ANSWER & RATIONALE GUIDE

Use after finishing each mini exam. Each item links to a primary clinical reference.

A practice percentage is feedback for studying, not a CPJE pass prediction. Review the rationale even for questions you guessed correctly; then revisit the cited source when a dosing or guideline detail is unfamiliar.

EXAM 1 | ANSWERS

1. C - Treat with an appropriate antibiotic based on the culture

Pregnancy is a key exception to the usual rule against treating asymptomatic bacteriuria; IDSA recommends screening and treatment.

Primary reference: idsociety.org

2. C - Diphenhydramine

Diphenhydramine is a sedating, anticholinergic antihistamine. Its OTC label specifically says to ask a doctor before use if the patient has trouble urinating due to an enlarged prostate gland.

Primary reference: dailymed.nlm.nih.gov

3. D - 30 mg subcutaneously once daily

For prophylaxis during acute illness in medical patients with CLcr below 30 mL/min, the label specifies enoxaparin 30 mg subcutaneously once daily. The 1 mg/kg regimen is a treatment dose, not this prophylaxis regimen.

Primary reference: dailymed.nlm.nih.gov

4. D - At least 3 days before surgery

The Farxiga label says to withhold dapagliflozin at least 3 days before surgery or procedures involving prolonged fasting, if possible; restart once stable and eating.

Primary reference: dailymed.nlm.nih.gov

5. A - Fidaxomicin

Fidaxomicin is preferred for an initial episode because it improves sustained response; oral vancomycin remains an acceptable alternative when needed.

Primary reference: idsociety.org

6. A - Contact the treating clinicians because the combination is contraindicated

Rifampin reduces bictegravir exposure and may cause loss of HIV treatment effect and resistance. The Biktarvy label lists coadministration with rifampin as contraindicated; separating doses does not solve enzyme induction.

Primary reference: dailymed.nlm.nih.gov

7. B - Avoid adding that product without revising the plan; the combined daily acetaminophen could exceed 4,000 mg

The scheduled acetaminophen alone totals 4,000 mg/day. The additional 650 mg would bring the 24-hour total to 4,650 mg; the FDA advises no more than 4,000 mg from all products and checking labels for duplicate acetaminophen.

Primary reference: fda.gov

8. C - Reduce azathioprine to approximately one-third to one-fourth of its usual dose

Allopurinol inhibits xanthine oxidase metabolism of azathioprine, raising toxicity risk. Its label calls for azathioprine reduction to about one-third to one-fourth of usual dose.

Primary reference: dailymed.nlm.nih.gov

9. C - Start oseltamivir as soon as possible without waiting for influenza testing

Hospitalized patients with suspected or confirmed influenza should receive prompt antiviral therapy; treatment can still help after 48 hours and should not await testing.

Primary reference: cdc.gov

10. B - A proton-pump inhibitor, bismuth, tetracycline, and metronidazole

The 2024 ACG guideline recommends 14 days of optimized bismuth quadruple therapy in treatment-naive patients. Empiric clarithromycin triple therapy is discouraged without demonstrated susceptibility.

Primary reference: gi.org

11. C - 1,500 mg twice daily

A CLcr of 30–50 mL/min calls for a 25% dose reduction. Seventy-five percent of 2,000 mg is 1,500 mg twice daily; verify tablets and the actual oncology protocol.

Primary reference: dailymed.nlm.nih.gov

12. C - Rinse the mouth with water and spit it out after inhalation

Rinsing the mouth with water without swallowing after inhaled fluticasone/salmeterol lowers the risk of oropharyngeal candidiasis.

Primary reference: dailymed.nlm.nih.gov

13. A - Two doses of recombinant zoster vaccine, typically 2–6 months apart

Prior shingles does not replace the two-dose recombinant zoster series recommended for immunocompetent adults 50 and older.

Primary reference: cdc.gov

14. C - 5 mL

The product's chart gives 5 mL for children weighing 24–35 lb and aged 2–3 years. The concentration is 160 mg per 5 mL; use the product's supplied syringe.

Primary reference: dailymed.nlm.nih.gov

15. A - Provide hydration and assess kidney function, serum electrolytes including magnesium, and hearing as indicated

Cisplatin can cause dose-related nephrotoxicity, electrolyte loss, and ototoxicity. The label calls for adequate hydration, renal tests and electrolytes including magnesium, and consideration of audiometric monitoring.

