

AIHA Pharma Round Robin 38- Diflunisal

Table 1a: [BV Novi] ASAP Spikes (µg/sample)

RR38	Theory (µg)	Spike 1 (µg)	Spike 2 (µg)	Spike 3 (µg)	Spike 4 (µg)	Spike 5 (µg)	Spike 6 (µg)	Average (µg)	CV (%)
Conc. 1	1.50	1.534	1.515	1.462	1.554	1.509	1.488	1.5	2.18
Conc. 2	3.76	3.81	3.90	3.8	3.7	3.64	3.65	3.8	2.76
Conc. 3	18.78	17.84	17.94	18.15	17.93	18.04	18.13	18.00	0.68
Conc. 4	55.43	54.13	53.01	55.31	57.83	52.70	54.32	54.55	3.41
Conc. 5	150.20	156.2	155.3	157.5	156.5	153.9	153.3	155.5	1.04
Conc. 6	300.40	314.59	314.17	309.89	312.88	314.32	307.40	312.21	0.94

Table 1c: [Company] Supplemental Study Spik

RRxx	Theory (µg)	Spike 1 (µg)	Spike 1 (%)
Conc. 1	1.50		0.0
Conc. 2	3.76		0.0
Conc. 3	18.78		0.0
Conc. 4	55.43		0.0
Conc. 5	150.20		0.0
Conc. 6	300.40		0.0

Table 1b: [BV Novi] ASAP Spikes (% Recovery)

RR38	Theory (µg)	Spike 1 (%)	Spike 2 (%)	Spike 3 (%)	Spike 4 (%)	Spike 5 (%)	Spike 6 (%)	Average (%)	CV (%)
Conc. 1	1.50	102.1	100.9	97.3	103.5	100.5	99.0	100.6	2.18
Conc. 2	3.76	101.6	103.8	101.9	98.8	96.9	97.3	100.1	2.76
Conc. 3	18.78	95.0	95.5	96.7	95.5	96.1	96.6	95.9	0.68
Conc. 4	55.43	97.7	95.6	99.8	104.3	95.1	98.0	98.4	3.41
Conc. 5	150.20	104.0	103.4	104.9	104.2	102.4	102.1	103.5	1.04
Conc. 6	300.40	104.7	104.6	103.2	104.2	104.6	102.3	103.9	0.94

Diflunisal Method Recovery:

Table 2a: Participant Results (µg/sample)

RR38	Theory (µg)	Lab-001 (µg)	Lab-002 (µg)	Lab-003 (µg)	Lab-004 (µg)	Lab-005 (µg)	Lab-006 (µg)	Lab-007 (µg)	Lab-008 (µg)	Lab-009 (µg)	Lab-010 (µg)	Lab-011 (µg)
Conc. 1	1.50	1.49	1.34	1.69	1.6	1.53	1.54	1.15	1.48	1.7124	1.60	1.61
Conc. 2	3.76	3.66	3.45	3.43	3.8	3.61	3.07	2.82	3.39	3.5453	3.73	3.55
Conc. 3	18.78	19.3	17.4	16.9	17.7	18.8	20.3	15	16.9	17.6	17.7	19.1
Conc. 4	56.33	57.9	52.0	54.8	55.2	56.2	58.5	36.49	51.3	50.2588	51.6	56.5
Conc. 5	150.20	156	137	150	149.2	153	160	124.8	140	144.7333	151	154.1
Conc. 6	300.40	310	280	300	307.8	310	319	228.73	293	286.2034	295	273.6
Blank		<1.12	<0.4	<1	<1	<0.403	<0.4	<0.28	ND	<0.3	<1	ND

Analytical

Table 2b: Participant Results (% Recovery)

RR38	Theory (µg)	Lab-001 (%)	Lab-002 (%)	Lab-003 (%)	Lab-004 (%)	Lab-005 (%)	Lab-006 (%)	Lab-007 (%)	Lab-008 (%)	Lab-009 (%)	Lab-010 (%)	Lab-011 (%)	Average (%)	CV (%)
Conc. 1	1.50	99.2	89.2	112.5	106.5	101.9	102.5	76.6	98.5	114.0	106.5	107.2	101.3	10.6
Conc. 2	3.76	97.5	91.9	91.3	101.2	96.1	81.8	75.1	90.3	94.4	99.3	94.5	92.1	8.3
Conc. 3	18.78	102.8	92.7	90.0	94.3	100.1	108.1	79.9	90.0	93.7	94.3	101.7	95.2	8.1
Conc. 4	56.33	102.8	92.3	97.3	98.0	99.8	103.9	64.8	91.1	89.2	91.6	100.3	93.7	11.5
Conc. 5	150.20	103.9	91.2	99.9	99.3	101.9	106.5	83.1	93.2	96.4	100.5	102.6	98.0	6.8
Conc. 6	300.40	103.2	93.2	99.9	102.5	103.2	106.2	76.1	97.5	95.3	98.2	91.1	96.9	8.6
Average(%)		101.6	91.8	98.5	100.3	100.5	101.5	75.9	93.4	97.2	98.4	99.6		
CV (%)		2.5	1.5	8.2	4.2	2.5	9.7	8.2	4.0	8.9	5.3	5.9		

