

3.2.P.8. ESTABILIDAD

3.2.P.8.1. Resumen de estabilidad y conclusiones

Resumen de estabilidad

Se realizaron pruebas de estabilidad en los siguientes lotes de acetato de metilprednisolona 40 mg/ml SAE (suspensión acuosa estéril) en viales de 1 ml almacenados a $25^{\circ}\text{C} \pm 2^{\circ}\text{C}$ y $60\% \pm 5\%$ HR.

Tabla 3.2.P.8.1-1. Lotes de estabilidad probados – Vial de 1 ml almacenado a $25^{\circ}\text{C} \pm 2^{\circ}\text{C}$ y $60\% \pm 5\%$ HR

Número de lote	Fecha de elaboración	Fecha de inicio	Datos (meses)	Tamaño del lote (unidades)	Sitio de elaboración	Situación
GK1138	01-12-1999	15-12-1999	60	490.010	Pfizer Belgium	Completo
HK0152	12-01-2000	15-01-2001	60	543.615	Pfizer Belgium	Completo
HK0153	01-01-2001	29-01-2001	60	236.515	Pfizer Belgium	Completo

Especificaciones de calidad para la vida útil propuesta

Vea la [Sección 3.2.P.5.1](#) para consultar las especificaciones.

Evaluación de métodos

Las metodologías utilizadas son las mismas que las que se analizan/describen en la [Sección 3.2.P.5.2](#).

Resultados de las pruebas

Los resultados de estabilidad se presentan en la [Sección 3.2.P.8.3](#). Todos los lotes cumplieron con los criterios en cada uno de los puntos temporales de las pruebas.

Conclusiones

Según los resultados de los parámetros físicos (pH y tamaño de la partícula) y el ensayo del principio activo, acetato de metilprednisolona, una vida útil propuesta de 60 meses es aceptable cuando se almacena por debajo de 25°C , ya que no se ha detectado una degradación de importancia estadística del principio activo.

Vida útil

Según los resultados, se justifica el siguiente período de vencimiento para el acetato de metilprednisolona 40 mg/ml SAE:

Envasado: Viales de vidrio

Vida útil: 60 meses

Condiciones de almacenamiento: Almacenar por debajo de 25°C

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Stability Test report of **DEPO-MEDROL 40 MG/ML 1ML VIAL**


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Stability Report: P0280003006II	Pfizer Puurs Belgium STABILITY	
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Contents

- 1. Study information**
- 2. Schedule**
- 3. Currently registered procedures and limits on stability**
- 4. Stability Test results at $25^{\circ}\text{C} \pm 2^{\circ}\text{C} - 60 \pm 5\% \text{ RH}$**
- 5. Conclusion**

Stability Report: P0280003006II	Pfizer Puurs Belgium STABILITY	
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1. Study information

Study Number	Manufacturing Lot Nnumber	Storage Condition	Storage Period	Container	Closure	Lot Quantity	Start Date	Manufacturing Date	Manufacturing Place
GK1138.CRT	GK1138	25°C ± 2°C – 60 ± 5% RH	60 MONTHS	GLASS VIAL	RUBBER STOPPER	490010	15/12/1999	01/12/1999	PFIZER BELGIUM
HK0152.CRT	HK0152	25°C ± 2°C – 60 ± 5% RH	60 MONTHS	GLASS VIAL	RUBBER STOPPER	543615	15/01/2001	01/12/2000	PFIZER BELGIUM
HK0153.CRT	HK0153	25°C ± 2°C – 60 ± 5% RH	60 MONTHS	GLASS VIAL	RUBBER STOPPER	236515	29/01/2001	01/01/2001	PFIZER BELGIUM

2. Schedule

		DESCRIPTION	pH	METHYLPREDNISOLONE ACETATE	PARTICLE SIZE LESS THAN 10 MCM	PARTICLE SIZE LESS THAN 20 MCM	STERILITY
GK1138.CRT	00 MONTHS	X	X	X	X	X	X
	12 MONTHS	X	X	X	X	X	
	24 MONTHS	X	X	X	X	X	
	36 MONTHS	X	X	X	X	X	
	48 MONTHS	X	X	X	X	X	
	60 MONTHS	X	X	X	X	X	X
HK0152.CRT	00 MONTHS	X	X	X	X	X	X
	12 MONTHS	X	X	X	X	X	
	24 MONTHS	X	X	X	X	X	
	36 MONTHS	X	X	X	X	X	
	48 MONTHS	X	X	X	X	X	
	60 MONTHS	X	X	X	X	X	X
HK0153.CRT	00 MONTHS	X	X	X	X	X	X
	12 MONTHS	X	X	X	X	X	
	24 MONTHS	X	X	X	X	X	
	36 MONTHS	X	X	X	X	X	
	48 MONTHS	X	X	X	X	X	
	60 MONTHS	X	X	X	X	X	X

3. Currently registered procedures and limits on stability

Test	Test method	Limits
Description	Visual	White suspension
Methylprednisolone acetate	TA5376	36 to 44 mg/ml
pH	Potentiometrically	3.0 to 7.0
Particle size less than 10 mcm	USP	Not less than 75 %
Particle size less than 20 mcm	USP	Not less than 99 %
Sterility	USP	Meets USP requirements

4. Stability Test results at 25°C ± 2°C – 60 ± 5% RH

Note: Test periods that are not scheduled for a study are reported as Not Scheduled (NS).

