

STABILITY SUMMARY AND CONCLUSIONS: STORAGE CONDITION AND RETEST DATE

1. RECOMMENDED STORAGE CONDITIONS

Based on the available stability test results no special storage requirements for oseltamivir phosphate are necessary.

2. RETEST DATE

Based on the available stability test results a retest date of 60 months is justified.

3. RETEST PROTOCOL

Item	Retest	
Appearance	Yes	
Colour	Yes	
Identity (oseltamivir and phosphate)		No
Specific optical rotation	Yes	
Water Content	Yes	
Heavy Metals		No
Residual Organic Solvents		No
Organic Impurities: only degradation products	Yes	
Assay	Yes	