DETERMINATION OF PREFORMULATION STUDIES IN THE GIVEN GRANULES

AIM

To determine and report the Preformulation parameters for the given granules.

REQUIREMENTS

Measuring cylinder, Beaker, Funnel, Burette stand and Granules. AND Mortar, Pestle.

PRINCIPLE

Powder flow and packing of granules in the die cavity are the key requirements for Pharmaceutical manufacturing process specifically in solid dosage form. Tablets are often manufactured on a rotary multi-station tablet press by filling the tablet die with powders or granules based on volume. Thus, the flow of powder from the hopper into the dies often determines weight, hardness and content uniformity of tablets. In case of capsules manufacturing, similar volume filling of powders or granules is widely used. Understanding of powder flow is also crucial during mixing, packaging and transportation. And thus, it becomes essential to measure the flow properties of these materials prior to tabletting or capsule filling.

There are various methods used to measure the powder flow. The compendial methods include measurements of angle of repose, bulk density, tapped density, carr's compressibility index or Hausner's ratio.

PROCEDURE

a) Bulk Density

Apparent bulk density of the granules were determined by placing the measured quantity of granules in a graduated cylinder and the initial

(bulk) volume was noted. Bulk density of the granules was calculated by

$$\text{Bulk Density} = \frac{\text{Mass of the powder (gm)}}{\text{Bulk volume (ml)}}$$

b) Tapped Density

It is determined by placing the known mass of powder in a graduated cylinder. It was placed in the tapped density tester USP and subjected to constant tapping at a rate of 200 drops/min, until the difference between the initial and final volumes should be less than 2%. It was recorded as the final (tapped) volume (VT) and various flow properties were calculated with the following formulae.

$$\text{Tapped Density} = \frac{\text{Mass of the powder (gm)}}{\text{Tapped volume. (ml)}}$$

c) Carr's Index

It was calculated by using the following formula.

$$\text{Carr's Index} = \frac{\text{Tapped Density} - \text{Bulk Density}}{\text{Tapped density}}$$

d) Hausner's Ratio

It was calculated by using the following formula.

$$\text{Hausner's Ratio} = \frac{\text{Tapped Density}}{\text{Bulk Density}}$$

e) Angle of Repose

It was determined by using a funnel whose tip was fixed at a constant height (H) of 6 cm from horizontal surface. The granules and the powder were passed separately through the funnel until the tip

of the conical pile touches the tip of the funnel. The radius of the base of the conical pile is measured as R (cm). It is determined with the formula,

$$\text{Angle of Repose } \theta = \tan^{-1} \frac{h}{r}$$

REPORT

The preformulation parameters in the given granules was determined and was found to be

* Bulk density = 0.569 gm/ml
* Tapped density = 0.65 gm/ml
* Carr's index = 0.23
* Hausner's ratio = 1.3
* Angle of repose = 28°. 51'.

OBSERVATION AND CALCULATION

TABLE 1 : SCALE OF FLOW ABILITY DETERMINED BY DIFFERENT METHODS

Flow properties	Angle of Repose	Carr's compressibility Index	Hausher's Ratio
Excellent	25 - 30	< 10	1.00 - 1.11
Good	31 - 35	11 - 15	1.12 - 1.18
Fair	36 - 40	16 - 20	1.19 - 1.25
Passable	41 - 45	21 - 25	1.26 - 1.34
Poor	46 - 55	26 - 31	1.35 - 1.45
Very poor	56 - 65	32 - 37	1.46 - 1.59
Very very poor	> 60	> 38	> 1.6

a) Bulk Density

S. NO	Mass of the powder (gm)	Bulk volume (ml)	Bulk density (gm/ml)
1)	15	26	0.576
2)	15	26	0.576
3)	15	27	0.555

Average = 0.569 gm/ml

b) Tapped Density

* Mass of the powder = 15gm
* Initial volume of the powder = 25 ml
* Final volume of the powder (After tapping) = 23 ml
* Tapped volume = 25-23 = 2ml

$$\text{Tapped Density} = \frac{\text{Mass of the powder (gm)}}{\text{Tapped volume (ml)}}$$

$$= \frac{15}{23}$$

$$\boxed{\text{Tapped Density} = 0.65 \text{ gm/ml}}$$

c) Carr's Index

$$= \frac{\text{Tapped Density} - \text{Bulk Density}}{\text{Tapped Density}}$$

$$= \frac{0.65 - 0.5}{0.65}$$

$$\boxed{\text{Carr's Index} = 0.23}$$

d) Hausner's Ratio

$$= \frac{\text{Tapped Density}}{\text{Bulk Density}}$$

$$= \frac{0.65}{0.5}$$

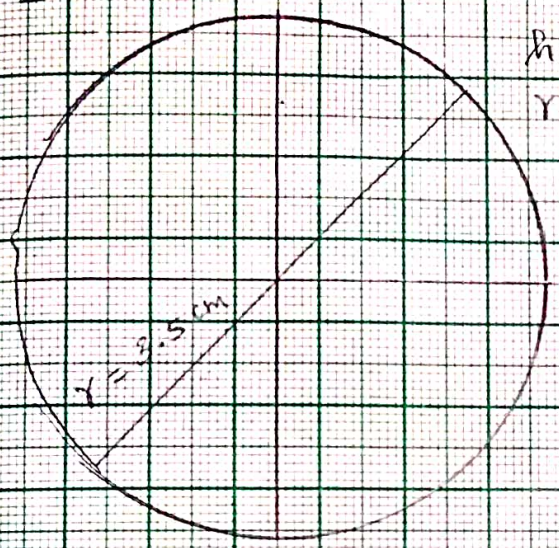
$$\boxed{\text{Hausner's Ratio} = 1.3}$$

