

SEQ Practice and NMRA Act

40 selected questions from the EduRase SEQ 300 bank

බාහිර ඖෂධවේදී විභාගය සඳහා ප්‍රශ්න ලිවීමේ පුහුණුව සහ NMRA පැහැදිලි කිරීම්

Lecturer Pradeep Dissanayake

21 October 2026 • Online seminar starts 8:00 AM Sri Lanka

READ THE QUESTION

PLAN THE POINTS

WRITE CLEARLY

CHECK AND REPAIR

Use this tutorial to connect the NMRA rules to pharmacy decisions and turn your knowledge into clear, relevant SEQ answers. Attempt the questions before reading the model points, then repair the specific gaps you find.

මෙහි මුල් SEQ අංක තබා ඇති ප්‍රශ්න 40ක්, NMRA පාඩම් 13ක්, model answers, calculations, කාලයට ලිවීමේ අභ්‍යාස සහ නැවත පුහුණු වීමේ සැලැස්මක් තිබෙනවා.

What you should be able to do

Distinguish the legal bodies and permissions; explain recall, licensing and inspection decisions; solve calculations with units; and write only the points requested by each subpart.

How to use the priorities

A marks the 24 questions to attempt first. B adds 16 questions for wider coverage. These are lecturer study priorities based on available past-paper themes, syllabus coverage and pharmacy importance. They are not probabilities or a guarantee of examination questions.

Teaching scope

The SEQs are tutor-authored model material from our bank, not official CMCC questions. Practice marks are lecturer allocations. Legal teaching uses the 2015 Act, the named 2019 Regulations and cited guidance. Use current official requirements for an actual transaction.

Seminar teaching time 18 hours in total; continues on 22 October if needed.

Edition 1.1 | Revised 20 October 2026 | Student name _____

Seminar learning route

The seminar combines explanation, discussion and independent writing. The sequence below allocates 18 teaching hours; breaks are additional. Begin on 21 October at 8:00 AM and complete any remaining teaching on 22 October as announced.

Block	Teaching focus	Hours
1	Diagnostic and the SEQ writing method	0.75
2	NMRA lessons 01–13 with pharmacy cases	5.75
3	Priority A questions with developed answers	7.00
4	Priority B questions and rapid comparisons	2.00
5	Timed writing and answer review	1.00
6	Repair work and final retrieval practice	1.50
Total	Teaching time excluding breaks	18.00

Use the same cycle for every SEQ

Read the command word and requested number of items. Plan a short list. Write with the answer covered. Compare each subpart with the model. Mark the missing idea and practise that idea again. The original bank numbers are retained even though the questions are grouped for this seminar.

සියලු පිළිතුරු සටහන් කරගැනීම පමණක් නොව, ඔබට අඩු වූ point එක හඳුනාගැනීම වැදගත්. නැවත කියවීමෙන් පසු answer එක නොබලා ලියා බලන්න.

Exam focus For learning, allow 10–12 minutes for a full 20-mark bank question. For speed practice, use the separate 30-minute five-question exercise. These are teaching timings, not a replacement for CMCC instructions.

Selected SEQ question index 1

Original Q numbers are unchanged. A = attempt first; B = wider coverage. Page references point to the question and its model answer.

SEQ	Topic	Priority	Page
Q001	Recall of Medicines and Regulatory Action	A	28
Q003	Licensing and Operation of a Community Pharmacy	A	29
Q004	Legal Classification and Supply of Medicines	A	30
Q011	Electronic / Messaging-App Prescription Scenario	B	31
Q036	Pharmacovigilance and Suspected Adverse Drug Reactions	B	32
Q062	Pharmacy Inspection, Non-Compliance and Corrective Action	B	33
Q092	Registration and Marketing Authorisation of Medicines	A	34
Q123	Medicine Samples, Donations and Promotional Supply Controls	B	35
Q271	National Medicines Regulatory Authority and National Medicines Quality Assurance Laboratory: Regulatory Roles	B	36
Q272	Authorised Officers, Inspection Powers and Evidence Handling	A	37
Q002	Authenticity and Legality of a Prescription	A	38
Q006	Professional Ethics in Medicine Supply	A	39
Q009	Patient Counselling and Written Medicine Information	A	40
Q010	Antibiotic Dispensing and Counselling	A	41

Selected SEQ question index 2

Original Q numbers are unchanged. A = attempt first; B = wider coverage. Page references point to the question and its model answer.

SEQ	Topic	Priority	Page
Q065	Dispensing Labels, Auxiliary Labels and Safe Packaging	B	42
Q018	Concentration and Dilution Calculations	A	43
Q019	Paediatric Dose and Dose-Volume Calculation	A	44
Q020	Drug Base and Salt Calculations	A	45
Q021	Infusion and Flow-Rate Calculations	B	46
Q022	pH, pKa and Drug Ionisation	A	47
Q023	Pharmaceutical Buffers	A	48
Q048	Alligation and Strength Adjustment	B	49
Q083	Reconstituted Oral Antibiotic: Course Quantity Calculation	A	50
Q012	Pharmaceutical Excipients in Tablets	A	51
Q013	Tablet Manufacturing	B	52
Q015	Solutions, Suspensions and Emulsions	A	53
Q016	Ointments, Creams and Semisolid Preparations	A	54
Q017	Pharmaceutical Incompatibilities	A	55

Selected SEQ question index 3

Original Q numbers are unchanged. A = attempt first; B = wider coverage. Page references point to the question and its model answer.

SEQ	Topic	Priority	Page
Q042	Size Reduction, Trituration and Powder Mixing	A	56
Q222	Fluidised-Bed Drying of Pharmaceutical Materials	A	57
Q025	Storage, Packaging and Protection of Medicines	A	58
Q026	Sterilisation and Aseptic Processing	B	59
Q053	Quality Assurance, Quality Control and GMP	B	60
Q055	Cold-Chain Storage and Temperature Excursions	B	61
Q040	Metered-Dose Inhaler Technique and Device Counselling	B	62
Q057	Diabetes Medicines and Hypoglycaemia Safety	B	63
Q058	Asthma Medicines and Reliever/Controller Use	B	64
Q088	Anticoagulant and Antiplatelet Medicine Safety	B	65
Q029	Immunity and Infection Prevention	A	66
Q030	Crude Drugs and Natural Medicinal Products	A	67

Keep the index as a checklist. A question is complete only when you can answer it again without the model.

Understanding a Structured Essay Question

SEQ means Structured Essay Question. One question is divided into numbered subparts. Each subpart asks for a particular task, such as a definition, a list, an explanation or a calculation. Read and answer every subpart separately.

SEQ එකක ලොකු මාතෘකාවක් ගැන ඔබ දන්නා සියල්ල ලියන්න අවශ්‍ය නැහැ. එක් එක් උපප්‍රශ්නයෙන් ඉල්ලන දේ හඳුනාගෙන, ඒකට අදාළ පිළිතුරක් ලියන්න. එකම ප්‍රශ්නයේ උපප්‍රශ්නවල command words වෙනස් විය හැකියි.

Part of the question	What to look for
Stem or scenario	The situation and facts you must use
Subpart number	The exact part you are answering, for example 1.2
Command word	The action required, for example State or Explain
Topic and limits	What the answer must cover and any stated conditions
Number and marks	How many items are requested and the expected depth

Read a real example from Q001

1.2 State four circumstances in which a medicine may need to be recalled from the market. [8 marks]

මෙහි State යනු කරුණු දක්වන්න යන්නයි. Four නිසා එකිනෙකට වෙනස් circumstances හතරක් අවශ්‍යයි. Topic එක medicine recall. මෙහි recall එකේ definition එක පමණක් ලිවීමෙන් 1.2ට පිළිතුරු ලැබෙන්නේ නැහැ.

The useful plan is four distinct recall circumstances. Do not substitute the four statutory sources in Regulation 91 unless the question asks for those sources.

Exam focus Before writing, identify five things: subpart number, command, topic, requested number and marks.

Command words for short answers

The command word tells you the form of the answer. The guidance below describes usual teaching meanings. The wording of the actual question and its marking scheme still control the answer.

Command word	What the answer should do	How to approach it
Define	Give the precise meaning and essential feature.	අර්ථ දැක්වීම ලියන්න. උදාහරණ පමණක් ප්‍රමාණවත් නැහැ.
State	Give a clear, direct fact or point.	ඉල්ලන කරුණ සෘජුව දක්වන්න. අනවශ්‍ය හැඳින්වීමක් අවශ්‍ය නැහැ.
List or Name	Provide the requested items or names.	ඉල්ලන ගණනට වෙනස් items දෙන්න. එකම අදහස නැවත ලියන්න එපා.
Identify	Recognise and name the relevant item or issue.	දී ඇති තොරතුරුවලින් අදාළ දේ හඳුනාගෙන නම් කරන්න.
Outline	Give the main features or steps briefly.	ප්‍රධාන කරුණු හෝ පියවර කෙටියෙන් දක්වන්න.
Give examples	Supply valid examples of the requested category.	අදාළ category එකට ගැළපෙන උදාහරණ දෙන්න. Definition එක පමණක් ලියන්න එපා.

Notice the requested number

“State two records” needs two distinct records. “Give two examples” needs two examples. A broad phrase such as “keep details” is less useful than naming the exact information, such as the product/batch and the quantity recovered.

Command word එකට අමතරව two, four, reasons, examples, advantages සහ responsibilities වැනි වචනක් බලන්න. ඒවා පිළිතුරේ ගණන සහ වර්ගය තීරණය කරනවා.

Exam focus For a short list, use one clear item per line. Make each item specific enough to show what you mean.

Command words for developed answers

Command word	What to include	Useful writing pattern
Describe	An organised account of features, events or steps.	සිදුවීම හෝ පියවර අනුපිළිවෙළට දක්වන්න.
Explain	A fact linked to why or how it happens.	කරුණාට හේතුව හෝ ප්‍රතිඵලය සම්බන්ධ කරන්න.
Compare	Relevant similarities and differences on shared features.	එකම ලක්ෂණ යටතේ සමානකම් සහ වෙනස්කම් දක්වන්න.
Differentiate	Clear differences between the named items.	එකම ලක්ෂණයට අදාළව දෙපස වෙනස දක්වන්න.
Discuss	Relevant aspects, reasoning and a supported conclusion where needed.	අදාළ පැති හේතු සහිතව සාකච්ඡා කරන්න.
Justify	Support a decision with relevant reasons.	තීරණයට හේතු හෝ සාක්ෂි දක්වන්න.
Calculate	The method, working, final value and unit.	සූත්‍රය, පියවර, පිළිතුර සහ ඒකකය දක්වන්න.
Draw or Label	A clear relevant diagram with accurate labels.	රූපයක් ඇඳ ඉල්ලන කොටස් නම් කරන්න.

