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~~Stability from ICH and~~

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Analysis with Examples

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Products Examining the

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For purposes of this document, the term OOS results includes all test results that fall outside the specifications or acceptance criteria established in drug applications, drug master files (DMFs ...

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~~Results for ...~~

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production areas and
have an air handling
system separated from
the production areas.

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laboratories should be
designed and have
sufficient space to suit
the operations carried
out in them and to avoid
mix ups, contamination
and cross
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-Review the
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has announced the
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guidance to help drug
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