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Discontinued subjects

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Disposition (all subjects)

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Screening failures

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Listing 16.2.1- 4

Subject visits (all subjects)

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Protocol deviations

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Demographics

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Medical history (all subjects)

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Listing 16.2.4- 3

Prior medications (part 1, all subjects)

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Listing 16.2.4- 6

Concomitant medications (part 2, all subjects)

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Listing 16.2.4- 7

Height, weight and BMI at screening (all subjects)

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Listing 16.2.4- 8 Alcohol screening (all subjects)

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Drug screening (all subjects)

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Hepatitis B (all subjects)

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Listing 16.2.4- 11

Hepatitis C (all subjects)

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HIV 1 and 2 (all subjects)

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Listing 16.2.5- 2

Plasma levels – nicotine (all subjects)

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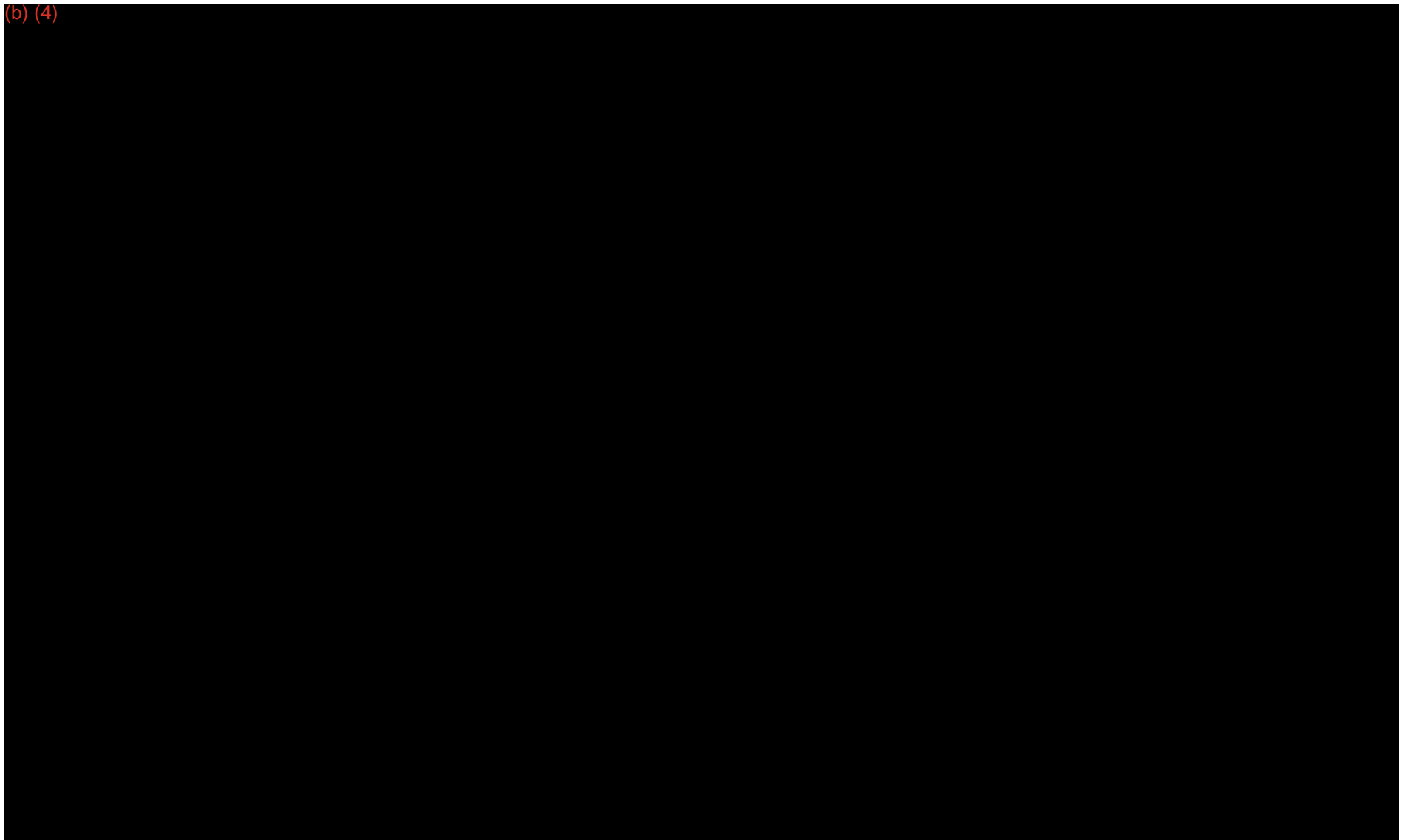