State and explain need different depth

State one action after a recall notice: "Quarantine the affected batch."

Explain that action: "Quarantine the affected batch to prevent further supply while the authorised recall instructions are carried out."

Explain අසන විට action එක නම් කිරීමෙන් නවතින්න එපා. එය කරන්නේ ඇයි, එයින් සිදුවන්නේ කුමක්ද කියා සම්බන්ධ කරන්න. Describe අසන විට පියවර නිවැරදි අනුපිළිවෙළට ලියන්න.

Exam focus "Because", "therefore" and "so that" can help connect ideas, but the reason itself must be accurate and relevant.

Planning the answer from numbers and marks

First follow the task and the requested number of items. Then use the marks to judge the detail needed. Do not assume that every sentence or bullet automatically earns one mark. The official marking scheme determines examination marks.

Worked planning example from Q001 part 1.2

The question asks for four recall circumstances and carries eight practice marks. Plan four different circumstances, described clearly enough to show the actual problem. These are example model points:

- 1 Contamination or failure of sterility.
- 2 Incorrect strength or active-ingredient content.
- 3 Incorrect or unsafe labelling or packaging.
- 4 A new safety signal showing an unacceptable risk.

“Quality problem”, “bad quality” සහ “quality defect” කියා ලිවීමෙන් වෙනස් circumstances තුනක් ලැබෙන්නේ නැහැ. නිශ්චිත defect එක නම් කරන්න. ඉල්ලන කරුණු හතර වෙන්ව පෙනෙන ලෙස ලියන්න.

Match the answer shape to the task

If asked for	A useful plan
A definition	Meaning plus the essential feature
Four reasons or examples	Four distinct relevant points
Three actions described	Three actions with enough detail to show how each is done
Two items differentiated	Shared comparison headings with both sides completed
A calculation	Working and units, followed by the requested result

අඩු ලකුණු ඇති කොටසකට දිගු essay එකක් ලියමින් අනෙක් කොටස් අතපසු කරන්න එපා. අදාළ කරුණු පැහැදිලිව ලියා, ඉතිරි උපප්‍රශ්න සඳහා කාලය තබාගන්න.

This example uses the original Q001 bank wording and lecturer practice marks. It is not an official CMCC marking allocation.

A practical method for writing SEQ answers

Read and plan before writing

Read the full question once. Check every subpart and its marks. Mark the command word and the number requested. Use any scenario facts. Make a brief plan, then answer with the correct subpart numbers.

Answer එක 1.1, 1.2 ලෙස නිවැරදි අංක යටතේ ලියන්න. ප්‍රශ්නයේ patient, batch, dose හෝ licence type ගැන දී ඇති තොරතුරු පිළිතුරට අදාළ නම් ඒවා යොදාගන්න.

Choose a method that fits the task

Task	Method
Law or pharmacy case	Identify the issue → give the applicable rule → state the action and reason.
Calculation	Write the quantity needed → convert units → show formula and substitution → check the result.
Comparison	Choose shared features → complete both sides under each feature.
Process	Give steps in a sensible order → include checks or precautions when requested.

Use the final check

Have I answered every subpart? Is the requested number complete? Are the points distinct? Does an explanation contain a reason? Are calculation units correct? Is the answer legible and inside the available space?

Current October 2026 examination notice

CMCC's current notice gives a 9:00 AM start, collection of MCQ materials at 11:30 AM and collection of SEQ scripts at 12:00 noon. There are five SEQs. Write legibly and concisely in the space provided and follow the paper and invigilator instructions.

මෙම ටිප්ප් එකේ practice timings ඉගෙනීම සඳහායි. විභාගයේදී එදින අදාළ නිල උපදෙස් පිළිපදින්න. පෙර විභාගයක කාල සීමාව මෙවරට ස්වයංක්‍රීයව යොදාගන්න එපා.

[E1] CMCC October 2026 Special Notice and examination procedure, checked 20 October 2026.

Calculation method and error checks

Task	Useful relationship	Check
Percentage w/v	$\text{grams} = \% \times \text{final mL} / 100$	% w/v means g per 100 mL
Ratio strength	1 in N w/v = 1 g in N mL	Keep units and basis consistent
Simple dilution	$C_1V_1 = C_2V_2$	Make up to final volume
Daily weight-based dose	$\text{mg/day} = \text{kg} \times \text{mg/kg/day}$	Divide by doses/day if required
Dose volume	$\text{mL/dose} = \text{mg/dose} \div \text{mg/mL}$	Use the actual stock strength
Salt from base	$\text{salt mass} = \text{base mass} \times \text{MW salt/MW base}$	Use the stated stoichiometry
Infusion	$\text{mL/hour} = \text{mL} \div \text{hours}$	Convert minutes before division
Drops/minute	$\text{mL} \times \text{drop factor} \div \text{minutes}$	Round to a practical whole number
Weak acid	$\text{ionised/unionised} = 10^{(\text{pH} - \text{pKa})}$	Convert ratio to fraction when asked
Acid buffer	$\text{pH} = \text{pKa} + \log_{10}(\text{salt/acid})$	Ratio and capacity are different

A consistent four-step method

1 Name the quantity and unit needed. 2 Convert to compatible units. 3 Show the formula, substitution and working. 4 Check the final size and unit.

mg/kg/day එකක් දීලා තිබෙන විට එය එක් dose එකකට යොදන්න එපා. Bottle ගණන සොයන විට අවශ්‍ය මුළු volume එක ලැබෙන සේ ඉහළට round කරන්න. Dilution එකක final volume එක සහ එකතු කරන diluent ප්‍රමාණය වෙන්කර හඳුනාගන්න.

Exam focus Practise Q018–Q023, Q048 and Q083. These are educational calculations, not doses for an actual patient.

NMRA 01 Three permissions and the purpose of NMRA

The National Medicines Regulatory Authority Act No 5 of 2015 creates the NMRA. Its public-health purpose includes access to efficacious, safe, good-quality therapeutic products at affordable prices and their rational use. Registration is one part of a wider system that also covers manufacture, import, storage, distribution, information and post-market control.

Institution	Main role	Do not confuse with
NMRA	Product and activity regulation; pharmacy premises licensing	The professional register of pharmacists
SLMC	Professional registration under the Medical Ordinance	A retail pharmacy premises licence
CMCC	External Pharmacists examination and relevant certification	Product registration or import permission

Pharmacist කෙනෙකුගේ professional registration එක, pharmacy premises licence එක සහ medicine product registration එක වෙනම අවසර තුනකි. එකක් තිබීමෙන් අනෙක් දෙක ස්වයංක්‍රීයව ලැබෙන්නේ නැහැ.

Five functions to explain

Evaluate and authorise products; license relevant premises and activities; monitor quality and safety; take regulatory action such as recall; and support rational use, education and appropriate local manufacture. Connect each function to patient protection rather than listing words without meaning.

Worked case

A newly registered pharmacist rents a shop and purchases registered medicines. Can the shop start trading immediately?

Reasoned response No. Professional status and product registration do not establish the shop's location approval, retail licence or other operational requirements. Obtain the appropriate premises/activity authorisation before operation.

Exam focus Apply the three checks to every case: PERSON → PREMISES AND ACTIVITY → PRODUCT AND SUPPLY ROUTE. Practise Q003, Q092 and Q271.

[N1] Act ss 2, 3, 14, 113, 119; Medical Ordinance professional registration provisions; existing NMRA seminar lessons 04 and 05.

NMRA 02 Authority membership divisions and technical advice

Authority membership in the 2015 Act

Section 4 provides 13 members: three ex officio and ten appointed. The ex officio members are the Director General of Health Services, the Secretary to the Treasury or nominee, and the CEO, who is Secretary to the Authority. The appointed group comprises four specialist clinicians, a pharmacology professor, a pharmacy professor or senior lecturer, and four eminent professionals.

The Minister appoints the Chairman from the appointed members in consultation with the Authority. The normal appointed term is three years; the Authority quorum is seven. Conflict-of-interest conditions in section 6 must be kept distinct from membership qualifications.

Body	Function to remember
Medicines Evaluation Committee	Evaluates efficacy, safety, quality, need and cost; provides technical recommendations
NMQAL	Tests submitted articles and reports analytical quality findings
Authority	Makes the applicable regulatory decision on the evidence
National Advisory Committee	Advises on policy and implementation; it is not the MEC

Divisions named by section 30

NMQAL; Medicines; Medical Devices; Borderline Products; Clinical Trials; Information Education Communication and Research; Inspectorate and Enforcement; Pharmacovigilance; Pharmacies; Manufacturing; and Organization Development. The Act also permits organisational changes; this statutory list is not a claim that the current office must always contain exactly eleven units.

NMQAL test report එකෙන් sample එකේ quality පිළිබඳ තොරතුරු ලැබෙනවා. MEC තාක්ෂණික ඇගයීම කරනවා. Regulatory decision එක Authority එකේ කාර්යයක්. මේවා එකම ආයතනයේ සමාන බලතල ලෙස ලියන්න එපා.

Exam focus Learn number with context: Authority 13 members; Authority quorum 7; MEC quorum 5 excluding Panel of Experts members. Practise Q271.

[N1] Act ss 4–6, 10, 30–37, 43–45; existing seminar lessons 06 and 07.

NMRA 03 Products quality and regulatory classification

Term	Meaning for an examination answer
Medicine	A substance/product within the statutory definition used for a therapeutic, preventive, diagnostic or relevant physiological purpose
Medical device	An instrument or related article with the intended medical purpose; its principal intended action is not achieved by pharmacological, immunological or metabolic means, although these may assist
Borderline product	A product whose characteristics place it at a regulatory boundary; the Authority's classification matters
Substandard	An authorised medical product that fails its quality standards/specifications
Falsified	A product deliberately or fraudulently misrepresenting identity, composition or source
Unregistered	Not evaluated/approved for the market under the applicable legal conditions

Do not assume a cream is a cosmetic from appearance alone. Composition, intended use, claims and mode of action help determine its regulatory route. Likewise, a poor-quality genuine product is not automatically falsified.

Substandard කියන්නේ නියමිත quality standard එකට නොගැළපීමයි. Falsified කියන්නේ identity, composition හෝ source ගැන හිතාමතා වැරදි නිරූපණයක් තිබීමයි. එකම product එකක ගැටලු කිහිපයක් තිබිය හැකි නමුත් මේ වචන සමාන පද නොවේ.

Registration is a wider assessment

The dossier addresses administrative accountability, manufacturing and pharmaceutical quality, safety/efficacy evidence, equivalence where relevant, stability

and product information. A passing laboratory test alone does not replace the wider authorisation decision.

Worked case

A product labelled “herbal” claims to treat a disease. Is it automatically outside all NMRA controls?

Reasoned response No. Do not use a blanket exemption. Check the statutory scope, composition/claims and the Authority’s classification, including the relevant system of medicine.

