

Extended stability for Pemetrexed Dr. Reddy's 100mg & 500mg Powder for Concentrate for Solution for Infusion (pemetrexed ditromethamine)

The physical and chemical stability of Pemetrexed Dr. Reddy's 100mg & 500mg Powder for Concentrate for Solution for Infusion when reconstituted and diluted in 5% glucose has been investigated at refrigerated and ambient conditions.

Stability was studied up to 28 days.

Pemetrexed Dr. Reddy's 100mg & 500mg Powder for Concentrate for Solution for Infusion are reconstituted and then diluted in 5% glucose, are stored at $5\pm3^{\circ}\text{C}$ and $25\pm2^{\circ}\text{C}$ in the absence of light and then tested as follows:

Ambient conditions:

	0hrs	24hrs	48hrs	72hrs	4 days	7 days	14 days	21 days	28 days
Diluted lyophilisate	X	X	X	X	X	X	X	X	X

Refrigerated conditions:

	0hrs	24hrs	48hrs	72hrs	4 days	7 days	14 days	21 days	28 days
Reconstituted lyophilisate	X	X	X	X	X	X	X	X	X
Diluted lyophilisate	X	X	X	X	X	X	X	X	X

Reconstituted lyophilisate is stored in re-stoppered and re-crimped vials.

Diluted lyophilisate is stored in 100ml infusion bags.

Results:

The reconstituted 25mg/ml solutions in 20ml and small vials (both stored refrigerated) and also the 10mg/ml diluted solution in the 100ml infusion bags stored under refrigerated conditions remain within specification over the 28 day period with respect to the specifications provided.

The 10mg/ml ambient study and both the 1mg/ml ambient and refrigerated studies all fail for potency and in the 10mg/ml study for total impurities as well. The 1mg/ml ambient study had already failed for impurity at the 14 day time point.

The summary table below provides a list of justified shelf lives for both reconstituted and diluted solutions in the vials and infusion bags.

Product	Storage	Justified shelflife
25mg/ml in 500mg Vial	Refrigerated	28 days
25mg/ml in 100mg vial	Refrigerated	28 days*
10mg/ml in 100ml Infusion bag	Refrigerated	28 days
10mg/ml in 100ml Infusion bag	Ambient	14 days
1mg/ml in 100ml Infusion bag	Refrigerated	14 days
1mg/ml in 100ml Infusion bag	Ambient	7 days

*The result of the analysis at the 28 day time point was at the lower end of the specification so taking the exhibited variance into consideration it may be prudent to reduce the shelf life to 14 days for this variant.

Source: Data on file