Primary reference: dailymed.nlm.nih.gov

16. B - Reserve it for inadequate response or intolerance to alternatives because serious neuropsychiatric events can occur

For allergic rhinitis, the montelukast label reserves use for patients who cannot tolerate or have an inadequate response to alternatives because of serious neuropsychiatric risks.

Primary reference: dailymed.nlm.nih.gov

17. A - Give Tdap now during this pregnancy

One Tdap dose is recommended during every pregnancy, preferably early in gestational weeks 27–36, regardless of prior Tdap history.

Primary reference: cdc.gov

18. D - Discuss a gradual withdrawal plan with the prescriber because abrupt withdrawal may increase seizure frequency or cause status epilepticus

The levetiracetam label advises gradual withdrawal to reduce the risk of increased seizure frequency and status epilepticus. A prescriber should direct any taper.

Primary reference: dailymed.nlm.nih.gov

19. B - Contact the prescriber because concurrent use is contraindicated in renal impairment and a different regimen is needed

Clarithromycin strongly inhibits both CYP3A4 and P-glycoprotein, which can greatly increase colchicine exposure; fatal interactions have occurred. The colchicine label contraindicates this combination in patients with renal or hepatic impairment. Spacing doses does not resolve inhibition.

Primary reference: dailymed.nlm.nih.gov

20. D - Sildenafil with any organic nitrate is contraindicated because of potentially severe hypotension

PDE5 inhibition amplifies nitrate-induced hypotension; sildenafil is contraindicated with nitrates, whether taken regularly or intermittently.

Primary reference: dailymed.nlm.nih.gov

21. B - Discontinue metformin

Both immediate- and extended-release metformin are contraindicated when eGFR is below 30 mL/min/1.73 m^2; treatment should be discontinued.

Primary reference: dailymed.nlm.nih.gov

22. B - Take 15 g fast-acting carbohydrate and recheck glucose in 15 minutes

For a conscious person with glucose below 70 mg/dL, the 15–15 rule is 15 g of rapid carbohydrate, then recheck in 15 minutes and repeat if still low.

Primary reference: cdc.gov

23. D - Most adults with type 1 diabetes require basal plus prandial insulin, or a suitable pump regimen

Most adults with type 1 diabetes need continuous subcutaneous insulin infusion or multiple daily doses including both basal and prandial insulin.

Primary reference: pmc.ncbi.nlm.nih.gov

24. D - Sitagliptin

Concurrent DPP-4 inhibitor (such as sitagliptin) and GLP-1 receptor agonist therapy is not recommended because the combination provides no additional glucose lowering.

Primary reference: pmc.ncbi.nlm.nih.gov

25. A - Warfarin

A vitamin K antagonist such as warfarin is recommended for mechanical heart valves; direct oral anticoagulants are generally preferred for AF only outside the mechanical-valve and relevant mitral-stenosis exceptions.

Primary reference: acc.org

26. A - 2.5 mg orally twice daily

The patient meets two apixaban AF dose-reduction criteria (age ≥80 years and weight ≤60 kg), so the labeled dose is 2.5 mg twice daily.

Primary reference: accessdata.fda.gov

27. B - 10 mg twice daily for 7 days, then 5 mg twice daily

Adult DVT/PE treatment starts with apixaban 10 mg twice daily for 7 days, followed by 5 mg twice daily; this differs from AF dose-reduction rules.

Primary reference: accessdata.fda.gov

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28. B - SGLT2 inhibitor

SGLT2 inhibitors are among the four foundational HFrEF medication classes, and benefit is not restricted to patients with diabetes.

Primary reference: professional.heart.org

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29. A - Defer initiation and address hyperkalemia; guideline initiation criteria require potassium below 5.0 mEq/L

The HFrEF guideline recommends an MRA when eGFR is >30 and serum potassium is <5.0 mEq/L; this patient's potassium is above the initiation threshold.

Primary reference: professional.heart.org

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30. D - Atorvastatin 80 mg

Atorvastatin 80 mg daily is high-intensity statin therapy; the other listed doses are lower-intensity regimens.

Primary reference: tools.acc.org

EXAM 2 | ANSWERS

1. B - 75 mg twice daily

For nonvalvular atrial fibrillation with CrCl 15–30 mL/min, the U.S. Pradaxa capsule label recommends 75 mg twice daily. This does not apply to acute DVT/PE treatment.