Exam focus Be precise about the question: define the legal term when asked for the Act definition; use quality terminology when asked about defects. Practise Q092 and Q271.

[N1] Act s 146 and applicable product chapters; [N5] WHO quality terminology; existing seminar lessons 08–10; audit findings F15–F19 and F28.

NMRA 04 Retail pharmacy licensing and renewal

From approval to operation

Seek NMRA location approval and premises assessment. Complete the retail application with the required ownership and Responsible Pharmacist details. Obtain the appropriate premises/activity authorisation before commencing operation.

Issue	Core distinction
Who may hold the retail licence	A Sri Lankan registered pharmacist, or a qualifying Sri Lankan-owned person/corporate body employing a registered pharmacist for the relevant operation
Premises and outlets	Each outlet requires the appropriate separate application/licence; one licence does not automatically cover other outlets
Transfer	Premises-specific authorisation is not casually transferable; prior written approval is required where specified
Professional work	The pharmacist must carry out/supervise the regulated professional functions; an apprentice is not an independent replacement

Two different renewal calendars

Authorisation	Rule in the named source
Retail pharmacy licence	2019 Regulation 101: one-year validity unless earlier suspended/cancelled; renewal application three months before expiry
Medicine registration/related licence	Act ss 64–65: use the relevant six-month-before-expiry renewal provision
Current application	Check the live NMRA pharmacy page, official checklist/portal and applicable fee notice

Retail pharmacy licence එක සහ medicine product registration එකේ renewal කාල සීමා එකට මිශ්‍ර කරන්න එපා. Licence type එක, expiry date එක සහ අදාළ source එක මුලින් ලියන්න.

Worked case

An owner says that employing a pharmacist removes the need for a retail licence.

Reasoned response Employment meets only one requirement. The premises, licence and operational conditions must also be satisfied.

Exam focus Verify current application procedures, forms and fees. Practise Q003 and Q062.

[N1] Act ss 113, 114, 119; [N2] rr 96–101; [N3] current pharmacy page; audit F29–F35.

NMRA 05 Medicine supply classes

Regulation 10 provides the supply framework below. The Authority's applicable Order supplies the individual product classifications. Do not assign a real medicine to a class from guesswork or from a loose OTC/POM label.

Class	Prescription	Who and where	Condition to retain
Schedule I	Not required	The specified premises licence exemption may apply	Original unopened manufacturer packs; normal stability and no special storage need

Class	Prescription	Who and where	Condition to retain
Schedule II Group A	Not required	Pharmacist in a licensed retail pharmacy	Pharmacy-only supply remains controlled
Schedule II Groups B and C	Valid prescription required	Pharmacist in a licensed retail pharmacy	Use an authorised prescriber and applicable prescription controls
Schedule III	Valid prescription required	Pharmacist in a licensed retail pharmacy	Apply additional relevant controlled-drug legislation

“Prescription අවශ්‍ය නැහැ” යන්නෙන් “මිනෑම කඩයකින් විකිණිය හැකියි” කියන අදහස ලැබෙන්නේ නැහැ. Schedule II A සඳහා licensed retail pharmacy එක සහ pharmacist අවශ්‍යයි.

Be clear which Schedule you mean

The schedules attached to the 2019 Regulations also contain application/licence forms. Their Schedule I form is not the same thing as Schedule I medicine supply classification in the Authority Order referred to by Regulation 10. Name the instrument and rule.

Worked case

An Authority-classified Schedule II A medicine is offered by an ordinary grocery because no prescription is required.

Reasoned response The proposed route does not satisfy the pharmacist and licensed retail premises requirements for that class. The absence of a prescription requirement does not remove those controls.

Exam focus A strong comparison uses the same headings for both classes: prescription, supplier, premises and special conditions. Practise Q004.

[N2] r 10; [N1] ss 54, 60, 113; existing seminar lesson 11.

NMRA 06 Prescriptions generic choice labels and electronic supply

Check the prescription and the patient

Verify patient and prescriber identity, authority/signature, date, medicine/strength/form, directions and quantity. Investigate unclear text or suspicious alteration. Then check allergies, indication, dose, interactions, contraindications and relevant patient factors. Authenticity and clinical suitability are separate checks.

Generic choice needs a suitable product

Distinguish the generic name from the brand name. The Act's generic-prescribing and patient-choice provisions do not authorise casual changes to dose, route or release characteristics. Confirm the appropriate active ingredient, strength, dosage form, release type, authorisation and any clinical or prescriber restrictions.

Labels must support actual use

A manufacturer label and a pharmacy dispensing label have different purposes. The dispensed pack should identify the patient and medicine and provide clear directions, relevant warnings, storage and in-use information under the applicable requirements. Explain abbreviations in ordinary language and use teach-back.

Abbreviation	Patient-facing meaning
b.i.d. / t.i.d.	Twice daily / three times daily, with the intended timing explained
q.h. / STAT	Every hour / immediately as directed
PO / PRN	By mouth / when required for the stated reason, with safe dose limits where prescribed

Messaging apps do not bypass controls

Check the lawful electronic/home-delivery route and any prior approval, identity, authenticity, completeness, secure records and medicine-specific restrictions. A photograph on a screen is not sufficient evidence on its own.

Prescription එකේ දෝෂයක් හෝ නොපැහැදිලි කොටසක් තිබේ නම් අනුමාන කර dispense කරන්න එපා. නිවැරදි channel එකෙන් clarification ලබාගෙන, කවුද කවදා මොනවා තහවුරු කළේද කියා record කරන්න.

Exam focus When explaining a decision, write the uncertainty, the verification action and the safe supply/referral outcome. Practise Q002, Q009, Q011 and Q065.

[N1] ss 54–60 and applicable supply provisions; [N2] electronic supply/retail provisions; [N3] pharmacy guidance; existing seminar lessons 12, 13, 16 and 17.

NMRA 07 Stock information special imports and donations

Storage and segregation

Buy through authorised traceable sources, inspect deliveries and follow each product's labelled storage conditions. Use expiry-based rotation where appropriate. Segregate suspect, expired, damaged, returned and recalled stock. A normal appearance does not prove that temperature-exposed stock is usable.

Advertising and claims

Apply the relevant approval and medicine-class restrictions. A social-media post can still be an advertisement. Educational wording does not excuse an unauthorised therapeutic claim or a misleading public promotion of a prescription-controlled product.

Exceptional import permission is purpose-specific

Normal registration/import requirements and exceptional permissions must be distinguished. A personal-use permission does not authorise routine retail resale. Check the patient, product, permitted quantity, purpose and conditions of the actual approval. Do not treat a trial import, donation approval or personal-use route as interchangeable.

Donations and physician samples

Assess the recipient's need, authorised source, registration/permission, batch and expiry, storage chain, suitable labelling and usable quantity. Reject unsuitable or untraceable products. A free price does not remove safety or legal requirements. Physician samples and State-marked goods must not be treated as ordinary private sale stock.

Donations ලැබෙන නිසාම stock එකට එක්කරන්න එපා. අවශ්‍යතාව, නිල අවසර, quality, expiry සහ traceability පරීක්ෂා කරන්න. අවසර ලැබුණු purpose එක වෙනස් කර සාමාන්‍ය retail sale කිරීම නිවැරදි යැයි නොසිතන්න.

Worked case

A donor offers a large amount of medicine with short remaining shelf life and no temperature history.

Reasoned response Estimate the quantity that can appropriately be used in time, verify the storage history and applicable approval, and document acceptance or rejection. Do not accept merely because it is free.

Exam focus A practical answer should state CHECK → HOLD IF UNCERTAIN → VERIFY → DOCUMENT → AUTHORISED DISPOSITION. Practise Q025, Q055 and Q123.

[N1] relevant quality, advertising and special-supply provisions; [N3–N4] official pharmacy, medicines and donation guidance; existing seminar lessons 20–24.

NMRA 08 Recall grounds and suspension

Meaning and scope

A recall removes or corrects an affected marketed medicine at the required supply-chain level because of a defect, safety concern or regulatory reason. It may concern part of a consignment, one batch, several batches or the whole product. Regulation 93 permits temporary or permanent removal, including correction of a labelling defect.

Section 108 action

Where a product fails the required standard or continued use creates serious health problems, section 108 provides for immediate cessation of distribution, withdrawal, notification to professionals/users and the prescribed disposition. Read the actual notice to identify its scope.

Four sources in Regulation 91

Source	What the answer should identify
1 Analyst evidence	Report/certificate of an Approved Analyst or Additional Approved Analyst
2 MEC	Recommendation of the Medicines Evaluation Committee
3 Safety committee	Recommendation of the Safety of Medicines and Risk Evaluation Sub Committee
4 External safety alert	Safety alert from WHO or another National Regulatory Agency

“Recall විය හැකි product problems හතරක්” අසන ප්‍රශ්නයන් “Regulation 91 අනුව grounds හතර” අසන ප්‍රශ්නයන් එකම පිළිතුරක් ඉල්ලන්නේ නැහැ. Contamination වැනි defect එකක් සහ recall තීරණයට හේතුවන statutory source එක වෙනස් ලෙස හඳුනාගන්න.

When suspension may be revoked

Under Regulation 95(2), the Authority must be satisfied that the manufacturer has taken adequate corrective and preventive actions, confirmed through a GMP inspection of the manufacturing plant. A manufacturer’s promise or a single satisfactory-looking pack is insufficient.

Exam focus For the January 2026 style response, retain adequate CAPA + confirmation by GMP inspection + Authority satisfaction. Practise Q001, then explain how its wording differs from a Regulation 91 question.

[N1] ss 65, 108; [N2] rr 90–95; existing seminar lessons 25 and 26; January 2026 SEQ Q1.

NMRA 09 Pharmacy recall response and pharmacovigilance

The pharmacy response in order

1 Verify product, strength, dosage form, batch, expiry and notice scope. 2 Stop affected supply and quarantine stock. 3 Reconcile quantities and relevant distribution/patient records. 4 Follow the notice for communication, return, recovery and disposition. 5 Record all actions and retain evidence of completion. Do not release stock without the required authorised decision.

Record	Reason
Product and batch	Identifies exactly what is affected
Received on hand supplied returned	Reconciles the stock and extent of recovery
Supplier and recipient contacts	Supports traceability and required communication
Dates actions and final disposition	Shows what was done and closes the action trail

Pharmacovigilance is not limited to confirmed causation

Document an identifiable patient and reporter, the suspected medicine and the reaction. Add onset, dose, route, dates, other medicines, relevant history and outcome. Report a clinically important suspected reaction through the current NMRA route; proof of causality is not required before a suspected report. Arrange urgent care first if necessary.

