Ans 3] Differentiate NDA & ANDA

N.D.A means new drug Application.

:- when the sponsor of a new drug believes that enough evidence on the drugs safety & effectiveness has been obtained to meet the FDA's requirements for marketing approval, the sponsor submits ~~it~~ to the FDA a New drug application (NDA).

:- In other words, when a pharmaceutical company creats a new drug the company must contact the FDA & demonstrate that the new drug has ~~be~~ a particular quality and that the drug is safe and effective.

:- The ~~sett~~ Comprehensive analysis of clinical trial data and other information prepared by the FDA drug application reviewers.

:- A review is divided in to Sections on medical analysis, Chemistry, Clinical pharmacology bio pharmaceutics, pharmacology, Statistics & microbiology.

ANDA :- means Abbreviated New Drug Application.

:- An Abbreviated new drug application (ANDA) Contains data that, Submitted to FDA, provides for the review and ultimate approval of a ~~generic~~ generic drug product.

:- Generic drug applications are called abbreviated because they are not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness.

:- A generic applicant must Scientifically demonstrate that its product is bioequivalent.

:- Once approved an applicant may manufacture & market the generic drug product to provide a Safe, effective, low cost alternative to the public.