Primary reference: dailymed.nlm.nih.gov

2. A - Incision and drainage

For a mild cutaneous abscess, incision and drainage is the recommended treatment; adjunctive systemic antibiotics depend on severity and host factors.

Primary reference: idsociety.org

3. D - 600–1,200 mL

CDC guidance for mild to moderate dehydration recommends 50–100 mL/kg of oral rehydration solution over 2–4 hours, plus replacement of ongoing losses. For 12 kg, that is 600–1,200 mL, starting with small frequent volumes if vomiting occurs.

Primary reference: cdc.gov

4. C - 100 minutes

1,000 mg ÷ 10 mg/min = 100 minutes, which also exceeds the 60-minute minimum. Faster infusion increases infusion-related reactions.

Primary reference: dailymed.nlm.nih.gov

5. A - Concomitant hydrochlorothiazide is contraindicated because it increases dofetilide exposure and QT prolongation

The dofetilide label contraindicates hydrochlorothiazide, alone or in combination products, because it raises dofetilide concentrations and prolongs the QT interval.

Primary reference: dailymed.nlm.nih.gov

6. C - 400–600 mg·h/L

The multisociety vancomycin monitoring guideline recommends an AUC/MIC of 400–600 for serious MRSA infection when the MIC is 1 mg/L.

Primary reference: idsociety.org

7. B - Do not combine the drugs; a proton-pump inhibitor can substantially lower rilpivirine exposure

The Edurant label contraindicates proton-pump inhibitors, including omeprazole, because increased gastric pH lowers rilpivirine concentrations and may cause virologic failure and resistance. Dose separation does not correct the sustained pH effect; coordinate a different acid-suppression plan with the treating team.

Primary reference: dailymed.nlm.nih.gov

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8. C - 475 mg

Calvert dose = target AUC × (GFR + 25) = 5 × (70 + 25) = 475 mg. The result is a total milligram dose, not mg/m².

Primary reference: dailymed.nlm.nih.gov

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9. D - At term, nitrofurantoin is contraindicated because of possible hemolytic anemia in the newborn

The nitrofurantoin label contraindicates use at 38–42 weeks, during labor/delivery, or when labor is imminent because of infant hemolytic anemia risk.

Primary reference: dailymed.nlm.nih.gov

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10. B - No additional pneumococcal dose

For a PCV-naïve adult 50 or older, PCV20 alone completes the pneumococcal vaccination recommendation; PPSV23 is not indicated afterward.

Primary reference: cdc.gov

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11. C - Take one tablet each morning before eating, every day for 14 days; this is not an immediate-relief medicine

The OTC omeprazole 20-mg delayed-release label directs one tablet before morning food every day for 14 days; it is not intended for immediate relief and the tablet should not be crushed.

Primary reference: dailymed.nlm.nih.gov

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12. D - Serial serum methotrexate concentrations at specified times plus renal function

Methotrexate clearance and kidney function guide the leucovorin dose and duration. Delayed elimination or rising creatinine may require intensified rescue, hydration, and urine alkalinization; CBC and symptoms are valuable but cannot replace timed methotrexate levels.

Primary reference: dailymed.nlm.nih.gov

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13. A - Put one capsule in the HandiHaler and inhale its contents twice through the device

HandiHaler capsules are for inhalation only, not swallowing; the labeled dose is two inhalations from the contents of one 18-mcg capsule once daily.

Primary reference: dailymed.nlm.nih.gov

14. A - Offer a two-dose recombinant zoster vaccine series because immunosuppressed adults age 19 or older are eligible

CDC recommends two doses of recombinant zoster vaccine for adults 19 or older who are or will be immunodeficient or immunosuppressed due to disease or treatment.

Primary reference: cdc.gov

15. B - Children younger than 2 years have a markedly increased risk of fatal hepatotoxicity, particularly with multiple anticonvulsants

Valproic acid labeling warns that children under two have a considerably increased risk of fatal hepatotoxicity, especially with multiple anticonvulsants. The choice requires extreme caution, review of alternatives, and close clinical/liver-test monitoring.

Primary reference: dailymed.nlm.nih.gov

16. D - Measure LVEF before therapy and about every 3 months during therapy

The Herceptin label recommends LVEF assessment before initiation and every 3 months during treatment; further follow-up depends on therapy context and results.

