QUALITY ASSURANCE

IPQC
(IN PROCESS QUALITY CONTROL)

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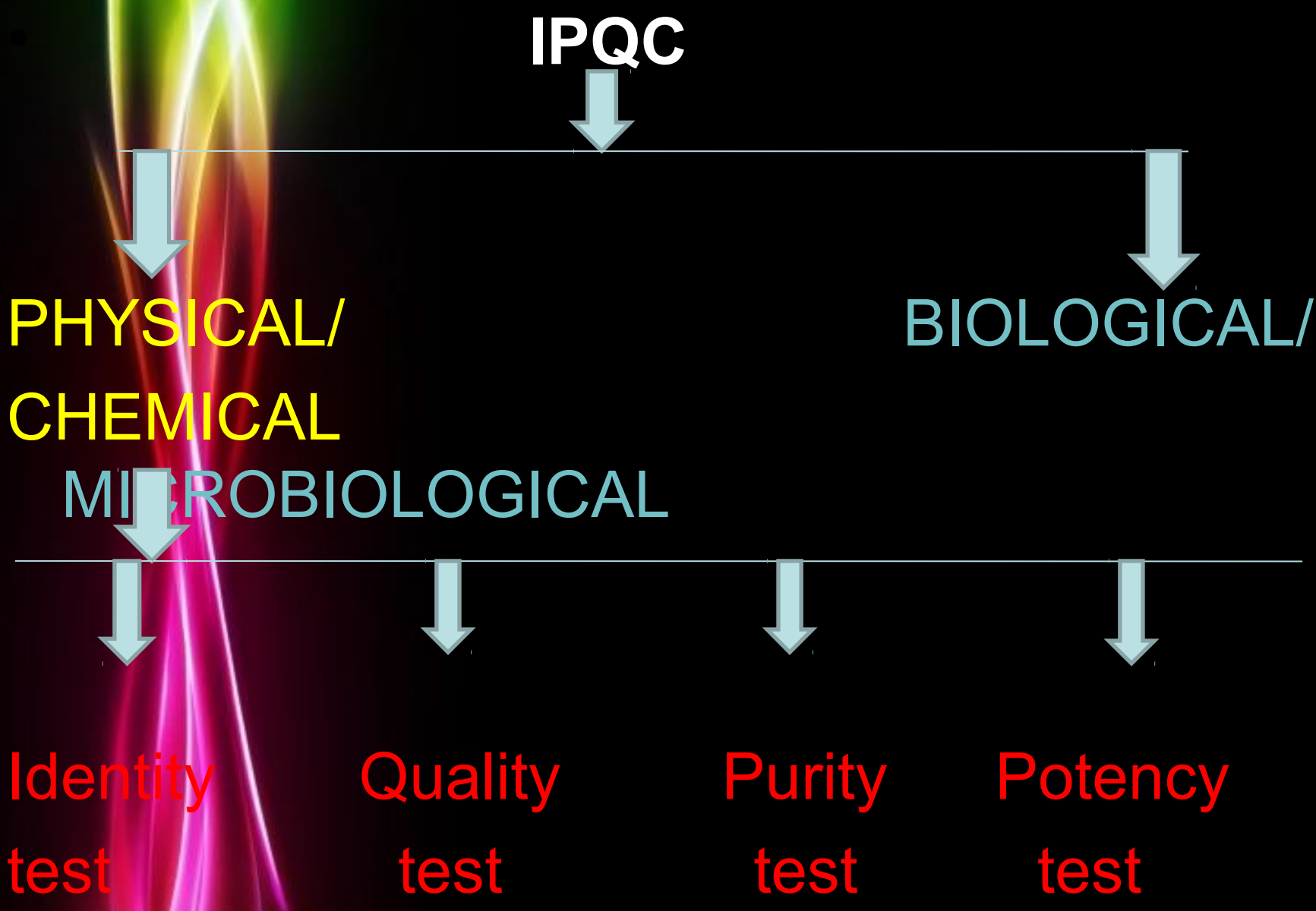
IPQC

- IPQC is concerned with providing accurate, specific and definite description of the procedures to be employed from the receipt of raw materials to the release of the finished dosage form.

