

Amendments under consideration for the next edition of IP

UPDATED ON: 01.03.2011

Bisacodyl Tablets. Page 917

Title and line 1

Change **from:** Bisacodyl Tablets

to: Bisacodyl Enteric-coated Tablets

Para 1, lines 3 and 4

Delete “The tablets are rendered gastro-resistant by enteric coating or by other means”

Carbamazepine Extended-release Tablets. Page 978

Title, line 1 and 4

Change **from:** Carbamazepine Extended-release Tablets

to: Carbamazepine Prolonged-release Tablets

Cefaclor Sustained-release Tablets. Page 997

Title

Change **from:** Cefaclor Sustained-release Tablets

to: Cefaclor Prolonged-release Tablets

Para 1 and 2

Change **to:** “*Cefaclor Prolonged-release Tablets manufactured by different manufacturers, whilst complying with the requirements of the monograph, are not interchangeable.*”

Cefaclor Prolonged-release Tablets contain not less than 90.0 per cent and not more than 105.0 per cent of the stated amount of cefaclor, $C_{15}H_{14}ClN_3O_4S$.

Disopyramide Phosphate Sustained-release Capsules. Page 1238

Title

Change **from:** Disopyramide Phosphate Sustained-release Capsules

to: Disopyramide Prolonged-release Capsules

Para 1 and 2

Change **to:** Disopyramide Phosphate Prolonged-release Capsules; Disopyramide Phosphate Sustained-release Capsules

“*Disopyramide Prolonged-release Capsules manufactured by different manufacturers, whilst complying with the requirements of the monograph, are not interchangeable.*”

Disopyramide Prolonged-release Capsules contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of disopyramide, $C_{21}H_{29}N_3O$.

Dissolution. Change **to:**

Dissolution (2.5.2). Complies with the test stated under tablets.

Divalproex Sustained-release Tablets. Page 1241

Title

Change **from:** Divalproex Sustained-release Tablets

to: Divalproex Delayed-release Tablets

Lines 1 and 2

Change **from:** Divalproex Sodium Sustained-release Tablets; Sodium Valproate Sustained-release Tablets
to: Divalproex Sodium Delayed-release Tablets

Para 2

Change **to:** Divalproex Delayed-release Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of valproic acid, C₈H₁₆O₂. The tablets are enteric coated.

Uniformity of content. Delete the requirement

Erythromycin Tablets. Page 1291

Title and line 1

Change **from:** Erythromycin Tablets
to: Erythromycin Enteric-coated Tablets

Para 1, line 3

Delete “The tablets are enteric-coated”

Esomeprazole Tablets. Page 1296

Title, synonym and line 1

Change **from:** Esomeprazole Tablets
to: Esomeprazole Enteric-coated Tablets

Para 1, line 3

Delete “The tablets are enteric-coated”

Felodipine Sustained-release Tablets. Page 1335

Title

Change **from:** Felodipine Sustained-release Tablets
to: Felodipine Prolonged-release Tablets

Para 1

Change **to:** “*Felodipine Prolonged-release Tablets manufactured by different manufacturers, whilst complying with the requirements of the monograph, are not interchangeable.*”

Felodipine Prolonged-release Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of felodipine, C₁₈H₁₉Cl₂NO₄.

Dissolution. Change **to:**

Dissolution (2.5.2). Complies with the test stated under tablets.

Lamotrigine Sustained-release Tablets. Page 1567

Title

Change **from:** Lanotrigine Sustained-release Tablets
to: Lamotrigine Prolonged-release Tablets

Para 1

Change **to:** “*Lamotrigine Prolonged-release Tablets manufactured by different manufacturers, whilst complying with the requirements of the monograph, are not interchangeable.*”

Lamotrigine Prolonged-release Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of lamotrigine, C₉H₇Cl₂N₅.

Dissolution. Change **to:**

Dissolution (2.5.2). Complies with the test stated under tablets.

Lansoprazole Sustained-release Capsules. Page 1570

Title, line 1

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

to: Lansoprazole Enteric-coated Capsules

Metformin Hydrochloride Sustained-release Tablets. Page 1659

Title

Change **from:** Metformin Hydrochloride Sustained-release Tablets

to: Metformin Hydrochloride Prolonged-release Tablets

Para 1

Change **to:** “*Metformin Hydrochloride Prolonged-release Tablets manufactured by different manufacturers, whilst complying with the requirements of the monograph, are not interchangeable.*”

Metformin Hydrochloride Prolonged-release Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of metformin hydrochloride, $C_4H_{11}N_5 \cdot HCl$.

Dissolution. Change **to:**

Dissolution (2.5.2). Complies with the test stated under tablets.

Neomycin Eye Drops. Page 1764

Usual strength. Line 1

Change **from:** 0.5 per cent w/v (3500 Units per ml). **to:** 3500 Units per ml

Labelling.

Change **from:** **Labelling.** The strength is stated in terms of percentage w/v as well as the number of Units per ml. **to:**

Labelling. The strength is stated in terms of number of Units per ml.

Neomycin Eye Ointment. Page 1765

Usual strength. Line 1

Change **from:** 0.5 per cent w/w (3500 Units per g). **to:** 3500 Units per g

Labelling.

Change **from:** **Labelling.** The strength is stated in terms of percentage w/v as well as the number of Units per ml. **to:**

Labelling. The strength is stated in terms of number of Units per g.

Nifedipine Sustained-release Tablets. Page 1781

Title

Change **from:** Nifedipine Sustained-release Tablets

to: Nifedipine Prolonged-release Tablets

Para 1

Change **to:** “*Nifedipine Prolonged-release Tablets manufactured by different manufacturers, whilst complying with the requirements of the monograph, are not interchangeable.*”

Nifedipine Prolonged-release Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of nifedipine, $C_{17}H_{18}N_2O_6$.

Dissolution. Change **to:**

Dissolution (2.5.2). Complies with the test stated under tablets.

Pantoprazole Sustained-release Tablets. Page 1857

Title and line 1

Change **from:** Pantoprazole Sustained-release Tablets

to: Pantoprazole Delayed-release Tablets

Para 1

Change **to:** Pantoprazole Delayed-release Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of pantoprazole, C₁₆H₁₅F₂N₃O₄S. The tablets are enteric coated.

Rabeprazole Tablets. Page 2037

Title, synonym and line 1

Change **from:** Rabeprazole Tablets

to: Rabeprazole Enteric-coated Tablets

Para 1, lines 3 and 4

Delete "The tablets are enteric coated"