e) Angle of Repose, $\theta = \tan^{-1} \frac{h}{r}$

Angle of Repose $\Rightarrow$ $\boxed{\theta = 28^\circ . 51'}$

Pre - Formulation Studies of the Given Granules

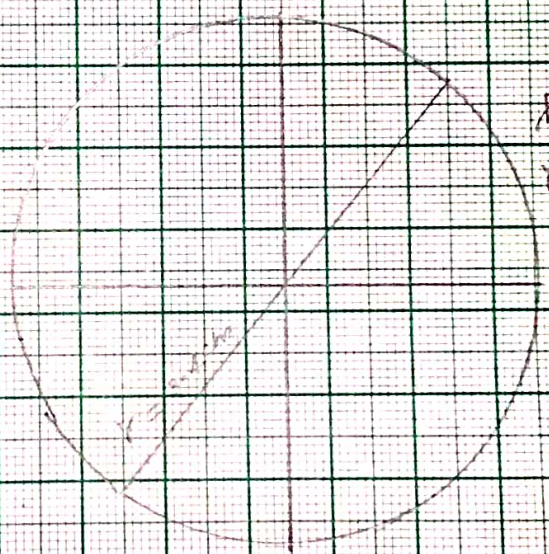
I



h = 2 cm

r = 3.5 cm

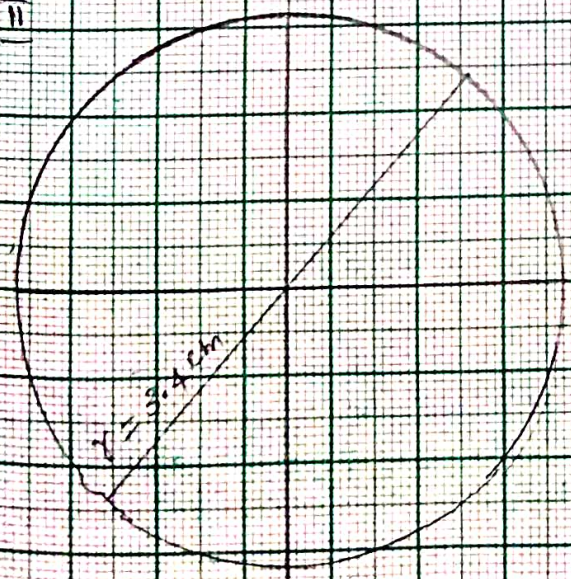
III



h = 1.8 cm

r = 3.4 cm

II



h = 1.7 cm

r = 3.2 cm

Trials :-

$$\text{Angle of Repose } \theta = \tan^{-1} \frac{h}{r}$$

1) $\theta_1 = \tan^{-1} h/r$

$= \tan^{-1} 2/3.5$

$= \tan^{-1} 0.571$

$\boxed{\theta = 29^\circ.72'}$

2) $\theta_2 = \tan^{-1} h/r$

$= \tan^{-1} 1.8/3.4$

$= \tan^{-1} 0.529$

$\boxed{\theta = 27^\circ.87'}$

3) $\theta_3 = \tan^{-1} h/r$

$= \tan^{-1} 1.7/3.2$

$= \tan^{-1} 0.531$

$\boxed{\theta = 27^\circ.96'}$

$$\text{Average}, \theta = \frac{\theta_1 + \theta_2 + \theta_3}{3}$$

$$= \frac{29.72 + 27.87 + 27.96}{3}$$

$\boxed{\text{Average}, \theta = 28^\circ.51'}$

PREPARATION OF PARACETAMOL TABLETS BY WET GRANULATION METHOD

AIM

To prepare and submit 20 paracetamol tablets by wet granulation method.

REQUIREMENTS

Mortar and pestle ; spatula , beaker and sieve.

PRINCIPLE

Tablet is an important solid dosage form which is usually prepared with the aid of suitable pharmaceutical excipients.

Tablets may vary with size, shape ,cut, hardness and thickness. Their disintegration and dissolution characteristics and other aspects change depending on their intended use and method of manufacturing.

Compressed tablets are mainly prepared by 3 basic methods.

(i) Wet granulation
(ii) Dry granulation
(iii) Direct compression

Wet granulation is the widely used method for the production of compressed tablets. Steps involved in wet granulation method are

a) Weighing and blending of ingredients.
b) Preparing a damp mass by adding wet binder.
c) converting the damp mass into wet granules
d) Drying of granules.
e) Sizing the granules by dry screening
f) Addition of lubricants
g) Formation of tablets by compression.

During the preparation process each step may influence the quality of tablet produced. In this preparation paracetamol used as

(i) API - Active Pharmaceutical Ingredient (Anti-pyretic)
(ii) Lactose as adjuvant
(iii) Starch (Purified) as binding agent
(iv) Starch monohydrate as disintegrant
(v) Magnesium stearate as lubricant
(vi) Talc as glidant.

PROCEDURE

a) Preparation of starch mucilage : Dissolve 5mg of starch in 100ml of distilled water then resulting mixture is heated on a water bath until the starch is gelatinized by the formation of mucilage.

b) Divide disintegrating agent (starch monohydrate) into 2 portions to incorporate during wet granulation and after drying of granules to act as intragranular and extra granular disintegrant.

c) Wet Granulation : Accurately weigh and mix the specified amount of paracetamol and other excipients (except half of the disintegrating agent and lubricant) until uniform powder is formed by geometric mixing.

d) A damp mass of the mixture is prepared by adding appropriate amount of the 5% starch mucilage and kneading by hand.

e) Wet mass is subsequently passes through a 6/10 mesh sieve / screen to form wet granules. Resulted granules are spread evenly on a large piece of paper in a tray and dried at 40°c - 60°c for 30 mins in an oven.

f) Dried granules are passed through a sieve 16 or 20 # and mixed with remaining half of disintegrating agent and lubricant.

g) Resulting granules mixture is compressed in a tablet compression into (machine), obtained the tablets.

h) Prepared tablets are stored properly for further evaluation.

REPORT

20 Paracetamol tablets by wet granulation method was prepared and submitted with suitable label.

OBSERVATION AND CALCULATION

TABLE 1 : COMPOSITION OF PARACETAMOL TABLETS

S. NO	Ingredients	Master Formula (1 tablet)	Working Formula (20 tablets)
1)	Paracetamol (Drug - API)	125 mg	2,500 mg
2)	Lactose (Diluent)	375 mg	7,500 mg
3)	Dry starch (Binder and Disintegrant)	48 mg	960 mg
4)	Talc (Glidant)	40 mg	800 mg
5)	Magnesium stearate (Lubricant)	12 mg	240 mg
6)	5% Starch (Binding agent)	Q.S	Q.S

For example

* paracetamol $\Rightarrow \frac{125 \times 20}{1} = 2,500$ mg

* Lactose $\Rightarrow \frac{375 \times 20}{1} = 7,500$ mg

* Dry starch $\Rightarrow \frac{48 \times 20}{1} = 960$ mg

* Talc ⇒ $\frac{40 \times 20}{1} = 800$ mg

* Magnesium stearate ⇒ $\frac{12 \times 20}{1} = 240$ mg

LABEL

PARACETAMOL TABLETS I.P.	
Ingredients Paracetamol ------ 2,500mg Lactose ------ 7,500mg Dry starch ------ 960mg Talc ------ 800mg Magnesium stearate -- 240mg 5% starch ---- Q.S Category Anti-Pyretic Storage Stored in cool and dry place Direction Directed by physician	Batch No: 21KGIPC Lic No: 00021KGIPC MFG DATE: 08/07/2024 EXP. DATE: 08/06/2025
MFG BY: SPJ PHARMA COMPANY	

EVALUATION OF COMMERCIAL UNCOATED PARACETAMOL TABLETS BY FRIABILITY AND WEIGHT VARIATION TEST

AIM

To evaluate of commercial uncoated Paracetamol tablets (20).

REQUIREMENTS

Beaker, Test tubes and Test apparatuses ; Roche Friabilator and Weighing Balance.

EVALUATION PARAMETERS

Friability Test

1) The friability of tablets was determined using Roche Friabilator.
2) It is express in percentage (%). Ten or Twenty tablets were initially weighed and revolved at 25 rpm for 4 mins.
3) The tablets were then reweighed after removal of fines and the percentage of weight loss was calculated.
4) The % friability was then calculated by

$$F = \frac{(W_{Initial} - W_{Final})}{W_{Initial}} \times 100$$

Acceptance criteria for % friability of % weight loss should be less than 1%.

Weight variation Test

Twenty tablets were selected randomly from each batch and weighed individually on electronic balance. The individual weighed is

then compared with average weighed for the weight variations. The following percentage deviation in weight variation is allowed (U.S.P).

$$\text{Weight variation Test} = \frac{\text{Individual Weight} - \text{Average weight}}{\text{Average Weight}} \times 100$$

PROCEDURE

Friability Test

* Select 20 tablets randomly and weighed
* Place the tablet in the friabilator drum, switch ON the apparatus, adjusting the times at mins and the speed at 25 rpm.
* End of this operator remove the tablets from the friability de dust and weighed.
* Any tablet that breacks up should be rejected before reweighing
* Friability is expressed as the percentage loss in not

$$\% \text{ loss} = \frac{W_0 - W}{W} \times 100$$

If the value of friability (% loss) is less than or equal to % the batch is accept.

