

NEW DRAFT AMENDMENTS - 26th October 2022 onwards

2.2.9. Microbial Contamination in Non sterile Products. Page 40

Enumeration of aerobic microorganisms present in the product

Pour-plate method. Line 11

Change **from:** Then select the plates corresponding to a given dilution and showing the highest number of colonies but less than 250 for aerobic microorganisms and 25 colonies for fungi.

to: Then select the plates corresponding to a given dilution and showing the highest number of colonies but less than 250 for aerobic microorganisms and 50 colonies for total fungal count.

Barium Sulphate Oral Suspension. Page 1579

Microbial Contamination (2.2.9)

Change **from:** The total aerobic viable count is not more than 100 cfu per ml, the total combined molds and yeasts count is not more than 10 cfu per ml. 1 g is free from *Staphylococcus aureus* and *Pseudomonas aeruginosa* and 10 g is free from *Salmonella* species.

to: The total aerobic viable count is not more than 100 cfu per ml, the total combined molds and yeasts count is not more than 10 cfu per ml. 1 g is free from *Escherichia coli*, *Staphylococcus aureus* and *Pseudomonas aeruginosa* and 10 g is free from *Salmonella* species.

Microcrystalline Cellulose. Page 2937

Add after **Loss on Drying**

Microbial Contamination (2.2.9). The total aerobic viable count is not more than 1000 cfu per g and total fungal count is not more than 100 cfu per g. 1 g is free from *Escherichia coli*, *Staphylococcus aureus* and *Pseudomonas aeruginosa* and 10 g is free from *Salmonella* and *Shigella*.

Phenylephrine Injection. Page 3257

Bacterial Endotoxin (2.2.3)

Change **from:** Not more than 25.0 Endotoxin Units per mg of phenylephrine.

to: Not more than 25.0 Endotoxin Units per mg of phenylephrine hydrochloride.

Starch. Page 4303

Microbial Contamination (2.2.9)

Change **from:** 1 g is free from *Escherichia coli* and 10 g is free from *Salmonella* and *Shigella*.

to: The total aerobic viable count is not more than 1000 cfu per g, the total fungal count is not more than 100 cfu per g, determined by plate count. 1 g is free from *Escherichia coli* and 10 g is free from *Salmonella* and *Shigella*.