ADR එකක් suspected වුණාම report කළ හැකියි. “Unexpected” වීම සෑම ADR එකකම අනිවාර්ය කොන්දේසියක් නොවේ. Quality complaint එකක් report කිරීමටත් කෙනෙකුට හානි වන තුරු බලා සිටින්න අවශ්‍ය නැහැ.

Worked case

A recall identifies batch B07. The shop has B07 and B08. Can the pharmacist simply place B07 back because B08 looks normal?

Reasoned response No. Apply the notice to B07, quarantine it and follow the authorised instructions. The condition of B08 does not authorise release of B07.

Exam focus Regulation 94’s 24-hour voluntary-recall notification duty belongs to the certificate holder initiating that recall. Do not turn it into a universal deadline for every pharmacist ADR complaint. Practise Q001 and Q036.

[N2] rr 90–95; [N4] NMRA pharmacovigilance and recall information; existing seminar lessons 26 and 27; audit F26–F28.

NMRA 10 Authorized Officers sampling and evidence

Appointment and lawful powers

Section 124 provides Ministerial appointment from the listed categories: Provincial/Regional Directors of Health Services, Medical Officers of Health, Divisional Pharmacists, Food and Drugs Inspectors, Drugs Inspectors and pharmacists attached to the Authority. Being a pharmacist or staff member alone does not establish the statutory appointment.

Section 125 includes entry and examination at a reasonable hour in the stated circumstances, opening relevant receptacles, examining/copying records including electronic data, vehicle examination and sampling/seizure or detention subject to the law. Produce authority when required. The person in charge must provide reasonable assistance; obstruction or knowingly false information is prohibited.

Ordinary sample division and the exception

Route	Required distinction
Regulation 86	Notify intention to submit for analysis; divide into three sealed parts when division does not interfere with the test
Three destinations	Owner/person sampled; officer's retained court part; analyst's part under appropriate storage
Regulation 87 exception	Where division interferes with analysis, seal and forward the whole quantity as prescribed
Court retained sample	Section 127 has its own process, including the analyst response within 28 days of receipt

Sample එක හැමවිටම කොටස් තුනකට බෙදනවා කියා ලියන්න එපා. බේදීමෙන් analysis එකට බාධා වන අවස්ථාවට exception එක තිබෙනවා. Seals, labels, storage සහ chain of custody රැකගන්න.

Worked case

An appointed officer asks for invoice and batch records during a lawful inspection.

Reasoned response Verify authority when required, provide reasonable assistance and preserve accurate records. Do not obstruct, alter documents or tamper with detained stock.

Exam focus An inspection power is not a blanket power to impose a criminal fine or destroy every seized article. Follow the specific seizure and disposal provisions. Practise Q062 and Q272.

[N1] ss 124–130, 137–138; [N2] rr 85–89; existing seminar lessons 28 and 29; audit F32–F33.

NMRA 11 Offences and statutory maximum penalties

The court determines conviction and sentence. The following are maxima in the supplied 2015 Act, not automatic or universal fines. Read the offence-specific wording as well as the general section.

Offence	Maximum fine LKR	Maximum imprisonment	Act
Breach of the s 108(1) withdrawal order	1,000,000	3 years	s 108(3)
Offence involving injury to public health	200,000	3 years	s 131(1)(a)
Unauthorised State logo/mark use	100,000	3 years	s 131(1)(b)
Operating pharmacy without licence	100,000	3 years	s 131(1)(c)
Other offence first conviction	100,000	3 months	s 131(1)(d)(i)
Other offence second/subsequent conviction	200,000	6 months	s 131(1)(d)(ii)

The applicable provisions permit fine or imprisonment or both. Section 131 also contains public-apology and specified repeat-offence publication/cancellation provisions. Administrative licensing action and a criminal sentence are different processes.

A supplier invoice is not a complete defence

For the specific section 134 defence, the seller must meet the original-package/condition and reasonable-diligence conditions. Within 30 days of detection, written notice to the detecting Authorized Officer must identify the intended defence, supplier name/address and purchase date. A company also does not automatically shield relevant officers; section 136 contains its own consent/concurrence and due-diligence test.

“සෑම වරදකටම රු 100,000 සහ වසර 2” ලෙස මතක තබාගන්න එසා. Offence එක සහ අදාළ section එක අනුව maximum වෙනස් වෙනවා. Maximum එක සෑම අවස්ථාවකම අනිවාර්ය දඬුවමක් නොවේ.

Worked case

An inspector identifies expired stock and the owner immediately treats the table's maximum as a fixed on-the-spot fine.

Reasoned response That conclusion is wrong. Identify the actual offence and legal process. Distinguish immediate stock control, Authority licensing decisions and a court-imposed criminal penalty.

Exam focus Use “not exceeding” when explaining a statutory maximum. Do not invent a fixed penalty for every inspection finding.

[N1] ss 108, 130–136; existing seminar lesson 30; accuracy audit F01–F05.

NMRA 12 Appeals other powers and clinical trials

The general appeal route

Under section 122, first ask the Authority in writing to reconsider its decision within one month of receiving it. If dissatisfied with that decision, use the Appeals Committee route. One calendar month is not automatically the same as 30 days.

The Minister appoints the three-member Appeals Committee: a retired Supreme Court or Court of Appeal judge as Chairman, the Secretary of Health, and a distinguished retired Medical Consultant. The Committee communicates its decision to the Authority, which informs the appellant and acts accordingly.

Provision	Correct association
s 107	Residual shelf life of imported therapeutic products at entry; not the clinical-trial chapter
s 118	Pricing Committee and relevant pricing process; check current gazettes for actual prices
s 141	Rules made by the Authority with required Ministerial approval/publication
s 142	Regulations made by the Minister; Gazette and Parliamentary process apply
ss 144–145	Repeal and transitional continuity, subject to the specified conditions

Clinical trials use their own framework

Distinguish trial authorisation, ethics review, the investigational product and permission for ordinary retail marketing. Do not cite section 107 as the clinical-trial section. The 2019 Clinical Trials Regulations are a separate instrument from the Medicines Regulations. Do not teach blanket claims that every new medicine must undergo a local trial or that every research project has the same NMRA route.

Appeal එකක් දමා තිබීම පමණින් operating permission එක ස්වයංක්‍රීයව ලැබෙන්නේ නැහැ. Decision එක, එහි conditions සහ නීත්‍යනුකූලව වෙනස් කළ තත්ත්වය පරීක්ෂා කරන්න.

Worked case

An owner phones a friend about an adverse licence decision and calls that an appeal.

Reasoned response Use the written statutory route with grounds and supporting records. An informal request does not establish reconsideration or permission to disregard the decision.

Exam focus Learn the document name with the number: a section in the Act and a regulation in a Gazette are different references.

[N1] ss 107, 118, 122–123, 141–145; [N2] and Clinical Trials Regulations 2145/2; existing lesson 31; audit F06–F14.

NMRA 13 NMRA rapid recall and self check

Number or period	Applies to	Source
13 / 7	Authority membership / meeting quorum	Act ss 4 / 10
5	MEC quorum excluding expert-panel members	Act s 44
6 months before expiry	Relevant medicine registration/licence renewal	Act ss 64–65
3 months before expiry	Retail pharmacy licence renewal application	R r 101
1 year	Retail licence validity unless earlier action	R r 101
1 month from receipt	Written request for Authority reconsideration	Act s 122
24 hours after initiation	Certificate holder's voluntary-recall notification	R r 94
28 days from receipt	Analyst response for the retained court sample	Act s 127
30 days from detection	Written notice for the specific seller defence	Act s 134

Answer aloud without looking

1 Which institution maintains the pharmacist professional register? 2 Does Schedule II A permit ordinary grocery sale? 3 Does a normal-looking pack prove acceptable cold-chain quality? 4 Does a passing NMQL result issue registration? 5 Is the recall

24-hour rule a universal pharmacist ADR deadline? 6 Does every sample need division even if analysis is affected? 7 Who imposes a criminal sentence? 8 What comes before the general Appeals Committee route?

Check your answers

1 SLMC. 2 No: pharmacist and licensed retail pharmacy. 3 No: assess excursion data and authorised stability evidence. 4 No. 5 No: distinguish the certificate holder's voluntary recall. 6 No: the prescribed whole-sample exception applies. 7 The court. 8 Written reconsideration request to the Authority within the statutory month.

අංකය පමණක් මතක තබාගන්න එපා. කාටද අදාළ, කුමන ලියවිල්ලේද, කාලය ගණන් ගන්නේ කුමන සිදුවීමෙන්ද යන්නත් එකට කියන්න.

Exam focus Write the weakest three rules in your repair log and explain them again without the table. Recalling the reason is more useful than memorising an isolated number.

Revision of existing seminar lesson 33 and the corrected legal anchors used in lessons 01–12.

Q001 — Recall of Medicines and Regulatory Action

[20 marks]

Original EduRase SEQ300 number Q001 | Priority A | NMRA and pharmacy law

1.1 Define the term recall of a medicine. [4 marks]

1.2 State four circumstances in which a medicine may need to be recalled from the market. [8 marks]

1.3 State two responsibilities of a community pharmacist after receiving an authorised recall notice concerning a medicine stocked in the pharmacy. [4 marks]

1.4 State two records or items of information that should be maintained during the recall process. [4 marks]

Model answer and marking points

1.1 A recall is an organised removal or correction of an affected marketed medicine because of a quality defect, safety risk or regulatory reason. It may cover selected batches or the whole product and may be temporary or permanent.

1.2 Four examples: contamination or sterility failure; incorrect strength or composition; incorrect or unsafe labelling; and a serious safety concern. Where the question specifically asks for Regulation 91 grounds, use the four statutory sources listed in NMRA lesson 08.

1.3 Stop supply and quarantine the affected batch. Check the notice and stock records, then follow its return, notification and other instructions.

1.4 Record product and batch details, quantities received/remaining/returned, supplier, dates, action taken and relevant patient or distribution contacts.

මතක තබාගන්න Recall එකේ හේතුව, ක්‍රියාත්මක කරන පියවර සහ තබන records වෙන්කර ලියන්න. Regulation 91 අසන විට එහි නිශ්චිත grounds හතර දෙන්න.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q003 — Licensing and Operation of a Community Pharmacy [20 marks]

Original EduRase SEQ300 number Q003 | Priority A | NMRA and pharmacy law

- 3.1 State four areas that should be considered when determining whether premises are suitable for operation as a community pharmacy. [4 marks]
- 3.2 State four requirements or controls important for the lawful and safe operation of a licensed pharmacy. [8 marks]
- 3.3 State two responsibilities of the pharmacist relating to storage and control of medicines within the pharmacy. [4 marks]
- 3.4 State two consequences that may arise when a pharmacy is operated without complying with applicable regulatory requirements. [4 marks]

Model answer and marking points

- 3.1** Consider suitable location and layout; adequate clean space; appropriate storage and environmental control; and facilities for safe dispensing, security and patient communication.
- 3.2** Maintain the correct premises/activity licence; employ the registered Responsible Pharmacist for professional operations; obtain authorised, traceable stock; and follow prescription, storage, labelling and record requirements.
- 3.3** Maintain labelled storage conditions and monitor excursions. Segregate expired, damaged, returned or recalled stock and maintain traceable records.
- 3.4** Non-compliance can cause patient harm or product deterioration, regulatory suspension/cancellation and prosecution where an offence is established. A criminal penalty is imposed by the court, not automatically by an inspector.