Weight variation Test

* Select 20 tablets randomly from the batch provided and weigh the tablet individually.

* Weigh the 20 tablets together and calculate the average weight.

* Compare the average weight, calculate to previous tablet to determine the maximum % difference allow.

* Calculate the upper and lower limit at the % difference

Upper limit = W + [(% 100) (W)]
Lower limit = W − [(% 100) (W)]

compare the individuals weight of the tablets to the upper and lower limits.

* calculate the % difference allowed and at double that %.

* Comment on the result.

REPORT

commercial uncoated Paracetamol tablets by Friability and Weight variation Test was evaluated. And was found to be

* Friability (F) [% of Loss] = 0.99 %

* Weight variation → Average = 602 mg
Upper limit = 662.2 mg
Lower limit = 541.8 mg

OBSERVATION AND CALCULATION

Friability Test

* Initial weight of 20 tablets (W_1) = 602 mg
* Final weight of 20 tablets (W_2) = 596 mg
* Weight loss = Initial weight - Final weight

Weight loss = 602 - 596 = 6 mg

$$\text{Friability (F)} = \frac{(W_{Initial} - W_{Final})}{W_{Initial}} \times 100$$

$$= \frac{602 - 596}{602} \times 100$$

$$\boxed{\text{Friability (F) (\% of loss)} = 0.99\ \%}$$

TABLE 1 : LIMITS FOR WEIGHT VARIATION TEST AS PER I.P, B.P AND U.S.P.

Average Mass (mg)		Percentage Deviation. (%)
IP / BP	USP	
80 mg or less than 80mg	130 mg or less than 130 mg	± 10 %
80mg to 250 mg	130 mg to 324 mg	± 7.5 %
250 mg or More than 250mg	324 mg or More than 324 mg	± 5 %

Weight variation Test

Tablet NO	1	2	3	4	5	6	7	8	9	10
Weight (mg)	600	610	600	590	610	620	600	600	610	600

Tablet	11	12	13	14	15	16	17	18	19	20
Weight (mg)	610	590	580	600	610	610	600	610	600	590

Average = 602 mg

* Weight variation Test $= \frac{620 - 602}{602} \times 100 = 2.99\ \%$

* Weight variation Test $= \frac{610 - 602}{602} \times 100 = 1.32\ \%$

* Weight variation Test $= \frac{590 - 602}{602} \times 100 = -1.99\%$

* Remarks → Passes.

i) Upper limit $\Rightarrow 602 + \left[602 \times \frac{10}{100}\right]$

$\Rightarrow 602 + [60.2]$

$\Rightarrow 662.2$ mg

ii) Lower limit $\Rightarrow 602 - \left[602 \times \frac{10}{100}\right]$

$\Rightarrow 602 - [60.2]$

$\Rightarrow 541.8$ mg

EVALUATION OF COMMERCIAL UNCOATED PARACETAMOL TABLETS BY HARDNESS, THICKNESS AND DISINTEGRATION TIME TEST

AIM

To evaluate of commercial uncoated Paracetamol tablets (20).

REQUIREMENTS

Beaker, Test tubes, Test apparatuses, Monsanto hardness tester, vernier cap calliper and weighing Balance.

EVALUATION PARAMETERS

Hardness Test

The tablet hardness is defined as the force required to break a tablet in a diametric direction. A tablet was placed between two anvils Force was applied to anvils and crushing strength that causes the tablet to break was recorded. The hardness was measured using Monsanto hardness tester.

Thickness Test

The thickness of tablets was determined using a vernier calliper. Three tablets from each batch were used and average values were calculated

Disintegration Time Test

It was determine using USP tablet disintegration test apparatus. using 900ml of distilled water without disk at room temperature. Test was performed on 6 tablets. One tablet each is kept in all six tubes. The tubes travel upward and downward in water at 37°c ± 2°c. The time taken for all the six tubes in six tablets to break down and pass through the mesh at the bottom of the tube is noted. The

tablets pass the test if all the six tablets disintegrate within the prescribed time (less than 30 mins for uncoated tablets as per U.S.P).

PROCEDURE

Hardness Test

* Carry out the test on that batch of tablets provided using monsanto hardness tester. calculate the mean crushing strength of 20 tablets (taken randomly)

Conventional tablets	=	2.5 - 5.0 kg/cm^2
chewable by dispersed tablets	=	2.0 - 2.5 kg/cm^2
Percentage of extended release tablet	=	5.2 - 7.5 kg/cm^2

Thickness Test

* Thickness of individual tablets may be measured by a micrometers (μm), other technique involve placing to 20 tablets in a holding tray, where their total thickness should be controlled with a ± 5% variation of a standard. Its expressed in mm.

Disintegration Test

* Place one tablet in each of the 6 tubes of the basket (tablets are selected randomly).

* position of basket rack in 1-1 beaker containing distilled water (as the disintegration medium maintain 37°c.

* Start the apparatus to move the basket assembly containing the tablets and record the times required for all the 6 tablets to break into particles and top all to the disintegration medium.

REPORT

Commercial uncoated Paracetamol tablets by hardness, thickness and disintegration time test was evaluated And was found to be

* Hardness = 6.833 Kg/cm²

* Thickness = 4.029 mm

* Disintegration Time = 1 minute
(So, the given tablets is orodispersible).

OBSERVATION AND CALCULATION

Hardness Test

For example :-

S. NO	TABLETS	INDIVIDUAL PRESSURE	AVERAGE
1)	1	6	$\Rightarrow \frac{20.5}{3}$
2)	2	5.5	
3)	3	9	$\Rightarrow$ 6.833 Kg/cm²

Thickness Test

Tablets No	1	2	3	4	5	6	7	8	9	10
Thickness (mm)	4.15	4.02	4.13	4.18	3.77	4.10	4.11	4.16	3.77	3.84

Tablets NO	11	12	13	14	15	16	17	18	19	20
Thickness (mm)	4.11	3.84	4.15	4.18	3.77	3.77	4.16	4.11	4.10	4.02

$$\text{Average} = \frac{80.58}{20} = 4.029 \text{ mm}$$

TABLE 1 : LIMITS FOR DISINTERATION TIMES OF TABLETS AS PER IP, BP And USP.

S. NO	Categories of Tablets	Disintegration Time (minutes)		
		IP	BP	USP
1)	Uncoated Tablets	15	15	5 - 30 mins
2)	Coated Tablets	60	60	1 - 2 hrs
3)	Enteric coated Tablets	60	-	1 hr or as per individual monographs
4)	Film coated Tablets	30	-	30 mins or as per individual monographs
5)	Effervescent Tablets	5	5	Less than 3 mins or as per individual monographs
6)	Soluble Tablets	3	3	-
7)	Dispersible Tablets	3	3	Less than 3 mins or as per individual monographs.

Disintegration Test

* The tablets should be disintegrate within 15 minutes (uncoated tablets).
* If 4 tablets fails to disintegrate within 15 mins.
* The disintegration test is repeated completely on 12 additional tablets not less than 16, out of the total 18 tablets - Test that disintegration completely within 15 mins.