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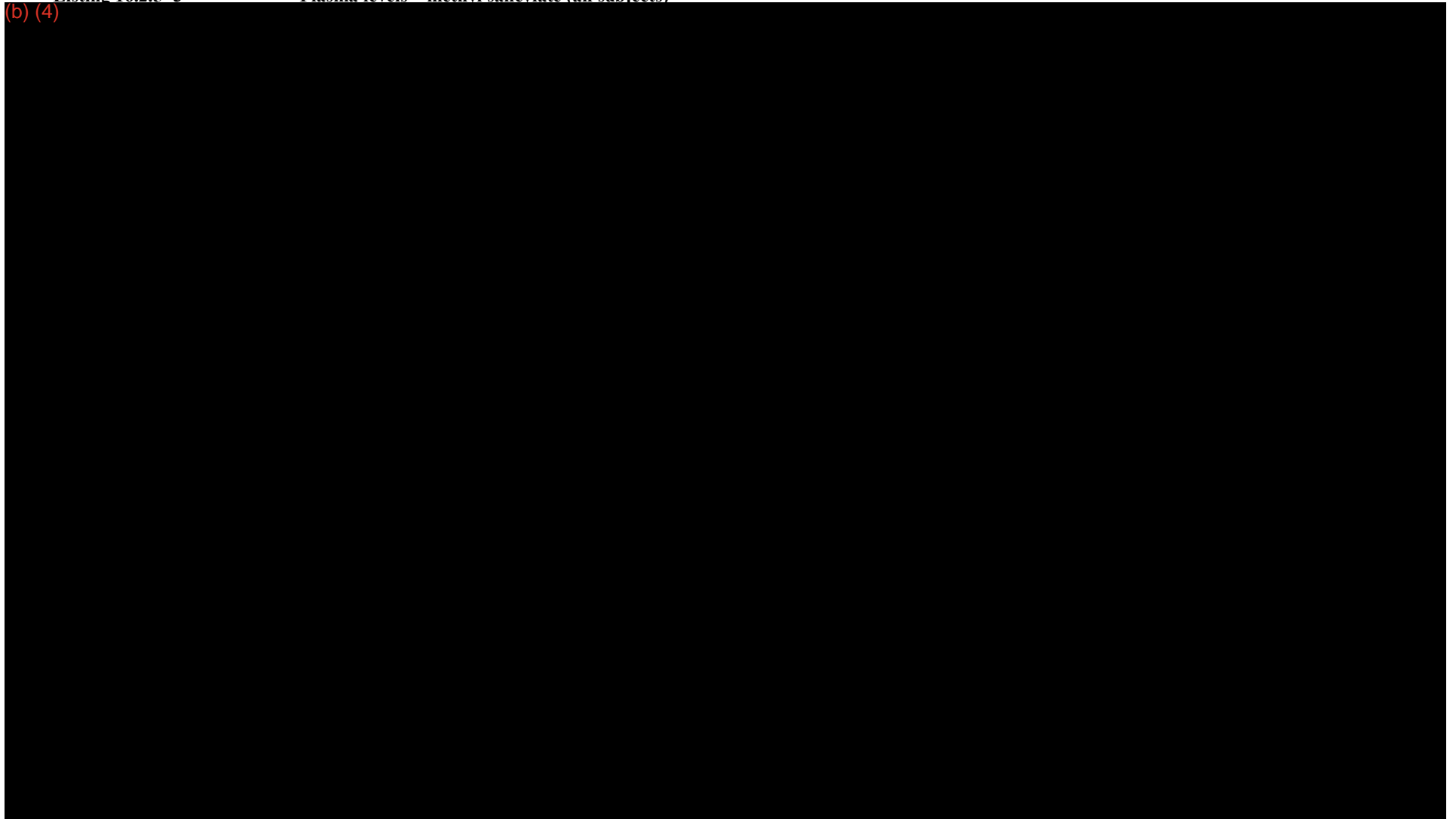