මතක තබාගන්න Person registration, premises licence සහ product registration එකිනෙකට වෙනස් බව සම්බන්ධ කර ලියන්න.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q004 — Legal Classification and Supply of Medicines

[20 marks]

Original EduRase SEQ300 number Q004 | Priority A | NMRA and pharmacy law

- 4.1 State the main purpose of legally classifying medicines according to the level of control required for their supply. [4 marks]
- 4.2 Using the current applicable medicines legislation and regulations, select two classes of medicines subject to different levels of control and differentiate them under four suitable headings. [8 marks]
- 4.3 State two responsibilities of a pharmacist when supplying a medicine subjected to prescription control. [4 marks]
- 4.4 Explain why the legal classification of a medicine should be confirmed from an authorised current source when there is uncertainty. [4 marks]

Model answer and marking points

- 4.1** Classification matches supply restrictions to risk, professional supervision and the need for an authorised prescription; it supports safe and rational medicine use.
- 4.2** Compare Schedule II Group A with Schedule II Group B/C under Regulation 10. Prescription: not required for II A, required for II B/C. Supplier: pharmacist in both. Premises: licensed retail pharmacy in both. Control: pharmacy-only non-prescription supply versus prescription-controlled supply. Medicine-specific classification must be verified.
- 4.3** Verify prescription authenticity and clinical appropriateness. Supply, label, counsel and document according to the applicable class and other controls.
- 4.4** Classification and conditions can change. An old pack, advertisement or informal OTC label does not establish current lawful supply status.

මතක තබාගන්න Prescription අවශ්‍ය නැති සියලු ඖෂධ සාමාන්‍ය කඩයක විකිණිය හැකි බව ලියන්න එපා.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q011 — Electronic / Messaging-App Prescription Scenario [20 marks]

Original EduRase SEQ300 number Q011 | Priority B | NMRA and pharmacy law

A patient arrives at a community pharmacy and displays on a mobile phone an image of a prescription sent through a messaging application.

11.1 State four matters that should be checked before deciding whether the prescription can lawfully and safely be used for dispensing. [4 marks]

11.2 Describe three reasons why an image displayed on a mobile phone may require additional verification. [6 marks]

11.3 Describe three actions the pharmacist should take when authenticity or legal validity cannot be confirmed. [6 marks]

11.4 State two items that should be documented when clarification is obtained from an authorised prescriber or other authorised source. [4 marks]

Model answer and marking points

11.1 Check the authorised electronic-supply route and any required prior approval; prescriber identity; patient identity and complete prescription details; and authenticity, current validity and medicine-specific restrictions.

11.2 An image can be altered, incomplete or unclear. The same image may be reused at several pharmacies. The sender or apparent signature may not establish the prescriber's identity.

11.3 Pause the affected supply, verify through an independent reliable prescriber channel, and document or refer if the uncertainty cannot be resolved. Urgency does not remove the need for a lawful safe route.

11.4 Record who was contacted and when, what was confirmed, the authorised directions and the supply/referral decision. A phone image alone is not a blanket authorisation.

මතක තබාගන්න WhatsApp image එකක් තිබීම පමණින් dispensing අවසර ලැබෙන්නේ නැහැ.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q036 — Pharmacovigilance and Suspected Adverse Drug Reactions [20 marks]

Original EduRase SEQ300 number Q036 | Priority B | NMRA and pharmacy law

36.1 Define pharmacovigilance. [4 marks]

36.2 State six items of information that are useful when documenting a suspected adverse drug reaction. [6 marks]

36.3 Describe three actions a pharmacist should take after identifying a clinically important suspected adverse drug reaction. [6 marks]

36.4 State two public-health benefits of reporting suspected adverse drug reactions. [4 marks]

Model answer and marking points

36.1 Pharmacovigilance is the science and activities of detecting, assessing, understanding and preventing adverse effects and other medicine-related problems.

36.2 Useful fields: patient details, reaction/onset, suspected medicine with dose/route and dates, other medicines, relevant history and outcome. Include an identifiable reporter and batch details where relevant.

36.3 Assess urgency and arrange care; review the medicines and possible causes without unsafe abrupt withdrawal of essential therapy; document and report through the current NMRA route. Suspected causality is sufficient to report.

36.4 Reports help detect rare or new risks and support regulatory warnings, risk reduction and safer medicine use. A report is not by itself proof that the medicine caused the event.

මතක තබාගන්න ADR report කිරීමට හේතුව සම්පූර්ණයෙන් ඔප්පු කරන තුරු බලා සිටීමට අවශ්‍ය නැහැ.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q062 — Pharmacy Inspection, Non-Compliance and Corrective Action [20 marks]

Original EduRase SEQ300 number Q062 | Priority B | NMRA and pharmacy law

62.1 State four areas that may be reviewed during a regulatory or professional inspection of a community pharmacy. [4 marks]

62.2 State four examples of pharmacy non-compliance that may compromise medicine quality, patient safety or lawful operation. [8 marks]

62.3 Describe two immediate actions that should be taken after a significant non-compliance is identified. [4 marks]

62.4 State two features of an effective corrective and preventive action (CAPA) plan. [4 marks]

Model answer and marking points

62.1 Inspectors may assess current premises/licence and pharmacist arrangements; stock/source traceability; storage and cleanliness; and prescription, labelling and record systems.

62.2 Examples: unauthorised operation; expired or recalled stock mixed with usable stock; temperature failures without assessment; and inappropriate prescription-only supply. Explain the safety or legal consequence of each.

62.3 Stop or contain the unsafe activity and segregate affected products. Notify the responsible person/authority as appropriate, document the issue and implement authorised correction.

62.4 A CAPA plan identifies the root cause and assigns a responsible person, deadline and measurable action. Verify effectiveness and keep evidence, rather than merely promising improvement.

මතක තබාගන්න CAPA එකේ root cause, action, responsible person සහ effectiveness check එක තිබිය යුතුයි.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q092 — Registration and Marketing Authorisation of Medicines [20 marks]

Original EduRase SEQ300 number Q092 | Priority A | NMRA and pharmacy law

92.1 State four purposes of requiring medicines to be registered or otherwise authorised before lawful marketing and supply. [4 marks]

92.2 List four categories of information that a regulatory authority may require when assessing a medicine for registration or marketing authorisation. [8 marks]

92.3 State two responsibilities of a pharmacy when there is uncertainty about whether a marketed medicine is currently authorised for supply. [4 marks]

92.4 State two reasons why a current regulatory source should be checked rather than relying only on an old package, advertisement or past-paper statement. [4 marks]

Model answer and marking points

92.1 Authorisation evaluates quality, safety and efficacy/benefit-risk; verifies identity and formulation; controls product information; and establishes accountable post-market responsibilities.

92.2 Four dossier groups: applicant/manufacture and administrative data; quality/manufacture/specifications/stability; non-clinical and clinical safety/efficacy or equivalence evidence; and labelling/product information with relevant pharmacovigilance data.

92.3 Hold the uncertain product from supply. Verify current NMRA status, the authorised source and any exceptional approval or restrictions, keeping the evidence.

92.4 Registration may be suspended, cancelled or varied. An old pack/advertisement does not prove current authorisation, correct ownership or permitted supply conditions.

මතක තබාගන්න Old package එකක් තිබීම වර්තමාන authorisation එකට සාක්ෂියක් නොවේ.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q123 — Medicine Samples, Donations and Promotional Supply Controls [20 marks]

Original EduRase SEQ300 number Q123 | Priority B | NMRA and pharmacy law

123.1 State four risks associated with accepting or supplying medicines solely because they were provided as free samples or donations. [4 marks]

123.2 Describe four checks that should be completed before a donated or promotional medicine is considered suitable for lawful and safe use. [8 marks]

123.3 State two ethical principles that should guide a pharmacist when a commercial promotion conflicts with the patient's best interest. [4 marks]

123.4 State two reasons why untraceable or inadequately documented donated medicines should not enter normal pharmacy stock. [4 marks]

Model answer and marking points

123.1 Risks include short expiry, unsuitable medicines, unknown storage, poor traceability and inappropriate promotional influence. A free product can still be unsafe or unlawful.

123.2 Verify authorised source/approval; product, batch, expiry and pack integrity; storage history; and recipient need, usable quantity, labelling and the applicable sample/donation rules. Document acceptance or rejection.

123.3 Apply beneficence and non-maleficence: select for patient need and safety. Justice, transparency and professional independence prevent commercial incentives from overriding that decision.

123.4 Unknown history prevents quality assessment. Missing records obstruct recall and accountability. Physician samples are not ordinary sale stock; a "donation" label does not waive controls.

මතක තබාගන්න Donation හෝ sample යන නම නිසා quality, legality සහ traceability පරීක්ෂාව අත්හැරිය නොහැකියි.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q271 — National Medicines Regulatory Authority and National Medicines Quality Assurance Laboratory: Regulatory Roles [20 marks]

Original EduRase SEQ300 number Q271 | Priority B | NMRA and pharmacy law

271.1 State four broad regulatory functions of the National Medicines Regulatory Authority in relation to therapeutic products. [4 marks]

271.2 State three functions of the National Medicines Quality Assurance Laboratory. [6 marks]

271.3 Explain three situations in which regulatory and laboratory functions must work together. [6 marks]

271.4 State two reasons why a pharmacist should distinguish regulatory authorisation from laboratory quality testing. [4 marks]

Model answer and marking points

271.1 NMRA functions include registration/authorisation; licensing and inspection; post-market safety/quality control including recalls; and regulation of product information, pricing and other activities within its statutory mandate.

271.2 NMQUAL tests regulatory samples; assesses compliance with quality standards; and supports investigation of quality complaints or suspected falsification, reporting analytical findings.

271.3 The two work together for registration-sample assessment, post-market surveillance and quality-defect/recall investigations. The Authority considers analytical evidence together with other regulatory evidence.

271.4 A laboratory test concerns the sample and tested parameters. Market authorisation is a wider legal decision; a passing test neither issues a product registration nor authorises an unlicensed pharmacy.