PREPARATION OF ASPIRIN TABLETS BY WET GRANULATION METHOD (UNCOATED TABLETS)

AIM

To prepare and submit 20 Aspirin tablets by wet granulation method. (uncoated Tablets)

REQUIREMENTS

Mortar and Pestle ; spatula, beaker and sieve.

PRINCIPLE

Tablet is an important solid dosage form which is usually Prepared with the aid of suitable Pharmaceutical excipients. Tablets may vary with size, shape, cut, hardness, thickness. Their disintegration and dissolution characteristics and other aspects change depending on their intended use and method of manufacturing.

compressed tablets are mainly prepared by 3 basic methods.

(i) Wet granulation
(ii) Dry granulation
(iii) Direct compression.

Wet granulation is the widely used method for the Production of compressed tablets. steps involved in wet granulation method are

a) Weighing and blending of ingredients
b) Preparing a damp mass by adding wet binder
c) converting the damp mass into wet granules
d) Drying of granules
e) Sizing the granules by dry screening
f) Addition of lubricants
g) Formation of tablets by compression

During the preparation process each step may influence the quality of tablet produced. In this Preparation of Aspirin used as API (Aspirin

also known as acetylsalicylic acid, is a medication used to treat pain, fever or inflammation), lactose as adjuvant, acacia as binding agent, starch monohydrate as disintegrant, magnesium stearate as lubricant and talc as glidant.

PROCEDURE

a) Divide disintegrating agent (starch monohydrate) into 2 portions to incorporate during wet granulation and after drying of granules to act as an intragranular and extra granular disintegrant.
b) Wet granulation : Accurately weigh and mix the specified amount of aspirin and other excipients (except of half of the disintegrating agent and lubricant) until uniform powder is formed by geometric mixing.
c) Wet mass is subsequently passes through a 6/10 mesh sieve/screen to form wet granules. Resulted granules are spread evenly on a large piece of paper in a tray and dried at 40°c - 60°c for 30 mis in an oven. [Before the point, A damp mass of the mixture is prepared by adding appropriate amount of the acacia and drop wise addition of water].
d) Dried granules are passed through a sieve 16 or 20 # and mixed with remaining half of the disintegrating agent and lubricant.
e) Resulting granules mixture is compressed in a tablet compression machine to obtain tablets.
f) Prepared tablets are stored properly for further evaluation.

REPORT

20 Aspirin tablets by wet granulation method was prepared and submitted with suitable label.

OBSERVATION AND CALCULATION

TABLE 1 : COMPOSITION OF ASPIRIN TABLETS

S. NO	Ingredients	Master Formula (For 1 tablet) mg	Working Formula (20 tablets) mg
1)	Aspirin (API)	100 mg	2,000 mg
2)	Acacia	50 mg	1,000 mg
3)	Lactose monohydrate	25 mg	500 mg
4)	Starch monohydrate	25 mg	500 mg
5)	Talc	Q.S	Q.S
6)	Magnesium Stearate	Q.S	Q.S

For Example :-

* Aspirin $\Rightarrow \frac{100 \times 20}{1} = 2,000$ mg

* Acacia $\Rightarrow \frac{50 \times 20}{1} = 1,000$ mg

* Lactose monohydrate $\Rightarrow \frac{25 \times 20}{1} = 500$ mg

* Starch monohydrate $\Rightarrow \frac{25 \times 20}{1} = 500$ mg

LABEL

ASPIRIN TABLETS I.P	
Ingredients Aspirin ------- 2,000 mg Acacia ------- 1,000 mg Lactose monohydrate -- 500 mg Starch monohydrate -- 500 mg Talc ------- Q.s Magnesium stearate ... Q.s Category Anti-coagulant, Anti-Pyretic Storage Stored in dry and cool place Direction Directed by physician.	Batch No : 21KGPC Lic No : 00021KGPC MFG DATE : 02/09/2024 EXP DATE : 02/08/2026
MFG BY : SPJ PHARMA COMPANY	

EVALUATION OF COMMERCIAL UNCOATED ASPIRIN TABLETS BY FRIABILITY AND WEIGHT VARIATION TEST

AIM

To evaluate of commercial uncoated aspirin tablets (20).

REQUIREMENTS

Beaker, Test tubes, Test apparatuses, Roche friabilator and weighing balance.

EVALUATION PARAMETERS

Friability Test

The friability of tablets was determined using Roche Friabilator. It is express in percentage (%). Ten or Twenty tablets are initially weighed and revolved at 25 rpm for 4 mins. The tablets were then reweighed after removal of fines and the percentage of weight loss was calculated. The % friability was then calculated by,

$$F = \frac{(W_{Initial} - W_{Final})}{W_{Initial}} \times 100$$

Acceptance criteria for % friability % weighed loss should be less than 1 %.

Weight variation Test

Twenty tablets were selected randomly from each batch and weighed individually on electronic balance. The individual weighed is then compared with average weight for the weight variations. The following percentage deviation in weight variation is allowed (U.S.P).

$$\text{Weight variation Test} = \frac{\text{Initial Weight} - \text{Average Weight}}{\text{Average Weight}} \times 100$$

PROCEDURE

Friability Test

* Select 20 tablets randomly and weighed.

* Place the tablet in the friabilator drum, switch on the apparatus, adjusting the times at mins and the speed at 25 rpm.

* End of this operation remove the tablets from the friability de dust and weight.

* Any tablet that breaks up should be rejected before reweighing.

* Friability is expressed as the percentage loss in not

$$\% \text{ Loss} = \frac{W_o - W}{W_o} \times 100$$

If the value of friability (% loss) is less than or equal to % the batch is accept.

Weight variation Test

* Select 20 tablets randomly from the batch provided and weigh the tablet individually.

* Weigh the 20 tablets together and calculate the average weight.

* Compare the average weight calculate to previous tablet to determine the maximum % difference allow.

* calculate the upper and lower limit at the % difference.

Upper limit = W + [(% 100) (W)]
Lower limit = W − [(% 100) (W)]

Compare the individuals weight of the tablets to the upper and lower limits.

* calculate the % difference allowed and at double that %.

* comment on the result.

REPORT

Commercial uncoated Aspirin tablets by Friability and Weight variation test was evaluated And was found to be

* Friability (F) [% of loss] = 0.052 %

* Weight variation ⇒ Average = 182.75 mg
Upper limit = 201.025 mg
Lower limit = 164.475 mg

OBSERVATION AND CALCULATION

Friability Test

* Initial weight of 20 tablets (W_1) = 190 mg
* Final weight of 20 tablets (W_2) = 180 mg
* Weight loss = Initial weight − Final weight = 190 − 180 = 10 mg

$$\text{Friability (F)} = \frac{(W_{Initial} - W_{Final})}{W_{Initial}} \times 100$$

$$= \frac{190 - 180}{190} \times 100$$

$$\boxed{\text{Friability (F)}_{(\% \text{ of loss})} = 0.052\ \%}$$

Weight variation Test

Tablet No	1	2	3	4	5	6	7	8	9	10
Weight (mg)	190	188	180	190	160	189	170	189	173	180

Tablet No	11	12	13	14	15	16	17	18	19	20
Weight (mg)	180	174	190	188	190	173	187	185	189	190

$$\text{Average} = \frac{3,655}{20} = 182.75 \text{ mg.}$$

* Remarks ⇒ Passes.