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Listing 16.2.5- 3 Plasma levels – methyl salicylate (all subjects)

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Estimated exposure to study product, nicotine extraction (Full analysis set)

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Listing 16.2.6- 2

Used pouch nicotine content (all subjects)

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Listing 16.2.6- 3

Pharmacokinetic parameters – nicotine (non-baseline adjusted data, per protocol set)

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Listing 16.2.6- 4

Pharmacokinetic parameters – nicotine (baseline adjusted data, per

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Adverse events (part 1, all subjects)

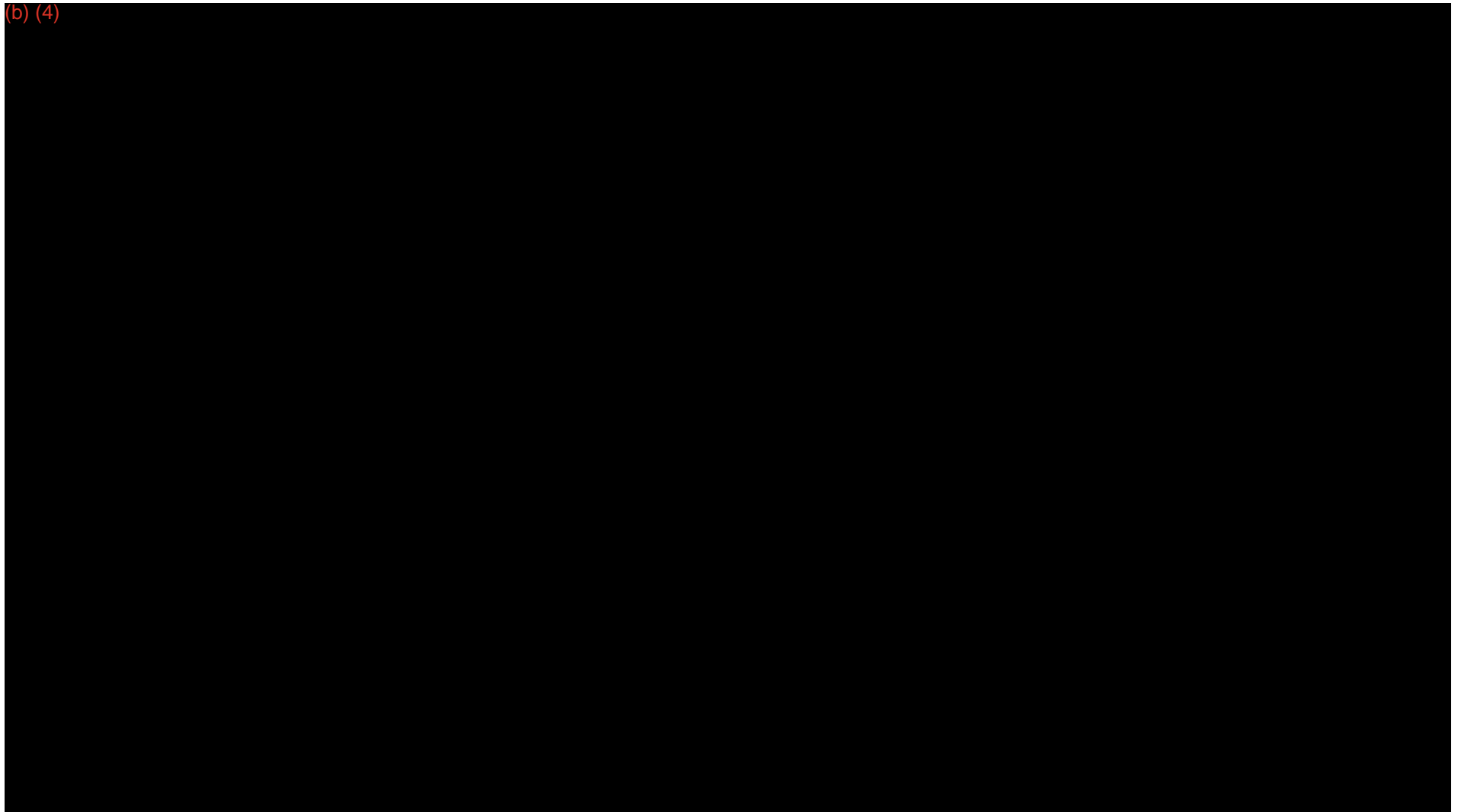
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Listing 16.2.7- 2

