

ADME NTP Study S0161 Glycidol

The contract laboratory did not use any abbreviation for the test article.

Sex/Species: adult male F344 rats.

Vehicles: intravenous, distilled water; oral, distilled water.

CASRN 556-52-5

Radiolabeled with carbon-14 at the 1 and 3 position; Glycidol, [1,3-¹⁴C]-

Studies Performed:

- Single 37.5 or 75 mg/kg oral gavage dose in rats with sacrifice 24 hours (h) postdose. (N=4)
- Single 37.5 or 75 mg/kg oral gavage dose in rats with sacrifice 72 hours postdose. (N=4)
- Single 75 mg/kg oral gavage dose in rats with sacrifice 48 hours postdose. (CO₂ collection, N=3)
- Single 37.5 or 75 mg/kg intravenous dose in rats with sacrifice 24 hours postdose. (N=4)
- Single 37.5 or 75 mg/kg intravenous dose in rats with sacrifice 72 hours postdose. (N=4)

After removal of the gastric contents, the stomach was washed with water and then divided into the fore and glandular regions.

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Table 1: Urinary excretion of ¹⁴C radioactivity by male Fischer 344 rats after p.o. and i.v. administration of [¹⁴C]glycidol

Time (hr) ^a	37.5 mg/kg		75 mg/kg	
	p.o.	i.v.	p.o.	i.v.
Mean ± SD dose excreted (%)^b				
0-4	14.4 ± 3.6	15.8 ± 2.2	12.1 ± 4.9	17.2 ± 10.6
4-8	11.3 ± 2.8	11.8 ± 2.9	10.0 ± 6.8	13.7 ± 4.7
8-24	11.8 ± 2.7	11.7 ± 0.7	17.0 ± 3.6	12.1 ± 2.3
24-48	1.7 ± 0.3	2.9 ± 0.7	1.9 ± 0.2	3.7 ± 1.6
48-72	0.8 ± 0.2	1.2 ± 0.2	0.9 ± 0.1	1.3 ± 0.3
Mean ± SD dose excreted (cumulative %)				
0-4	14.4 ± 3.6	15.8 ± 2.2	12.1 ± 4.9	17.2 ± 10.6
0-8	25.7 ± 1.8	27.6 ± 3.2	22.0 ± 3.8	30.9 ± 8.2
0-24	37.5 ± 1.8	39.3 ± 3.3	39.0 ± 2.1	43.0 ± 6.5
0-48	39.1 ± 2.0	42.2 ± 2.6	40.9 ± 2.3	46.7 ± 8.0
0-72	40.0 ± 2.0	43.3 ± 2.5	41.8 ± 2.3	48.0 ± 8.3

^aTime after administration.

^bMean of data from four animals, each with duplicate analyses.

Table 2: Fecal excretion of ¹⁴C radioactivity by male Fischer 344 rats after p.o. and i.v. administration of [¹⁴C]glycidol

Time (hr) ^a	37.5 mg/kg		75 mg/kg	
	p.o.	i.v.	p.o.	i.v.
	Mean ± SD dose excreted (%)^b			
0-4	0.5 ± 0.8	0.0 ± 0.0	0.1 ± 0.1	0.0 ± 0.0
4-8	1.3 ± 1.4	0.2 ± 0.5	0.3 ± 0.5	1.0 ± 1.8
8-24	9.5 ± 0.8	4.8 ± 1.6	8.8 ± 3.6	2.6 ± 2.9
24-48	0.5 ± 0.3	0.9 ± 0.5	0.9 ± 0.4	1.2 ± 0.6
48-72	0.1 ± 0.0	0.3 ± 0.1	0.1 ± 0.1	0.5 ± 0.7
	Mean ± SD dose excreted (cumulative %)			
0-4	0.5 ± 0.8	0.0 ± 0.0	0.1 ± 0.1	0.0 ± 0.0
0-8	1.8 ± 1.1	0.2 ± 0.5	0.4 ± 0.5	1.0 ± 1.8
0-24	11.3 ± 1.6	5.1 ± 1.8	9.2 ± 3.2	3.6 ± 4.6
0-48	11.7 ± 1.3	6.0 ± 1.6	10.1 ± 3.1	4.8 ± 4.1
0-72	11.8 ± 1.3	6.2 ± 1.5	10.3 ± 3.1	5.3 ± 3.7

^aTime after administration.

^bMean of data from four animals, each with duplicate analyses.

