

OptiMelt References

Measurement and Theory

1. Kenneth Nolon Carter and Kenneth N. Carter, Jr., "Meaningful Melting Points", *J. Chem. Educ.* 72 (1995) 647. Note: A very careful study of MP determinations and the proper way to observe and document results and observations.
2. Martin Davidson, "Avoiding Errors in Melting Point Determinations", *International Labmate*, vol. 23, issue 4, July 1998.
3. Gail Karet, "Make the Most of Melting Point Measurements", *R&D Magazine*, July 1999, p. 61
4. Sharp, J. T., Gosney J. and Rowley A. G., "Practical Organic Chemistry, A Student Handbook of Techniques", 1999, Chapman & Hall, NY, USA.
5. Donal Pavia, et. Al., "Introduction to Organic Laboratory Techniques: A Microscale Approach", 1st edition, Saunders College Publishing, Philadelphia, USA, 1990.
6. R. L. Shriner, R. C. Fuson and D. Y. Curtin, "Systematic Identification of Organic Compounds", 5th edition, 1966, Wiley International, NY, USA, Chapter 4, p. 28-34.
9. W. J. Criddle, Gwynn P. Ellis, "Spectral and Chemical Characterization of Organic Compounds: A Laboratory Handbook", 3rd edition, 1990, Wiley, John and Sons.
7. Harding, Ken E., "Melting Point Range and Phase Diagrams- Confusing Laboratory Textbook Descriptions", *J. Chem. Educ.* 76 (1999) 224.
8. Brown, R. J. C.; Brown, R. F. C., "Melting Point and Molecular Symmetry", *J. Chem. Educ.* 77(2000) 724.
10. George V. D. Tiers, "Melting Points are Uncorrected"-True or False?, *J. Chem. Educ.*, 67 (1990) 258



11. George V. D. Tiers, "Calibration of capillary melting point apparatus to the International Temperature Scale of 1990 (ITS-90) by use of fluxed highly pure metals", *Analytica Chimica Acta*, 237 (1990) 241
12. "OECD Guidelines for the Testing of Chemicals, Test No. 102: **Melting Point/ Melting Range**", *OECD Organisation for Economic Co-operation and Development*, January 2001, vol. 1, no. 1, pp. 1-8 (8 pages). **Note:** The OECD Guidelines for the Testing of Chemicals are a collection of about 100 of the most relevant internationally agreed testing methods used by government, industry and independent laboratories to identify and characterize potential hazards of new and existing chemical substances, chemical preparations and chemical mixtures. Adopted in 1981, the Guidelines have become the recognized reference tool for professionals working on the testing of chemicals and the assessment of their potential hazards. Purchase guidelines on-line at: <http://www.sourceoecd.org/>
13. Randal A. Gauthier, "Time to Learn your RTDs", *Sensors*, May 2003, p. 53. Note: Pt RTDs are discussed in detail, along with some aging guidelines.

MP Tables

1. W. Utermark, "Melting Point Tables of Organic Compounds". 2nd revised and supplemented edition. Interscience: New York, 1963. **Note:** Provides data for over 7000 compounds, arranged by increasing melting point temperatures. While not used much today for research purposes, this work is still valuable as a teaching tool.
2. David R. Lide, "The Handbook of Chemistry & Physics", CRC Press, 2003.
3. Patricia Heckelman, Ann Smith (Editor), Maryadele J. Oneil (Editor), "Merck Index: An Encyclopedia of Chemicals, Drugs & Biologicals- 13th Edition ", Merck Publishing Group , Merck &Company Inc., 2001.