- IPQC is the activity performed between QC and QA which involved-----

- To control the procedure involved in manufacturing
- To maintain the quality of product.
- To monitor all features which affect the quality
- To detect errors when occurs by others.


IPQC
PHYSICAL/
CHEMICAL
MICROBIOLOGICAL
BIOLOGICAL/
Identity test
Quality test
Purity test
Potency test

Identity Test- These tests are qualitative chemical method used to confirm the actual presence of compound. Eg- colour formation , precipitation.

Quality test– These tests are physical method used to measure accurate the characteristics properties of drug .eg- absorbance,refractive index.

Purity test- It is deigns to estimate the level of all known and significant impurities and contamination in the drug substances. Eg- test for clarity of solution, acidity/alkalinity.

Potency test- these tests always estimate the quality of an active ingredient in drug.

Biological and microbiological - It included macro and micro biological ways and test for safety , toxicity , pyrogenicity , sterility, antiseptic activities and antimicrobial preservative effectiveness test.

Biological test of drug can be qualitative or quantitative in nature .It involves the animals preparation isolated by living tissues.

OFFICIAL QUALITATIVE BIOLOGICAL TEST

Product to be tests	Test
1-Preperation of liver Or stomach	antianemia test
2-Antiseptics ,disinfectant	antibacterial

OFFICIAL QUANTITATIVE BIOLOGIC TEST-

Insuline	Rabbits
Digitalis	Pigeon

OFFICIAL QUALITATIVE MICROBIOLOGIC

Drug and D.S organism	Test
Calcium pentothenate	Lactobacillus plantarum

CONDITIONS FOR DESIGNING OF IPQC-

- Identify the types of formulation (tab , liquids, ointments).
- Identify the critical steps involved in manufacturing of the product.
- Identify the specification of parameters which conform the parameters are within control.
- Define the frequency of checking for each parameter.

PURPOSE OF IPQC

- To ensure detectable and significance human errors.
- Equipment failure
- Abnormal interpretation .
- Adoption of given procedure .

IMPORTANCE OF IPQC

- To minimise human error.
- To accurate, specific, definite description of the procesure to be employed.
- It is a planned system to identify material equipment processes and operation.

- To detect the error.
- To enforce the flow of manufacturing and packaging operation according to established route and practice.
- To pin point the responsibility.
- To detect any abnormality immediately.

IPQC TESTS IN DIFFERENT DOSAGE FORM

1- SOLID DOSAGE FORM

TABLETS

- Wt. variation
- Hardness
- Thickness
- Friability
- Content uniformity
- Disintegration time
- Dissolution test
- Potency test
- Blister or strip sealing test

CAPSULES

- Wt variation
- Assays
- Content uniformity
- Dissolution test
- Disintegration time
- Moisture content
- Bloom strength
- Iron test
- Hardness and flexibility of shell
- Loss on drying

- Stability testing at different temperature
- Blister and strip sealing

SEMISOLID DOSAGE FORM

SUSPENSIONS

- Appearance – colour , odour, taste
- Product is checked for uniform distribution of colour absence of air bubbles
- Clarity
- Particles size of disperse phase
- Rheology
- QC of water being used
- Sedimentation volume
- Sedimentation rate

- pH of different vehicles before and after mixing
- Drug content
- Zeta potential mean
- Stability test
- Redispersibility
- Compatibility of product and container/closure

EMULSION

- Appearance-colour, odour, taste
- Drug content
- Rheology
- Stability
- Clarity
- QC of water to be used
- pH of different vehicles
- Compatibility of product/container/closure
- Breaking and cracking

PARENTERALS

- pH
- Volume check
- Clarity test
- Content uniformity
- Integrity of seals
- Particulate matter
- Pyrogen test

- Conductivity test
- Liquid loss test
- Fill volume test

IDENTIFICATION OF PROBLEM AND TROUBLE SHOOTING

OF DIFFERENT DOSAGE

FORM

IN IPQC

TABLETS

PROBLEMS	TROUBLESHOOTING
CAPPING	PRECOMPRESSION SLOWING TABLETING RATE REDUCING COMPRESSION PRESSURE

LAMINATION

REGRANULATION

PRESSURE ADJUSTMENT

REDUCE MACHINE SPEED

ARRANGMENT OF DIES AND PUNCHES

PICKING

REDUCING LIQUID APPLICATION RATE

INCREASING AIR TEMP.