Table 3: Exhalation of ¹⁴C radioactivity as CO₂ by male Fischer 344 rats after i.v. administration of [¹⁴C]glycidol

Time (hr) ^a	Dose (mg/kg)	
	37.5	75.0
	Mean ± SD dose excreted (%)^b	
0-1	2.1 ± 0.2	1.1 ± 0.4
1-2	3.1 ± 0.2	3.3 ± 0.0
2-4	1.9 ± 1.4	5.4 ± 0.4
4-8	7.3 ± 1.4	4.6 ± 0.2
8-12	5.4 ± 0.2	4.3 ± 0.3
12-24	4.9 ± 1.0	5.0 ± 1.0
24-32	0.8 ± 0.2	1.1 ± 0.4
32-48	0.7 ± 0.2	1.0 ± 0.4
48-56	0.1 ± 0.2	0.3 ± 0.0
56-72	0.4 ± 0.1	0.4 ± 0.1
	Mean ± SD dose excreted (cumulative %)	
0-1	2.1 ± 0.2	1.1 ± 0.4
0-2	5.2 ± 0.3	4.4 ± 0.5
0-4	7.0 ± 1.5	9.8 ± 0.8
0-8	14.4 ± 0.8	14.4 ± 0.9
0-12	19.8 ± 0.9	18.7 ± 1.1
0-24	24.7 ± 1.7	23.7 ± 1.4
0-32	25.5 ± 1.9	24.7 ± 1.6
0-48	26.2 ± 2.1	25.7 ± 1.8
0-56	26.3 ± 2.3	26.0 ± 1.9
0-72	26.7 ± 2.4	26.4 ± 1.9

^aTime after administration.

^bMean of data from four animals, each with duplicate analyses.

Table 4: Exhalation of ^{14}C radioactivity as CO_2 by male Fischer 344 rats after p.o. administration of [^{14}C]glycidol at 75 mg/kg^a

Time (hr)	Mean \pm SD dose excreted (%)^b
0-8	20.4 \pm 3.7
8-24	8.4 \pm 0.6
24-32	1.2 \pm 0.3
32-48	1.5 \pm 0.2
	Mean \pm SD dose excreted (cumulative %)
0-8	20.4 \pm 3.7
0-24	28.7 \pm 3.2
0-32	29.9 \pm 3.2
0-48	31.5 \pm 3.3

^aOnly 0.1 \pm 0.0% of the dose was found in the trap for volatile organics.

^bMean of data from three animals, each with duplicate analyses.

Table 5: Concentration of [¹⁴C]glycidol equivalents in tissues of male Fischer 344 rats at ca. 24 and 72 hr after p.o. and i.v. administration of [¹⁴C]glycidol

Tissue	Time (hr)	nmol/g fresh tissue (mean ± SD) ^a			
		37.5 mg/kg		75 mg/kg	
		p.o.	i.v.	p.o.	i.v.
Plasma	24	45.6 ± 2.3	45.7 ± 4.4	90.6 ± 2.5	127.7 ± 25.2
	72	16.1 ± 0.7	25.7 ± 3.3	39.0 ± 4.1	53.0 ± 7.2
Blood cells	24	208.2 ± 11.3	388.6 ± 16.0	457.7 ± 18.2	954.4 ± 64.8
	72	176.5 ± 16.8	358.3 ± 31.2	398.9 ± 22.5	762.3 ± 15.8
Liver	24	135.5 ± 7.0	149.2 ± 10.1	285.3 ± 24.4	335.8 ± 17.1
	72	53.0 ± 4.6	118.8 ± 53.4	127.8 ± 11.3	165.5 ± 44.1
Kidney	24	127.4 ± 10.4	118.5 ± 6.0	266.9 ± 13.8	289.9 ± 30.2
	72	63.3 ± 2.2	85.3 ± 7.4	159.4 ± 7.0	171.5 ± 17.7
Heart	24	57.4 ± 1.8	77.4 ± 9.3	126.8 ± 6.6	238.3 ± 44.5
	72	38.3 ± 0.8	78.9 ± 15.6	114.9 ± 20.5	165.5 ± 30.4
Lung	24	76.7 ± 2.3	113.6 ± 8.5	164.8 ± 7.2	265.6 ± 26.0
	72	47.6 ± 3.3	87.7 ± 10.8	107.7 ± 7.3	173.3 ± 14.7
Brain	24	50.9 ± 1.6	105.5 ± 41.9	113.5 ± 11.8	203.4 ± 32.3
	72	24.4 ± 1.5	47.8 ± 5.9	69.5 ± 3.6	102.2 ± 14.7
Adipose tissue	24	27.4 ± 7.8	25.7 ± 10.4	65.7 ± 16.4	49.2 ± 27.2
	72	36.4 ± 7.8	23.8 ± 3.5	63.3 ± 4.5	50.7 ± 12.6
Skeletal muscle	24	30.5 ± 3.3	45.0 ± 12.7	75.0 ± 10.5	91.7 ± 4.2
	72	24.7 ± 3.3	31.2 ± 3.0	55.5 ± 4.5	65.0 ± 3.4
Spleen	24	93.8 ± 5.7	91.6 ± 12.0	220.0 ± 11.9	271.9 ± 27.3
	72	63.0 ± 5.6	93.3 ± 11.3	141.0 ± 9.4	226.1 ± 42.1
Testes	24	65.2 ± 4.7	80.3 ± 1.9	141.0 ± 13.8	198.4 ± 13.6
	72	29.2 ± 4.0	40.3 ± 4.0	67.6 ± 3.5	81.6 ± 10.9
Thyroid	24	164.8 ± 54.0	151.4 ± 31.6	298.3 ± 40.6	265.5 ± 43.3
	72	67.7 ± 9.9	190.4 ± 70.0	166.4 ± 24.5	255.9 ± 124.9
Seminal vesicles	24	81.3 ± 6.1	82.2 ± 8.0	202.8 ± 15.4	190.5 ± 20.7
	72	42.6 ± 4.5	51.6 ± 6.4	116.4 ± 11.3	82.7 ± 42.2
Skin	24	76.0 ± 13.5	52.6 ± 2.8	166.6 ± 11.3	130.2 ± 10.5
	72	45.4 ± 3.4	45.8 ± 2.0	91.0 ± 32.0	95.6 ± 8.9
Forestomach	24	89.6 ± 11.4	68.1 ± 3.9	219.8 ± 18.3	164.3 ± 6.6
	72	35.6 ± 3.7	39.7 ± 4.1	85.8 ± 14.1	83.8 ± 5.4
Glandular stomach	24	76.2 ± 2.0	100.0 ± 39.7	160.6 ± 8.5	126.5 ± 39.2
	72	30.5 ± 1.2	52.9 ± 7.1	83.6 ± 12.0	103.6 ± 11.3