මතක තබාගන්න NMQUAL laboratory report එකක් product registration හෝ pharmacy licence එකකට සමාන නොවේ.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q272 — Authorised Officers, Inspection Powers and Evidence Handling [20 marks]

Original EduRase SEQ300 number Q272 | Priority A | NMRA and pharmacy law

272.1 Define the role of an authorised regulatory officer in general terms. [4 marks]

272.2 State three types of action an authorised officer may be empowered to take during a lawful inspection or investigation, subject to the current Act and regulations. [6 marks]

272.3 Describe three principles for collecting, sealing, documenting or transferring a regulatory sample or other evidence. [6 marks]

272.4 State two reasons why exact enforcement powers must be checked against the current legislation rather than memorised from an old past paper. [4 marks]

Model answer and marking points

272.1 An Authorized Officer is a person formally appointed under the applicable law to carry out specified inspection, sampling or enforcement functions. For the NMRA Act use the Minister's appointment under section 124.

272.2 Section 125 includes entry/examination at a reasonable hour, examination/copying of relevant records, and sampling or seizure/detention within the stated conditions. A job title alone does not confer every enforcement power.

272.3 Identify the product, batch, source and time; seal/label and document correctly; and preserve storage conditions and a traceable chain of custody. Use the sample-division rule and its exception correctly.

272.4 Powers and conditions are specific and may change. Exceeding powers or mishandling evidence can undermine enforcement and patient protection.

මතක තබාගන්න Officerගේ appointment සහ අදාළ powers වෙනිකර මතක තබාගන්න. Evidence chain එක රැකගන්න.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q002 — Authenticity and Legality of a Prescription

[20 marks]

Original EduRase SEQ300 number Q002 | Priority A | Dispensing and patient communication

A patient presents a prescription for a prescription-only medicine. The pharmacist notices that some information on the prescription is unclear.

- 2.1 State four basic features that should be checked when assessing the legality and authenticity of a prescription. [4 marks]
- 2.2 State six additional patient- or medicine-related checks that should be completed before dispensing. [6 marks]
- 2.3 Describe three actions that should be taken when an important item on the prescription cannot be verified. [6 marks]
- 2.4 State two reasons why a pharmacist should not guess or independently alter an unclear prescription. [4 marks]

Model answer and marking points

- 2.1** Check patient identity; an authorised identifiable prescriber and authentic signature/authentication; date; and clear medicine, strength, dose, directions and quantity. Check suspicious alterations and any applicable validity condition.
- 2.2** Six checks: indication; allergies; age and weight when relevant; dose and frequency; interactions or duplication; and contraindications. Renal function, pregnancy, treatment duration and dosage form may also matter.
- 2.3** Withhold the affected supply while a material safety or legal uncertainty remains. Contact the prescriber through a reliable channel. Record the clarification, decision and follow-up or referral.
- 2.4** Guessing may harm the patient. Unauthorised alteration also breaches accountability and may breach legal or professional requirements.

මතක තබාගන්න Prescription එක පැහැදිලිව කියවිය හැකි වීම පමණක් ප්‍රමාණවත් නැහැ. Authenticity සහ clinical safety දෙකම පරීක්ෂා කරන්න.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q006 — Professional Ethics in Medicine Supply [20 marks]

Original EduRase SEQ300 number Q006 | Priority A | Dispensing and patient communication

6.1 State four ethical principles relevant to professional pharmacy practice. [4 marks]

A regular customer asks the pharmacist to supply a medicine without the documentation normally required. The customer states that the medicine has been used previously and promises to bring the required documentation later.

6.2 Discuss four ethical or professional considerations that should guide the pharmacist's decision. [8 marks]

6.3 State two appropriate actions the pharmacist may take to assist the patient without compromising professional standards. [4 marks]

6.4 State two reasons why maintaining patient confidentiality is important in pharmacy practice. [4 marks]

Model answer and marking points

6.1 Autonomy; beneficence; non-maleficence; justice. Confidentiality, honesty and professional independence are also relevant duties.

6.2 Apply beneficence by helping the patient obtain appropriate treatment; non-maleficence by avoiding unsafe supply; justice by applying controls fairly; and professional accountability by checking the required documentation. Familiarity with the customer is not proof of lawful supply.

6.3 Contact the authorised prescriber or arrange appropriate referral. Explain lawful alternatives and the steps needed to obtain valid documentation, with a record of the decision.

6.4 Confidentiality protects privacy and trust. Share information only on a valid basis and only to the necessary extent.

මතක තබාගන්න Ethical principle එකේ නම සමඟ මේ සිද්ධියේ එය යොදන ආකාරයත් ලියන්න.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q009 — Patient Counselling and Written Medicine Information [20 marks]

Original EduRase SEQ300 number Q009 | Priority A | Dispensing and patient communication

9.1 State four objectives of counselling a patient when a medicine is supplied. [4 marks]

9.2 List six important areas of information that should normally be considered when counselling a patient about a newly prescribed medicine. [6 marks]

9.3 State three characteristics of effective written medicine information provided to a patient. [6 marks]

9.4 Explain two methods that a pharmacist can use to confirm that the patient has understood the instructions. [4 marks]

Model answer and marking points

9.1 Promote correct use, improve adherence, reduce avoidable harm and help the patient recognise when to seek advice.

9.2 Explain purpose/name; dose and timing; route and administration; duration; important adverse effects and action; and interactions/precautions. Add storage and missed-dose advice appropriate to the medicine.

9.3 Written information should be accurate and medicine-specific, readable in language the patient understands, and clear about essential actions and warnings.

9.4 Use teach-back: ask the patient to explain the plan in their own words. Ask for a demonstration when a device or measuring technique is involved, then correct errors.

මතක තබාගන්න “තේරුණාද” කියා ඇසීමට වඩා රෝගියාට උපදෙස් නැවත කියන්න හෝ කර පෙන්වන්න කියන්න.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q010 — Antibiotic Dispensing and Counselling [20 marks]

Original EduRase SEQ300 number Q010 | Priority A | Dispensing and patient communication

A patient presents a valid prescription for an oral antibiotic.

10.1 State four items that should be checked before the antibiotic is dispensed. [4 marks]

10.2 Describe six counselling points that should be given to improve safe and effective use of the antibiotic. [6 marks]

10.3 State three practices that contribute to inappropriate antibiotic use and explain briefly why each should be avoided. [6 marks]

10.4 State two situations during antibiotic treatment in which the patient should be advised to obtain further professional or medical assessment. [4 marks]

Model answer and marking points

10.1 Check the valid prescription and indication, allergy history, dose/strength/formulation, and important interactions or patient factors such as renal function.

10.2 Explain the correct dose and interval; prescribed duration; administration/food instructions for that product; suitable missed-dose action; important adverse effects and referral signs; and product-specific storage or reconstitution. Follow the prescribed course unless an authorised clinician changes it.

10.3 Avoid non-indicated or unauthorised use, which exposes patients to harm and selects resistance; sharing/using leftovers, which may give the wrong treatment; and inappropriate dose or duration, which can cause treatment failure or toxicity.

10.4 Urgent assessment is needed for breathing difficulty, facial swelling or other severe allergy signs. Seek review for severe/persistent diarrhoea, deterioration or failure to improve as expected.

මතක තබාගන්න Antibiotic එකට අදාළ food, storage සහ duration උපදෙස් වෙන වෙනම පරීක්ෂා කරන්න.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q065 — Dispensing Labels, Auxiliary Labels and Safe Packaging [20 marks]

Original EduRase SEQ300 number Q065 | Priority B | Dispensing and patient communication

65.1 State six items of information that should normally be considered for inclusion on a dispensed-medicine label, subject to current applicable requirements. [6 marks]

65.2 Give three examples of auxiliary instructions that may be necessary on medicine labels and state the purpose of each. [6 marks]

65.3 State two factors that should be considered when selecting a container for a dispensed medicine. [4 marks]

65.4 State two reasons why the final labelled package should be checked against the prescription before supply. [4 marks]

Model answer and marking points

65.1 Consider patient name; medicine name/strength/form; dose; route/frequency and other clear directions; quantity and relevant dates; and dispensing pharmacy/contact details. Include storage, warnings and in-use period as applicable under current requirements.

65.2 “Shake well” redistributes a suspension. “For external use only” reduces wrong-route use. “May cause drowsiness” warns about driving/machinery when relevant. Use the instruction appropriate to the product, not every warning on every pack.

65.3 Consider compatibility/protection against light, moisture or evaporation, and a suitable secure closure that the patient can use. Route, sterility needs and child safety also matter.

65.4 The final check detects wrong patient/product/strength/quantity. It also confirms that the label agrees with the authorised prescription and gives understandable safe directions.

මතක තබාගන්න PRN වැනි කෙටි යෙදුම් පමණක් නොදී රෝගියාට තේරෙන පැහැදිලි directions ලියන්න.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q018 — Concentration and Dilution Calculations [20 marks]

Original EduRase SEQ300 number Q018 | Priority A | Calculations and physical pharmacy

Show all calculations and units.

18.1 Calculate the quantity of drug required to prepare 250 mL of a 3.2% w/v solution. [6 marks]

18.2 Calculate the volume of a 1 in 500 stock solution required to prepare 600 mL of a 1 in 2500 solution. [6 marks]

18.3 Express a 1 in 2000 w/v solution as a percentage strength. [4 marks]

18.4 State two precautions that reduce calculation or measurement errors when preparing a dilution from a concentrated stock solution. [4 marks]

Model answer and marking points

18.1 $3.2 \text{ g per } 100 \text{ mL} \times 250 \text{ mL} = 8.0 \text{ g}$. Dissolve and make up to a final volume of 250 mL.

18.2 Drug needed = $600/2500 = 0.24 \text{ g}$. Stock contains 1 g per 500 mL, so stock volume = $0.24 \times 500 = 120 \text{ mL}$. Dilute to 600 mL final volume.

18.3 $1 \text{ g in } 2000 \text{ mL} = 0.05 \text{ g in } 100 \text{ mL} = 0.05\% \text{ w/v}$.

18.4 Independently check units, concentration and arithmetic. Use calibrated equipment and make up to final volume; do not assume the final volume equals the volume of water added.

මතක තබාගන්න Dilute to final volume යන්න සහ add that much water යන්න එකම දෙයක් නොවේ.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q019 — Paediatric Dose and Dose-Volume Calculation [20 marks]

Original EduRase SEQ300 number Q019 | Priority A | Calculations and physical pharmacy

A child weighing 24 kg is prescribed a medicine at 15 mg/kg/day, administered in three equally divided doses. The medicine is available as an oral liquid containing 125 mg in 5 mL.

19.1 Calculate (a) the total daily dose in mg, (b) the amount of drug in mg per dose, and (c) the volume in mL required per dose. [8 marks]

19.2 Calculate the minimum total volume of medicine required for five complete days of treatment, assuming no wastage. [6 marks]

19.3 State three checks that should be completed before supplying a paediatric liquid medicine based on a calculated dose. [6 marks]

Model answer and marking points

19.1 Daily dose = $24 \times 15 = 360$ mg/day. Each of three doses = $360/3 = 120$ mg.
Concentration = $125/5 = 25$ mg/mL. Volume = $120/25 = 4.8$ mL per dose.