Primary reference: dailymed.nlm.nih.gov

17. C - Serotonin syndrome from the serotonergic drug interaction

Linezolid can interact with serotonergic agents; fever, agitation, hyperreflexia, and clonus are characteristic warning signs of serotonin syndrome and warrant immediate evaluation.

Primary reference: dailymed.nlm.nih.gov

18. B - A GLP-1 receptor agonist with demonstrated cardiovascular benefit

The ADA recommends including a GLP-1 receptor agonist and/or SGLT2 inhibitor with demonstrated cardiovascular benefit in type 2 diabetes with established ASCVD irrespective of A1C.

Primary reference: pmc.ncbi.nlm.nih.gov

19. D - Take levothyroxine and patiromer at least three hours apart

Patiromer can bind levothyroxine and reduce its exposure. The Veltassa label lists levothyroxine as a clinically important interaction and directs at least three hours of separation from interacting oral drugs.

Primary reference: dailymed.nlm.nih.gov

20. B - Offer naloxone and coordinate a review of the concurrent sedatives with the care team

The CDC opioid guideline urges particular caution with opioids plus benzodiazepines and recommends offering naloxone to people at elevated overdose risk, including this combination. Any changes to an established regimen require coordinated, individualized care.

Primary reference: cdc.gov

21. B - Avoid omeprazole or esomeprazole; separation by 12 hours does not prevent reduced antiplatelet activity

Omeprazole inhibits CYP2C19-mediated clopidogrel activation. The label advises avoiding omeprazole/esomeprazole and notes reduced platelet inhibition even at 12-hour separation.

Primary reference: dailymed.nlm.nih.gov

22. A - Ozempic is contraindicated with a personal or family history of medullary thyroid carcinoma

Ozempic has a boxed warning for thyroid C-cell tumors and is contraindicated with personal or family history of medullary thyroid carcinoma or MEN2.

Primary reference: dailymed.nlm.nih.gov

23. A - Bupropion is contraindicated with current or prior bulimia because seizure incidence is higher

The Wellbutrin XL label contraindicates use in current or past bulimia or anorexia nervosa because of increased seizure risk.

Primary reference: dailymed.nlm.nih.gov

24. A - Contact the prescriber immediately to discontinue lisinopril as soon as possible and choose pregnancy-appropriate therapy

ACE inhibitors acting on the renin-angiotensin system can injure or kill the fetus; the lisinopril label directs discontinuation as soon as pregnancy is detected.

Primary reference: dailymed.nlm.nih.gov

25. D - Valproate is contraindicated for migraine prevention during pregnancy

Valproate is contraindicated for prophylaxis of migraine headaches in pregnant patients because of fetal risks.

Primary reference: dailymed.nlm.nih.gov

26. D - Low-dose aspirin 81 mg once daily, starting after 12 weeks of gestation

Chronic hypertension is a high-risk factor; the USPSTF recommends aspirin 81 mg daily after 12 weeks of gestation for patients at high risk of preeclampsia.

Primary reference: uspreventiveservicestaskforce.org

27. C - Defer MMR until after pregnancy because it is a live vaccine contraindicated during pregnancy

MMR is a live attenuated vaccine and is contraindicated during pregnancy; nonimmune patients can be vaccinated after pregnancy.

Primary reference: cdc.gov

28. B - Clarify the order immediately; arthritis treatment is generally once weekly and inadvertent daily methotrexate has caused deaths

The methotrexate label specifies weekly dosing for rheumatoid arthritis; unintended daily administration has caused fatal toxicity.

Primary reference: dailymed.nlm.nih.gov

29. C - Do not give undiluted; the concentrate must be diluted appropriately before IV administration

Undiluted IV potassium chloride concentrate can cause fatal arrhythmia or arrest; the label requires dilution before administration.

Primary reference: dailymed.nlm.nih.gov

30. C - During treatment and for one week after the final dose

The methotrexate tablet label instructs patients not to breastfeed during treatment and for one week after the final dose because of potential serious reactions in the infant.

Primary reference: dailymed.nlm.nih.gov

EXAM 3 | ANSWERS

1. D - 42 mL/min

For a man, CLcr = [(140 − age) × weight in kg] ÷ [72 × serum creatinine] = (75 × 80) ÷ (72 × 2) = 41.7 mL/min. The case explicitly instructs use of the stated weight; in practice, weight choice and kidney-function estimates require clinical judgment.

