

REFERENCES

- Allison SD, Chang B, Randolph TW, Carpenter JF. Hydrogen bonding between sugar and protein is responsible for inhibition of dehydration-induced protein unfolding. *Arch Biochem Biophys* 1999; 365: 289-98.
- Allison SD, Manning MC, Randolph TW, Middleton K, Davis A, Carpenter JF. Optimization of storage stability of lyophilized actin using combinations of disaccharides and dextran. *J Pharm Sci* 2000; 89: 199-214.
- Allison SD, Randolph TW, Manning MC, Middleton K, Davis AS, Carpenter JF. Effects of drying methods and additives on structure and function of actin: Mechanisms of dehydration-induced damage and its inhibition. *Arch Biochem Biophys* 1998; 358: 171-81.
- Atwood JG, Marshall HW. Factors in serum that limit speed and precision in ultramicro enzyme rate measurements. *Lab Med Newslett* 1973; 22: 456-60.
- Beckman instruction manual. Beckman Coulter, Inc. CA: Fullerton, 1996.
- Bowers GN Jr, Burnett RW, McComb RB. Preparation and use of human serum control materials monitoring precision in clinical chemistry. *Sel Methods Clin Chem* 1977; 8: 21-7.
- Bowers GN Jr, Kelley ML, McComb RB. Precision estimates in clinical chemistry. I. Variability of analytic results in a survey reference sample related to the use of nonhuman serum alkaline phosphatase. *Clin Chem* 1967; 14: 595-607.
- Browning DM, Hill PG, Vazquez R, Olazabal DA. Preparation of stabilized liquid quality control serum to be used in clinical chemistry. World Health Organization Document 1986; Lab/86.4: 1-14.

- Burstein M, Samaiele J. Sur la clarification du serum lipemique par l'heparine *in vitro*. C.R. Acad Sci; 1955; 241: 66.
- Chang BS, Fischer NL. Development of an efficient single-step freeze-drying cycle for protein formulations. Pharm Res 1995; 12: 831-7.
- Chang BS, Beauvais RM, Dong A, Carpenter JF. Physical factors affecting the storage stability of freeze-dried interleukin-1 receptor antagonist: Glass transition and protein conformation. Arch Biochem Biophys 1996; 331: 249-58.
- Crowe JH, Carpenter JF, Crowe LM. The role of vitrification in anhydrobiosis. Annu Rev Physiol 1998; 60: 73-103.
- Crowe JH, Hockstra FA, Crowe LM. Anhydrobiosis. Annu Rev Physiol 1992; 54: 579-99.
- Duddu SP, Monte PRD. Effect of glass transition temperature on the stability of lyophilized formulations containing a chimeric therapeutic monoclonal antibody. Pharm Res 1997; 14: 591-5.
- Fakes MG, Dali MV, Haby TA, Morris KR, Varia SA, Serajuddin ABU TM. Moisture sorption behavior of selected bulking agents used in lyophilized products. PDA J Pharm Sci Technol 2000; 54: 144-51.
- Fasce CF Jr, Rej R, Copeland WH, Vanderlinde RE. A discussion of enzyme reference materials: Applications and specifications. Clin Chem 1973; 19: 5-9.
- Frajola WJ, Maurukas J. A stable liquid human reference serum. Health Lab Sci 1976; 13: 25-33.
- Fraser CG, Fudge AN, Penberthy LA. Evaluation of precision using lyophilized quality control materials. Ann Clin Biochem 1978; 15: 121-2.
- Grannis GF, Miller WG. On the design of clinical chemistry quality-control sera. Clin Chem 1976; 22: 500-12.