19.2 Five days $\times$ three doses = 15 doses. Required volume = $15 \times 4.8 = 72$ mL, assuming no wastage.

19.3 Verify current weight and mg/kg/day versus mg/kg/dose; check the prescribed indication, safe dose/maxima and patient factors; verify the actual product strength, duration and an appropriate measuring device. This question supplies a hypothetical dose, not a treatment recommendation.

මතක තබාගන්න mg/kg/day සහ mg/kg/dose අතර වෙනස මුලින් බලන්න. දිනපතා dose එක බෙදීමට අමතක කරන්න එපා.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q020 — Drug Base and Salt Calculations [20 marks]

Original EduRase SEQ300 number Q020 | Priority A | Calculations and physical pharmacy

A prescription requires 180 mg of a drug expressed as the active base. The available material is the hydrochloride salt. The molecular weight of the base is 300 and that of the hydrochloride salt is 360.

20.1 Calculate the mass of the hydrochloride salt required to provide 180 mg of active base. [8 marks]

20.2 Calculate the amount of active base present in 300 mg of the hydrochloride salt. [6 marks]

20.3 State three pharmaceutical reasons why a drug may be formulated and supplied as a salt rather than as the free acid or free base. [6 marks]

Model answer and marking points

20.1 Assuming one active-base molecule per salt molecule: salt required = $180 \times 360/300$ = 216 mg hydrochloride salt.

20.2 Base equivalent = $300 \times 300/360$ = 250 mg active base.

20.3 A suitable salt can improve solubility/dissolution, improve stability, or facilitate crystallisation/handling and manufacture. The effect depends on the particular salt; no salt improves every property.

මතක තබාගන්න Salt mass සොයන විට $MW \text{ salt} \div MW \text{ base}$ යොදන්න. ලැබෙන mass එක base mass එකට වඩා වැඩි වීම මෙහි සාධාරණයි.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q021 — Infusion and Flow-Rate Calculations [20 marks]

Original EduRase SEQ300 number Q021 | Priority B | Calculations and physical pharmacy

Show all calculations and units.

21.1 An intravenous infusion containing 750 mL is to be administered over 6 hours. Calculate the infusion rate in mL/hour. [4 marks]

21.2 The infusion set delivers 20 drops/mL. Calculate the required rate in drops/minute. Give an appropriate whole-number answer. [4 marks]

21.3 A second infusion of 100 mL must be administered over 30 minutes. Calculate the rate in mL/hour. [6 marks]

21.4 State three factors, other than the mathematical calculation itself, that should be checked before an infusion rate is applied to a patient. [6 marks]

Model answer and marking points

21.1 $750 \text{ mL} / 6 \text{ hours} = 125 \text{ mL/hour}$.

21.2 $6 \text{ hours} = 360 \text{ minutes}$. Rate = $750 \times 20 / 360 = 41.67 \text{ drops/minute}$, approximately 42 drops/minute.

21.3 $30 \text{ minutes} = 0.5 \text{ hours}$. Rate = $100/0.5 = 200 \text{ mL/hour}$.

21.4 Verify patient, medicine/solution and dose; correct route, access, compatibility and delivery device; and clinical fluid limits plus monitoring. A mathematically correct rate can still be clinically inappropriate.

මතක තබාගන්න Hours සහ minutes එකම equation එකට යොදන විට units නිවැරදිව මාරු කරන්න.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q022 — pH, pKa and Drug Ionisation [20 marks]

Original EduRase SEQ300 number Q022 | Priority A | Calculations and physical pharmacy

22.1 Define (a) pH and (b) pKa. [4 marks]

22.2 Using the Henderson-Hasselbalch relationship, calculate the ratio of ionised to unionised drug for a weak acid having a pKa of 4.8 at a pH of 6.8. [8 marks]

22.3 Calculate the approximate percentage of the drug that is in the ionised form under the conditions in Question 22.2. [4 marks]

22.4 State two ways in which drug ionisation may influence a pharmaceutical or biological property of a drug. [4 marks]

Model answer and marking points

22.1 pH is the negative base-10 logarithm of hydrogen-ion activity. pKa is $-\log_{10} K_a$ and describes acid dissociation strength; when the relevant conjugate forms are equal, pH equals pKa.

22.2 For a weak acid: $\text{pH} = \text{pKa} + \log_{10}([A^-]/[HA])$. Thus ionised/unionised = $10^{(6.8 - 4.8)} = 100:1$.

22.3 Ionised percentage = $100/(100 + 1) \times 100 = 99.01\%$, approximately 99%.

22.4 Ionisation changes aqueous solubility and passive lipid-membrane permeation. It can also influence distribution/excretion. Absorption is not determined by pH alone.

මතක තබාගන්න Weak acid සඳහා ionised/unionised = $10^{(\text{pH} - \text{pKa})}$. Ratio එක percentage එකක් නොවේ.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q023 — Pharmaceutical Buffers [20 marks]

Original EduRase SEQ300 number Q023 | Priority A | Calculations and physical pharmacy

23.1 Define a buffer solution. [4 marks]

23.2 State three reasons for using buffers in pharmaceutical formulations. [6 marks]

23.3 State three factors that influence the pH or buffering performance of a pharmaceutical buffer system. [6 marks]

23.4 A weak acid has a pKa of 4.76. Calculate the required ratio of salt : acid to prepare a buffer of pH 5.06, using the Henderson-Hasselbalch equation. [4 marks]

Model answer and marking points

23.1 A buffer contains a weak acid/base and its conjugate partner and resists substantial pH change after small additions of acid or alkali within its useful range.

23.2 Buffers may improve chemical stability, maintain solubility and support suitable tolerability or preservative performance. Choose the system and capacity for the product.

23.3 pH depends on conjugate-pair ratio and pKa, which can vary with temperature/ionic conditions. Total concentration mainly affects buffer capacity; added acid/alkali and dilution affect performance.

23.4 $5.06 = 4.76 + \log_{10}(\text{salt/acid})$. Ratio = $10^{0.30} = 1.995$, approximately 2:1 salt to acid.

මතක තබාගන්න Buffer pH සහ buffer capacity එකම සංකල්පය නොවේ. Ratio එක සහ total concentration එකේ භූමිකා වෙන් කරන්න.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q048 — Alligation and Strength Adjustment [20 marks]

Original EduRase SEQ300 number Q048 | Priority B | Calculations and physical pharmacy

48.1 Using alligation, calculate the quantities of a 20% w/w ointment and a 2% w/w ointment required to prepare 500 g of an 8% w/w ointment. [10 marks]

48.2 Verify the final strength by calculating the total mass of active ingredient contributed by the two components. [6 marks]

48.3 State two practical precautions when combining the two ointments to obtain a uniform final product. [4 marks]

Model answer and marking points

48.1 Parts of 20% = $8 - 2 = 6$. Parts of 2% = $20 - 8 = 12$. Ratio = 1:2. For 500 g: 20% ointment = 166.67 g; 2% ointment = 333.33 g.

48.2 Drug mass = $(0.20 \times 166.67) + (0.02 \times 333.33) = 40.00$ g approximately. Strength = $40/500 \times 100 = 8.00\%$ w/w.

48.3 Weigh accurately and incorporate portions thoroughly using a suitable method. Check base compatibility, avoid transfer losses and inspect uniformity. Round only at the final practical weighing step.

මතක තබාගන්න Alligation ratio එක යොදලා අවසානයේ active mass එකෙන් strength එක නැවත තහවුරු කරන්න.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q083 — Reconstituted Oral Antibiotic: Course Quantity Calculation [20 marks]

Original EduRase SEQ300 number Q083 | Priority A | Calculations and physical pharmacy

83.1 After reconstitution, an oral liquid contains 250 mg in 5 mL and each bottle contains 100 mL. A patient is prescribed 375 mg every 8 hours for 7 days. Calculate the volume required per dose. [4 marks]

83.2 Calculate the total volume required for the complete 7-day course, assuming no wastage. [6 marks]

83.3 Calculate the minimum number of 100 mL bottles that must be supplied. [4 marks]

83.4 Calculate the total mass of active drug, in mg, administered over the 7-day course. [4 marks]

83.5 State one final check that should be made when interpreting a reconstituted-product label. [2 marks]

Model answer and marking points

83.1 Concentration = $250/5 = 50$ mg/mL. Dose volume = $375/50 = 7.5$ mL.

83.2 Every 8 hours means 3 doses/day. Total = $7 \times 3 \times 7.5 = 157.5$ mL.

83.3 $157.5/100 = 1.575$ bottles; round up to 2 bottles of 100 mL.

83.4 Total drug = $375 \times 3 \times 7 = 7875$ mg.

83.5 Check that the strength and final volume apply after reconstitution; confirm the product's in-use period covers the course or arrange an appropriate staged supply. Follow product-specific storage instructions.

මතක තබාගන්න Every 8 hours = දිනකට doses 3යි. Bottle ගණන සොයන විට ඉහළ සම්පූර්ණ අගයට round කරන්න.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q012 — Pharmaceutical Excipients in Tablets [20 marks]

Original EduRase SEQ300 number Q012 | Priority A | Pharmaceutics and compounding

12.1 Define the term pharmaceutical excipient. [2 marks]

12.2 For each of the following excipient classes, state its principal function and give one suitable example: (a) diluent/filler, (b) binder, (c) disintegrant, (d) lubricant. [8 marks]

12.3 State three additional properties or functions that excipients may provide in a tablet formulation. Give one suitable example for each. [6 marks]

12.4 Explain two ways in which unsuitable selection or excessive use of an excipient may adversely affect tablet quality or drug release. [4 marks]

Model answer and marking points

12.1 A pharmaceutical excipient is a formulation component other than the active medicinal ingredient, used for a defined manufacturing, stability, delivery or acceptability function.

12.2 Diluent adds bulk: lactose. Binder holds particles together: povidone. Disintegrant promotes tablet breakup: sodium starch glycolate. Lubricant reduces die-wall friction: magnesium stearate.

12.3 Glidant improves powder flow: colloidal silica. Film former provides a coating: hypromellose. Sweetener improves taste: saccharin sodium. Other valid, suitable function-example pairs may be used.

12.4 Excess hydrophobic lubricant or over-lubrication may reduce wetting/dissolution. Excess binder or an unsuitable excipient interaction may delay disintegration or damage stability. Excipients are functional, not automatically harmless.

