

**§ 429.12 Distinguishing colors on packages.**

(a) The outside containers or wrappers of the packages, and the labels on the immediate containers of each potency of insulin injection shall be distinguished by the following colors:

Red, if it contains 40 U.S.P. Units of insulin per milliliter.

White, if it contains 100 U.S.P. Units of insulin per milliliter.

Narrow (at least 5 but not more than 20 to each inch) brown and white diagonal stripes, if it contains 500 U.S.P. Units of insulin per milliliter.

But if the master lot used was in crystalline form, the distinguishing colors, instead of those prescribed above, may be the following:

Red and gray, if it contains 40 U.S.P. Units of insulin per milliliter.

(b) The outside containers or wrappers of the packages, and the labels on the immediate containers of each potency of protamine zinc insulin suspension shall be distinguished by the following colors:

Red and white, if it contains 40 U.S.P. Units of insulin per milliliter.

Black and white, if it contains 100 U.S.P. Units of insulin per milliliter.

(c) The outside containers or wrappers of the packages, and the labels of the immediate containers of each potency of globin zinc insulin injection shall be distinguished by the following colors:

Red and brown, if it contains 40 U.S.P. Units of insulin per milliliter.

Black and white, if it contains 100 U.S.P. Units of insulin per milliliter.

(d) The outside containers or wrappers of the packages, and the labels of the immediate containers of each potency of isophane insulin suspension shall be distinguished by the following colors:

Red and blue, if it contains 40 U.S.P. Units of insulin per milliliter.

Black and white, if it contains 100 U.S.P. Units of insulin per milliliter.

(e) The outside containers or wrappers of the packages, and the labels of the immediate containers, of insulin zinc suspension, prompt insulin zinc suspension, and extended insulin zinc suspension shall bear a mark or design

to distinguish each drug, and each potency of these drugs shall be distinguished by the following colors:

Red and lavender, if it contains 40 U.S.P. Units of insulin per milliliter.

Black and white, if it contains 100 U.S.P. Units of insulin per milliliter.

[39 FR 11750, Mar. 29, 1974, as amended at 39 FR 40286, Nov. 15, 1974; 44 FR 55170, Sept. 25, 1979]

**Subpart C—Product Standards****§ 429.25 Standards of quality and purity for protamine.**

When protamine is dried to constant weight at 100° C., its total nitrogen content is not less than 22.5 percent and not more than 25.5 percent, and its sulfate content, calculated as SO<sub>4</sub>, is not less than 16 percent and not more than 19 percent.

**§ 429.26 Standards of quality and purity for globin hydrochloride.**

The ash content of globin hydrochloride is not more than 0.3 percent; its nitrogen content, calculated to moisture, ash, and hydrochloric acid free basis, is not less than 16.0 percent and not more than 17.5 percent.

**Subpart D—Tests and Methods****§ 429.30 Tests and methods of assay.**

The following tests and methods of assay are prescribed for the purposes of the regulations in this part 429. (All reagents specified in this section shall be of U.S.P. quality or better.)

(a) *Tests and methods of assay for insulin injection, protamine zinc insulin suspension, globin zinc insulin injection, isophane insulin suspension, insulin zinc suspension, prompt insulin zinc suspension, and extended insulin zinc suspension.* The tests and methods of assay for insulin injection, protamine zinc insulin suspension, globin zinc insulin injection, isophane insulin suspension, insulin zinc suspension, prompt insulin zinc suspension, and extended insulin zinc suspension shall be those set forth therefor in the U.S.P. or N.F., except that alternative test procedures may be employed when such have been authorized by the Commissioner.

(b) [Reserved]