* Weight variation Test $= \frac{190 - 182.75}{182.75} \times 100 = 3.96$ mg

* Weight variation Test $= \frac{160 - 182.75}{182.75} \times 100 = -12.44$ mg

i) Upper limit ⇒ $182.75 + \left[182.75 \times \frac{10}{100}\right]$

⇒ $182.75 + [18.275]$

⇒ 201.025 mg

ii) Lower limit $\Rightarrow 182.75 - \left[182.75 \times \frac{10}{100}\right]$

$\Rightarrow 182.75 - [18.275]$

$\Rightarrow 164.475$ mg

EVALUATION OF COMMERCIAL UNCOATED ASPIRIN TABLETS BY HARDNESS, THICKNESS AND DISINTEGRATION TIME TEST

AIM

To evaluate of commercial uncoated aspirin tablets (2o).

REQUIREMENTS

Beaker, Test tubes, Test apparatuses, Monsanto hardness tester, Vernier calliper and Weighing balance.

EVALUATION PARAMETERS

Hardness Test

The tablet hardness is defined as the force required to break a tablet in a diametric direction. A tablet was placed between two anvils. Force was applied to anvils and crushing strength that causes the tablet to break was recorded. The hardness was measured using Monsanto hardness tester.

Thickness Test

The thickness of tablets was determined using vernier calliper. Three tablets from each batch were used, and average values were calculated.

Disintegration Time Test

It was determine using USP tablet disintegration test apparatus, using 900ml of distilled water without disk at room temperature. Test was performed on 6 tablets. One tablet each is kept in all six tubes. The tubes travel upward and downward in water at 37°c ± 2°c. The time taken for all the six tablets to break down and pass through the mesh at the bottom of the tube is noted. The tablets pass the test

if all the six tablets disintegrate within the prescribed time (less than 30 mins for uncoated tablets as per U.S.P).

PROCEDURE

Hardness Test

* carryout the test on that batch of tablets provided using monsanto hardness tester. calculate the mean crushing strength of 20 tablets (taken randomly)

conventional Tablets	=	2.5 - 5.0 kg/cm^2
chewable by dispersed Tablets	=	2.0 - 2.5 kg/cm^2
Percentage of extended Release Tablets	=	5.2 - 7.5 kg/cm^2

Thickness Test

* Thickness of individual tablets may be measured by a micrometer (μm), other technique involve placing to 20 tablets in a holding tray, where their total thickness should be controlled with a ± 5% variation of a standard. Its expressed in mm.

Disintegration Test

* Place one tablet in each of the 6 tubes of the basket (tablets are selected randomly).

* Position of basket rack in 1-1 beaker containing distilled water as the disintegration medium maintain 37°c.

* Start the apparatus to move the basket assembly containing the tablets and record the times required for all the 6 tablets to break into particles and top all to the disintegration medium.

REPORT

Commercial uncoated Aspirin tablets by Hardness, Thickness and Disintegration test (Time) was evaluated And was found to be

* Hardness = 5.966 kg/cm²

* Thickness = 3.023 mm

* Disintegration Time = 1 minute
(So, the given tablets is orodispersible)

OBSERVATION AND CALCULATION

Hardness Test

For example :-

S. No	Tablets	Individual Pressure	Average
1)	1	4	$\Rightarrow \frac{17.9}{3}$
2)	2	5.9	
3)	3	8	$\Rightarrow$ 5.966 Kg/cm^2

Thickness Test

Tablets No	1	2	3	4	5	6	7	8	9	10
Thickness (mm)	3.15	3.02	3.13	3.18	2.77	3.10	3.11	3.16	2.77	2.84

Tablets No	11	12	13	14	15	16	17	18	19	20
Thickness (mm)	2.77	2.84	3.13	3.02	3.15	3.11	3.16	2.77	3.18	3.10

$$\text{Average} = \frac{60.46}{20} = 3.023 \text{ mm}$$

Disintegration Test

* The tablets should be disintegrate within 15 mins. (uncoated tablets)

* If 4 tablets fails to disintegrate within 15 mins.

* The disintegration test is repeated completely on 12 additional tablets, not less than 16, out of the total 18 tablets - Test that disintegration completely within 15 mins.

EVALUATION OF COMMERCIAL CAPSULE OF TETRACYCLINE BY WEIGHT VARIATION TEST

AIM

To evaluate of commercial capsule of Tetracycline (20).

REQUIREMENTS

Beaker, Test tubes, Test apparatuses and weighing balance.

PRINCIPLE

Capsule is designed to contain a specific amount of drug in specific formula. Weight variation is performed to collect the amount of drug present in the capsules. This test is considered as an indication of dosage uniformity. Weight variation in capsule generally occurs due to poor flow of granules causing poor filling of capsules. Improper mixing of capsules, If size of granules are larger than size are not filled uniformity. The given capsules having average weight and percentage variation according to IP.

Less than 300 mg ⇒ 10 %
300mg /more ⇒ 7.5 %

PROCEDURE

* Hard gelatin capsules are usually weighed individually and the contents are removed.
* The empried shell are individually weighed and the net weight by the contents is calculated by subtracting the weight of shell from the respective gross weight.
* The content of the active ingredient in each capsule may be determined by calculation based on the percent drug content in the

formulation.

OBSERVATION

The given sample of marketted hard gelatins were tested for weight variation test.

REPORT

* The given sample of marketted hard gelatin capsules was tested for weight variation test.

* The given commercial capsules of tetracycline by the weight variation test as per I.P. standard.

OBSERVATION AND CALCULATION

Capsule NO	Weight (mg)	Average Weight	Remarks
1.	0.739		
2.	0.695		
3.	0.722		
4.	0.705		
5.	0.715		
6.	0.706		
7.	0.711		
8.	0.702	0.713 mg	Passes
9.	0.712		
10.	0.702		
11.	0.702		
12.	0.394		
13.	0.714		
14.	0.698		
15.	0.716		
16.	0.715		
17.	0.712		
18.	0.703		
19.	0.718		
20.	0.721		

$$\text{Weight variation Test} = \frac{\text{Individual Weight} - \text{Average Weight}}{\text{Average Weight}} \times 100$$

For example:-

* Weight variation Test $= \frac{0.739 - 0.713}{0.713} \times 100 = 3.646$ mg

* Weight variation Test $= \frac{0.394 - 0.713}{0.713} \times 100 = -4.474$ mg

i) upper limit $= W + [(\% 100)(W)]$

ii) Lower limit $= W - [(\% 100)(W)]$

* Average weight of capsule $= 0.713$ mg

* Average Weight > 300 mg

* Standard weight of capsule $= \pm 7.5\%$

$$0.713 \times \frac{7.5}{100} = 0.053475 \text{ mg}$$

i) $0.713 + 0.053475 = 0.766$ mg

ii) $0.713 - 0.053475 = 0.659$ mg

$\therefore$ $0.659 - 0.766 \rightarrow$ Passes.

PREPARATION OF CALCIUM GLUCONATE INJECTION

AIM

To prepare and submit 10ml of calcium gluconate injection. (2 Ampoule - Each ampoule contain 10ml)

REQUIREMENTS

Beaker, Glass rod, Funnel, Filter paper and Ampoule.

PRINCIPLE

Injections are sterile solutions, emulsions or suspensions.

They are prepared by dissolving, emulsifying or suspending an active ingredient and any other substances in water for injection. Injecting is the act of giving medication by use of syringe and needle to obtain the desired therapeutic effect taking into account the patient's safety and comfort. It is suitable for those drugs that are altered or not absorbed by other methods of administration.

