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# Specification Drug Substances Products Development

**specifications: test procedures and acceptance criteria ...** - related to drug substance and drug product materials and components, facility and equipment operating conditions, in-process controls, finished product specifications, and the **ich harmonised tripartite guideline** - the quality of drug substances and drug products is determined by their design, development, in-process controls, gmp controls, and process validation, and by specifications applied to them throughout development and manufacture. **ich q6a guideline - ikev** - ich q6a guideline specifications: test procedures and acceptance criteria for new drug substances and new drug products comments for its application . ich q6a c 102 specifications: test procedures and acceptance criteria ich q6a 1.1 objective of the guideline establishment of a single set of global specifications for new drug substances and products. guidance on the setting and justification ... **guidance for industry - food and drug administration** - new drug substances and new drug products: chemical substances, addresses specifications and other criteria for chemical substances. this document does not recommend specific test procedures or ... **specification of drug substances and products development ...** - specification of drug substances and products development and validation of analytical methods edited by christopher m. riley, riley and rabel consulting services, **fda guidance for industry: dissolution testing and ...** - for drug products in both bcs classes 1 and 3, usp disintegration testing can be used in lieu of the dissolution test if the product is shown to meet a dissolution specification of **guidance document - canada** - manufacturing] portion of ndss and andss for drug substances of synthetic or semi-synthetic origin and their corresponding drug products that are filed with health canada pursuant to division c.08 of the food and drug regulations . **guidance 18: impurities in drug substances and drug products** - therapeutic goods administration guidance 18: impurities in drug substances and drug products v1.0 august 2013 page 3 of 13 version history version description of change author effective date

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