The types of studies conducted, protocols used, and the results of the studies should be summarized. The summary should include, for example,

* conclusions with respect to storage conditions
* conclusions with respect to shelf-life, and
* in-use storage conditions
* In use shelf-life.

# **Stabilty summary and conclusion** QdrugInjectable solution

## **Stability summary and conclusion**

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**Table 1: Summary of Stability Study Batches of Qdrug Injectable solution**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Batch # | Manufacturing date | API Lot | Fill volume/ Vial volume | Batch size | Use | Long term Stability | Photostability | Short term Stability | In use Stability |
| B123 | 1/1/2016 | 90338245 | 0.5 mL fill/ 0.8 ml vial | 1kg | Phase III | 36M at 5±3°C/ARH | Not performed | 3 months at 5±7°C/ARH | Not performed |
| B234 | 1/2/2016 | 90338345 | 0.5 mL fill/ 0.8 ml vial | 1kg | Registration stability | 24M at 5±3°C/ARH | Not performed | 3M at 21±3°C/ARH | Not performed |
| B345 | 1/3/2016 | 90338245 | 0.5 mL fill/ 0.8 ml vial | 2kg | Registration stability | 24M at 5±3°C/ARH | Not performed | 3M at 21±3°C/ARH | Not performed |
| Batchnr4:B456 | 1/4/2016 | 90338245 | 0.5 mL fill/ 0.8 ml vial | 2kg | Registration stability | 24M at 5±3°C/ARH | Not performed | 3M at 21±3°C/ARH | Not performed |

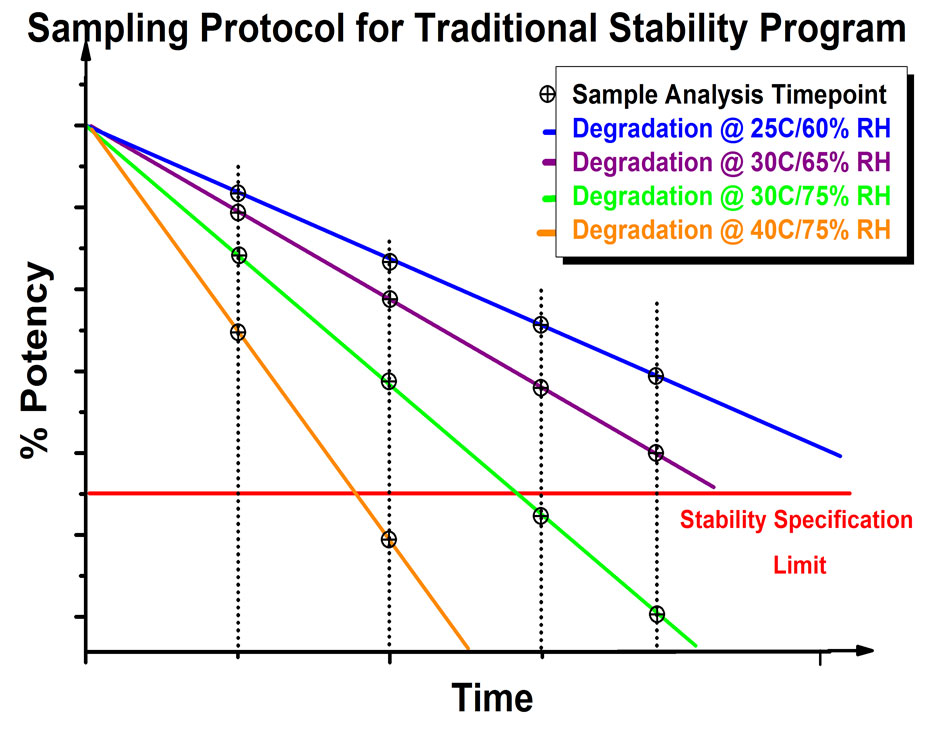
### **Long term stability**

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Long term stability studies have been performed, the product can be stored at LongtermStorageDuration:24M at LongtermStorageCondition:5±3°C/ARH.

Figure 1 Stability results by storage conditions



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### **Photostability**

PhotostabilityConclusion: No photostability studies have been performed, so the product must be protected from light.

### **Short term stability**

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Short term stability studies have been performed, the product can be stored at ShorttermStorageDuration:3M at ShorttermStorageCondition21±3°C/ARH.

### **In use stability**

In-useStabilityConclusion:In-use stability studies have been performed, so the product must be used immediately.

## **Overall conclusion**

All stability testing results obtained for registration batches (BatchNumber:B123, BatchNumber:B234, BatchNumber:B345, BatchNumber:B456), met the stability specifications Based on the stability study results DrugProduct:Qdrug DosageForm:Injectable solution can be stored for LongtermStorageDuration:24M at LongtermStorageConditions:5±3°C/ARH or at ShorttermStorageDuration:3M at ShorttermStorageCondition21±3°C/ARH

In-useConclusion:After first opening the medicinal product should be used immediately.

PhotostabilityConclusion:No photostability studies have been performed, so the product must be protected from light.

In-useStabilityConclusion:In-use stability studies have not been performed, so the product must be used immediately.