4. Amyand David Buckingham (Editor), Finlay J. MacDonald (Editor), "Dictionary of Organic Compounds", CRC Press, 1995.
5. John A. Dean, Norbert Adolph Lange, "Lange's Handbook of Chemistry", The McGraw-Hill Companies, 1998.
6. W. L. F. Armargo and D. D. Perrin, "Purification of Laboratory Chemicals", 4th edition, Butterworth Heinemann, Woburn, MA, USA, 1998.
7. R. L. Shriner, R. C. Fuson and D. Y. Curtin, "Systematic Identification of Organic Compounds", 5th edition, 1966, Wiley International, NY, USA, Chapter 4, p. 28-34.
8. "Aldrich Handbook of Fine Chemicals and Laboratory Equipment", Sigma-Aldrich Fine Chemicals, P.O. Box 355, Milwaukee, WI 53201, USA, 2003-2004 (www.sigma-aldrich.com.)
9. W. J. Criddle, Gwynn P. Ellis, "Spectral and Chemical Characterization of Organic Compounds: A Laboratory Handbook", 3rd edition, 1990, Wiley, John and Sons.
10. Zvi Rappoport (Editor), "Handbook of Tables for Organic Compound Identification", CRC Press, 1966.
11. Farmilo, C. G. and Levi, L.: Part IA:" Introduction to identification of narcotics by physical methods", Bulletin on Narcotics, Vol. V, No. 4. Note: Farmilo and Levi have written several articles on the identification of narcotics centered around melting point determinations.
12. Beilstein Files, <http://info.cas.org/ONLINE/DBSS/beilstein.html>. Database provided by: MDL Information Systems GmbH, Theodor-Heuss-Allee 108, D-60486 Frankfurt, Germany, STNmail: HLPBEILK, Phone:(+49) 69/5050-4252, Fax:(+49) 69/5050-4245, E-mail: hotline@mdli.com. Note: this database includes over 8 million compounds but requires subscription and dedicated client software.



Quality Control

GLP and GMP

1. Ludwig Huber, "Validation and Qualification in Analytical Laboratories", Interpharm Press, Buffalo Grove, IL, USA, 1998.
2. Ludwig Huber, "A primer - Good Laboratory Practice and Current Good Manufacturing Practice", Publication # 5968-6193E, Agilent Technologies, Germany, March 2000.
3. Ludwig Huber, "Validation of Computerized Analytical and Networked Systems", CRC Press, 2002.
4. Michael Anisfeld, "International Drug GMPs", Interpharm Press, Buffalo Grove, IL, USA, August 1993.
5. Michael H. Anisfeld (Editor), "International GLPs", CRC Press, 1993.

Pharmacopoeias

1. "International Pharmacopoeia: Tests, Methods, and General Requirements: Quality Specifications for Pharmaceutical Substances, Excipients, and Dosage Forms", 3rd edition, volume 5, published by WHO Staff, www.who.int (order at www.bookorders.who.int).
2. "United States Pharmacopoeia", USP 27–NF 22, 2004 edition, published by US Pharmacopoeia Convention, www.usp.org. Note: USP-NF standards are continuously revised and updated. Only the latest annual edition, USP 27–NF 22, will help you comply with official FDA requirements for 2004 in the United States.
3. "British Pharmacopoeia", published by the Stationary Office of the British Pharmacopoeia, 2002, www.pharmacopoeia.org.uk.

21 CFR Part 11

1. "21 CFR Part 11—Electronic Records; Electronic Signatures," Final Rule; Federal Register, 62 FR :13430–13466, March 20, 1997. Please consult www.21CFRPart11.com for the latest revision of the rules and regulations.
2. General Principles of Software Validation: Guidance for Industry”, FDA, Rockville, MD, 2002.
3. “Summary of FDA Public Meeting on Industry Experience Implementing Technical Provisions of 21 CFR Part 11”, FDA, Rockville, MD, 2000.
4. “21 CFR Part 11; Electronic Records; Electronic Signatures—Validation: Guidance for Industry”, FDA, Rockville, MD, 2001.
5. “21 CFR Part 11; Electronic Records; Electronic Signatures—Timestamps: Guidance for Industry”, FDA, Rockville, MD, 2002.
6. “21 CFR Part 11; Electronic Records; Electronic Signatures—Glossary of Terms: Guidance for Industry”, FDA, Rockville, MD, 2001.
7. “21 CFR Part 11: Enforcement Policy: Electronic Records; Electronic Signatures—Compliance Policy Guide: Guidance for FDA Personnel”, FDA, Rockville, MD, 1999.
8. "Practical Laboratory Remediation Strategies for FDA's 21 CFR Part 11 Regulation" [Webcast on-line], Taratec Development Corp., Bridgewater, NJ, April 17, 2002; available from Internet: <http://www.taratecuniversity.com> .
9. “Truth and Misconceptions: The Federal Electronic Records Statute , Report 0502 0077”, Gartner Inc, Stamford, CT, May 2002.