INCREASING DRY AIR VOLUME

CHIPPING

REPLACE THE WARN OUT PUNCHES AND DIES

ADD POLISHING AGENTS

MOTTLING

CHANGE SOLVENT SYSTEM

CHANGE BINDER SYSTEM

REDUCE THE DRYING TEMP

GRIND TO A SMALL PARTICLES SIZE

HARDNESS VARIATION	PROPER ADJUSTMENT BETWEEN THE UPPER AND LOWER PUNCH AT THE MOMENT OF COMPRESSION PROCESS
WEIGHT VARIATION	PROPER FLOW OF GRANULES PROPER MIXING OF LUBRICANTS AND INGREDIENTS

IMPROPER COMPRESSION FORCE	PROPER DIE FILLING PROCESS
DOUBLE IMPRESSION	PREVENT UNNECESSARY ROTATION OF LOWER AND UPPER PUNCHES USE ANTITURING DEVICES

POOR FLOW	ADDITION OF GLIDANTS ATTACH VIBRATORS TO THE HOPPER SIDE
ORANGE PEEL EFFECT	THINNING OF THE SOLUTION WITH ADDITIONAL SOLVENTS
BRIDGING	↑ es THE PLASTILISERS CONTENT CHANGING PLASTICIZERS

FILLING	MONITORING OF FLUIDS APPLICATION RATE THROUGH MIXING OF TABLETS
BLISTERING	MILDER DRYING CONDITION
CRACKING	ADJUSTING PLASTICIZERS TYPE AND CONC. PIGMENT TYPE AND CONC.

CAPSULES

PROBLEMS	TROUBLE SHOOTING
BRITTLENESS	MAINTAINS OPTIMUM MOITURE CONDITION
UNUSUAL SOFTENING	MAINTIANS OPTIMUM MOISTURE CONDITION HUMIDITY RANGE-(30-40%)

STABILITY OF INGREDIENTS	ADJUST THE pH WITH SMALL QUNTITY OF CITRIC ACID,LACTIC ACID ,TARTARIC ACIDS
DISCOLORING	USE CLEAR COLOURS
DARK SPOTS	CHANGING TYPE OF GELATINE SOLUTION OR FILL MATERIALS FORMULATION

IMPROPER SEALING	DO PROPER SEALING
IMPROPER LOCKING	USE PROPER METHOD
UNSTABILITY OF DRUGS	MIXED WITH SUITABLE INGREDIENTS

EMULSION/SUSPENSION

PROBLEMS	TROUBLE SHOOTING
CREAMING	REDUCING GLOBULES SIZE REDUCING DIFFERENCE IN DENSITY B/W EXTERNAL AND INTERNAL PHASE INCREASING VISCOSITY

CRACKING	ADD EMULSIFYING AGENT PREVENT DECOMPOSION PPT OF EMULSIFYING AGENTS
FLOCCULATION	USE OF EMULGENTS

PHASE INVERSION

MAINTANCE THE CONC. OF INTERNAL PHASE B/W (30-60%)

STORE IN COOL PLACE

USE PROPER EMULGENT IN ADEQUATE CONC.

PARENTERAL

PROBLEM	TROUBLE SHOOTING
LEAKAGE OF AMPULES	DO PROPER SEALING USE NEW AMPULES
PERFORATION IN FILTER	CHANGE FILTER
PARTICLES/DUST	USE MEMBRANE FILTER

FIBRES	USE MEMBRANE FILTER
pH	USE BUFFER SOLUTION
LEACHING	INTERNAL COATING OF GLASS CONTAINER
LABELING PROBLEM	USE SPECIFIC QTY OF GUM

IPQC DURING PACKAGING

- Line clearance must be given before starting packaging operation.
- Directions given to operations people should be easy and clear.
- Print details on labels must be certified.
- Leak testing bottles , ampoules , vials , must be performed.

- Details of measuring cups , spoons, droppers etc must be checked.
- No. of unit strips , corton, bottles etc must be checked.
- All directions related to quantity of sampling and methods of sampling must be cleared.
- Results must be recorded in standard formats.

THANK YOU