^aMean of data from four rats.

Table 6: Percentage of dose of ^{14}C radioactivity in tissues of male Fischer 344 rats at ca. 24 and 72 hr after p.o. and i.v. administration of [^{14}C]glycidol

Tissue	Time (hr)	Fraction of dose (mean \pm SD) ^a			
		37.5 mg/kg		75 mg/kg	
		p.o.	i.v.	p.o.	i.v.
Plasma	24	0.34 \pm 0.02	0.33 \pm 0.03	0.32 \pm 0.01	0.44 \pm 0.09
	72	0.12 \pm 0.00	0.17 \pm 0.01	0.14 \pm 0.01	0.18 \pm 0.02
Blood cells	24	1.52 \pm 0.09	2.78 \pm 0.17	1.64 \pm 0.07	3.31 \pm 0.23
	72	1.32 \pm 0.11	2.37 \pm 0.15	1.45 \pm 0.13	2.52 \pm 0.06
Liver	24	1.12 \pm 0.11	1.14 \pm 0.12	1.20 \pm 0.06	1.12 \pm 0.13
	72	0.48 \pm 0.03	0.66 \pm 0.31	0.56 \pm 0.04	0.48 \pm 0.16
Kidney	24	0.20 \pm 0.02	0.17 \pm 0.01	0.20 \pm 0.01	0.21 \pm 0.13
	72	0.10 \pm 0.00	0.11 \pm 0.01	0.13 \pm 0.01	0.11 \pm 0.01
Heart	24	0.04 \pm 0.01	0.05 \pm 0.01	0.04 \pm 0.00	0.08 \pm 0.01
	72	0.03 \pm 0.01	0.06 \pm 0.02	0.04 \pm 0.01	0.06 \pm 0.01
Lung	24	0.07 \pm 0.01	0.09 \pm 0.01	0.06 \pm 0.00	0.11 \pm 0.01
	72	0.04 \pm 0.00	0.09 \pm 0.01	0.05 \pm 0.01	0.08 \pm 0.01
Brain	24	0.08 \pm 0.01	0.16 \pm 0.05	0.09 \pm 0.01	0.16 \pm 0.03
	72	0.04 \pm 0.01	0.07 \pm 0.01	0.06 \pm 0.01	0.07 \pm 0.01
Adipose tissue	24	0.50 \pm 0.10	0.47 \pm 0.18	0.87 \pm 0.16	0.44 \pm 0.24
	72	0.72 \pm 0.16	0.40 \pm 0.06	0.54 \pm 0.10	0.43 \pm 0.11
Skeletal muscle	24	2.82 \pm 0.30	4.07 \pm 1.11	3.42 \pm 0.49	4.04 \pm 0.24
	72	2.34 \pm 0.26	2.62 \pm 0.26	2.55 \pm 0.20	2.73 \pm 0.17
Spleen	24	0.05 \pm 0.01	0.04 \pm 0.00	0.05 \pm 0.01	0.06 \pm 0.01
	72	0.03 \pm 0.00	0.04 \pm 0.01	0.04 \pm 0.01	0.05 \pm 0.01
Testes	24	0.15 \pm 0.01	0.17 \pm 0.02	0.16 \pm 0.02	0.22 \pm 0.02
	72	0.07 \pm 0.01	0.09 \pm 0.01	0.08 \pm 0.01	0.09 \pm 0.01
Thyroid	24	c	c	c	c
	72	c	c	c	c
Seminal vesicles	24	0.01 \pm 0.00	0.02 \pm 0.01	0.02 \pm 0.00	0.02 \pm 0.01
	72	0.01 \pm 0.00	0.01 \pm 0.01	0.01 \pm 0.00	0.01 \pm 0.01
Skin	24	2.22 \pm 0.38	1.30 \pm 0.55	2.39 \pm 0.18	1.87 \pm 0.56
	72	1.37 \pm 0.07	1.18 \pm 0.32	1.31 \pm 0.42	1.39 \pm 0.35
Forestomach	24	0.03 \pm 0.00	0.06 \pm 0.00	0.03 \pm 0.00	0.07 \pm 0.00
	72	0.01 \pm 0.00	0.03 \pm 0.00	0.01 \pm 0.01	0.03 \pm 0.00
Glandular stomach	24	0.06 \pm 0.00	0.03 \pm 0.01	0.07 \pm 0.01	0.03 \pm 0.02
	72	0.03 \pm 0.00	0.01 \pm 0.01	0.04 \pm 0.01	0.01 \pm 0.00