Table 3: Participant Report Date & Extraction Efficiency (% Recovery)

RR38	Lab-001	Lab-002	Lab-003	Lab-004	Lab-005	Lab-006	Lab-007	Lab-008	Lab-009	Lab-010	Lab-011
Received by Due Date	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Extraction Efficiency (EE)	96.40%	98.00%	100.0%	96.7%	92.40%	98%	100.00%	97.8%	100.00%	100.00%	96.1%

* Outlier

Pharmaceutical Round Robin Proficiency Testing Program Round 38

Mar. 2010
Rnd 36

Round	Analyte	Lab	Mcg Found	Mcg Added	% Recovery	Round Score ^A Result	% Accept.	Three Round Score ^{AA} No. Passing	Proficiency
36	Niacin	100531	30.0	31.2	96.1	A	100%	Round 36 only - not rated	
		100531	60.8	65.6	92.7	A	Pass		
		100531	101.0	101.5	99.5	A			
		100531	15.1	15.6	96.7	A			
		100531	11.2	11.7	95.6	A			
		100531	72.9	72.6	100	A			

Performance Limit Range^P: 90 - 110% Recovery

Round Performance Statistics [*] : (n=72)				Round Performance [*] :
Mean	98.8	A	99%	A
SD	3.5	L	1%	
CV (%)	3.6	H	0%	

Oct. 2010
Rnd 37

Round	Analyte	Lab	Mcg Found	Mcg Added	% Recovery	Round Score ^A Result	% Accept.	Three Round Score ^{AA} No. Passing	Proficiency
37	Glipizide	100531	197.6	199.96	98.8	A	83%	Rounds 36 & 37 only	P
		100531	99.5	99.98	99.5	A	Pass		
		100531	54.8	49.99	110	A			
		100531	25.0	25.00	100	A			
		100531	0.00	12.50	0.00	NR			
		100531	6.33	6.25	101	A			

Performance Limit Range^P: 90 - 110% Recovery

Round Performance Statistics [*] : (n=65)				Round Performance [*] :
Mean	99.3	A	92%	A
SD	13.1	L	5%	
CV (%)	13.2	H	3%	

Lab-003 in summary results

May 2011
Rnd 38

Round	Analyte	Lab	Mcg Found	Mcg Added	% Recovery	Round Score ^A Result	% Accept.	Three Round Score ^{AA} No. Passing	Proficiency
38	Diflunisal	100531	1.69	1.50	112.5	H	83%	3/3	P
		100531	3.43	3.76	91.3	A	Pass		
		100531	16.9	18.78	90.0	A			
		100531	54.8	55.43	98.9	A			
		100531	150	150.20	99.9	A			
		100531	300	300.40	99.9	A			

Performance Limit Range^P: 90 - 110% Recovery

Round Performance Statistics [*] : (n=66)				Round Performance [*] :
Mean	96.5	A	95%	A
SD	8.9	L	12%	
CV (%)	9.3	H	3%	

* 4 of 11 labs failed @ 150 µg level
Method used (LC-037, Issue 5) was evaluated only down to

2.02 µg
~~1.50 µg~~ LDQ listed = 0.403 µg.

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Pharmaceutical Round Robin Proficiency Testing Program Round 38

Notes:

***Round Performance - All Labs:**

Revised performance limit range from Pharmaceutical Round Robin Meeting, AIHce 2007.

n: Number of reported results (reported by due date) by all labs for the round

A: Percent of acceptable results by all labs for the round

L: Percent of low (unacceptable) results by all labs for the round

H: Percent of high (unacceptable) results by all labs for the round

A: Round meets performance criteria and is acceptable

N: Round does not meet performance criteria and is not acceptable

^Round Score for Lab:

A: Result acceptable

H: Result > upper performance limit, not acceptable

L: Result < lower performance limit, not acceptable

NR: Not reported by due date, not acceptable

Pass: Round Score \geq 75%

Fail: Round Score < 75%

^^Three-Round Score for Lab:

Number of rounds with passing score in last 3 consecutive rounds

P: Proficient (passing score in two (2) of the last three (3) consecutive PT rounds)

N: Not Proficient (failing score in two (2) of the last three (3) consecutive PT rounds)