

StabilityReport

Stability Study Results Summary

Anonymous Pharma 10134 Forth North User, No. Alaska,
NZ 400451-331

Purpose:	36-Month Stability Study on a Phase III ABCD Clinical Active Batch		
Study:	StudyName	Study Description:	Lot-12345687 Lot 10mg (Lot C) 100ct bottle
Manufacturer:	Anonymous Pharma	Manufacturing Date:	20-Sep-2020
Product Description:	DrugProduct 10mg		
Batch:	No-123456789	Batch Description:	(Lot C) 100ct bottle-ABC Container
Container:	100cc bottle	Description:	100ct ABCD 100cc Bottle
Condition:	5°C	Orientation :	Upright
Start Date:	30-Nov-2020	Status:	Running
Initial Quantity:	40	Current Containers:	26

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Condition:	25 °C/60% RH	Orientation :	Upright
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Start Date:	30-Nov-2020	Status:	Running
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Initial Quantity:	57	Current Containers:	40
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Test	Parameter	Limit	Replicate	Time Zero	1 Month	3 Months	6 Months
Disintegration, USP <701>	Disintegration Test	Report result	(Rep 01)	N/A	N/A	N/A	N/A
	Maximum Disintegration Time		(Rep 01)	12 minutes	11 minutes	13 minutes	12 minutes
000279 Total Aerobic Microbial Count	Total Aerobic Microbial Count (CFU/g)	NMT 1QA3 CFU/g	(Rep 01)	LT100 CFU/g	NS	NS	NS
000285 Yeast and Mold Count	Yeast and Mold Count	NMT 10A2 CFU/g	(Rep 01)	LT100 CFU/g	NS	NS	NS
000287 E. Coli	Escherichia coli	Absent in 1 g	(Rep 01)	Absent in 1g	NS	NS	NS
000383 Water Content	Water Content	Report result	(Rep 01)	1.5 %	1.5 %	1.5 %	1.8 %
000687 Appearance (Color, Shape, Fill, Print, Leakage, Other)	Fill	Clear solution with colorless to slight yellow tint	(Rep 01)	Satisfactory	Satisfactory	Satisfactory	Satisfactory
	Leakage	No evidence of leakage	(Rep 01)	Satisfactory	Satisfactory	Satisfactory	Satisfactory
	Print	No print	(Rep 01)	Satisfactory	Satisfactory	Satisfactory	Satisfactory
	Shape	Oblong	(Rep 01)	Satisfactory	Satisfactory	Satisfactory	Satisfactory
	Color	Opaque red	(Rep 01)	Satisfactory	Satisfactory	Satisfactory	Satisfactory
	Other	Report as satisfactory if no defects or minor acceptable defects are observed	(Rep 01)	Satisfactory	Satisfactory	Satisfactory	Satisfactory

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Method A Antioxidant Assay (dl-Alpha Tocopherol)	dl-alpha tocopherol	Report Results	(Rep 01)	11.55 mg	11.67 mg	11.43 mg	11.64 mg
	dl-alpha tocopherol (%)	Report Results	(Rep 01)	92%	93%	90 %	92%
Method B Assay	Assay	54-63 mg	(Rep 01)	60 mg	60 mg	60 mg	60 mg
	% Label Claim	90.0 - 105.0% of label claim	(Rep 01)	97.1 %	98.0 %	97.7 %	96.8 %
Method B Related Substances	IQ8000	NMT 0.5%	(Rep 01)	ND%	LTLOQ %	0.06 %	0.13 %
	No 1234567 vu1	NMT 1.0%	(Rep 01)	0.05 %	LTLOQ %	LTLOQ %	LTLOQ %
	No 1234567 vu2	NMT 1.0%	(Rep 01)	LTLOQ %	LTLOQ %	LTLOQ %	LTLOQ %
	No 1234567 vu3	NMT 2.5%	(Rep 01)	0.12 %	0.14 %	0.18 %	0.26 %
	Total Degradation Products	NMT 4.0%	(Rep 01)	0.18 %	0.10 %	0.26%	0.42 %
Method C Dissolution at 10 minutes Tier 1	Dissolution	Report Results	(Rep 01)	N/A	N/A	N/A	N/A
	% RSD		(Rep 01)	9.3 %	18.1 %	31.5 %	42.4 %
	Average		(Rep 01)	79%	80 %	67 %	70%
	Dissolution Maximum		(Rep 01)	84 %	93%	87 %	98%
	Dissolution Minimum		(Rep 01)	65%	56%	36 %	13 %
	Individual Unit		(Rep 01)	83%	91 %	36 %	94%
			(Rep 02)	80 %	78%	87 %	97%
			(Rep 03)	64%	56%	86 %	65%
			(Rep 04)	73 %	92%	45 %	82%

