

## Requirements for Composition Review

- 1- Separate active and inactive ingredients
- 2- Arrange items of composition as the following:

Ingredient	Quantity	Specification

- 3- Unify units of ingredient quantity
- 4- Specify the adjusted pH in case of presence of alkalinizer or any other pH adjuster
- 5- In case of Film Coated Tablet separate core and coat
- 6- In case of Hard Gelatin Capsule separate cap and body and revise the color of both with sample
- 7- In case of presence of pellets write the composition of it.
- 8- Check spelling of Trade name & Active ingredient according to under registration approval
- 9- Write the dosage form as in the under registration approval.
- 10- The composition must be on Applicant paper (not manufacturer).
- 11- Write the ingredient without abbreviations or chemical name.
- 12- In case of presence of ethyl alcohol write evaporated during manufacturing.

13- Determine the grade of the following ingredient:

Povidone  
Hydroxy propyl methyl cellulose (HPMC)  
Hypromellose  
Methacrylic acid and any acrylate ester  
Methyl cellulose  
Hydroxy ethyl cellulose  
Microcrystalline cellulose (MCC)  
Polyethylene glycol  
Poly vinyl pyrrolidone (PVP)  
Lactose ( monohydrate - anhydrous)  
Powdered cellulose  
Colloidal silicon dioxide (aerosil)  
Sipernat  
Ethagon  
Tatrazine  
Citric acid

14- Determine color index for color as in the following:

Titanium dioxide  
Ferric oxide red

15- Determine the type of the following:

Type of starch  
Type of gelatin

- 16- In case of presence of any alcohol (only in solid dosage form) write \* above it and write under composition evaporated during manufacturing
- 17- In case of presence of mixture of two cellulose write ratio between them beside it
- 18- In case of presence amount equivalence should written beside its material not under quantity column
- 19- In case of addition of equivalence to that mentioned in under registration approval, The company must give the reference that declare the amount of salt that equivalent to base or reference that declare the molecular weight of salt & base and the calculation .
- 20- Check the manufacturer name if present in composition paper as registration approval