

Handbook of Pharmaceutical Manufacturing Formulations



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An authoritative and practical guide to the art and science of formulating drugs. With thoroughly revised and expanded content, this Second Edition six-volume set compiles volumes from FDA New Drug Applications, patent applications, and other sources of generic and proprietary formulations to cover the broad spectrum of issues concerning drug manufacturing. A must-have collection for pharmaceutical manufacturers, educational institutions, and regulatory authorities, this set is an excellent platform for drug companies to benchmark their products and for generic companies to formulate drugs coming off patent. As the largest reference on pharmaceutical formulations, this handbook also provides guidelines on how to file aNDAs in the shortest possible time, helping pharmaceutical companies to cut costs in the areas of pharmaceutical research and development. Divided conveniently into two parts-regulatory and manufacturing guidelines, and formulations-each volume in the set covers: ULLlcGMP compliance/LILlpre-approval inspections/LILlstability and bioequivalence testing/LILlpackaging commodity development/LILlcommon difficulties in formulating drugs/LILlchanges to aNDAs/LI/UL

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