- Heller MC, Carpenter JF, Randolph TW. Protein formulation and lyophilization cycle design: prevention of damage due to freeze-concentration induced phase separation. *Biotechnol Bioeng* 1999; 63: 166-74.
- Izutsu K-I, Yoshioka S. Stabilization of protein pharmaceuticals in freeze-dried formulations. *Drug Stability* 1995; 1: 11-21.
- Izutsu K-I, Yoshioka S, Kojima S, Randolph TW, Carpenter JF. Effects of sugars and polymers on crystallization of poly(ethylene glycol) in frozen solutions: Phase separation between incompatible polymers. *Pharm Res* 1996; 13: 1393-400.
- Kanluan T, Tangvorasittichai O, Tangvorasittichai S. Preparation of an optically clear lyophilized human control material. *J Med Lab Sci* 1992; 6: 21-4.
- Kaplan LA, Pesce AJ (eds). *Clinical Chemistry: theory, analysis, and correlation*. St. Louis: The C.V. Mosby Company, 1984.
- Klein B, Weissman M. Study of dialyzed reconstituted dried serum as a clinical chemistry standard. *Clin Chem* 1958; 4: 194-9.
- Korey DJ, Schwartz JB. Effects of excipients on the crystallization of pharmaceutical compounds during lyophilization. *J Parenter Sci Technol* 1989; 43: 80-3.
- Kreilgaard L, Frokjaer S, Flink JM, Randolph TW, Carpenter JF. Effects of additives on the stability of *Humicola lanuginosa* lipase during freeze-drying and storage in the dried solid. *J Pharm Sci* 1999; 8: 281-90.
- Lin JJ, Meyer JD, Carpenter JF, Manning MC. Stability of human serum albumin during bioprocessing: denaturation and aggregation during processing of albumin paste. *Pharm Res* 2000; 17: 391-6.
- Livesey RG, Rowe TWGA. Discussion of the effect of chamber pressure on heat and mass transfer in freeze-drying. *J Parenter Sci Technol* 1987; 41: 169-71.

- Louderback AL, Anido G (eds). International criteria for diagnostic material. In: Quality control in clinical chemistry. New York : Walter de Gruyter, 1975: 385-95.
- MacKenzie AP, Luyet BJ. Freeze-drying and protein denaturation in muscle tissue; losses in protein solubility. *Nature* 1967; 215: 83-4
- Nail SL. The effects of chamber pressure on heat transfer in the freeze-drying of parenteral solutions. *J Parenter Drug Assoc* 1980; 34: 358-68.
- Nimsung R, Saisawaddi S, Haesungcharern A. Bovine serum matrix control material: The study for commercial production. The National Research Council of Thailand (NRCT). 1996-1999.
- Oncley JL, Gurd, FRN, Melin M. Preparation and properties of serum and plasma protein. XXV. Composition and properties of human serum, beta-lipoprotein. *J Am Chem Soc* 1950; 72: 458.
- Pichel W. Physical-chemical processes during freeze-drying of proteins. *Am Soc Heat Refrig Aircond Eng J* 1965; 7: 68-71.
- Pikal MJ. Use of laboratory data in freeze-drying process design: Heat and mass transfer coefficients and the computer simulation of freeze-drying. *J Parenter Sci Technol* 1985; 39: 115-39.
- Pikal MJ, Dellerman K, Roy ML. Formulation and stability of freeze-dried proteins: Effects of moisture and oxygen on the stability of freeze-dried formulations of human growth hormone. In: May JC, Brown F (eds), International Symposium on Biological Product Freeze-Drying and formulation. Basel: Karger, 1991: 21-38.
- Pikal MJ, Roy ML, Shah S. Mass and heat transfer in vial freeze-drying of pharmaceuticals: Role of the vial. *J Pharm Sci* 1984; 73: 1224-37.
- Pikal MJ, Shah S. The collapse temperature in freeze-drying: Dependence on measurement methodology and rate of water removal from the glassy phase. *Int J Pharm* 1990; 62: 165-86.

