APOTEX
Canadian-Based
Global Health Company

COMMON DEFICIENCIES FOR ANDAS AND SUPPLEMENTS

Houri Simonian PhD, Sr Director GR&D

October 27th, 2025

Disclaimer

The opinions expressed in this presentation and on the following slides are solely those of the presenter and not necessarily those of Apotex. Apotex does not guarantee the accuracy or reliability of the information provided herein.

APOTEX

Contents

Overview of ANDA Deficiencies – CMC

- Drug Substance
- Drug Product & Manufacturing
- Complex Products

APOTEX

DRUG SUBSTANCE

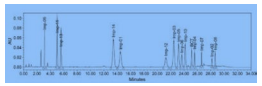
DMF

Deficiency in the referenced DMF for the drug substance – closed portion

PHYSICAL PROPERTIES

Request for additional controls data for the drug substance or characterization data to demonstrate the structure

IMPURITIES



Analytical method may require additional method validation based on specifications

Justification/controls to be revised

APOTEX

DRUG PRODUCT & MANUFACTURING

MANUFACTURING

Increasing trend of deficiency for additional information and controls for manufacturing process parameters and masters

PACKAGING

Additional testing for packaging components

Additional information on the batch packaging records and packaging integrity throughout the packaging process.

EXTRACTABLES & LEACHABLES

Additional information on the analytical method such as sensitivity, LOQ, etc.

Controls for the leachables, including data for assessing the safety/toxicological evaluation

NITROSAMINES

Acceptable controls for the API and Drug product to confirm the presence of a nitrosamine drug substance related impurity (NSDRI)/other nitrosamines in the drug product based on the FDA guidance (CPCA)

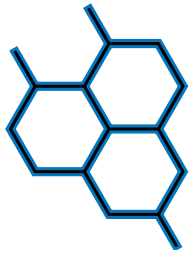
APOTEX

DRUG SUBSTANCE

NITROSAMINES

Acceptable controls for the API and Drug product to confirm the presence of a nitrosamine drug substance related impurity (NSDRI)/other nitrosamines in the drug product based on the FDA guidance (CPCA)

PHYSICAL PROPERTIES



Request for additional controls data for the drug substance or characterization data to demonstrate the structure

IMPURITIES

Analytical method may require additional method validation based on specifications

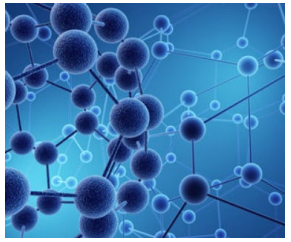
Justification/controls to be revised

APOTEX

COMPLEX GENERICS

GUIDANCE

Agency guidance is limited to certain formulations or Product specific guidance – limitations and challenges

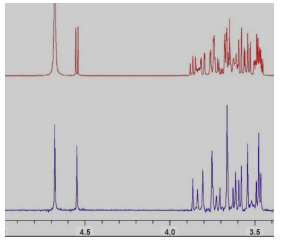


API SAMENESS

Requirement for the *Totality of Evidence* approach to demonstrate the API sameness

Characterization and link to the RLD

Deficiency in analytical methods including specificity and selectivity of the characterization methods



PHYSIOCHEMICAL CHARACTERIZATION

Use of orthogonal methods to confirm the physiochemical property and reduce uncertainty

APOTEX

APOTEX
Global Health Company

THANK YOU