Printed by: Le Tran

Official Date: Official as of 01-Nov-2020 Document Type: GENERAL CHAPTER

@2021 USPC 1

(731) LOSS ON DRYING

Change to read:

The procedure set forth in this chapter determines the amount of volatile matter of any kind that is driven off under the conditions specified, ≜which is defined as Loss on Drying value. (USP 1-Aug-2020) For substances appearing to contain water as the only volatile constituent, the procedure given in *Water Determination* (921) is appropriate, and is specified in the individual monograph.

Unless otherwise directed in the individual monograph, conduct the determination of Loss on Drying on a 1- to 2-g test specimen. Mix the substance to be tested and, if it is in the form of large particles, reduce the particle size to about 2 mm by \$\blacktriangle \Lambda (USP 1-Aug-2020)\$ crushing before weighing \$\blacktriangle \text{it} \Lambda (USP 1-Aug-2020)\$ out. \$\blacktriangle \Lambda (USP 1-Aug-2020)\$ Tare an appropriate glass-stoppered \$\blacktriangle \Lambda (USP 1-Aug-2020)\$ weighing bottle that has been dried for about 30 min under the same conditions to be employed in the determination and cooled to room temperature in a desiccator. Put the test specimen in the bottle, replace the \$\blacktriangle \text{stopper}, \Delta (USP 1-Aug-2020)\$ and accurately weigh the \$\blacktriangle \text{stoppered} \Delta (USP 1-Aug-2020)\$ bottle and the contents. By gentle, sidewise shaking, distribute the test specimen as evenly as practicable to a depth of about 5 mm generally, and NMT 10 mm in the case of \$\blacktriangle \text{low} bulk density \Delta (USP 1-Aug-2020)\$ materials. Place the loaded bottle in the drying chamber, \$\blacktriangle \text{remove} \Delta (USP 1-Aug-2020)\$ the stopper and \$\blacktriangle \text{leave} \Delta (USP 1-Aug-2020)\$ it also in the chamber. Dry the test specimen at the \$\blacktriangle \text{specified} \Delta (USP 1-Aug-2020)\$ temperature and time \$\blacktriangle \text{conditions}.

[Note—The Loss on Drying value is a function of both temperature and time. Therefore, these values must be identified and reported. $_{\Delta (USP\ 1-Aug-2020)}$ The temperature specified in the monograph is to be regarded as being within the range of $\pm 2^{\circ}$ of the stated $^{\Delta}$ value. $_{\Delta (USP\ 1-Aug-2020)}$]

When "dry to constant weight" is specified in a monograph, drying shall be continued until two consecutive weighings do not differ by more than 0.50 mg/g of *specimen taken, where the second weighing follows (USP 1-Aug-2020) an additional hour of drying. Upon opening the chamber, *reapply the same stopper to the bottle, (USP 1-Aug-2020) and allow it to come to room temperature in a desiccator before weighing *accurately. (USP 1-Aug-2020) If the substance melts at a lower temperature than that specified for the determination of Loss on Drying, maintain the bottle

If the substance melts at a lower temperature than that specified for the determination of Loss on Drying, maintain the bottle with its contents for 1–2 h at a temperature 5°–10° below the melting temperature, then dry at the specified temperature.

Where capsules are to be tested, use a \triangle representative sample mixture, excluding the capsule shell, from $not_{\triangle (USP \ 1-Aug-2020)}$ fewer than 4 capsules.

Where tablets are to be tested, use ▲a representative sample mixture (USP 1-Aug-2020) from NLT 4 crushed tablets.

Where the individual monograph directs that Loss on Drying be determined by thermogravimetric analysis, a

^suitable (USP 1-Aug-2020) balance is to be used ^(see Balances (41). (USP 1-Aug-2020)

Where drying under vacuum over a desiccant is directed in the individual monograph, a vacuum desiccator or a vacuum drying pistol, or other suitable vacuum drying apparatus, is to be used.

Where drying in a desiccator is specified, exercise particular care to ensure that the desiccant is $^{\blacktriangle}_{\bot}$ (USP 1-Aug-2020) fully effective.

▲ (USP 1-Aug-2020)

Where drying in a capillary-stoppered bottle¹ under vacuum is directed in the individual monograph, use a bottle or tube fitted with a stopper having a 225 ± 25 - μ m diameter capillary, and maintain the heating chamber at a pressure of 5 mm or less of mercury. At the end of the heating period, admit dry air to the heating chamber, remove the bottle, and with the capillary stopper still in place allow it to cool to room temperature in a desiccator before weighing.

¹ Available as an "antibiotic moisture content flask" from Kimble ▲Chase Life Science and Research Products, ▲ (USP 1-Aug-2020) 1022 Spruce St., Vineland, NJ ▲08360. ▲ (USP 1-Aug-2020)