- Premachandra J, Wood PL, Hill PG, Browning DM, Vazquez R Olazabal DA. Preparation and stability of low-cost liquid quality-control serum stabilized with ethanediol. *Clin Chem* 1987; 33: 851-2.
- Prestrelski SJ, Pikal KA, Arakawa T. Optimization of lyophilization conditions for recombinant human interleukin-2 by dried-state conformational analysis using Fourier-transform infrared spectroscopy. *Pharm Res* 1995; 12: 1250-9.
- Prestrelski SJ, Tedeschi N, Arakara T, Carpenter JF. Dehydration-induced conformational transitions in proteins and their inhibition by stabilizers. *Biophys J* 1993; 65: 661-71.
- Pridgar EM, Moses GC, Henderson AR. Purification of lactate dehydrogenase isoenzymes one, two, and three from human erythrocytes. *Clin Chem* 1984; 30: 1353-7.
- Proksch GJ, Bonderman DP. Preparation of optically clear lyophilized human serum for use in preparing control material. *Clin Chem* 1976; 22: 456-60.
- Rakwatin C. Data analysis for the study of pharmaceutical stability: Accelerated and long-term stability test. Department of Scientific Medicine. Ministry of Public Health. 1995.
- Randolph TW. Phase separation of excipients during lyophilization: effects on protein stability. *J Pharm Sci* 1997; 86: 1198-203.
- Rej R, Fasce CF Jr, Vanderlinde RE. Interlaboratory proficiency, intermethod comparison, and calibrator suitability in assay of serum aspartate aminotransferase activity. *Clin Chem* 1975; 21: 1141-58.
- Rockville MD. Guidelines for submitting documentation for the stability of human drugs and biologics: Center for Drugs and Biologics, FDA. Department of Health and Human Services. 1987.
- Rush RL, Vlastelica DL. Turbidity reduction in serum and plasma samples using polyoxyethylated lauric acid compounds. U.S. Patent No.3,853,465; December 10, 1974.

- Sampedro JG, Guerra G, Pardo JP, Uribe S. Trehalose-mediated protection of the plasma membrane H⁺-ATPase from *Kluyveromyces lactis* during freeze-drying and rehydration. *Cryobiology* 1998; 37: 131-8.
- Schultz AL, Gates L. III. Preparation of an HbsAg negative serum standard for use with the SMA 6/60. *Lab Med* 1978; 9: 19-20.
- Shotton E, Ridgway IS. The formulation of pharmaceutical preparations. In: *Physical pharmaceutics*. Clarendon Press, Oxford. 1974: 313-31.
- Stamm D. Calibration and quality control materials. *J Clin Chem Clin Biochem* 1974; 12: 137-45.
- Sun WQ, Davidson P, Chan HSO. Protein stability in the amorphous carbohydrate matrix: relevance to anhydrobiosis. *Biochem Biophys Acta* 1998; 1425: 245-54.
- Tanaka K, Takeda T, Miyajima K. Cryoprotective effect of saccharides or denaturation of catalase by freeze-drying. *Chem Pharm Bull* 1991; 39: 1091-4.
- Terlingen JBA, Van Dreumel HJ, Van Heiningen A, Boerma GJM, Koedam JC. Improved preparation of cholesterol calibration and control sera. *Clin Chem* 1985; 31: 1201-3.
- Tietz NW (ed). *Fundamentals of clinical chemistry*. 3rd ed, Philadelphia: W.B. Saunders Company, 1987.
- Tonks DB. *Quality control in laboratories: with special reference to clinical chemistry laboratories*. Ontario: Diagnostic reagents division, 1970.
- Uldall A, Glavind-Kristensen S, Bak S. Preparation of fresh frozen human sera for external quality assessment. *Scand J Clin Lab Invest* 1989; 49: 11-4.
- Wang W. Lyophilization and development of solid protein pharmaceuticals. *Int J Pharm* 2000; 203: 1-60.

Whitehead TP. Principles of quality control. World Health Organization Document 1976; Lab/76.1: 1-49.

Yalow RS. Heterogeneity of peptide hormones: Its relevance in clinical radioimmunoassay. Adv Clin Chem 1978; 29: 1-47.

Yoshioka S, Aso Y, Kojima S, Tanimoto T. Effect of polymer excipients on the enzyme activity of lyophilized bilirubin oxidase and beta-galactosidase formulations. Chem Pharm Bull (Tokyo) 2000; 48: 283-5.