2.0.03 FRIDAY APRIL 25

Code of Federal Regulations

CFR is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Goverment.

Code is divided into 50 titles.

Titles are subdivided into chapters. → further subdivided into parts covering specific regulatory areas.

Each vol. of code is revised once in a year and issue on a Quarterly basis as follows

Title	1 - 16	January 1
	17 - 27	April 1
	28 - 41	July 1
	42 - 50	October 1.

Legal Status:

↳ Contents of CFR are required to be judicially noticed (44 USC 1507).

How to use the CFR

CFR is kept up to date by the individual issue of the Federal register. These two publications must be used together to determine the latest version of any given rule.

Effective & Expiration Dates:

OMB Control Numbers:

Title 21 → Food & Drugs composed of Nine Volumes.

Parts in Nine volumes

1 - 99
100 - 169
170 - 199
200 - 299
300 - 499
500 - 599
600 - 799
800 - 1299
1200 - End

Children are like wet cement. Whatever falls on them makes an impression.

Sub chapters:

200 - General

201 - Labeling

202 - Prescription drug advertising

205 - Guidelines for state licensing of wholesale prescription drug.

207 - Registration of producers of drugs & listing of drugs in Commercial distribution.

210 : CGMP in manufacturing, processing, packing or holding of drugs.

211 : CGMP for finished pharmaceuticals.

27 SUNDAY

2.0.0.3 MONDAY APRIL 28 '17

211 Current GMP for finished Product:

Subpart (A) General Provisions

Scope

Definition

(B) Organisation & Personnal

- Responsibility of QC unit.
- Personnal Qualification
- Personnel responsibilities
- Consultants

(C) Building and Facilities

- Design & Construction features
- Lighting
- Ventilation, air filtration, air heating & cooling
- Plumbing
- Sewage & refuse
- Washing & toilet facilities
- Sanitation
- Maintenance

(D) Equipments

- Equipment design, size and Location
- Equipment Construction
- Equipment Cleaning & maintenance
- Automatic, mechanical & Electronic Equipment
- Filters

(E) Control of Components and Drug Product Containers and Closures

- General requirement.
- Testing and approval ~~of~~ or rejection of components, drug product containers and closures
- Use of approved components, drug product containers and closures.
- Retesting of approved components, container & closures.
- Rejected Components, containers & Closures.

Hospitality must be extended even towards an enemy who comes to your house.

- Drug product Containers & Closures.

29 APRIL TUESDAY 2.0.03

APRIL

MO	TU	WE	TH	FR	SA	SU	WK
	1	2	3	4	5	6	14
7	8	9	10	11	12	13	15
14	15	16	17	18	19	20	16
21	22	23	24	25	26	27	17
28	29	30					18

(F) Production and Process control
- Intritten Procedure deviation
- Change-in of components
- Calculation of yield
- Equipment identification
- Sampling & testing of in-process material & drug product
- Time limitation on production
- Control of microbiological contamination
- Reprocessing

(G) Packaging & Labelling control
- Material Examination & Usage criteria.
- Labelling issuance
- Packaging & labeling operations.
- Temper resistance packaging requirement for OTC human drug product.
- Drug product inspection
- Expiration dating

(H) Holding & Distribution
- Warehousing procedures
- Distribution procedures

(I) Laboratory control
- General requirements
- Testing & release for distribution
- Stability testing
- Reserve samples
- Laboratory animals
- Penicillin contamination

(J) Records & Reports.

Anger is a short-term madness.

- General requirement
- Equipment cleaning & use log.
- Component, drug product container, closure & labeling records
- Master prodn & control records
- Batch prodn & control records
- Production record review
- Laboratory records
- Distribution records
- Complaints files.

(K) Returned & Salvaged Drug product:

- Returned Drug product
- Drug product salvaging.