

Stability Summary for 27865 - EasyCorp KureItAll Tablets

Product / Strength:	KureItAll® / 100 mg	Lot # / Mfg. Date:	Lot 12973 / Nov 04, 2005
Mfg. By / Site:	Acme Gesellschaft, GmbH	Packager / Site:	Acme Gesellschaft, GmbH
Batch Size:	1,000,000 vials	Packaging Date:	Nov 07, 2006
Project Number:	34DS32	Packaging Quantity:	100,000 cases
Purpose of Study:	Japanese Study	Study Start Date:	Nov 22, 2005
Expiration Date:	Apr 2008	Study Duration:	36 month
Active Ingredient (API):	AltQEnzyme	Container / Supplier:	50 cc clear vial (Container) / Fisher Scientific
API Mfg. / Lot# (s):	Sigma - Aldrich / Lot 12872A	Closure / Supplier:	Aluminum Crimp top seal / Fisher Scientific
Test Location(s):	BenTek® QC Lab, Northeastern Labs, R&D Lab		Grey Rubber Induction Seal / Fisher Scientific

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

Specifications			Stability Intervals				
Test	Method	Acceptance Criteria	Initial	2 hour	1 month	3 month	6 month
Appearance Packaging	TM001	Clear vial with grey rubber stopper and crimp seal with a plastic flip top intact	Conforms	Not Required per Protocol	Conforms	Conforms	Conforms
Appearance Reconstituted - Appearance Powder	TM001	Clear colorless solution free of visible particulate matter	Conforms	Not Required per Protocol	Conforms	Conforms	Conforms
Assay - Progain	TM002	92.0 to 110.0 % l.c.	100.0 % l.c.	Not Required per Protocol	99.9 % l.c.	99.1 % l.c.	98.7 % l.c.
Moisture	TM003	8.0 to 10.0 %	0.9 %	Not Required per Protocol	1.1 %	1.2 %	1.3 %
pH	TM004	6.6 to 9.0	7.0	Scheduled [1] 7.0 (RESAMPLE)	7.1	7.1	9.0 (OOS)
Particulate Testing - 10 µm	USP 788	≤ 6000 Counts per container	259 Counts per container	Not Required per Protocol	499 Counts per container	475 Counts per container	399 Counts per container
Particulate Testing - 25 µm	USP 788	≤ 600 Counts per container	23 Counts per container	Not Required per Protocol	24 Counts per container	83 Counts per container	78 Counts per container
Micro - Escherichia coli	NF001	Absent	Absent	Not Required per Protocol	Absent	Not Required per Protocol	Not Required per Protocol

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

Specifications			Stability Intervals				
Test	Method	Acceptance Criteria	Initial	2 hour	1 month	3 month	6 month
Micro - Pseudomonas aeruginosa	NF001	Absent	Absent	Not Required per Protocol	Absent	Not Required per Protocol	Not Required per Protocol
Pull Date(s)			Jan 29, 2007	Sep 07, 2011	Feb 28, 2007	Apr 28, 2007	Jul 28, 2007
Test Date(s)			Jan 29, 2007	Sep 28, 2011	Feb 28, 2007	Apr 28, 2007	Jul 28, 2007
Comments							
1	Dropped some HCl in here. Number 2343						

Stability Summary for 27865 - EasyCorp KureItAll Tablets

Stability Condition / Orientation: 25°C ± 2°C/60% RH ± 5% RH Inverted

Specifications			Stability Intervals			
Test	Method	Acceptance Criteria	Initial	1 month	3 month	6 month
Appearance Packaging	TM001	Clear vial with grey rubber stopper and crimp seal with a plastic flip top intact	Conforms	Not Required per Protocol	Not Required per Protocol	Not Required per Protocol
Appearance Reconstituted - Appearance Powder	TM001	Clear colorless solution free of visible particulate matter	Conforms	Conforms	Conforms	Conforms
Assay - Progain	TM002	92.0 to 110.0 % I.c.	100.0 % I.c.	99.8 % I.c.	98.6 % I.c.	98.7 % I.c.
Moisture	TM003	8.0 to 10.0 %	0.9 %	Not Required per Protocol	Not Required per Protocol	Not Required per Protocol
pH	TM004	6.6 to 9.0	7.0	Not Required per Protocol	Not Required per Protocol	Not Required per Protocol
Particulate Testing - 10 µm	USP 788	≤ 6000 Counts per container	259 Counts per container	3100 Counts per container	3200 Counts per container	3400 Counts per container
Particulate Testing - 25 µm	USP 788	≤ 600 Counts per container	23 Counts per container	390 Counts per container	329 Counts per container	324 Counts per container
Micro - Escherichia coli	NF001	Absent	Absent	Not Required per Protocol	Not Required per Protocol	Not Required per Protocol
Micro - Pseudomonas aeruginosa	NF001	Absent	Absent	Not Required per Protocol	Not Required per Protocol	Not Required per Protocol
Pull Date(s)			Jan 29, 2007	Feb 28, 2007	Apr 28, 2007	Jul 28, 2007
Test Date(s)			Jan 29, 2007	Feb 28, 2007	Apr 28, 2007	Jul 28, 2007

Stability Summary for 27865 - EasyCorp KureItAll Tablets

Stability Condition / Orientation: 40°C ± 2°C/75% RH ± 5% RH

Specifications			Stability Intervals			
Test	Method	Acceptance Criteria	Initial	1 month	3 month	6 month
Appearance Packaging	TM001	Clear vial with grey rubber stopper and crimp seal with a plastic flip top intact	Conforms	Conforms	Conforms	Conforms
Appearance Reconstituted - Appearance Powder	TM001	Clear colorless solution free of visible particulate matter	Conforms	Conforms	Conforms	Conforms
Assay - Progain	TM002	92.0 to 110.0 % I.c.	100.0 % I.c.	99.0 % I.c.	98.4 % I.c. Scheduled (RETEST) Scheduled (RESAMPLE)	97.1 % I.c.
Moisture	TM003	8.0 to 10.0 %	0.9 %	1.2 %	1.4 %	1.8 %
pH	TM004	6.6 to 9.0	7.0	6.8	7.3	7.3
Particulate Testing - 10 µm	USP 788	≤ 6000 Counts per container	259 Counts per container	378 Counts per container	348 Counts per container	456 Counts per container
Particulate Testing - 25 µm	USP 788	≤ 600 Counts per container	23 Counts per container	129 Counts per container	45 Counts per container	57 Counts per container
Micro - Escherichia coli	NF001	Absent	Absent	Pending Approval	Not Required per Protocol	Not Required per Protocol
Micro - Pseudomonas aeruginosa	NF001	Absent	Absent	Scheduled	Not Required per Protocol	Not Required per Protocol
Pull Date(s)			Jan 29, 2007	Feb 28, 2007	Apr 28, 2007	Jul 28, 2007
Test Date(s)			Jan 29, 2007	Feb 28, 2007	Apr 28, 2007	Jul 28, 2007

Signatures:

Reviewed By _____

Date _____

Approved By _____

Date _____