Adverse events (part 2, all subjects)

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Listing 16.2.7- 3

Adverse events occurring during wash-out (part 1, all subjects)

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Listing 16.2.7- 4

Adverse events occurring during wash-out (part 2, all subjects)

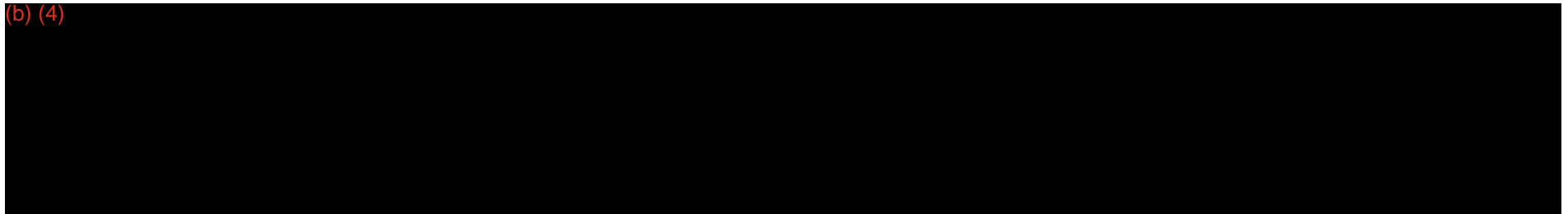
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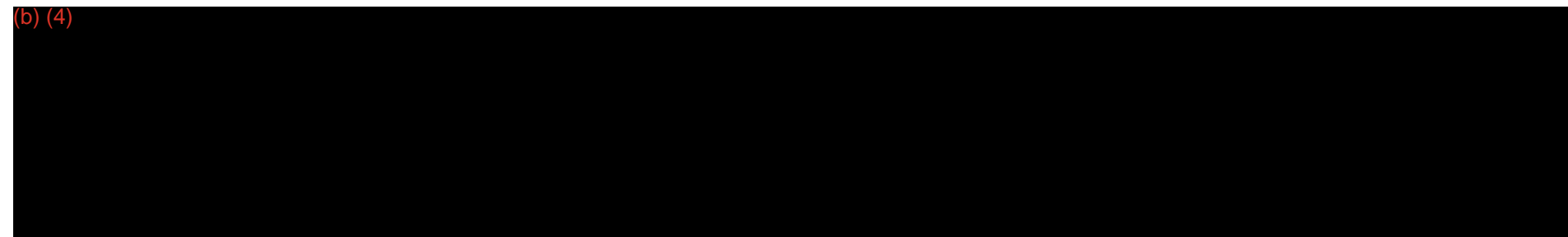


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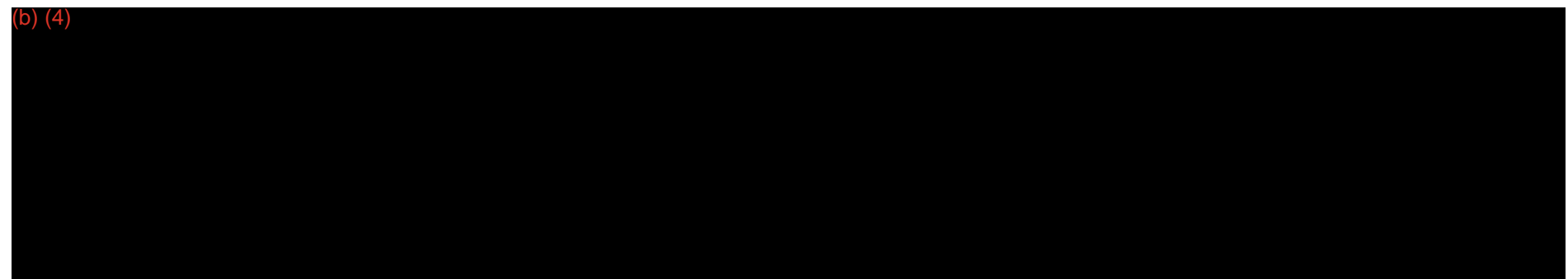
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Carbon monoxide (all subjects)

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