

# **Pemetrexed Injection 25mg/ml (Yellow to Greenish Coloration)**

# Business Unit – API

## Introduction of Pemetrexed Injection

### **Usage:-**

- Treatment of Cancer.
- Given in combination with Cisplatin (anti-cancer medicine -malignant pleural mesothelioma)
- Also given with Cisplatin for initial treatment of patients with advanced stage of Lung Cancer.

### **Instruction for use, handling and disposal**

- Single use only
- Perform Visual Inspection for particulate matter & discoloration.
- Do not administer, If particulate matter is observed.



### **Compounding Process**

- Appropriate Vol. of Pemetrexed (I) must be diluted to 100 ml with sodium chloride 9 mg/ml (0.9 %) solution for injection or 5% glucose intravenous infusion.  
(Administer as an intravenous infusion over 10 minutes)
- Pemetrexed infusion solution is compatible with polyvinyl chloride and polyolefin lined administration sets and infusion bags.



# Business Unit – API

## Appearance of Pemetrexed Injection

### Description:-

Solution is clear.

Ranges in color (colorless to yellow or green-yellow) without adversely affecting product quality.

### Leaflet Instructions:-

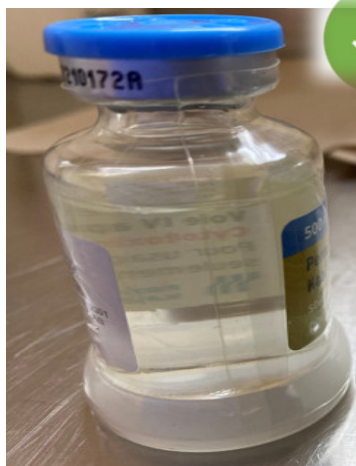
Mentioned as a solution to dilute for infusion (sterile concentrate) contents in a glass bottle.

It is a colorless to slightly yellowish solution or yellow greenish solution.

### Physical appearance

Inherent tendency of green coloration.

**Product solution of the Pemetrexed Injection is acceptable for the below depicted appearance**



**Clear Solution**



**Light Greenish**



**Greenish**



**Light Yellowish**

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## Impact and Acceptance

- The change of color (colorless to yellow/yellowish green solution) is generally observed on storage at the recommended temperature over a period of time.
- All the quality attributes of the product remain intact and well within qualified acceptable criteria. Color of the product changes during shelf-life of the product.
- There is no risk on the patient safety due to discoloration as this is the part of shelf life of product specification.
- The change in color of drug product with Pemetrexed API is well-known phenomena and is cited in Patient information leaflets of the innovator (ALIMTA) and various generics stating that the “solution is clear and ranges in color from colorless to yellow or green-yellow without adversely affecting product quality”.
- Literature report of Pemetrexed also supports the discoloration of product solution throughout the shelf life.
- The product can be used for further intended purpose by the patient even if color changed from colorless to yellow or yellowish green.
- There is no impact the product quality as well as patient safety due to greenish coloration of Pemetrexed Injection.

