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INDIAN PHARMACOPOEIA COMMISSION
MIN. OF HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA
SECTOR -23, RAJ NAGAR, GHAZIABAD - 201002

No. IPC/7021/IP-2014/ER-010 **Dated**: 19-05-2016

To,

1. **DCG (I)/ CDSCO, Zonal Offices**
2. **All State Drug Controllers**
3. **Members of Scientific Body of the IPC**
4. **Members of Sub-committee of Scientific Body of the IPC**
5. **Government Analysts**
6. **Director of Drug Laboratories**
7. **IDMA/OPPI/BDMA/FSSAI/Small Scale Industry Associations**

ERRATA – 010 for IP 2014

As you are aware that the 7th edition of Indian Pharmacopoeia has become official from 1st April, 2014. Based on scientific inputs, some monographs, appendices needed corrections, accordingly an Errata – 010 is issued containing minor corrections. This is for notice and immediate compliance.

Yours faithfully,

(Dr. G. N. Singh)
Secretary-cum-Scientific Director

Encl:
ERRATA – 010 for IP 2014

CC to: Publication Division to put up on IPC website.

Errata-010 to IP-2014

(Volume IV, Veterinary Pharmacopoeia)

Veterinary Non Biological Monographs

Acepromazine Maleate. Page 3477

Dose

Change **from** : *Farm animals*. By intramuscular or slow intravenous injection, the equivalent of 50 to 100 mg of acepromazine per kg body weight. *Dogs and cats.* Orally, the equivalent of 1 to 3 mg of acepromazine per kg of body weight;by intramuscular or intravenous injection, the equivalent of 125 to 250 mg of acepromazine per kg of body weight.

to : *Farm animals*. By intramuscular or subcutaneous injection, the equivalent of 0.05 mg to 0.1 mg of acepromazine per kg body weight. *Dogs and cats.* Orally equivalent of 1.0 mg to 3.0 mg of acepromazine per kg of body weight;by intravenous, intramuscular or subcutaneous injection, the equivalent of 0.05 mg to 0.22 mg of acepromazine per kg of body weight.

Acepromazine Injection. Page 3477

Usual strengths.

Change **from**: The equivalent of 200 mg of acepromazine in 20 ml and of 20 mg of acepromazine in 10 ml.

to: The equivalent of 10 mg of acepromazine per ml.

Ampicillin Veterinary Oral Powder. Page 3485

Uniformity of Weight.

Change **from**: When supplied in containers intended for use on one occasion, complies with the test for uniformity of weight described under Parentral Preparations (Powders for Injections).

to: When supplied in containers intended for use on one occasion, complies with the requirements *of uniformity of weight of single dose preparations (*2.5.4).

Amprolium Hydrochloride. Page 3486

Mol. wt.

Change **from**: 315.2

to: 315.3

Calcium Magnesium Borogluconate Injection. Page 3493

Labelling.

Change **from**: The label states (1) the strength in terms of the equivalent amount of calcium and magnesium in a suitable dose-volume.

to: The label states (1) the strength in terms of the equivalent amount of calcium**,** magnesium and dextrose in a suitable dose-volume.

Carprofen. Page . 3493

Related substances. Last Para, lines7 & 8

Change **from**: Ignore any peak with an area of the principal peak.

to : Ignore any peak with an area less than the area of the principal peak.

Cefoperazone Sodium Intramammary Suspension. Page 3494

Para 2

from: Cefaperazone contains not less than 90.0 per cent and not more than 110.0 per cent of Cefoperazone $C_{25}H_{27}N_90_8S_2$

to: Cefaperazone contains not less than 90.0 per cent and not more than 120.0 per cent of Cefoperazone, $C_{25}H_{27}N_90_8S_2$.

