

3.2.P.8. STABILITY

3.2.P.8.1. STABILITY SUMMARY AND CONCLUSION

Overall Summary

Stability tests for Depot Medroxyprogesterone Acetate-Sub Cutaneous (DMPA-SC) 104 mg/0.65 mL Suspension for Injection commercial batches packaged in pre-filled single use injection system have been carried out under International Conference on Harmonisation (ICH) Zone IVb (30°C ± 2°C/75% ± 5% relative humidity [RH]) and accelerated (40°C ± 2°C /75% ± 5% RH) conditions. Stability studies have been completed with long-term data available and reported through the shelf life (36 months) and accelerated data through 6 months.

Summaries of the drug product batches that were used for formal stability studies are provided in Table 3.2.P.8.1-1.

Table 3.2.P.8.1-1. Summaries of DMPA-SC 104 mg/0.65 mL Pre-Filled Injection System Batch Information Commercial Batches Used in Stability Studies

Lot Number	Storage Conditions	Storage Period	Available Data	Mfg Date	Study Start Date	Lot Size (Units)	Mfg Place
Z03940	30°C/75%RH	36 months	36 months	06/2012	08/2012	102482	Pfizer Manufacturing Belgium, Puurs, Belgium
	40°C/75% RH	6 months	6 months				
Z03941	30°C/75%RH	36 months	36 months	06/2012	09/2012	101795	Pfizer Manufacturing Belgium, Puurs, Belgium
	40°C/75% RH	6 months	6 months				
Z03942	30°C/75%RH	36 months	36 months	06/2012	09/2012	102960	Pfizer Manufacturing Belgium, Puurs, Belgium
	40°C/75% RH	6 months	6 months				

RH = relative humidity.

Container Closure System

The DMPA-SC 104 mg/0.65 mL pre-filled single use injection system is packaged in a foil pouch (secondary packaging).

Characteristics Studied and Quality Specifications

Depot Medroxyprogesterone Acetate-Sub Cutaneous (DMPA-SC) 104 mg/0.65 mL Suspension for Injection packaged in pre-filled single use injection system stability samples have been tested according to the proposed shelf-life specifications presented in [Section 3.2.P.5.1 Specifications](#).

Evaluation of Methods

The methods used for testing the stability samples are the same methods used for testing finished product and are described in [Section 3.2.P.5.2 Analytical Procedures](#).

Storage Conditions and Testing Frequency

The stability protocol designs for the stability studies, including storage conditions and checkpoints, are described in Table 3.2.P.8.1-2.

Table 3.2.P.8.1-2. Stability Protocol for Batches Z03940, Z03941, and Z03942

Storage Condition	Checkpoint (Months)							
	Initial	3	6	9	12	18	24	36
30°C/75% RH	A	B	B	B	B	B	B	A
40°C/75% RH	B	B	B	---	---	---	---	---

Scheduled tests applied in accordance with the above protocols include:

- A: Description, assay, degradation products, methionine content, particle size distribution, and sterility.
- B: Description, assay, degradation products, methionine content and particle size distribution.

Bracketing

DMPA-SC will only be provided at one commercial strength, fill volume, and packaging type; therefore, a bracketing design was not applicable to the registration stability program.

Results of Testing

All results are within specifications. The stability results are presented in [Section 3.2.P.8.3 Stability Data](#).

Conclusions

All data remain within the acceptance criteria up to 36 months for samples stored at 30°C/75% RH and up to 6 months for samples stored at 40°C/75% RH. No negative trends have been observed.

The stability data support a shelf life of 36 months for DMPA-SC 104 mg/0.65 mL sterile aqueous suspension, packaged in a pre-filled single use injection system and stored in a foil pouch. As the results (both long-term and accelerated) are all within the acceptance criteria with no significant changes, no particular storage conditions are required.

Storage Conditions

No special condition for storage is required due to the good stability profile displayed by DMPA-SC pre-filled injection system at both long-term and accelerated conditions. However, the recommended storage condition statement will be determined by local labeling guidelines. As this product is an aqueous suspension, the advice “do not refrigerate or freeze” is recommended.