

**Mycophenolate Mofetil
Film-Coated Tablets
500 mg**

3.2.P.8.1 Stability Summary and Conclusion

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1 Test Batches

Batch No.	Batch Size (units)	Date of Manufacture	Start of Stability Testing	Packaging*
KW06E083	140,000	May 2006	May 2006	PVC/PE/PVdC/Al blister
KW06E093	140,000	May 2006	May 2006	PVC/PE/PVdC/Al blister
KW06E18N	140,000	May, 2006	June 2006	PVC/PE/PVdC/Al blister

* Please refer Module 3.2.P.7 for details on packing materials.

2 Study Schedule

Real Time Tests		
Packaging	Storage Conditions [°C / % r. h.]	Testing points [months]
PVC/PE/PVdC/Al blister	25/60	0, 3, 6, 9, 12, 18, 24, 36, 48, 60
PVC/PE/PVdC/Al blister	30/65	0, 3, 6, 9, 12, 18, 24, 36, 48, 60
PVC/PE/PVdC/Al blister	40/75	0, 1, 2, 3, 6

During the stability program the following parameters are tested:

1.0 Appearance:

PVC/PE/PVdC/Al blister:

25°C/60%RH : 0, 3, 6, 9, 12, 18, 24, 36, 48, 60

30 °C ± 2°C / 65 %R.H. ± 5%: 0, 3, 6, 9, 12, 18, 24, 36, 48, 60

40°C/75%RH : 0, 1, 2, 3, 6

2.0 Dissolution:

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PVC/PE/PVdC/Al blister:

25°C/60%RH : 0, 3, 6, 9, 12, 18, 24, 36, 48, 60

30 °C ± 2°C / 65 %R.H. ± 5%: 0, 3, 6, 9, 12, 18, 24, 36, 48, 60

40°C/75%RH : 0, 1, 2, 3, 6

3.0 Microbial Contamination :

PVC/PE/PVdC/Al blister:

25°C/60%RH : 0, 12, 24, 36, 48, 60

30 °C ± 2°C / 65 %R.H. ± 5%: 12, 24, 36, 48, 60

40°C/75%RH : Not Applicable

4.0 Related Substances:

PVC/PE/PVdC/Al blister:

25°C/60%RH : 0, 3, 6, 9, 12, 18, 24, 36, 48, 60

30 °C ± 2°C / 65 %R.H. ± 5%: 0, 3, 6, 9, 12, 18, 24, 36, 48, 60

40°C/75%RH : 0, 1, 2, 3, 6

5.0 Assay :

PVC/PE/PVdC/Al blister:

25°C/60%RH : 0, 3, 6, 9, 12, 18, 24, 36, 48, 60

30 °C ± 2°C / 65 %R.H. ± 5%: 0, 3, 6, 9, 12, 18, 24, 36, 48, 60

40°C/75%RH : 0, 1, 2, 3, 6

3 Discussion and Conclusion

3.1 Discussion of test results

Appearance:

No significant change in the appearance occurred in Trilaminar blister pack irrespective of the storage conditions.

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Dissolution:

The dissolution of Mycophenolate Mofetil Film Coated Tablets 500 mg remains within the specifications for all the storage conditions in PVC/PE/PVdC/Al blister pack.

Microbial Counts:

Microbial counts found within the specification specifications for all the storage conditions in PVC/PE/PVdC/Al blister pack.

Related substances:

The results indicate that related substances are within the specified limits specifications for all the storage conditions in PVC/PE/PVdC/Al blister pack.

Assay:

The content of Mycophenolate Mofetil in Mycophenolate Mofetil Film Coated Tablets 500 mg remains within the specifications for all the storage conditions in PVC/PE/PVdC/Al blister pack.

Stability statement

Based on the present knowledge the following storage conditions and shelf life are proposed:

Primary Packaging Material	Shelf Life	Storage Condition
PVC/PE/PVdC/Al blister	24 months	Do not store above 30°C