Cefpodoxime Tablets. Page.3495

Usual strengths. Lines 1 & 2
Change **from**: Cefpodoxime proxetil
to: Cefpodoxime

Cholecalciferol. Page.3501

Dose. Line 3
Change **from**: 250 mg
to: 250 mcg

Closantel Sodium Dihydrate. Page3503

Related substances. After Chromatographic system, part1
Last paragraph.
Change**from**: Inject reference solution (a). The test is not valid unless there is clear base line separation between the peaks due to impurity G and closantel is not separate baseline.
to: Inject reference solution (a). The test is not valid unless there is clear base line separation between the peaks due to impurity G and closantel.

Decoquinate. Page 3507

Mol. wt.
Change **from**: 417.5
to: 417.6
Light absorption. lines 5-8
Change **from**: with ethanol and examined in the range 230nm to 350 nm (2.4.7). The solution shows absorption maxima at about 265 nm is 0.38 to 0.42.Calculated on the basis of dried substance.
to: with absolute ethanol. The absorbance of the resulting solution at the maximum at about 265 nm is 0.38 to 0.42, calculated on the dried basis.

Dichlorophen Tablets. Page3512

Related substances. After chromatographic system.Part1, Line 3.
Change **from** : 4- dichlorophenol.
to : 4-chlorophenol.

Diclazuril. Page3513

Related substances.
Reference solution (a).
Change **from** : *diclazuril RS*
to : diclazuril for system suitability RS.

After Chromatographic system. Lines 1 &2
Change **from** : Flunixin impurity H^1
to: Diclazuril impurity H^1

Change **from**: Flunixin impurity D^2
to: Diclazuril impurity D^2.

Dicloxacillin Sodium. Page3514

Dose. Line 2.
Change **from**: cloxacillin
to: dicloxacillin**.**

Dinitolmide. Page3519

Related substances.
Last Para-line 6.
Change **from** : 354 nm
to: 254 nm.

Enrofloxacin. Page 3520

Appearance of solution. Last Line.
Change **from** : coloured than reference solution.
to : coloured than reference solution GYS4.

Furazolidone. Page3528

Dose. Line 1.
Change **from**: *Large animals*. 10 to 12 kg of body weight.
to: *Large animals.* 10 to 12 mg per kg of body weight.
Lines 3 &4
Change **from** : *Pigs (weaned) and claves*. Up to 400 mg per tonne.
to: *Pigs (weaned) and claves*. Up to 400 g per tonne.

Ivermectin Oral Paste. Page3534

Related substances. After chromatographic system.Para 2, line3.
Change **from** : the retention time of 1.3 to 1.5 relative to that of is not more than…
to: the retention time of 1.3 to 1.5 relative to that of the principal peak is not…

Ivermectin Injection. Page 3534

Assay
Change **from**: *Test solution*: Dilute a volume of the injection containing 5mg of Ivermectin to 100 ml with water.
to: *Test solution*: Dilute a volume of the injection containing 5mg of Ivermectin to 100 ml with methanol.

Ivermectin Pour on. Page 3535

Related Substances. After chromatographic system... Para 2, line3.
Change **from**: the retention time of 1.3 to 1.5 relative to that of is not more…..
to: the retention time of 1.3 to 1.5 relative to that of the principal peak is not more....

Levamisole Injection. Page 3536, Para 1

Change **from**: Leavamisole Injection is a sterile solution of Levamisole Hydrochloride in Water for Injections. It may contain suitable colouring agents.
to: Leavamisole Injection is a sterile solution of Levamisole Hydrochloride in Water for Injections.

Moxidectin. Page 3547

Heavy metals. *Reference solution*.Line1
Change **from**: stock solution
to: prescribed solution

Nitroxynil Injection. Page 3552

Inorganic Iodide. Lines 14 & 15
Change **from**: allowing to separate (500 rpm) (0.1 per cent w/v of iodide).
to:.allowing to separate (0.1 per cent w/v of iodide**).**

Oxytetracycline Hydrochloride Injection. Page 3557

Usual strengths.
Change **from**: 50 mg per ml in 30 ml and 100 ml vials; 100 mg per ml in 100 ml vials; 200 mg per ml in 30 ml, 50 ml and 100 ml vials.
to: 50 mg per ml in 30 ml and 100 ml vials;100 mg per ml in 100 ml vials.