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Method C Dissolution at 10 minutes Tier 1	Individual Unit		(Rep 05)	86 %	78%	79%	15 %
			(Rep 06)	79%	92%	78 %	96%
	Stage		(Rep 01)	1	1	1	1
	Tier		(Rep 01)	1	1	1	1
Method C Dissolution at 10 minutes Tier 2	Dissolution	Report Results	(Rep 01)	N/A	N/A	N/A	N/A
	Individual Unit		(Rep 01)	N/A %	N/A%	N/A%	N/A %
			(Rep 02)	N/A %	N/A%	N/A%	N/A %
			(Rep 03)	N/A %	N/A%	N/A%	N/A %
			(Rep 04)	N/A%	N/A%	N/A%	N/A%
			(Rep 05)	N/A %	N/A%	N/A%	N/A %
			(Rep 06)	N/A %	N/A%	N/A%	N/A %
	Tier		(Rep 01)	2	2	2	2
Method C Dissolution at 15 minutes Tier 1	Dissolution	Report Results	(Rep 01)	N/A	N/A	N/A	N/A
	% RSD		(Rep 01)	3.1 %	1.6 %	1.7 %	2.7%
	Average		(Rep 01)	98%	97%	97 %	96%
	Dissolution Maximum		(Rep 01)	98%	100 %	96 %	97%
	Dissolution Minimum		(Rep 01)	91 %	96%	93 %	92 %
	Individual Unit		(Rep 01)	92 %	98%	98 %	99%

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Method C Dissolution at 15 minutes Tier 1	Individual Unit		(Rep 02)	98%	97 %	93 %	96%
			(Rep 03)	94 %	96%	96 %	99%
			(Rep 04)	95 %	100 %	94 %	98%
			(Rep 05)	97%	95%	94 %	94 %
			(Rep 06)	97%	97%	95 %	94%
	Stage		(Rep 01)	1	1	1	1
	Tier		(Rep 01)	1	1	1	1
Method C Dissolution at 15 minutes Tier 2	Dissolution	Report Results	(Rep 01)	N/A	N/A	N/A	N/A
	Individual Unit		(Rep 01)	N/A%	N/A%	N/A%	N/A%
			(Rep 02)	N/A %	N/A%	N/A%	N/A %
			(Rep 03)	N/A %	N/A%	N/A%	N/A %
			(Rep 04)	N/A %	N/A%	N/A%	N/A %
			(Rep 05)	N/A %	N/A%	N/A%	N/A %
			(Rep 06)	N/A%	N/A%	N/A%	N/A%
	Tier		(Rep 01)	2	2	2	2
Method C Dissolution Tier 1	Dissolution	Report Results	(Rep 01)	N/A	N/A	N/A	N/A
	% RSD		(Rep 01)	3.3 %	1.6 %	0.8 %	3.2%
	Average		(Rep 01)	98%	97%	96 %	98%

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Test	Parameter	Limit	Replicate	Time Zero	1 Month	3 Months	6 Months
Method C Dissolution Tier 1	Dissolution Maximum		(Rep 01)	100 %	99 %	98 %	101 %
	Dissolution Minimum		(Rep 01)	94 %	96%	97 %	93%
	Individual Unit		(Rep 01)	92 %	97%	95 %	101 %
			(Rep 02)	100 %	96%	94 %	100 %
			(Rep 03)	95%	97 %	96 %	98%
			(Rep 04)	98%	100 %	96 %	96%
			(Rep 05)	98%	96%	95 %	92%
			(Rep 06)	97%	96%	94 %	100 %
	Stage		(Rep 01)	1	1	1	1
	Tier		(Rep 01)	1	1	1	1
Method C Dissolution Tier 2	Dissolution	Report Results	(Rep 01)	N/A	N/A	N/A	N/A
	Individual Unit		(Rep 01)	N/A %	N/A%	N/A%	N/A %
			(Rep 02)	N/A %	N/A%	N/A%	N/A %
			(Rep 03)	N/A%	N/A%	N/A%	N/A%
			(Rep 04)	N/A %	N/A%	N/A%	N/A%
			(Rep 05)	N/A %	N/A%	N/A%	N/A %
			(Rep 06)	N/A %	N/A%	N/A%	N/A %
	Tier		(Rep 01)	2	2	2	2