Calcium gluconate is a mineral supplement and medication. As a medication it is used by injection into a vein to treat low blood calcium, high blood potassium and magnesium toxicity. Supplementation is generally only required when there is not enough calcium in the diet.

Calcium gluconate is the calcium salt of glucoric acid, an oxidation product of glucose, and contains 9.3% calcium, which is about one-third of the calcium in strength of calcium chloride USP.

Since, it is soluble to the extent of only one part in 30 parts of cold water, the 10% solution is supersaturated and is stabilized by the addition of calcium saccharate tetrahydrate 0.4b % W/V.

PROCEDURE

* Calcium gluconate monohydrate and calcium saccharate tetrahydrate are dissolved in water for injection in a beaker and makes upto required volume.
* Filter it and take 1ml of the filtrate.
* Then, it is transferred into Previously sterilized ampoules, sealed properly and sterilized by autoclaving.

USE

It is used as mineral supplement and medication.

REPORT

10 ml of calcium gluconate injection was prepared and submitted with suitable label.

OBSERVATION AND CALCULATION

TABLE 1 : COMPOSITION OF CALCIUM GLUCONATE INJECTION

S. NO	Ingredients	Master Formula (For 1ml Injection)	Working Formula (For 10ml Injection)
1)	Calcium gluconate monohydrate	98 mg	980 mg
2)	calcium saccharate tetrahydrate	4.6 mg	46 mg
3)	Water for injection upto	1 ml	10 ml

For example :-

* calcium gluconate monohydrate $= \frac{98 \times 10}{1} = 980$ mg

* calcium saccharate tetrahydrate $= \frac{4.6 \times 10}{1} = 46$ mg

* Water for injection (upto) $= \frac{1 \times 10}{1} = 10$ ml

LABEL

CALCIUM GLUCONATE INJECTION 10ml	
Ingredients calcium gluconate monohydrate .... 980 mg calcium saccharate tetrahydrate .... 46 mg Water for Injection .... 10 ml Category Mineral supplement for calcium deficiency. Storage Stored in cool place Direction Directed by physician. FOR PARENTERAL USE ONLY	Batch No : 21KGPC Lic No : 0021KGPC MFG DATE : 23/09/2024 EXP DATE : 23/08/2025
MFG BY : SPJ PHARMA COMPANY	

PREPARATION OF ASCORBIC ACID INJECTION

AIM

To prepare and submit 10 ml of ascorbic acid injection.
(2 Ampoule - Each 2 ampoule contain 10 ml)

REQUIREMENTS

Beaker, Glass rod, Funnel, Filter paper and Ampoule.

PRINCIPLE

Injections are sterile solutions, emulsions or suspensions. They are prepared by dissolving, emulsifying or suspending an active ingredient and any other substances in water for injection.

Injecting is the act of giving medication by use of syringe and needle to obtain the desired therapeutic effect taking into account the patient's safety and comfort. It is suitable for those drugs that are altered or not absorbed by other methods of administration.

Ascorbic acid (vitamin c) is a water soluble vitamin. It occurs as a white or slightly yellow crystal or powder with a light acidic taste. It is an anti-scorbutic product.

Ascorbic acid injection is a clear, colourless to slightly yellow sterile solution of Ascorbic acid in water for injection, for intravenous, intramuscular or subcutaneous use.

PROCEDURE

* Ascorbic acid is dissolved in water for injection in a beaker and makes upto required volume.
* Filter it and take 2ml of the filtrate.
* Then it is transferred into previously sterilized ampoules, sealed properly and sterilized by autoclaving.

USE

It is used as anti-scurvy.

REPORT

10ml of Ascorbic acid injection was prepared and submitted with suitable label.

OBSERVATION AND CALCULATION

TABLE 1 : COMPOSITION OF ASCORBIC ACID INJECTION

S. No	Ingredients	Master Formula (For 1ml injection)	Working Formula (For 10ml injection)
1)	Ascorbic Acid	0.5 gm	5 gm
2)	Water for Injection, upto	2 ml	20 ml

For example :-

* Ascorbic acid $= \frac{0.5 \times 10}{1} = 5$ gm

* Water for injection (upto) $= \frac{2 \times 10}{1} = 20$ ml

LABEL

ASCORBIC ACID INJECTION 10ml	
Ingredients Ascorbic acid ----- 5gm Water for injection --- 20ml Category Anti-Scurvy Storage Stored in cool place Direction Directed by Physician FOR PARENTERAL USE ONLY	Batch No: 21KGPC Lic No: 00021KGPC MFG DATE: 23/09/2024 EXP DATE: 23/08/2025
MFG BY: SPJ PHARMA COMPANY	

Exp.No. 11.
Date : 30/09/2024

PREPARATION OF VANISHING CREAM

AIM

To prepare and submit 20 gms of vanishing cream (o/w type).

REQUIREMENTS

China dish, glass rod, beaker, bunsen burner and thermometer.

PRINCIPLE

1) vanishing cream is o/w type of emulsion, which when applied to the skin, it vanishes and leaves an almost invisible layer on it.
2) Hence, it is called as 'vanishing cream'. The layer left behind after application, acts as a base or foundation, for facial make up. Hence, vanishing creams are also called as foundation creams. Since water is an external phase, it will be quickely washed off with water.
3) The main ingredients of vanishing creams are stearic acid, alkali and water.
4) Stearic acid gives a pearly white shining appearance to the cream, which on application gives a thin white film of free stearic acid. Soap is prepared in-situ by the chemical reaction between alkali and stearic acid, which is used as emulsifying agent.
5) vanishing creams are o/w type emulsion; there is a possibility of evaporation of water from the external phase of emulsion.
6) Therefore, glycerine, polyethylene glycol or alcohol are incorporated as humectants, to prevent the drying out of cream, since external phase of vanishing cream is aqueous, it should be protected from the contamination from microorganisms by adding suitable preservatives, like methyl paraben or propyl paraben. These creams are also be scented pleasantly, using suitable

OBSERVATION AND CALCULATION

TABLE 1 : COMPOSITION OF VANISHING CREAM

S. No	Ingredients	Master formula (For 10gm)	Working formula (For 20gm)
1)	Stearic acid	2.4 gm	4.8 gm
2)	Potassium hydroxide	6.45 gm	12.9 gm
3)	Glycerine (Humectants)	100 mg	200 mg
4)	Methyl paraben	Q.S	Q.S
5)	Water	6.45 ml	12.9 ml

For example :-

* stearic acid → 2.4 X 2 = 4.8 gm
* potassium hydroxide → 6.45 X 2 = 12.9 gm
* Glycerin → 100 X 2 = 200 mg
* Water → 6.45 = 12.9 ml

Preservatives, Perfumes in small quantities.

PROCEDURE

* Melt stearic acid in china dish on water bath by heating up to 70°c.
* In a beaker, Dissolve KOH and methyl paraben (methyl para hydroxy benzoate) in water, add glycerin to it.
* Heat this aqueous solution up to 70°c on water bath.
* When both aqueous and oil phases reaches the same temperature 70°c, add aqueous phase to the melted stearic acid with continuous stirring.
* Remove the dish from heat and continue the stirring and when temperature reaches 40°c, add perfume.
* Mix uniformly until it becomes cool and homogenous cream is obtained.

DISPENSING

Weigh the prescribed quantity of cream on the butter paper and transfer to a wide mouthed, small, screw capped plastic or glass bottle or to collapsible tube, seal and label.

DIRECTION

Used for external application. Apply to skin where ever necessary.