Ronidazole Veterinary Oral Powder. Page 3564

Assay. Line 1.
Change **from**: Weigh a quantity of powder containing 2 g of Ronidazole,
to: Weigh a quantity of powder containing 0.2 g of Ronidazole,

Ronidazole. Page 3563

Water
Change **from**: Not more than 0.5 per cent , determined on 5 gm.
to: Not more than 0.5 per cent.

Spectinomycin Hydrochloride. Page 3566

Assay. After Chromatographic system. Line 4.
Change **from**: test solution (a)
to: test solution (b)

Sulphadimidine Tablets. Page 3576

Change **title to**: **Sulphadimidine Bolus Tablets**

Spectinomycin Injection. Page 3568

Dose. Line 1
Change **from**: 50 to 100 mg
to: 10 to 20 mg

Assay. After Chromatographic system.Para1, Line 4.
Change **from**: test solution (a)
to: test solution (b)

Spiramycin. Page3569

Heavy metals. Line 2
Change from : Method A
to : Method B

Tylosin. Page3581

Heavy metals. Line 5
Change **from**: 25ml
to: 20 ml
Last line. Add the following at the end,
using 10 ml of either lead standard solution(1ppm Pb).
Tyramine. Line 12
Change **from**: 35mg of *tyramine* per ml
to : 35 mg of *tyramine* per litre
Add the following at the end
(0.15 per cent). If intended for use in manufacture of parenteral preparations.

Tylosin Injection . Page 3582

Tyramine. Line 13
Change **from**: 30 mg of *tyramine* per ml
to: 30 mg of *tyramine* per litre.
Storage.
Change **from**: Store protected from moisture.
to: Store protected from light.

Tylosin Tablets. Page 3583

Tyramine. Lines 13 &14
Change **from**: 35mg of *tyramine* per ml
to: 35 mg of *tyramine* per litre.

Veterinary Biological Monographs

Avian Infectious Bronchitis Vaccine, Live. Page 3592

Water
Change **from**: Not more than 3.0 per cent.
to: Not more than 5.0 per cent.
Sterility.
Change **from**: Complies with the test for sterility.
to: Vaccines intended for administration by injection comply with the test for sterility prescribed in the monograph (2.2.11).

Fowl Cholera Vaccine, Inactivated. Page 3616

Inactivation.
Change **from**: The test shall consists at least two passages in production medium or if solid medium has been used for production, in suitable liquid medium. Incubate inoculated medium at 30° to 35° for 72 hours. The product complies with the test if no evidence of live *P.multocida* is observed.

to: An amplification test for residual live *Pasturella multocida* organism is carried out on each batch of antigen immediately after inactivation. Use suitable selective bacteriological broth or agar plates supporting growth of *P. multocida* for inactivation test. Carry out two subsequent passages in similar media for detection of growth of *P. multocida* organisms. No growth of *P. multocida* should observe to comply inactivation test.

Fowl Pox Vaccine, Live. Page 3616

Substrate for virus propagation
Add the following at the end.
The master seed lot complies with the tests for extraneous agents as described in the General monograph for Veterinary Vaccines.
Water.
Change **from**: Not more than 3.0 per cent.
to: Not more than 5.0 per cent.

Infectious Avian Encephalomyelitis Vaccine, Live. Page 3619

Water.
Change **from**: Not more than 3.0 per cent
to: Not more than 5.0 per cent
Sterility.
Change **from**: Complies with the test for sterility.
to: Vaccines intended for administration by injection comply with the test for sterility prescribed in the monograph (2.2.11).Vaccines not intended for administration by injection either comply with the test for sterility prescribed in the monograph (2.2.11) or with the following test: carry out the quantitative test for bacterial and fungal contamination; carry out identification tests for microorganisms detected in the vaccine; the vaccine does not contain pathogenic microorganisms and contain not more than 1 non pathogenic microorganisms per dose.

