

WD-001 Stability Summary for Generic Pharmaceuticals Inc.

Product / Strength:	Kuritall Tablets, 325 mg	Lot # / Mfg. Date:	3F1005 / Nov 01, 2002
Mfg. By / Site:	Metrics, Inc.	Packager / Site:	Metrics, Inc.
Batch Size:	500,000	Packaging Date:	Sep 20, 2005
Purpose of Study:	Production Support	Study Start Date:	Nov 05, 2002
Expiration Date:	TBD	Study Duration:	36 month
Active Ingredient (API):	Caffeine	Packaging Item(s) / Supplier:	12345 / Frank's Drugs
API Mfg. / Lot# (s):	Joe's Pharmaceutical Ingredients / 23786		23456 / (not specified) 76857 / Frank's Drugs
Test Location(s):	Metrics, Inc.		

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

Specifications			Stability Intervals				
Test	Method	Acceptance Criteria	Initial	3 month	6 month	12 month	18 month
Assay and Related Substances - Caffeine	AM/001-1, AM/001-2, AM/001, rev 01	90.0 to 110.0 % l.c.	99.6	98.5 Scheduled (RESAMPLE)	98.5	97.8, 96.9	99.0, 100.0
Assay and Related Substances - Aspirin	AM/001-1, AM/001-2, AM/001, rev 01	90.0 to 110.0 % l.c.	100.4	99.5 Scheduled (RESAMPLE)	98.9	97.3, 96.8	ND, N/A, <LOQ, <LOD
Assay and Related Substances - Impurity A	AM/001-1, AM/001-2, AM/001, rev 01	≤ 1.00 %	ND	0.18 Scheduled (RESAMPLE)	0.42	0.80, 0.33	ND, N/A, <LOD, <LOQ
Assay and Related Substances - Impurity B	AM/001-1, AM/001-2, AM/001, rev 01	≤ 1.00 %	< 0.05	0.05 Scheduled (RESAMPLE)	0.09	1.1 (OOS) [1]	0.99

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

Specifications			Stability Intervals				
Test	Method	Acceptance Criteria	Initial	3 month	6 month	12 month	18 month
Physical Examination - Physical Exam	AM/001-1, AM/001-2, AM/001, rev 01	White to off-white powder free of visible particulate matter.	Meets Test	Meets Test	Meets Test	Meets Test	Off white powder with visible particulate matter (OOS)
Dissolution - Aspirin, individual @ 45 min	AM/001-1, AM/001-2, AM/001	80 to 110 % l.c. dissolved	99, 97, 99, 99, 98, 98	98, 98, 97, 96, 97, 95	96, 96, 97, 97, 96, 96	96, 96, 96, 96, 95, 95	79, 81, 77, 76, 77 (OOS)
Dissolution - Aspirin, mean @ 45 min	AM/001-1, AM/001-2, AM/001	85 to 115 % l.c. dissolved	98	97	96	96	86
Dissolution - Aspirin, rsd @ 45 min	AM/001-1, AM/001-2, AM/001	≤ 6.0 %	2.8	3.4	3.0	2.1	5.0
Hardness	AM/001-1 Addendum	50.0 to 100.0 kp	67.1	Not Tested per Protocol	Not Tested per Protocol	86.0	Not Tested per Protocol
Pull Date(s)			Nov 05, 2002	Feb 06, 2003	May 05, 2003	Nov 05, 2003	Jan 26, 2006
Test Date(s)			Nov 06, 2002 to Nov 08, 2002	Feb 06, 2003 to Feb 07, 2003	May 05, 2003 to May 07, 2003	Nov 05, 2003 to Nov 14, 2003	Jan 26, 2006 to Feb 07, 2006
Comments							
1	Impurity B: Refer to OOS investigation 502923-B						

WD-001 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
Assay and Related Substances - Caffeine	AM/001-1, AM/001-2	90.0 to 110.0 % l.c.	99.6	97.6	99.6	91.2
Assay and Related Substances - Aspirin	AM/001-1, AM/001-2	90.0 to 110.0 % l.c.	100.4	99.0	99.0	89.0 (OOS)
Assay and Related Substances - Impurity A	AM/001-1, AM/001-2	≤ 1.00 %	ND	0.12	0.26	0.45
Assay and Related Substances - Impurity B	AM/001-1, AM/001-2	≤ 1.00 %	< 0.05	0.21	0.35	1.02 (OOS)
Physical Examination - Physical Exam	AM/001-1, AM/001-2	White to off-white powder free of visible particulate matter.	Meets Test	Meets Test	Meets Test	Off white powder with visible particulate matter (OOS) [1]
Dissolution - Aspirin, individual @ 45 min	AM/001-1, AM/001-2	80 to 110 % l.c. dissolved	99, 97, 99, 99, 98, 98	97, 97, 95, 96, 93, 98	97, 98, 98, 95, 96, 97	85, 86, 87, 88, 89, 90
Dissolution - Aspirin, mean @ 45 min	AM/001-1, AM/001-2	85 to 115 % l.c. dissolved	98	97	97	88
Dissolution - Aspirin, rsd @ 45 min	AM/001-1, AM/001-2	≤ 6.0 %	2.8	4.5	3.4	4.5
Hardness	AM/001-1 Addendum	50.0 to 100.0 kp	67.1	Not Tested per Protocol	Not Tested per Protocol	50.0
Pull Date(s)			Nov 05, 2002	Dec 05, 2002	Feb 06, 2003	May 05, 2003
Test Date(s)			Nov 06, 2002 to Nov 08, 2002	Dec 05, 2002 to Dec 06, 2002	Feb 06, 2003 to Feb 07, 2003	May 05, 2003 to May 08, 2003
Comments						
1	Refer to OOS investigation OOS-001					

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Signatures:

Reviewed By _____

Approved By _____