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Test	Parameter	Limit	Replicate	Time Zero	1 Month	3 Months	6 Months
Method C Dissolution Tier 1	Dissolution	Report Results	(Rep 01)	N/A	N/A	N/A	N/A
	% RSD		(Rep 01)	2.2 %	0.8%	0.7 %	2.5%
	Average		(Rep 01)	96%	99%	96 %	100 %
	Dissolution Maximum		(Rep 01)	100 %	100 %	98 %	101 %
	Dissolution Minimum		(Rep 01)	95%	97%	95 %	95%
	Individual Unit		(Rep 01)	94%	99%	96 %	101 %
			(Rep 02)	100 %	100 %	96 %	100 %
			(Rep 03)	95%	98%	95 %	102 %
			(Rep 04)	97%	100 %	97 %	96%
			(Rep 05)	97%	99%	97 %	96%
			(Rep 06)	100 %	96%	96 %	100 %
	Stage		(Rep 01)	1	1	1	1
	Tier		(Rep 01)	1	1	1	1
Method C Dissolution Tier 2	Dissolution	Report Results	(Rep 01)	N/A	N/A	N/A	N/A
	Individual Unit		(Rep 01)	N/A %	N/A%	N/A%	N/A%
			(Rep 02)	N/A %	N/A%	N/A%	N/A %
			(Rep 03)	N/A %	N/A%	N/A%	N/A %
			(Rep 04)	N/A %	N/A%	N/A%	N/A %

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Test	Parameter	Limit	Replicate	Time Zero	1 Month	3 Months	6 Months
Method C Dissolution Tier 2	Individual Unit		(Rep 05)	N/A %	N/A%	N/A%	N/A%
			(Rep 06)	N/A%	N/A%	N/A%	N/A %
	Tier		(Rep 01)	2	2	2	2
Method C Dissolution Tier 1	Dissolution	Report Results	(Rep 01)	N/A	N/A	N/A	N/A
	% RSD		(Rep 01)	54.2 %	200.3 %	123.7 %	60.6 %
	Average		(Rep 01)	1%	11 %	11 %	2%
	Dissolution Maximum		(Rep 01)	2%	64%	32 %	5%
	Dissolution Minimum		(Rep 01)	0%	1.2 %	1.3 %	0%
	Individual Uni!		(Rep 01)	1%	65%	1 %	2%
			(Rep 02)	1%	4%	2%	4%
			(Rep 03)	0%	2 %	24 %	2%
			(Rep 04)	2%	3%	1%	1%
			(Rep 05)	1%	1%	2%	0%
			(Rep 06)	1%	1%	31 %	4%
	Stage		(Rep 01)	1	1	1	1
	Tier		(Rep 01)	1	1	1	1
Method C Dissolution Tier 2	Dissolution	Report Results	(Rep 01)	N/A	N/A	N/A	N/A
	Individual Uni!		(Rep 01)	N/A %	N/A%	N/A%	N/A %

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Test	Parameter	Limit	Replicate	Time Zero	1 Month	3 Months	6 Months
Method C Dissolution Tier 2	Individual Unit		(Rep 02)	N/A %	N/A%	N/A%	N/A%
			(Rep 03)	N/A%	N/A%	N/A%	N/A %
			(Rep 04)	N/A %	N/A%	N/A%	N/A %
			(Rep 05)	N/A%	N/A%	N/A%	N/A %
			(Rep 06)	N/A %	N/A%	N/A%	N/A %
	Tier		(Rep 01)	2	2	2	2
Method C Dissolution Tier 1	Dissolution	Report Results	(Rep 01)	N/A	N/A	N/A	N/A
	% RSD		(Rep 01)	2.4 %	0.8%	0.4 %	1.6 %
	Average		(Rep 01)	96%	100 %	96 %	100 %
	Dissolution Maximum		(Rep 01)	100 %	100 %	98 %	100 %
	Dissolution Minimum		(Rep 01)	95%	96%	96 %	95%
	Individual Uni!		(Rep 01)	94%	100 %	97 %	99 %
			(Rep 02)	100 %	100 %	97 %	101 %
			(Rep 03)	96%	98%	96 %	100 %
			(Rep 04)	97%	100 %	96 %	100 %
			(Rep 05)	99%	96%	97 %	95%
			(Rep 06)	101 %	97%	95 %	100 %
	Stage		(Rep 01)	1	1	1	1