Primary reference: dailymed.nlm.nih.gov

2. C - 50 mg once daily

At eGFR 30 to less than 45 mL/min/1.73 m^2, the labeled sitagliptin dose is 50 mg once daily.

Primary reference: dailymed.nlm.nih.gov

3. A - Nitrofurantoin

Nitrofurantoin concentrates in urine but does not reach adequate renal tissue levels for pyelonephritis.

Primary reference: idsociety.org

4. B - 300 mg once daily

The gabapentin label lists 200–700 mg total daily, given once daily, for creatinine clearance greater than 15 to 29 mL/min. The other regimens exceed that range or use an inappropriate frequency.

Primary reference: dailymed.nlm.nih.gov

5. C - Flag ceftriaxone as contraindicated in this neonate and contact the prescriber for an alternative

In a neonate 28 days or younger who requires or is expected to require IV calcium, ceftriaxone is contraindicated because ceftriaxone-calcium precipitates can form. Separate lines or dosing times do not remove the neonatal contraindication.

Primary reference: dailymed.nlm.nih.gov

6. A - Avoid rivaroxaban in moderate hepatic impairment and contact the prescriber

The Xarelto label says to avoid use in Child-Pugh B or C hepatic impairment, or hepatic disease associated with coagulopathy.

Primary reference: dailymed.nlm.nih.gov

7. A - 100 mg by mouth twice daily for 5 days

Nitrofurantoin monohydrate/macrocrystals 100 mg twice daily for 5 days is a recommended regimen for acute uncomplicated cystitis; this case excludes pyelonephritis.

Primary reference: academic.oup.com

8. D - Withhold and contact the prescriber because the regimen is contraindicated

Mavyret is contraindicated in moderate or severe hepatic impairment (Child-Pugh B or C) and in anyone with a history of prior hepatic decompensation.

Primary reference: dailymed.nlm.nih.gov

9. C - Advise against self-starting oral naproxen and arrange evaluation of safer pain options

The naproxen Drug Facts warning identifies age 60 or older and a history of stomach ulcer or bleeding as factors that raise serious stomach-bleeding risk, and directs patients covered by the warning to ask a doctor before use. Food does not remove this risk; assess the pain and alternatives.

Primary reference: dailymed.nlm.nih.gov

10. D - Prednisolone 40–50 mg each morning for 5–7 days

GINA lists prednisolone 40–50 mg each morning for 5–7 days for adult exacerbations requiring oral corticosteroids. Courses shorter than 2 weeks generally need no taper.

Primary reference: ginasthma.org

11. A - PPSV23 approximately 1 year later

PCV15 is ordinarily followed by one PPSV23 dose 1 year later in an immunocompetent adult; the shortened 8-week interval is reserved for specified higher-risk circumstances.

Primary reference: cdc.gov

12. D - Do not use dextromethorphan now; the label says to avoid it for two weeks after stopping an MAOI

The dextromethorphan label says not to use the product while taking a prescription monoamine oxidase inhibitor or within two weeks of stopping one. Eight days is within that interval.

Primary reference: dailymed.nlm.nih.gov

13. D - Separate vincristine and prepare it only for IV administration in a clearly labeled flexible container

Vincristine is for IV use only; intrathecal administration is usually fatal. Its label directs dilution in a flexible plastic container with a prominent IV-only warning, and separation from intrathecal drugs prevents route mix-ups.

Primary reference: dailymed.nlm.nih.gov

14. B - As-needed low-dose inhaled corticosteroid/formoterol

GINA prefers an anti-inflammatory reliever for adults and adolescents, including as-needed low-dose ICS/formoterol at initial steps, even with infrequent symptoms.

Primary reference: ginasthma.org

15. D - Complete an age-appropriate hepatitis B vaccine series

Hepatitis B vaccination is routinely recommended for adults ages 19–59, without requiring an identified risk factor; series length depends on product.

Primary reference: cdc.gov

16. A - 25 mg every other day for weeks 1 and 2

For patients older than 12 years with epilepsy who are taking valproate, the lamotrigine adjunctive-therapy table starts at 25 mg every other day for two weeks. Valproate reduces lamotrigine clearance, and rapid escalation raises serious rash risk.

Primary reference: dailymed.nlm.nih.gov

17. D - Refer for medical evaluation of alarm symptoms instead of treating this as routine self-care

The OTC omeprazole Drug Facts label directs patients with trouble or pain swallowing, and other alarm symptoms, to seek medical advice. New dysphagia plus weight loss warrants evaluation rather than simply starting repeated OTC therapy.

