

**Stability Summary for 27865 - EasyCorp KureItAll Tablets**

Product: KureItAll® / 100 mg  
 Batch: Lot 12973 (1,000,000 vials)  
 Package Date: Nov 07, 2006  
 Study Description: SLIM Study for Demo

Storage Condition: 25°C ± 2°C/60% RH ± 5% RH  
 Manufacturing Site: Acme Gesellschaft, GmbH  
 Packaging Site: Acme Gesellschaft, GmbH

Date on Stability: Jan 28, 2007  
 Manufacturing Date: Nov 04, 2005  
 Expiry Date: Apr 2008

<u>Packaging Item:</u>	<u>Packaging Supplier:</u>	<u>Packaging Description:</u>
50 cc clear vial	Fisher Scientific	Container
Aluminum Crimp top seal	Fisher Scientific	
Grey Rubber Induction Seal	Fisher Scientific	

<u>Drug Substance:</u>	<u>Lot:</u>	<u>Lot Manufacture Site:</u>	<u>Lot Description:</u>
AltQEnzyme	Lot 12872A	Sigma - Aldrich	Triple Distilled

Test Category / Test Field	Appearance Packaging	Appearance Reconstituted Appearance Powder	Assay Progain	Moisture	pH	Particulate Testing 10 µm	Particulate Testing 25 µm	Micro Escherichia coli	Micro Pseudomonas aeruginosa
Specifications	Clear vial with grey rubber stopper and crimp seal with a plastic flip top intact	Clear colorless solution free of visible particulate matter	92.0 to 110.0 % l.c.	8.0 to 10.0 %	6.6 to 9.0	≤ 6000 Counts per container	≤ 600 Counts per container	Absent	Absent
Initial	Conforms	Conforms	100.0 % l.c.	0.9 %	7.0	259 Counts per container	23 Counts per container	Absent	Absent
2 hour	Not Required per Protocol	Not Required per Protocol	Not Required per Protocol	Not Required per Protocol	Scheduled 7.0	Not Required per Protocol	Not Required per Protocol	Not Required per Protocol	Not Required per Protocol
1 month	Conforms	Conforms	99.9 % l.c.	1.1 %	7.1	499 Counts per container	24 Counts per container	Absent	Absent
3 month	Conforms	Conforms	99.1 % l.c.	1.2 %	7.1	475 Counts per container	83 Counts per container	Not Required per Protocol	Not Required per Protocol
6 month	Conforms	Conforms	98.7 % l.c.	1.3 %	9.0	399 Counts per container	78 Counts per container	Not Required per Protocol	Not Required per Protocol

**Stability Summary for 27865 - EasyCorp KureItAll Tablets**

Product: KureItAll® / 100 mg

Storage Condition: 25°C ± 2°C/60% RH ± 5% RH

Date on Stability: Jan 28, 2007

Inverted

Batch: Lot 12973 (1,000,000 vials)

Manufacturing Site: Acme Gesellschaft, GmbH

Manufacturing Date: Nov 04, 2005

Package Date: Nov 07, 2006

Packaging Site: Acme Gesellschaft, GmbH

Expiry Date: Apr 2008

Study Description: SLIM Study for Demo

Packaging Item:
Packaging Supplier:
Packaging Description:

50 cc clear vial

Fisher Scientific

Container

Aluminum Crimp top seal

Fisher Scientific

Grey Rubber Induction Seal

Fisher Scientific

Drug Substance:
Lot:
Lot Manufacture Site:
Lot Description:

AltQEnzyme

Lot 12872A

Sigma - Aldrich

Triple Distilled

Test Category / Test Field	Appearance Packaging	Appearance Reconstituted Appearance Powder	Assay Progain	Moisture	pH	Particulate Testing 10 µm	Particulate Testing 25 µm	Micro Escherichia coli	Micro Pseudomonas aeruginosa
Specifications	Clear vial with grey rubber stopper and crimp seal with a plastic flip top intact	Clear colorless solution free of visible particulate matter	92.0 to 110.0 % l.c.	8.0 to 10.0 %	6.6 to 9.0	≤ 6000 Counts per container	≤ 600 Counts per container	Absent	Absent
Initial	Conforms	Conforms	100.0 % l.c.	0.9 %	7.0	259 Counts per container	23 Counts per container	Absent	Absent
1 month	Not Required per Protocol	Conforms	99.8 % l.c.	Not Required per Protocol	Not Required per Protocol	3100 Counts per container	390 Counts per container	Not Required per Protocol	Not Required per Protocol
3 month	Not Required per Protocol	Conforms	98.6 % l.c.	Not Required per Protocol	Not Required per Protocol	3200 Counts per container	329 Counts per container	Not Required per Protocol	Not Required per Protocol
6 month	Not Required per Protocol	Conforms	98.7 % l.c.	Not Required per Protocol	Not Required per Protocol	3400 Counts per container	324 Counts per container	Not Required per Protocol	Not Required per Protocol

**Stability Summary for 27865 - EasyCorp KureItAll Tablets**

Product: KureItAll® / 100 mg  
 Batch: Lot 12973 (1,000,000 vials)  
 Package Date: Nov 07, 2006  
 Study Description: SLIM Study for Demo

Storage Condition: 40°C ± 2°C/75% RH ± 5% RH  
 Manufacturing Site: Acme Gesellschaft, GmbH  
 Packaging Site: Acme Gesellschaft, GmbH

Date on Stability: Jan 28, 2007  
 Manufacturing Date: Nov 04, 2005  
 Expiry Date: Apr 2008

<u>Packaging Item:</u>	<u>Packaging Supplier:</u>	<u>Packaging Description:</u>
50 cc clear vial	Fisher Scientific	Container
Aluminum Crimp top seal	Fisher Scientific	
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<u>Drug Substance:</u>	<u>Lot:</u>	<u>Lot Manufacture Site:</u>	<u>Lot Description:</u>
AltQEnzyme	Lot 12872A	Sigma - Aldrich	Triple Distilled

Test Category / Test Field	Appearance Packaging	Appearance Reconstituted Appearance Powder	Assay Progain	Moisture	pH	Particulate Testing 10 µm	Particulate Testing 25 µm	Micro Escherichia coli	Micro Pseudomonas aeruginosa
Specifications	Clear vial with grey rubber stopper and crimp seal with a plastic flip top intact	Clear colorless solution free of visible particulate matter	92.0 to 110.0 % l.c.	8.0 to 10.0 %	6.6 to 9.0	≤ 6000 Counts per container	≤ 600 Counts per container	Absent	Absent
Initial	Conforms	Conforms	100.0 % l.c.	0.9 %	7.0	259 Counts per container	23 Counts per container	Absent	Absent
1 month	Conforms	Conforms	99.0 % l.c.	1.2 %	6.8	378 Counts per container	129 Counts per container	Pending Approval	Scheduled
3 month	Conforms	Conforms	98.4 % l.c. Scheduled Scheduled	1.4 %	7.3	348 Counts per container	45 Counts per container	Not Required per Protocol	Not Required per Protocol
6 month	Conforms	Conforms	97.1 % l.c.	1.8 %	7.3	456 Counts per container	57 Counts per container	Not Required per Protocol	Not Required per Protocol