PROTOCOL

IP DISSOLUTION APPARATUS CALIBRATOR, PREDNISONE TABLETS RS

Cat No.: PCT-001
Lot No.: IPRS/29/16

(10 mg nominal weight prednisone content per tablet)
FOR DISSOLUTION PERFORMANCE VERIFICATION TEST

The IP Prednisone Tablets RS is use for the Performance Verification Test for IP Apparatus 1 (Paddle Type) and Apparatus 2 (Basket Type) in the IP General Chapter on Dissolution (2.5.2.)

Storage Condition- Store at controlled room temperature not exceeding 25^0C and in dry place.

Dissolution medium- The preparation of the media for IP dissolution apparatus as follows:

1. Heat suitable amount of media (demineralised water), about 41-45^0C.
2. It should be filter under vacuum condition through a 0.45 um into a suitable flask equipped with a stirring device.
3. Seal the flask and apply the vacuum for additional 5 min while stirring.
4. The temperature of the dissolution medium should maintain at 37^0C ± 0.5^0C prior to the initiation of the test.

Procedure- [See DISSOLUTION (2.5.2) in current IP]

1. Determine the quantity of Prednisone, $C_{21}H_{26}O_5$, dissolved at 30 min. in each vessel, expressed as percent of the labeled amount.
2. 500 ml water use as dissolution media should not be stirred prior to the initiation of the test for the purpose of the equilibration.
3. Conduct the test at 37^0C ± 0.5^0C.
4. Each apparatus run at 50 rpm speed for 30 minutes.
5. With an aliquot of sample solution at 30 minutes and filter the solution immediately.
6. Measure the amount of Prednisone dissolved from filtered portions of the sample aliquots by **Method A or Method B.**

Note- An Amount of alcohol not to exceed 5% of the total volume of the standard solution may be used to bring the prednisone standard into solution**.**

Method A by the UV spectrophotometer

- Withdraw a suitable volume of the medium and filter.
- Measure the absorbance of the filtrate at the maxima at about 240 nm (2.4.7).
- Calculate the content of Prednisone comparison with a solution of known concentration of P*rednisone RS.*

Method B by the Liquid chromatography (2.4.14)

Chromatographic condition described under assay of Prednisone tablet IP.

- **Reference Solution-** Weighed a suitable quantity of *prednisone RS* and dissolve in a 50 per cent v/v solution of methanol to obtain a solution having a concentration of about 0.2 mg/ml. To 5.0 ml of this solution dilute to 50.0 ml with water.
- **Test Solution**- Withdraw a suitable volume of medium and filter properly.

- **Chromatographic System**
  - A stainless steel column 25 cm × 4 mm, packed with octadecylsilane bonded to porous silica (3 to 10 µm),
  - Mobile phase: a suitable mixture filtered mixture of 688 volumes of water, 250 volumes of peroxide-free tetrahydrofuran and 62 volumes of methanol,
  - Flow rate- 1 mL/minute the retention of prednisone is about 8 minute,

- Wavelength- 254 nm,
- Injection volume- 10 µl.

Inject the reference solution. The test is not valid unless the relative standard deviation for replicate injections is not more than 2.0 per cent.

Inject the reference solution and the test solution. Calculate the content of $C_{21}H_{26}O_5$ in the tablets.

Test interpretation – The apparatus is suitable for the dissolution if the each of individual calculated values for each apparatus is within the specified ranges shown in the Table.

These values are only applicable to Lot No: IPRS/29/16

Apparatus as per IP	**Percentage of the labeled amount of Prednisone dissolved at 30 minutes at 50 rpm**
Type 1 (Paddle Type)	25-45
Type 2 (Basket Type)	45-75