STORAGE

Store in a cool place.

AUXILIARY LABEL

FOR EXTERNAL USE ONLY

USES

Vanishing cream is used as foundation for holding the makeup preparation for longer period.

REPORT

20 gm of vanishing cream was prepared and submitted with suitable label.

OBSERVATION AND CALCULATION

TABLE 1 : COMPOSITION OF VANISHING CREAM

S. No	Ingredients	Master formula (For 10gm)	Working formula (For 20gm)
1)	Stearic acid	2.4 gm	4.8 gm
2)	Potassium hydroxide	6.45 gm	12.9 gm
3)	Glycerine (Humectants)	100 mg	200 mg
4)	Methyl paraben	Q.S	Q.S
5)	Water	6.45 ml	12.9 ml

For example :-

* stearic acid ⇒ 2.4 X 2 = 4.8 gm
* potassium hydroxide ⇒ 6.45 X 2 = 12.9 gm
* Glycerin ⇒ 100 X 2 = 200 mg
* Water ⇒ 6.45 = 12.9 ml.

LABEL

VANISHING CREAM	20 gm
Ingredients Stearic acid ------ 4.8 gm Potassium hydroxide ---- 12.9 gm Glycerine ------ 200 mg Methyl paraben ---- Q.S Water ------ 12.9 ml Category used as foundation for holding the makeup preparation for longer period. Storage Stored in a cool place Direction used for external application, Apply to skin where ever necessary FOR EXTERNAL USE ONLY	Batch No : 21KGPC Lic NO : 00021KGPC MFG DATE : 03/10/2024 EXP DATE : 03/09/2025
MFG BY : SPJ PHARMA COMPANY	

PREPARATION OF COLD CREAM

AIM

To prepare and submit 20 gm of cold cream (W/o type of emulsion).

REQUIREMENTS

Beaker, Glass rod, china dish, Mortar and pestle, Thermometer

PRINCIPLE

Cold cream is W/o type of emulsion, which when applied to the skin, a cooling effect is produced, due to the slow evaporation of water, present in emulsion. Cold cream is prepared by saponification reaction between and alkali-borax; i.e. borax reacts with free fatty acids of bees wax and produce borax soap in-situ (ester of fatty acid). this soap acts as emulsifying agent.

In cold cream, the internal phase is oil and external phase is water, hence it forms o/w type of emulsion. But after application on the skin, water evaporates and leads to phase inversion from o/w type to w/o type emulsion. Therefore oily phase, which is remaining (left) on the skin, gives emollient nature. Liquid paraffin is used as emollient and rose oil is used as perfume, to give a pleasant flavour to the cream.

PROCEDURE

* Since there will be little wastage (loss) during weighing and preparing, to manipulate these practical losses, calculate the ingredients for at least one or two grams extra than prescribed.
* Grate the white beeswax into small pieces. Weigh the required quantity of white beeswax and liquid paraffin and melt in china dish,

by heating on a water bath up to 70°c.

* In a glass beaker, dissolve borax in water and heat up to 70°c.
* When both oily and aqueous phases reach the same temperature (70°c), gradually, add broax solution to the melt of beeswax, with constant stirring.
* Stirr continuously until it becomes cool. When the temperature lowers to 40 - 45°c, incorporate rose oil and mix uniformly, until a homogenous semi-solid mass is obtained.

DISPENSING

Weigh the prescribed quantity of cream on a butter paper and transfer to an ointment jar or metallic / plastic collapsible tube, close it thoroughly and label.

DIRECTION

Apply to skin

USES

Cold cream is used as an emollient for the treatment of dry skin. Hence, this becomes quite popular in winter season.

STORAGE

Store in a cool place but do not allow to freeze.

AUXILIARY LABEL

FOR EXTERNAL USE ONLY

REPORT

20 gm of cold cream was prepared and submitted with suitable label.

OBSERVATION AND CALCULATION

TABLE 1 : COMPOSITION OF COLD CREAM

S. No	Ingredients	Master Formula (For 1000 gm)	Working Formula (For 20 gm)
1)	White Bees wax	200 gm	4 gm
2)	Liquid paraffin (Emollient)	600 gm	6 gm
3)	Borax	10 gm	0.2 gm
4)	Water	Q.S	Q.S

For example :-

* White Bees wax $\Rightarrow \frac{200 \times 20}{1000} = 4$ gm

* Liquid paraffin $\Rightarrow \frac{600 \times 20}{1000} = 6$ gm

* Borax $\Rightarrow \frac{10 \times 20}{1000} = 0.2$ gm

LABEL

COLD CREAM	20 gm
Ingredients White Bees wax ---- 4 gm Liquid paraffin ---- 6 gm Borax ------- 0.2 gm Water ------ Q.S Category Emollient for dry skin Storage Stored in cool place Direction Apply to skin FOR EXTERNAL USE ONLY	Batch NO : 21KGPC LIC NO : 00021KGPC MFG DATE : 03/10/2024 EXP DATE : 03/09/2025
MFG BY : SPJ PHARMA COMPANY	

Exp.No. 13
Date : 14/10/2024

PREPARATION OF ATROPINE SULPHATE EYE DROPS

AIM

To prepare and submit 10ml of Atropine sulphate eye drops.

REQUIREMENTS

Beaker, Glass rod, Measuring cylinder and conical flask.

PRINCIPLE

Eye drops are saline-containing drops used as an ocular route to administer. Depending on the condition being treated, they may contain steroids, anti-histamines, sympathomimetics, non-steroidal anti-inflammatory drugs (NSAIDs), anti-biotics, antifungal or topical anaesthetics. Eye drops sometimes do not have medications in them and are only lubricating and tear-replacing solutions. Eye drops are also used for stopping itching and redness of the eyes. Atropine eye drop is used before eye examinations (e.g., refraction) and to treat certain eye conditions (e.g., uveitis). It belongs to a class of drugs known as anti-cholinergic. Atropine works by widening (dilating) the pupil of the eye.

PROCEDURE

* Weigh the medicament and dissolve it in the bactericidal solution in a small conical flask.

* Transfer it to a 10ml measuring cylinder, rinse the flask and adjust the final volume with purified water.

* Sterilize it by autoclaving at 115°c for 30 mins.

PRECAUTION

Avoid contamination during use.

REPORT

10 ml of Atropine sulphate eye drops was prepared and submitted with suitable label.

OBSERVATION AND CALCULATION

TABLE 1 : COMPOSITION OF ATROPINE SULPHATE EYE DROPS

S. NO	Ingredients	Master Formula (For 100ml)	Working Formula (For 10ml)
1)	Atropine sulphate	1 gm	0.1 gm
2)	Phenyl mercuric nitrate solution, 0.004 % W/V	50 ml	5 ml
3)	purified water, upto	100 ml	10 ml

For example :-

* Atropine sulphate $\Rightarrow \frac{1 \times 10}{100} = 0.1$ gm

* Phenyl mercuric nitrate solution $\Rightarrow \frac{50 \times 10}{100} = 5$ ml

* purified water, upto $\Rightarrow \frac{100 \times 10}{100} = 10$ ml

LABEL

ATROPINE SULPHATE EYE DROPS 10ml	
Ingredients Atropine sulphate ----- 0.1gm Phenyl mercuric nitrate solution (0.004% W/V) ----- 5ml Purified water ---- 10ml Category Dilate the pupil of the eye. Storage stored in a cool place Direction Directed by physician FOR OPHTHALMIC USE ONLY	Batch NO : 21KG/PC Lic NO : 00021KG/PC MFG DATE : 14/10/2024 EXP DATE : 14/09/2025
MFG BY : SPJ PHARMA COMPANY	

PREPARATION OF PHYSOSTIGMINE SULPHATE EYE DROPS

AIM

To prepare and submit 10ml of Physostigmine sulphate eye drops.

