Risk-Assessment Drug Product Quality Attributes

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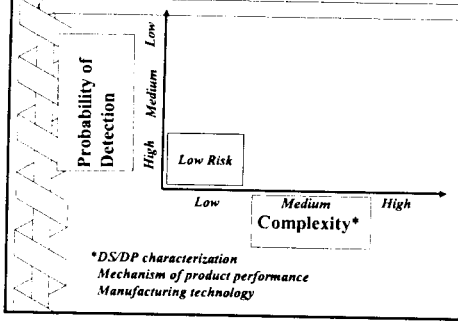
Drug Product Attributes

Drug substance assigned low risk status

General Principle Followed for Developing Drug Product Attributes



Drug Product Attributes

Dosage form Characteristics
Marketing History
Release and Stability Assessment

Drug Product Attributes

Dosage form Characteristics

Dosage Form
Strength
Physical Attributes

Drug Product Attributes

Dosage forms

IR oral solids
oral solutions
non sterile topical solutions
and
sterile solution of simple salts

Drug Product Attributes

Strength

IR Solids: Strength per unit NLT 1mg or 1% w/w
Oral/topical solutions drug substance concentration in drug vehicle is LT 50%
and
sterile solutions of simple salts
drug substance concentration in drug vehicle is LT 75%

Drug Product Attributes

Physical Attributes

Are differences in physical attr ibutes of ingredients used in manufacture of drug product reported to impact pro duct performance?

Drug Product Attributes

Marketing History

Has the DP been on market for five ye ars, with two years real time stabi lity data available on a minimum of three commercial batches?

Drug Product Attributes

Release and Stabi lity Assessme nt

Release & Stabi lity Specifications
Product Degradation Profile
Product Storage

Drug Product Attributes

Release and Stabi lity Specification

Does the drug product specification conform to contemporary standards?

Drug Product Attributes

Product Degradation Profile

Is the drug product degradation profile predictable and are degradants controlled?
No know toxic impur ities or degradants

Drug Product Attributes

Product Storage

Is the drug product stored at CRT and required no special packaging?

Drug Product Attributes

Drug product to qualify as candidate for low risk assignment

Dosage form Characteristics

Marketing History

Release and Stability Assessment

Acknowledgement

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