

29833 Stability Protocol Stability Summary for Generic Pharmaceuticals, Inc.

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	12 month
Appearance Packaging	TM001	Clear vial with grey rubber stopper and crimp seal with a plastic flip top intact	Conforms	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol
Appearance Reconstituted - Appearance Powder	TM001	Clear colorless solution free of visible particulate matter	Conforms	Conforms	Conforms	Conforms	Conforms
Assay - Prolastin	TM002	90.0 to 110.0 % l.c.	100.0	99.8	98.6	98.7	98.2
Moisture	TM003	NMT 2.0 %	0.9	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol
pH	TM004	6.6 to 7.4	7.0	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol
Particulate Testing - 10 µm	USP 788	NMT 6000 Counts per container	259	3100	3200	3400	3743
Particulate Testing - 25 µm	USP 788	NMT 600 Counts per container	23	390	329	324	398
Micro - Escherichia coli	NF001	Absent	Absent	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol
Micro - Pseudomonas aeruginosa	NF001	Absent	Absent	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol
Micro - Total Aerobic Count	NF001	Report Results	ND	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol
Test Date(s)			Jan 29, 2007	Feb 28, 2007	Apr 28, 2007	Jul 28, 2007	Jan 29, 2008

29833 Stability Protocol Stability Summary for Generic Pharmaceuticals, Inc.

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	12 month
Appearance Packaging	TM001	Clear vial with grey rubber stopper and crimp seal with a plastic flip top intact	Conforms	Conforms	Conforms	Conforms	Conforms
Appearance Reconstituted - Appearance Powder	TM001	Clear colorless solution free of visible particulate matter	Conforms	Conforms	Conforms	Conforms	Does not conform (OOS) [1]
Assay - Prolastin	TM002	90.0 to 110.0 % l.c.	100.0	99.0	98.4	97.1	89.6 (OOS) [2]
Moisture	TM003	NMT 2.0 %	0.9	1.2	1.4	1.8	1.9
pH	TM004	6.6 to 7.4	7.0	6.8	7.3	7.3	7.3
Particulate Testing - 10 µm	USP 788	NMT 6000 Counts per container	259	378	348	456	497
Particulate Testing - 25 µm	USP 788	NMT 600 Counts per container	23	129	45	57	145
Micro - Escherichia coli	NF001	Absent	Absent	Scheduled	Not Tested per Protocol	Not Tested per Protocol	Pending Approval
Micro - Pseudomonas aeruginosa	NF001	Absent	Absent	Scheduled	Not Tested per Protocol	Not Tested per Protocol	Pending Approval
Micro - Total Aerobic Count	NF001	Report Results	ND	Scheduled	Not Tested per Protocol	Not Tested per Protocol	Pending Approval
Test Date(s)			Jan 29, 2007	Feb 28, 2007	Apr 28, 2007	Jul 28, 2007	Jan 29, 2008
Comments							
1	Refer to LIR number 398.01						
2	Refer to LIR number 387.00						

29833 Stability Protocol Stability Summary for Generic Pharmaceuticals, Inc.

Stability Condition / Orientation: 5°C ± 3°C

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 - Prolastin	TM002	90.0 to 110.0 % l.c.	100.0	100.1	99.9	99.7
Moisture	TM003	NMT 2.0 %	0.9	0.9	1.0	1.0
pH	TM004	6.6 to 7.4	7.0	7.0	7.0	7.1
Particulate Testing - 10 µm	USP 788	NMT 6000 Counts per container	259	123	231	103
Particulate Testing - 25 µm	USP 788	NMT 600 Counts per container	23	21	43	12
Micro - Escherichia coli	NF001	Absent	Absent	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol
Micro - Pseudomonas aeruginosa	NF001	Absent	Absent	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol
Micro - Total Aerobic Count	NF001	Report Results	ND	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol
Test Date(s)			Jan 29, 2007	Feb 28, 2007	Apr 28, 2007	Jul 28, 2007

Signatures:

Reviewed By _____

Approved By _____