CMC, GENERAL REQUIREMENTS

Brainlike
regulatory strategy

ICH	ANVISA
ANALYTICAL METHOD VALIDATION ▪ summary of results	**ANALYTICAL METHOD VALIDATION** ▪ protocol ▪ report ▪ chromatograms
PROCESS VALIDATION ▪ declaration of process validation performance	**PROCESS VALIDATION** ▪ summary of process validation (as per Anvisa's guideline)
BATCH MANUFACTURING RECORD ▪ not required	**BATCH MANUFACTURING RECORD** ▪ required to present excuted batch record of higher and lower dose
STABILITY STUDY ▪ table of results	**STABILITY STUDY** ▪ protocol ▪ report ▪ forced degradation studies

ANALYTICAL METHOD VALIDATION

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RDC 166/17	ICH
Establishes criteria for validation of analytical methods.	Presents a discussion of the characteristics for consideration during the validation and does not necessarily seek to cover the testing that may be required for registration in and is not intended to provide direction on how to accomplish validation.
Applies to analytical methods used in pharmaceutical ingredients (including excipients)	Not discussed
Applied to the investigational products used in clinical trials	Not discussed
Additional documentation and tests may be requested at any time by Anvisa	Not discussed
All relevant data obtained during the performance of the analytical validation, as well as the formulas used for calculation, must be filed, together with the request of interest, for Anvisa's evaluation.	Summary is accepted
It will be accepted characterized standard, but not of working standard;	Not discussed
Protocol, analytical procedures, parameters, acceptance criteria, report, raw data (chromatograms) should be presented;	Summary is accepted

CMC, BRAZIL SPECIFIC REQUIREMENTS

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- ✓ **DEVELOPMENT REPORT**
  - FORCED DEGRADATION STUDIES – API AND FINISHED PRODUCT
  - RESIDUAL SOLVENTS
  - PILOT STUDIES AGAINST BRAZIL RLD

- ✓ **PROCESS VALIDATION AND BATCH MANUFACTURING RECORD FOR EACH STRENGHT, PHARMACEUTICAL FORM AND PACKING**

- ✓ **ANALYTICAL METHOD VALIDATION**
  - API AND FINISHED PRODUCT
  - PERFORMED AT ALL INVOLVED MANUFACTURER SITES (API AND FINISHED PRODUCT)
  - TEST PROCEDURE, VALIDATION PROTOCOL + REPORT AND RAW DATA MANDATORY
  - FOR PHARMACOPOEIC METHODS: METHOD VERIFICATION ON SAME BASE

- ✓ **STABILITY STUDIES**
  - ZONE IVB STABLITY IN 03 BATCHES
  - API STABLITY (FOR THE FP MANUFACTURER COUNTRY CLIMATIC ZONE)
  - ADITIONAL STUDIES (PHOTOSTABILITY, AFER RECONSTITUTION, OTHERS)
  - 6 MONTHS ACCELERATE AND PARTIAL LONG TERM FOR SUBMISSION
  - +36 MONTHS OF SHELF-LIFE ONLY WITH LONG TERM STABILITY REPORT

- ✓ **CoA FOR THE API AND FINISHED PRODUCT**