Primary reference: dailymed.nlm.nih.gov

18. A - Flag the contraindicated combination due to myopathy/rhabdomyolysis risk and contact the prescriber

Clarithromycin inhibits CYP3A4, increasing simvastatin exposure; concomitant use is contraindicated because of severe myopathy and rhabdomyolysis risk.

Primary reference: dailymed.nlm.nih.gov

19. C - SGLT2 inhibitor with demonstrated kidney benefit

For type 2 diabetes with CKD and eGFR in the 20–60 range or albuminuria, ADA recommends SGLT2 inhibitor or GLP-1 RA with proven benefit irrespective of A1C; an SGLT2 inhibitor is appropriate here.

Primary reference: pmc.ncbi.nlm.nih.gov

20. B - Promptly contact the treating clinician to address hyperkalemia and reassess or hold the spironolactone dose

Spironolactone can cause hyperkalemia. Its label instructs monitoring serum potassium and decreasing the dose or discontinuing spironolactone and treating hyperkalemia when it occurs; a confirmed 5.9 mEq/L result warrants prompt clinical review.

Primary reference: dailymed.nlm.nih.gov

21. C - Withhold pembrolizumab and institute appropriate management, often systemic corticosteroids

The Keytruda label directs withholding for Grade 2 pneumonitis and generally treating immune-mediated toxicity needing interruption with systemic corticosteroids. Grade 3 or 4 pneumonitis requires permanent discontinuation.

Primary reference: dailymed.nlm.nih.gov

22. B - Avoid aspirin in children and teenagers with flu-like illness because of Reye syndrome risk

Aspirin Drug Facts warn that children and teenagers who have or are recovering from influenza-like symptoms should not use aspirin because of Reye syndrome. Discuss another age-appropriate analgesic after checking the full clinical context.

Primary reference: dailymed.nlm.nih.gov

23. B - 8 AM the following morning

Lithium concentrations used for routine interpretation are commonly drawn about 12 hours after the prior dose, immediately before the next dose when relevant. Eight PM plus 12 hours is 8 AM; the exact regimen and timing must be documented.

Primary reference: dailymed.nlm.nih.gov

24. A - Chlorthalidone reduces lithium renal clearance, increasing toxicity risk; monitor lithium levels

The chlorthalidone label states that lithium renal clearance is reduced and advises monitoring serum lithium during concomitant use. Assess symptoms, renal function, and dose needs with the prescriber.

Primary reference: dailymed.nlm.nih.gov

25. C - Unbound (free) phenytoin concentration

Phenytoin is highly protein bound. In hypoalbuminemia or renal/hepatic disease, unbound concentrations can be more informative than total concentrations, particularly when toxicity signs conflict with the total level.

Primary reference: dailymed.nlm.nih.gov

26. C - Hypokalemia increases myocardial sensitivity to digoxin, so toxicity can occur even with a seemingly acceptable serum level

Potassium depletion predisposes to digoxin toxicity and can make toxicity occur even without a markedly elevated measured total digoxin level. Evaluate the patient, rhythm, electrolytes, kidney function, and drug exposure promptly.

Primary reference: dailymed.nlm.nih.gov

27. B - Chest radiograph/pulmonary testing, thyroid function, and liver enzymes

The amiodarone label recommends baseline chest radiograph and pulmonary function testing, thyroid tests, and liver aminotransferases, with ongoing monitoring as clinically indicated.

Primary reference: dailymed.nlm.nih.gov

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28. D - 12:30 PM

USP <797> permits administration of a qualifying immediate-use CSP to begin within 4 hours after the start of preparation. Four hours after 8:30 AM is 12:30 PM; a facility may impose a shorter limit.

Primary reference: pages.usp.org

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29. C - A primary engineering control in the segregated compounding area

Category 1 CSPs must be prepared in a primary engineering control, which may be located in an unclassified segregated compounding area or in a cleanroom suite. The PEC supplies the required clean air at the preparation site.

Primary reference: pages.usp.org

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30. B - An externally vented ISO Class 5 Class II biological safety cabinet or compounding aseptic containment isolator

For sterile hazardous-drug manipulation, USP <800> calls for an externally vented containment PEC providing ISO Class 5 or better air, such as a Class II BSC or CACI, in the appropriate containment secondary environment.

Primary reference: pages.usp.org