DESCRIPTION


	GK1138.CRT	HK0152.CRT	HK0153.CRT
00 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
12 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
23 MONTHS	NS	NS	MEETS TEST
24 MONTHS	TNR	MEETS TEST	TNR
25 MONTHS	MEETS TEST	NS	NS
36 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
48 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
60 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST

With the 24 months time point for studies GK1138.CRT and HK0153.CRT, "TNR" (= Test Not Run) is reported since the test was not performed exactly on schedule but one month before or after. All results within limits up to testing period: no problems reported.

METHYLPREDNISOLONE ACETATE

	GK1138.CRT	HK0152.CRT	HK0153.CRT
00 MONTHS	40.7	41.3	40.8
00 MONTHS	40.6	41.7	40.4
00 MONTHS	40.0	41.2	39.9
12 MONTHS	41.2	40.3	41.0
12 MONTHS	41.4	40.9	40.4
12 MONTHS	41.3	40.5	40.7
24 MONTHS	40.3	40.7	40.6
24 MONTHS	40.7	41.0	40.7
24 MONTHS	40.4	40.6	41.1
36 MONTHS	41.6	40.6	42.1
36 MONTHS	41.6	40.5	41.2
36 MONTHS	41.3	40.6	41.1
48 MONTHS	40.5	41.2	40.6
48 MONTHS	38.9	40.8	40.9
48 MONTHS	38.9	40.9	41.0
60 MONTHS	41.3	41.5	40.4
60 MONTHS	40.9	41.0	40.2
60 MONTHS	41.7	40.8	41.2

Tests were performed in triplicate and individual results are reported. All results within limits up to testing period: no problems reported.

Stability Report: P0280003006II	Pfizer Puurs Belgium STABILITY	
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pH

	GK1138.CRT	HK0152.CRT	HK0153.CRT
00 MONTHS	6.6	6.1	6.4
12 MONTHS	4.2	6.3	6.5
23 MONTHS	NS	NS	4.4
24 MONTHS	TNR	6.3	TNR
25 MONTHS	3.9	NS	NS
36 MONTHS	3.9	6.2	6.2
48 MONTHS	4.4	5.0	4.3
60 MONTHS	4.6	6.1	4.2

With the 24 months time point for studies GK1138.CRT and HK0153.CRT, "TNR" (= Test Not Run) is reported since the test was not performed exactly on schedule but one month before or after. All results within limits up to testing period: no problems reported.

PARTICLE SIZE LESS THAN 10 MCM

	GK1138.CRT	HK0152.CRT	HK0153.CRT
00 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
12 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
23 MONTHS	NS	NS	MEETS TEST
24 MONTHS	TNR	MEETS TEST	TNR
25 MONTHS	MEETS TEST	NS	NS
36 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
48 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
60 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST

With the 24 months time point for studies GK1138.CRT and HK0153.CRT, "TNR" (= Test Not Run) is reported since the test was not performed exactly on schedule but one month before or after. All results within limits up to testing period: no problems reported.

PARTICLE SIZE LESS THAN 20 MCM

	GK1138.CRT	HK0152.CRT	HK0153.CRT
00 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
12 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
23 MONTHS	NS	NS	MEETS TEST
24 MONTHS	TNR	MEETS TEST	TNR
25 MONTHS	MEETS TEST	NS	NS
36 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
48 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
60 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST

With the 24 months time point for studies GK1138.CRT and HK0153.CRT, "TNR" (= Test Not Run) is reported since the test was not performed exactly on schedule but one month before or after. All results within limits up to testing period: no problems reported.

Stability Report: P0280003006II	Pfizer Puurs Belgium STABILITY	
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STERILITY

	GK1138.CRT	HK0152.CRT	HK0153.CRT
00 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST
60 MONTHS	MEETS TEST	MEETS TEST	MEETS TEST

Sterility testing is only performed at the beginning and at the end of the stability study, no intermediate results are generated.

All results within limits up to testing period: no problems reported.

5. Conclusion

The results show that DEPO-MEDROL 40 MG/ML 1 ml vial is stable up to testing period when stored at 25°C ± 2°C – 60 ± 5% RH.

Stability Report: P0280003006II	Pfizer Puurs Belgium STABILITY	
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