

STANDARD TESTING PROCEDURE				
DEPARTMENT: QUALITY CONTROL				
NAME OF THE PRODUCT: AZITHROMYCIN 7.5 % GRANULES / POWDER				
STP NO.	REVISION	EFFECTIVE DATE	REVIEW DATE	PAGE NO
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NAME OF THE PRODUCT: AZITHROMYCIN 7.5 % GRANULES / POWDER

SPECIFICATIONS:

SR No.	TEST	SPECIFICATION
1	Description	White to slightly off white free flowing granular powder, which after reconstitution gives a white to off white coloured vanilla flavoured bitterless & sweet in taste suspension.
2	Identification	The retention time for Azithromycin test preparation in test corresponds to that exhibited in the Chromatogram of the standard preparation of the Assay.
3	Water (By Karl Fischer) (Reagent used: ethylene glycol monomethyl ether)	Limit: not more than 1.5%
4	pH (reconstituted Suspension)	Limit: 8.5 to 11.0
5	Assay: Each 100gm contains Azithromycin dihydrate USP/BP Eq. to Azithromycin..... 7.5 gm	6.75 gm to 8.25 gm (90.0 % to 110.0%)

Prepared by:

Name: Maheshkumar B. Mistry

Designation: Manager (Q.C)

Signature:



Date: 10/04/2024

Approved by:

Name: Nalin R Patel

Designation: AGM (Q.C)

Signature:



Date: 10/04/2024

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METHOD OF ANALYSIS

1-DESCRIPTION: White to slightly off white free flowing granular powder, which after reconstitution gives a white to off white coloured vanilla flavoured bitterless & sweet in taste suspension.

2-IDENTIFICATION: The retention time for Azithromycin test preparation in test corresponds to that exhibited in the Chromatogram of the standard preparation of the Assay.

3-WATER BY KARLFISCHER: (Limit: not more than 1.5%)

Determined on 100 mg of sample.

Fill the beaker of Karl Fischer apparatus with dry ethylene glycol monomethyl ether (about 20ml) to dip the electrode. Keep magnet in the bottom of the beaker. Fit the beaker with Karl Fischer apparatus. Fill Karl Fischer reagent in the bottle and fit the tube assembly. Switch on the Karl Fischer apparatus and set the required speed of the magnetic Stirrer. Press start green switch to start the addition of Karl Fischer reagent to neutralize the ethylene glycol monomethyl ether when the buzzle ring for the end of the titration, add 10 μ l (10mg) of distilled water and close the beaker and again press the green start button to start the titration. when the buzzle ring for the end of the Titration note the KFR reading, again add 10 μ l (10mg) of distilled water and close the beaker and again press the green start button to start the titration. When the buzzle ring for the end the titration note the KFR reading, than add accurately weighed about 100 mg of sample and repeat the same operation. First calculate the factor for Karl Fischer reagent.

Calculate factor and Water content by given formula.

FACTOR CALCULATION :

1. Wt. of water taken: μ l = mg B.R. [1] : ml

2. Wt. of water taken: μ l = mg B.R. [2] : ml

Factor: $\frac{\text{Wt. of water}}{\text{B.R.}}$ F1= ----- F2= -----
= ----- =-----

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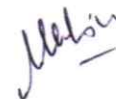
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$$\text{Mean of two factor} = \frac{F1 + F2}{2} =$$

1. Wt. of Sample taken: mg B.R. [1] : ml

2. Wt. of Sample taken : mg B.R. [2] : ml

$$\% \text{ Water} = \frac{\text{B.R.} \times \text{Factor} \times 100}{\text{Wt. of sample in mg}}$$

1. = ----- = -----

2. = ----- = -----

$$\text{Mean : } \frac{1+2}{2} = \text{-----}$$

4-pH: (reconstituted suspension) : (Limit 8.5 to 11.0)

Take 16.0 gm sample in 30 ml marked stopper test tube, add 20 ml purified water and shake well for 2 minutes till proper suspension is formed. Add sufficient water up to the mark to make volume 30 ml. shake and measure the pH with calibrated pH meter.

5-ASSAY (By HPLC): 6.75 gm to 8.25 gm
(90.0 % to 110.0 %)

PREPARATION OF MOBILE PHASE:

Buffer pH = 7.5, Weigh accurately 4.55 g Potassium di-hydrogen orthophosphate and dissolve in 1000 ml of purified water and mix. Adjust pH 7.5 with 10 % Sodium hydroxide solution.

PREPARATION OF MOBILE PHASE:

Prepare a mixture of Methanol: buffer pH 7.5 (v/v) in the ratio of 80: 20, filter through 0.45micron filter and then sonicate for 5 minutes.

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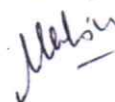
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STANDARD PREPARATION:

Weigh accurately about equivalent to 100mg Azithromycin (105mg of Azithromycin dihydrate) & transfer to a 100 ml volumetric flask add 80 ml mobile phase, sonicate for 5 minutes. Add sufficient mobile phase to make 100 ml sonicate for 5 minutes and filter it using 0.45 µm nylon membrane filter.

FOR DRY MIX: Weigh accurately about 1.35 g of sample (equivalent to 100 mg of Azithromycin) & transfer to a 100 ml volumetric flask add 80 ml mobile phase, sonicate for 15 minutes. Add sufficient mobile phase to make 100 ml sonicate for 5 minutes and filter it using 0.45 µm nylon membrane filter.

CHROMATOGRAPHIC CONDITION:

Detector: UV at 210 nm

Column: 4.6 mm X 250mm ,5 micron of C18 (Neosphere) or equivalent

Flow rate: 2 ml per minute

Injection volume: 20 µl

Column Temp: 50°C.

Inject 20µl of both standard and test preparation using test condition given above and record the chromatogram. Calculate the percentage in sample by given formula.

CALCULATION: (% as Azithromycin)

FOR DRY MIX:

$$\% \text{ ASSAY} = \frac{\text{Mean area of sample} \times \text{wt. of std} \times 100 \times \text{potency of std (as is basis) } \times 100}{\text{Mean area of std} \times \text{wt. of sample} \times 100 \times 100}$$

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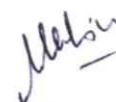
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