

BASIC TESTS FOR PHARMACEUTICAL SUBSTANCES

APPENDIX II

World Health Organization

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AMPICILLIN “Pen A”

Dissolve 0.10 g in 40 ml of water; a clear and colorless solution is produced.

AMPICILLIN SODIUM “Pen A/N”

Degradation test

Discoloration and a change in the physical aspect of the test substance (in particular, appearance of a hard, yellow mass) and non-compliance with the following test usually indicate gross degradation:

Dissolve 0.05 g in 1.0 ml of water, shake and add 0.10 ml of hydrochloric acid (— 70 g/l) TS; no precipitate is observed.

BENZYL PENICILLIN SODIUM “Pen G”

Degradation test

Discoloration and a change in the physical aspect of the test substance and non-compliance with the following test usually indicate gross degradation:

Dissolve 0.20 g in 1.0 ml of water; the solution is clear and colorless.

CEFALEXIN “Keflex”

Degradation test

Discoloration of the test substance usually indicates gross degradation.

DICLOXACILLIN SODIUM (MONOHYDRATE)

Degradation test

Discoloration of the test substance and non-compliance with the following test usually indicate gross degradation:

Dissolve 0.10 g in 20 ml of water; the solution is clear and colorless.

DOXYCYCLINE HYDROCHLORIDE

Degradation test

Discoloration of the test substance and non-compliance with the following test usually indicate gross degradation:

Dissolve 0.5 g in 20 ml of water; the solution is perfectly clear and has a yellow color.

OXYTETRACYCLINE HYDROCHLORIDE “Terramycin”

Degradation test

If the test substance does not pass the following test, this usually indicates that gross degradation has occurred:

Dissolve 0.5 g in 2.0 ml of water; it dissolves completely to give a clear and colorless solution.

PHENOXYMETHYLPENICILLIN “Pen V”

Degradation test

If the test substance does not pass the following test, this usually indicates that gross degradation has occurred:

Dissolve 0.5 g in 3.5 ml of ethanol (— 750 g/l) TS; a clear and colorless solution is produced.

PHENOXYMETHYLPENICILLIN POTASSIUM “Pen VK”

Degradation test

Discoloration of the test substance and non-compliance with the following test usually indicate gross degradation:

Dissolve 0.10 g in 100 ml of water; the solution is clear and colorless.

TETRACYCLINE HYDROCHLORIDE

Degradation test

If the test substance does not pass the following test, this usually indicates that gross degradation has occurred:

Dissolve 0.5 g in 5 ml of water; it dissolves completely to give a clear solution.