.

**Artesunate.** Page 838

**Related substances.** *Test solution*, line 2

Change **from:** *water* **to:** *acetonitrile*

*Reference solution*, line 2

Change **from:** *water* **to:** *acetonitrile*

**Bisacodyl.** Page 915

**Related substances.** *Test solution*, line 1

Change **from:** 0.5 g **to:** 50 mg

**Calcium Folate.** Page 963

**Heavy metals.** Line 1

Change **from:** 4.0 g **to:** 0.4 g

Line 2

Change **from:** 5 ppm **to:** 50 ppm

**Ciprofloxacin Injection.** Page 1091

Line 1

Change **from:** ciprofloxacin **to:** ciprofloxacin or ciprofloxacin hydrochloride

**Diacerein.** Page 1191

**Identification.** A, Last line

Change **from:** diacerein **to:** diacerein

**pH** (2.4.24)

Change **from:** solution **to:** suspension

**Diacerein Capsules.** Page 1193

**Dissolution.** Line 10

Change **from:** diacerin **to:** diacerein

**Related substances.** *Test solution*, line 2

Change **from:** diacerin **to:** diacerein

**Digitoxin Tablets.** Page 1217

**Uniformity of content.** Para 3, line 4

Change **from:** *L-ascorbic acid* **to:** *L-ascorbic acid*

**Digoxin Tablets.** Page 1220

**Dissolution.** Para 1, line 5

Change **from:** *L-ascorbic acid* **to:** *L-ascorbic acid*

**Uniformity of content.** Para 3, line 4

Change **from:** *L-ascorbic acid* **to:** *L-ascorbic acid*

**Domperidone Tablets.** Page.1247

Insert the following before **Assay**

**Uniformity of content** (*For tablets containing 10 mg or less*). Comply with the test stated under Tablets.

**Famotidine.** Page 1331

**Related substances.** Chromatographic system, line 11

**Delete** : “- flow rate. 2 ml per minute,”

After injection volume. 20 µl. gradient table

Change **to:**

Time (min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)	Flow rate (ml per min.)
0 - 23	100 → 96	0 → 4	1
23 - 27	96	4	1 → 2
27 - 47	96 → 78	4 → 22	2
47 - 48	78 → 100	22 → 0	2
48 - 54	100	0	2 → 1

**Fluoxetine Hydrochloride.** Page 1369

**Specific optical rotation.** Line 1

Change **from:** **Specific optical rotation** (2.4.22) **to:** **Optical rotation** (2.4.22).

**Gentamicin Injection.** Page 1413

**Composition of gentamicin sulphate.** Last para, line 7

Change **from:** C<sub>2</sub> in the eye drops **to:** C<sub>2</sub> in the injection

**Lansoprazole Sustained-release Capsules.** Page 1570

Title, line 1

Change **from:** Lansoprazole Sustained-release Capsules

**to:** Lansoprazole Capsules

Para 1, Insert the following at the end.

“The content of capsules is enteric coated.”

**Usual strengths.**

Change **from:** 500 mg **to:** 15 mg; 30 mg

**Levocetirizine Hydrochloride.** Page 1573

**Enantiomeric purity.** *Test solution*, line 2

Change **from:** 25 **to:** 25 ml

*Reference solution*, line 3

Change **from:** 25 **to:** 25 ml

**Nifedipine Capsules.** Page 1780

**Identification.** Last para, line 2

Change **from:** until the solvent **to:** until the odour of the solvent

**Ramipril and Hydrochlorothiazide Tablets.** Page 2041

**Related substances.** Last para, lines 5, 8 and 11

Change **from:** the principal peak **to:** the principal peak due to ramipril

**Rifampicin, Isoniazid and Ethambutol Tablets.** Page 2061

**Dissolution.** Line 1

Change **from:** Apparatus No. 2 **to:** Apparatus No. 1

**Tolnaftate.** Page 2238

**Related substances.** Insert the following before *Test solution (a)*

*Mobile phase. Toluene.*

**Tolterodine Tartrate.** Page 2240

**Specific optical rotation.** Line 2

Change **from:** +33° to +38° **to:** +27° to +34°