

Informal Reproducibility Study- Some Background:

December 2014- New Instrument completed. Tested with four ribbon batches provided by customer.

March 2015- Same instrument. Samples from same batches measured by technicians during training.

April 2015- Another new instrument completed. Measurements made on same batches of samples.

Outcome: Reliable, Reproducible Results.

Two Countries - Two Instruments- Multiple Operators, both experienced and inexperienced.

Samples From 4 Compactor Runs⁺

Runs 1A and 2A					Runs 3A and 4A				
Date	Country	Operator	Drug ID	Solid Fraction	Date	Country	Operator	Drug ID	Solid Fraction
29-Dec-14	USA	Developer	1A Sample 1	0.631	29-Dec-14	USA	Developer	3A Sample 1	0.570
29-Dec-14	USA	Developer	1A Sample 2	0.625	29-Dec-14	USA	Developer	3A Sample 2	0.558
29-Dec-14	USA	Developer	1A Sample 3	0.630	29-Dec-14	USA	Developer	3A Sample 3	0.568
29-Dec-14	USA	Developer	1A Sample 4	0.627	23-Mar-15	Denmark	Technician *	3A Sample 4	0.576
23-Mar-15	Denmark	Technician *	1A Sample 5	0.629	23-Mar-15	Denmark	Technician *	3A Sample 4	0.580
23-Mar-15	Denmark	Technician *	1A Sample 5	0.630	23-Mar-15	Denmark	Technician *	3A Sample 4	0.580
23-Mar-15	Denmark	Technician *	1A Sample 5	0.631	23-Mar-15	Denmark	Technician *	3A Sample 4	0.568
23-Mar-15	Denmark	Technician *	1A Sample 6	0.635	23-Mar-15	Denmark	Technician *	3A Sample 4	0.571
23-Mar-15	Denmark	Technician *	1A Sample 6	0.634	23-Mar-15	Denmark	Technician *	3A Sample 4	0.570
23-Mar-15	Denmark	Technician *	1A Sample 6	0.636	17-Apr-15	USA	Developer	3A Sample 5	0.579
23-Mar-15	Denmark	Technician *	1A Sample 6	0.635	19-Apr-15	USA	Developer	3A Sample 7	0.580
17-Apr-15	USA	Developer	1A Sample 7	0.636	19-Apr-15	USA	Developer	3A Sample 8	0.584
19-Apr-15	USA	Developer	1A Sample 8	0.640	19-Apr-15	USA	Developer	3A Sample 8	0.586
19-Apr-15	USA	Developer	1A Sample 9	0.637	19-Apr-15	USA	Developer	3A Sample 8	0.586
20-Apr-15	USA	Developer	1A Sample 9	0.636	19-Apr-15	USA	Developer	3A Sample 8	0.585
21-Apr-15	USA	Developer	1A Sample 9	0.634	20-Apr-15	USA	Developer	3A Sample 8	0.587
23-Apr-15	USA	Developer	1A Sample 9	0.629	20-Apr-15	USA	Developer	3A Sample 9	0.575
23-Apr-15	USA	Developer	1A Sample 9	0.629	21-Apr-15	USA	Developer	3A Sample 9	0.579
23-Apr-15	USA	Developer	1A Sample 9	0.629					
23-Apr-15	USA	Developer	1A Sample 9	0.629					
29-Dec-14	USA	Developer	2A Sample 1	0.741	29-Dec-14	USA	Developer	4A Sample 1	0.689
29-Dec-14	USA	Developer	2A Sample 2	0.743	29-Dec-14	USA	Developer	4A Sample 2	0.680
29-Dec-14	USA	Developer	2A Sample 2	0.743	29-Dec-14	USA	Developer	4A Sample 3	0.683
29-Dec-14	USA	Developer	2A Sample 3	0.749	23-Mar-15	Denmark	Technician *	4A Sample 4	0.673
23-Mar-15	Denmark	Technician *	2A Sample 4	0.750	23-Mar-15	Denmark	Technician *	4A Sample 4	0.675
23-Mar-15	Denmark	Technician *	2A Sample 4	0.752	23-Mar-15	Denmark	Technician	4A Sample 4	0.675
23-Mar-15	Denmark	Technician *	2A Sample 4	0.752	17-Apr-15	USA	Developer	4A Sample 5	0.673
17-Apr-15	USA	Developer	2A Sample 5	0.756	17-Apr-15	USA	Developer	4A Sample 5	0.677
19-Apr-15	USA	Developer	2A Sample 5	0.757	17-Apr-15	USA	Developer	4A Sample 5	0.676
19-Apr-15	USA	Developer	2A Sample 6	0.753	17-Apr-15	USA	Developer	4A Sample 5	0.677
20-Apr-15	USA	Developer	2A Sample 6	0.751	17-Apr-15	USA	Developer	4A Sample 5	0.676
21-Apr-15	USA	Developer	2A Sample 6	0.750	17-Apr-15	USA	Developer	4A Sample 5	0.679
21-Apr-15	USA	Developer	2A Sample 6	0.750	17-Apr-15	USA	Developer	4A Sample 5	0.677
22-Apr-15	USA	Developer	2A Sample 6	0.749	19-Apr-15	USA	Developer	4A Sample 5	0.675
					20-Apr-15	USA	Developer	4A Sample 5	0.671

* Measurements made by technicians with < 1/2 hr training

⁺Placebo (> 99% Microcrystalline Cellulose)