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Test	Parameter	Limit	Replicate	Time Zero	1 Month	3 Months	6 Months
Method C Dissolution Tier 1	Tier		(Rep 01)	1	1	1	1
Method C Dissolution Tier 2	Dissolution	Report Results	(Rep 01)	N/A	N/A	N/A	N/A
	Individual Unit		(Rep 01)	N/A %	N/A%	N/A%	N/A %
			(Rep 02)	N/A%	N/A%	N/A%	N/A %
			(Rep 03)	N/A %	N/A%	N/A%	N/A %
			(Rep 04)	N/A %	N/A%	N/A%	N/A %
			(Rep 05)	N/A %	N/A%	N/A%	N/A %
			(Rep 06)	N/A %	N/A%	N/A%	N/A %
	Tier		(Rep 01)	2	2	2	2
Method C Dissolution Q=75% of Tier 2	Dissolution	Q=75% of Tier 2 pepsin lest allowed	(Rep 01)	N/A	N/A	N/A	N/A
	Individual Unit		(Rep 01)	N/A %	N/A%	N/A%	N/A %
			(Rep 02)	N/A %	N/A%	N/A%	N/A %
			(Rep 03)	N/A %	N/A%	N/A%	N/A %
			(Rep 04)	N/A%	N/A%	N/A%	N/A%
			(Rep 05)	N/A %	N/A%	N/A%	N/A%
			(Rep 06)	N/A %	N/A%	N/A%	N/A %
	Tier		(Rep 01)	2	2	2	2

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Test	Parameter	Limit	Replicate	Time Zero	1 Month	3 Months	6 Months
Method C Dissolution Q=75% of Tier 1	Dissolution	Q=75% of Tier 2 pepsin test allowed	(Rep 01)	N/A	Passes	Passes	Passes
	% RSD		(Rep 01)	2.3%	1.3 %	0.7 %	3.3%
	Assessment		(Rep 01)	Passes	Passes	Passes	Passes
	Average		(Rep 01)	95%	100 %	95 %	98%
	Dissolution Maximum		(Rep 01)	101 %	100 %	98 %	102 %
	Dissolution Minimum		(Rep 01)	94 %	95%	96 %	92%
	Individual Uni!		(Rep 01)	92 %	101 %	96 %	101 %
			(Rep 02)	101 %	100 %	97 %	96%
			(Rep 03)	95%	99%	95 %	97%
			(Rep 04)	97%	100 %	97 %	94%
			(Rep 05)	99%	96%	97 %	94%
			(Rep 06)	100 %	98%	95 %	104 %
	Stage		(Rep 01)	1	1	1	1
	Tier		(Rep 01)	1	1	1	1
Method D Hardness	Hardness	Report result	(Rep 01)	8.0 N	7.5 N	8.0 N	9.1 N
			(Rep 02)	8.4 N	6.4 N	7.6 N	8.7 N
			(Rep 03)	8.4 N	7.7 N	8.5 N	8.0 N
			(Rep 04)	6.5 N	7.4 N	9.0 N	8.0 N

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Method D Hardness	Hardness	Report result	(Rep 05)	7.9 N	7.3 N	7.9 N	7.6 N
	Average		(Rep 01)	7.6 N	7.3 N	8.1 N	8.3 N

Method B Related Substances

Individual Unspecified Degradation Product

RRT	Parameter	Limit	Time Zero	1 Month	3 Months	6 Months
0.16	Individual Unspecified Degradation Product (Rep 01)	NMT0.2%	*	LTLOQ	LTLOQ	LTLOQ
0.25	Individual Unspecified Degradation Product (Rep 01)	NMT0.2%	LTLOQ	LTLOQ	LTLOQ	LTLOQ
0.43	Individual Unspecified Degradation Product (Rep 01)	NMT0.2%	*	*	LTLOQ	*
0.46	Individual Unspecified Degradation Product (Rep 01)	NMT0.2%	*	LTLOQ	*	*
0.54	Individual Unspecified Degradation Product (Rep 01)	NMT0.2%	LTLOQ	LTLOQ	LTLOQ	LTLOQ
0.63	Individual Unspecified Degradation Product (Rep 01)	NMT0.2%	*	*	LTLOQ	*
0.64	Individual Unspecified Degradation Product (Rep 01)	NMT0.2%	LTLOQ	LTLOQ	LTLOQ	LTLOQ
0.72	Individual Unspecified Degradation Product (Rep 01)	NMT0.2%	LTLOQ	LTLOQ	LTLOQ	LTLOQ
0.74	Individual Unspecified Degradation Product (Rep 01)	NMT0.2%	LTLOQ	LTLOQ	LTLOQ	*
0.72	Individual Unspecified Degradation Product (Rep 01)	NMT0.2%	*	*	LTLOQ	*
0.82	Individual Unspecified Degradation Product (Rep 01)	NMT0.2%	*	LTLOQ	LTLOQ	*
0.90	Individual Unspecified Degradation Product (Rep 01)	NMT0.2%	*	LTLOQ	*	*

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