Infectious Bursal Disease Vaccine, Inactivated. Page 3620

Inactivation
For vaccine prepared with embryo-adapted strains of the virus . Para 2
Change **from**: Inject into the allantoic cavity of each of the SPF embryonated hen eggs, between 9 to 11 days old, 0.2 ml of the pooled allantoic fluid from the live embryos or membrane from the dead embryos and incubate at 36°±1° for 6 days. Examine each embryo for lesions of infectious bursal disease. The vaccine complies with the test if, there is no evidence of lesions of infectious bursal disease.

to: Inject into the allantoic cavity or Chorio-allantoic membrane of each of the SPF embryonated hen eggs, between 9 to 11 days old, 0.2 ml of the pooled allantoic fluid or Chorio-allantoic membrane from the live embryos or membrane from the dead embryos and incubate at 36°±1° for 6 days. Examine each embryo for lesions of infectious bursal disease. The vaccine complies with the test if, there is no evidence of lesions of infectious bursal disease.

For vaccine prepared with cell culture-adapted strains of the virus. Page 3621

Change **from:** The formaldehyde in the test sample is neutralized with sodium metabisulphite. Five ml is tested for the presence of infective Gumboro Disease virus by inoculation of at least 800 square cm primary or secondary CEF. The cultures are incubated for 3 to 4 days at a temperature of 37°. After one cycle of freezing and thawing the supernatant from these cultures is passaged to a fresh CEF cultures. Three to four days latter this is repeated. Three to four days after final inoculation the cultures are inspected for CPE. A vital stain and overlay may be used. If no trace of CPE is detected, the inactivation of the antigen suspension is accepted to be completed.

to: The formaldehyde in the test sample is neutralizes with sodium metabisulphite. One ml is tested for the presence of infective Gumboro Disease virus by inoculation of at least 150 square cm primary or secondary CEF. The cultures are incubated for 3 to 4 days at a temperature of 37°. After one cycle of freezing and thawing the supernatant from these cultures is passaged to a fresh CEF cultures. Three to four days latter this is repeated. Three to four days after final inoculation the cultures are inspected for CPE. A vital stain and overlay may be used. If no traces of CPE is detected, the inactivation of the antigen suspension is accepted to be completed.

Infectious Bursal Disease Vaccine, Live. Page 3621

Water.

Change **from** : Not more than 3.0 per cent.

to: Not more than 5.0 per cent.

Sterility.

Change **from**: Complies with the test for sterility.

to: Vaccines intended for administration by injection comply with the test for sterility prescribed in the monograph (2.2.11).

Vaccines intended for administration by injection either comply with the test for sterility prescribed in the monograph (2.2.11) or with the following test: carry out the quantitative test for bacterial and fungal contamination; carry out identification tests for microorganisms detected in the vaccine; the vaccine does not contain pathogenic microorganisms and contain not more than 1 non pathogenic microorganisms per dose.

Infectious Chicken Anemia Vaccine, Live. Page 3623

Water.

Change **from**: Not more than 3.0 per cent.

to: Not more than 5.0 per cent.

Sterility.

Change from: Complies with the test for sterility

to: Vaccines intended for administration by injection comply with the test for sterility prescribed in the monograph (2.2.11).

Infectious Coryza Vaccine. Page 3623

Potency. Line 3

Change **from**: group at which vaccine is used, with minimum dose

to: group at which vaccine is used for each strain incorporated in vaccine, with minimum dose

Lines 10 & 14

Change from: Observe the chickens for 7 days for unilateral eye swelling,

to: Observe the chickens for 7 days for eye swelling,

Marek's Disease Vaccine, Live. Page 3624

Water.

Change from: Not more than 3.0 per cent (For Freeze dried vaccine only)

to: Not more than 5.0 per cent (For Freeze dried vaccine only)