REQUIREMENTS

Beaker, Glass rod, Measuring cylinder and conical flask

PRINCIPLE

Eye drops are saline-containing drops used as an ocular route to administer. Depending on the condition being treated, they may contain steroids, anti-histamines, sympathomimetics, non-steroidal anti-inflammatory drugs (NSAIDs), anti-biotics, anti-fungal or topical anaesthetics. Eye drops sometimes do not have medications in them and are only lubricating and tear-replacing solutions. Eye drops are also used for stopping itching and redness of the eyes. Physostigmine ophthalmic reduces pressure in the eye by increasing the amount of fluid that drains from the eye. It is used to treat glaucoma by lowering pressure inside the eye. Here, benzalkonium chloride is used as bactericide and sodium metabisulphite is used as reducing agent.

PROCEDURE

* Mix sodium metabisulphite and Benzalkonium chloride solution dissolve the medicament in the mixture and adjust the final volume with purified water.

* Filter the solution and packed in a previously sterilized suitable container or sterilize it after packing.

PRECAUTION

Avoid contamination during use

REPORT

10 ml of Physostigmine sulphate eye drops was prepared and submitted with suitable label.

OBSERVATION AND CALCULATION

TABLE 1 : COMPOSITION OF PHYSOSTIGMINE SULPHATE EYE DROPS

S. No	Ingredients	Master Formula (For 100ml)	Working Formula (For 10ml)
1)	Physostigmine Sulphate	0.5 gm	0.05 gm
2)	Sodium metabisulphite	0.2 gm	0.02 gm
3)	Benzalkonium chloride solution	0.02 gm	0.002 gm
4)	purified water, upto	100 ml	10 ml

For example :-

* physostigmine sulphate $\Rightarrow \frac{0.5 \times 10}{100} = 0.05$ gm

* Sodium metabisulphite $\Rightarrow \frac{0.2 \times 10}{100} = 0.02$ gm

* Benzalkonium chloride solution $\Rightarrow \frac{0.02 \times 10}{100} = 0.002$ gm

* Purified water, upto $\Rightarrow \frac{100 \times 10}{100} = 10$ ml

LABEL

PHYSOSTIGMINE SULPHATE EYE DROPS 10ml	
Ingredients Physostigmine sulphate ----- 0.05gm Sodium metabisulphite ---- 0.02gm Benzalkonium chloride solution ---- 0.002gm Purified water, upto ---- 10 ml Category Treatment of certain Glaucoma Storage Stored in cool place Direction Directed by physician FOR OPHTHALMIC USE ONLY	Batch No: 21KGPC Lic No: 00021KGPC MFG DATE: 14/10/2024 EXP DATE: 11/09/2025
MFG BY: SPJ PHARMA COMPANY	

EVALUATION OF GLASS CONTAINERS (AS PER I.P.)

AIM

To carryout different evaluate tests of glass containers as per I.P.

REQUIREMENTS

Glass containers, Beaker, conical flask, Burette, Mortar and pestle; And Sieve.

PRINCIPLE

Glass containers may be colourless or coloured. Neutral glass is a borosilicate glass containing significant amounts of boric oxide, aluminum oxide, alkali and/or alkaline earth oxides. It has a high hydrolytic resistance and a high thermal shock resistance. Soda-lime-silica glass is a silica glass containing alkali metal oxides, mainly sodium oxide and alkaline earth oxides, mainly calcium oxide. It has only a moderate hydrolytic resistance.

According to their hydrolytic resistance, glass containers are classified as :

* Type I glass containers - Which are of neutral glass, with a high hydrolytic resistance, suitable for most preparations whether or not for parenteral use.

* Type II glass containers - Which are usually of soda-lime-silica glass with high hydrolytic resistance resulting from suitable treatment of the surface. They are suitable for most acidic and neutral, aqueous preparations whether or not for parenteral use.

* Type III glass containers - which are usually of soda-lime-silica glass with only moderate hydrolytic resistance. They are generally suitable for non-aqueous preparations for parenteral use, for powders for parenteral use and for preparations not for parenteral use.

Glass containers intended for parenteral preparations may be ampoules, vials or bottles. Glass is a common material to be used in either non-sterile or sterile liquid dosage forms. It leaches alkali from its surface. Hence, a limit test for alkalinity is to be performed before using it for a particular product. USP and IP provide two tests to determine the chemical resistance of glass containers.

1) Powdered Glass Test

* From the glass containers, alkaline constituents (oxides of sodium, potassium, calcium, aluminum, etc) are leached into purified water under conditions of elevated temperatures. When the glass is powdered the leaching of alkali can be enhanced in the powdered is critical.

* The principle involved in the powdered glass test in estimate the amount of alkali leached from the glass powder.

* The amount of acid that is necessary to neutralize the released alkali (a specified limit) is specified in the Pharmacopoeia. The basic analysis is acid-base titration using methyl red indicator.

2) Water Attack Test

* This is only for treated soda-lime glass containers under the controlled humidity conditions which neutralize the surface alkali

and glass will become chemically more resistant.

* The principle involved in the water attack test is to determine whether the alkali leached from the surface of a container is within the specified limits or not.

* Since, the inner surface is under test entire container (ampoule) has to be used.

* The amount of acid that is necessary to neutralize the released alkali from the surface is estimated, the leaching of alkali is accelerated using elevated temperature for a specified time.

* Methyl red indicator is used to determine the end point. The basic is acid-base titration.

PROCEDURE

1) Powdered Glass Test

Step 1 : Preparation of glass specimen ⇒ Few containers are rinsed thoroughly with purified water and dried with stream of clean air. Grind the containers in a mortar to a fine powder and pass through sieve no. 20 and 50.

Step 2 : Washing the specimen ⇒ 10 gm of the above specimen is taken into 250ml conical flask and wash it with 30ml acetone. Repeat the washing, decant the acetone and dried ate specimen after which it is used within 48 hrs.

Step 3 : 10gm sample is added with 50ml of high purity water in a 250ml flask. place it in an autoclave at 121°C ± 2°C for 30 mins. cool it under running water. Decant the solution into another flask, wash again with 15ml high purity water and again decant. Titrate immediately with 0.02N sulphuric acid using methyl red as an indicator and record the volume.

2) Water Attack Test

* Rinse thoroughly with high purity water.

* Fill each container to 90 % of its overflow capacity with water and is autoclaved at 121°C for 30 mins, then it is cooled and the liquid is decanted which is titrated with 0.02 N sulphuric acid using methyl red as an indicator.

* The volume of sulfuric acid consumed is the measure of the amount of alkaline oxides present in the glass containers.

REPORT

The different evaluate tests of glass containers as per I.P. was performed.

OBSERVATION AND CALCULATION

TABLE 1 : LIMITS OF ALKALINITY FOR GLASS CONTAINERS

S. NO	Tests	Container	Volume of 0.02N H_2SO_4
1)	Powdered Glass Test	Type I	1.0
		Type II	8.5
		Type III	15.0
2)	Water Attack Test	Type II (100ml or below)	0.07
		Type II (Above 100ml)	0.02