^aMean of data from four rats.

^bPercentages were calculated from the organ weights and by assuming that plasma = 3.75%, blood cells = 3.75%, fat = 9.50%, skeletal muscle = 47.5%, and skin = 15% of body weight.

^cMean \pm SD not calculable because radioactivity was < 0.01% of the dose.

Table 7: Recovery of ¹⁴C radioactivity at ca. 24 hr after p.o. and i.v. administration of [¹⁴C]glycidol to male Fischer 344 rats

Sample ^b	Mean ± SD dose excreted (%) ^a			
	37.5 mg/kg		75 mg/kg	
	p.o.	i.v.	p.o.	i.v.
Urine	41.7 ± 1.5	38.6 ± 16.4	42.1 ± 2.3	48.8 ± 2.1
Feces	8.6 ± 0.5	5.1 ± 1.0	8.3 ± 1.2	1.5 ± 0.9
Cage rinse	1.4 ± 0.3	1.3 ± 0.5	1.4 ± 0.7	1.9 ± 0.2
Tissues	9.2 ± 0.1	10.9 ± 1.0	10.6 ± 0.6	12.2 ± 0.7
Total	60.8 ± 2.2	55.9 ± 16.1	62.4 ± 2.7	64.3 ± 1.5

^aUrine, feces, tissues and cage rinse were each collected at the time of sacrifice, at ca. 24 hr.

^bMean of data from four rats.

Table 8: Recovery of ¹⁴C radioactivity at ca. 72 hr after p.o. and i.v. administration of [¹⁴C]glycidol to male Fischer 344 rats

Sample ^b	Mean ± SD dose excreted (%) ^a			
	37.5 mg/kg		75 mg/kg	
	p.o.	i.v.	p.o.	i.v.
Urine	39.9 ± 1.9	43.3 ± 2.5	41.8 ± 2.3	48.0 ± 8.3
Feces	11.8 ± 1.3	6.2 ± 1.5	10.3 ± 3.1	5.3 ± 3.7
Cage rinse	0.9 ± 0.5	2.4 ± 0.6	0.9 ± 0.3	2.5 ± 1.5
Tissues	6.7 ± 0.4	7.9 ± 0.2	7.0 ± 0.4	8.2 ± 0.7
Exhaled ¹⁴ CO ₂		26.7 ± 2.4	31.5 ± 3.3 ^c	26.4 ± 1.9
Total	59.3 ± 2.9	86.5 ± 3.8	91.4^d	90.5 ± 7.5

^aMean of data from four rats, unless otherwise indicated.

^bUrine, feces and exhaled ¹⁴CO₂ were each collected at intervals up to the time of sacrifice at ca. 72 hr unless otherwise indicated. At sacrifice, tissues and cage rinse were collected.

^c¹⁴CO₂ was collected from a separate set of three rats at intervals up to 48 hr following dosing.

^dTotal includes all data from both sets of rats.