



Handbook of Pharmaceutical Manufacturing Formulations: Liquid Products (Volume 3 of 6)

By Sarfaraz K. Niazi



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The third volume in the six-volume Handbook of Pharmaceutical Manufacturing Formulations, this book covers liquid drugs, which include formulations of non-sterile drugs administered by any route in the form of solutions (monomeric and multimeric), suspensions (powder and liquid), drops, extracts, elixirs, tinctures, paints, sprays, colloidons, emulsions, aerosols, and other fluid preparations from publicly available but widely dispersed information from FDA New Drug Applications (NDA), patent applications, and other sources of generic and proprietary formulations. Each entry begins with a fully validated scaleable manufacturing formula and a summary of manufacturing process. The book provides a detailed discussion on the difficulties encountered in formulating and manufacturing liquid drugs and the common elements of formulation. The section on regulatory and manufacturing guidance deals with the topics of changes to approved NDAs and aNDAs, post-approval changes to semisolid drugs, global manufacturing practices and guidelines, compliance program guidance manual for FDA staff covering drug manufacturing inspections program, waiver of in vivo bioavailability studies for immediate release solid drugs based on a biopharmaceutics classification, in addition to providing quick tips on resolving the common problems in formulating uncompressed drugs.

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