මතක තබාගන්න Excipient නමක් පමණක් නොව function එක සහ නිවැරදි example එක යුගලයක් ලෙස ලියන්න.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q013 — Tablet Manufacturing [20 marks]

Original EduRase SEQ300 number Q013 | Priority B | Pharmaceuticals and compounding

13.1 Name two commonly used approaches for producing granules or preparing material before tablet compression. [4 marks]

13.2 Describe the principal stages involved in wet granulation followed by tablet compression. [8 marks]

13.3 State four in-process or finished-tablet properties that may be checked during tablet manufacture. [4 marks]

13.4 State two reasons why control of granule moisture before compression is important. [4 marks]

Model answer and marking points

13.1 Wet granulation and dry granulation are two granule-producing approaches. Direct compression is another material-preparation/compression approach when the formulation permits.

13.2 Dispense and sieve ingredients; dry mix; add binder liquid and wet mass; wet screen; dry to the validated endpoint; size the dried granules; blend with external-phase ingredients/lubricant; compress; and coat/package when required.

13.3 Four checks include tablet mass variation, crushing strength, friability and disintegration. Assay, content uniformity and dissolution are other appropriate checks.

13.4 Too much moisture can cause sticking or instability. Over-drying may impair compressibility and increase friability. Control moisture to the product/process specification.

මතක තබාගන්න Wet granulation පියවර අනුපිළිවෙළින් ලියන්න. Drying සහ final blending අමතක කරන්න එපා.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q015 — Solutions, Suspensions and Emulsions [20 marks]

Original EduRase SEQ300 number Q015 | Priority A | Pharmaceuticals and compounding

15.1 Differentiate among a solution, suspension and emulsion with respect to the physical state and distribution of the dispersed material. [6 marks]

15.2 State two important formulation or stability problems associated with each of the following: (a) suspensions, (b) emulsions, (c) aqueous solutions. [6 marks]

15.3 State four desirable properties of a pharmaceutical suspension intended for oral administration. [4 marks]

15.4 State four counselling or labelling instructions that may be important for a patient using an oral suspension. [4 marks]

Model answer and marking points

15.1 Solution: solute is molecularly or ionically dispersed in a single phase. Suspension: insoluble solid particles are dispersed in a liquid. Emulsion: droplets of one immiscible liquid are dispersed in another liquid.

15.2 Suspension: sedimentation/caking and crystal growth. Emulsion: creaming and coalescence/cracking. Aqueous solution: chemical degradation and microbial growth; precipitation is also possible.

15.3 Uniform dose after shaking; easy redispersion without hard caking; suitable particle size/palatability; and physical, chemical and microbiological stability.

15.4 Shake well; measure with a suitable oral device; use the prescribed dose/timing; and follow the labelled storage and in-use/beyond-use period. Refrigeration is product-specific.

මතක තබාගන්න Suspension එකේ solid particles තිබෙනවා. Emulsion එකේ immiscible liquid droplets තිබෙනවා.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q016 — Ointments, Creams and Semisolid Preparations [20 marks]

Original EduRase SEQ300 number Q016 | Priority A | Pharmaceuticals and compounding

16.1 Differentiate between an ointment and a cream using four suitable characteristics. [4 marks]

16.2 State three properties of a suitable ointment base and explain briefly why each property is desirable. [6 marks]

16.3 Describe three factors that should be considered when selecting a semisolid base for a particular medicinal product. [6 marks]

16.4 State four instructions that may be given to a patient to promote the safe and hygienic use of a topical semisolid medicine. [4 marks]

Model answer and marking points

16.1 Ointments are usually semisolid bases with little water; creams are semisolid emulsions. Ointments are often greasier and more occlusive; creams are often easier to spread. Washability depends on base type: O/W creams are usually water-washable. Both can deliver medicines topically.

16.2 A suitable base is non-irritant for tolerability, compatible/stable for product quality, and able to release the drug appropriately for its intended effect.

16.3 Consider drug solubility and stability; the skin/site and desired occlusion or washability; and the desired release, absorption, microbial protection and patient acceptability.

16.4 Use the directed amount and site; clean hands/applicators; avoid unintended eye/mucosal contact; and close the container to prevent contamination. Seek advice for significant irritation or deterioration.

මතක තබාගන්න සෑම cream එකක්ම එකම washability හෝ occlusion පෙන්වන්නේ නැහැ. Base type එක සලකන්න.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q017 — Pharmaceutical Incompatibilities [20 marks]

Original EduRase SEQ300 number Q017 | Priority A | Pharmaceuticals and compounding

17.1 Define pharmaceutical incompatibility. [4 marks]

17.2 Classify pharmaceutical incompatibilities into three major types and give one suitable example for each type. [6 marks]

17.3 For each observation, state one possible cause and one appropriate corrective or preventive measure: (a) precipitation after two liquids are mixed, (b) liquefaction of a powder mixture, (c) colour change during storage. [6 marks]

17.4 State two actions a pharmacist should take when an incompatibility affecting safety or product quality cannot be resolved. [4 marks]

Model answer and marking points

17.1 Pharmaceutical incompatibility is an undesirable physical, chemical or therapeutic interaction that makes a preparation or medicine combination unsuitable or compromises stability, efficacy or safety.

17.2 Physical: camphor and menthol may form a liquefied eutectic mixture. Chemical: oxidation of ascorbic acid during storage. Therapeutic: an NSAID added to anticoagulant therapy may increase bleeding risk.

17.3 Precipitation: altered pH/solubility; verify compatibility and use an authorised reformulation. Liquefaction: eutectic formation; use a suitable adsorbent/separate incorporation. Colour change: possible oxidation/light degradation; investigate and improve validated protection rather than masking the change.

17.4 Do not supply an unsafe or unstable preparation. Consult an authoritative compatibility source/prescriber, arrange a suitable alternative and document the action.

මතක තබාගන්න Observation එක, හේතුව සහ නිවැරදි action එක එකට සම්බන්ධ කරන්න. Colour change එක වසා දැමීම විසඳුමක් නොවේ.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q042 — Size Reduction, Trituration and Powder Mixing [20 marks]

Original EduRase SEQ300 number Q042 | Priority A | Pharmaceuticals and compounding

42.1 Define trituration and levigation. [4 marks]

42.2 State four reasons for reducing particle size during pharmaceutical compounding or manufacture. [8 marks]

42.3 Describe the principle of geometric dilution when a small quantity of potent powder must be mixed uniformly with a large quantity of diluent. [4 marks]

42.4 State two precautions that reduce segregation or non-uniformity in a powder mixture. [4 marks]

Model answer and marking points

42.1 Trituration is grinding/rubbing solids in a mortar to reduce particle size or mix powders. Levigation uses a small amount of suitable non-solvent liquid to make a smooth paste while reducing grittiness.

42.2 Particle-size reduction can improve dissolution, promote uniform mixing, reduce grittiness and increase extraction efficiency. The effect depends on the formulation; excessive fineness can create new flow/agglomeration problems.

42.3 Mix the small quantity of potent ingredient thoroughly with approximately an equal amount of diluent. Add diluent approximately equal to the existing mixture and mix again. Repeat until all diluent is incorporated.

42.4 Use appropriate particle sizes/mixing sequence and minimise segregation from vibration or large density differences. Scrape the mortar and transfer quantitatively. Validate uniformity for the formulation.

මතක තබාගන්න Geometric dilution වලදී එක්වරම මුළු diluent එක දාන්නේ නැහැ. දැනට තිබෙන mixture එකට ආසන්න කොටස් ලෙස එකතු කරන්න.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q222 — Fluidised-Bed Drying of Pharmaceutical Materials [20 marks]

Original EduRase SEQ300 number Q222 | Priority A | Pharmaceuticals and compounding

222.1 State the principle of fluidised-bed drying. [4 marks]

222.2 Describe the major steps by which wet granules are dried in a fluidised-bed dryer. [6 marks]

222.3 State three advantages of fluidised-bed drying compared with static tray drying. [6 marks]

222.4 State two process variables that should be controlled to prevent over-drying, attrition or non-uniform drying. [4 marks]

Model answer and marking points

222.1 Upward air at a suitable velocity suspends and mixes wet particles, creating fluid-like behaviour and efficient heat/mass transfer so moisture evaporates.

222.2 Load wet granules on the distributor; supply filtered, controlled warm air; establish uniform fluidisation; remove moist exhaust through filters; monitor product temperature/moisture; stop at the validated endpoint, cool and unload. Avoid excessive entrainment and attrition.

222.3 Compared with static tray drying: faster drying, efficient heat/mass transfer and better mixing/uniformity for suitable material. Performance still depends on load and process control.

222.4 Control airflow/fluidisation and inlet/product temperature. Load, inlet humidity, time and endpoint moisture are also important variables.

මතක තබාගන්න Air inlet, distributor, fluidised bed, filters සහ moist exhaust අනුපිළිවෙළ හඳුනාගන්න.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q025 — Storage, Packaging and Protection of Medicines [20 marks]

Original EduRase SEQ300 number Q025 | Priority A | Quality storage and sterility

25.1 State four environmental factors that may cause deterioration of medicines during storage. [4 marks]

25.2 Explain why each of the following may require special packaging or storage: (a) a light-sensitive medicine, (b) a hygroscopic powder, (c) a volatile preparation. [6 marks]

25.3 State three important actions that should be taken when a medicine has been stored outside its specified storage conditions. [6 marks]

25.4 State four items of storage information that may need to appear on a medicine label or accompanying information. [4 marks]

Model answer and marking points

25.1 Heat/temperature, light, moisture and oxygen can cause deterioration. Freezing or microbial contamination may also be relevant.

25.2 Light-sensitive medicine: use suitable light-resistant packaging. Hygroscopic powder: protect against moisture using a compatible tight container. Volatile preparation: prevent evaporation with an appropriate tight closure and labelled temperature.

25.3 Quarantine affected stock; establish the temperature/time and affected batches; obtain an authorised product-specific stability assessment; and document the decision before release, return or disposal.

25.4 Examples: storage temperature; protect from light; keep tightly closed/protect from moisture; and do not freeze or the in-use period after opening/reconstitution, as applicable.

මතක තබාගන්න Shelf එකට නැවත තැබීමට පෙර quarantine සහ authorised assessment අවශ්‍යයි.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q026 — Sterilisation and Aseptic Processing [20 marks]

Original EduRase SEQ300 number Q026 | Priority B | Quality storage and sterility

26.1 Differentiate between sterilisation and disinfection. [4 marks]

26.2 Compare moist-heat sterilisation and dry-heat sterilisation under four suitable headings. [8 marks]

26.3 A heat-sensitive aqueous medicine must be rendered sterile without exposing the medicine to a destructive sterilising temperature. State one suitable approach and describe the major steps required to minimise microbial contamination during subsequent handling. [4 marks]

26.4 State four factors that should be considered when selecting a sterilisation method for a pharmaceutical material or product. [4 marks]

Model answer and marking points

26.1 Sterilisation is a validated process intended to achieve the required absence of viable microorganisms. Disinfection reduces many pathogenic microorganisms on items/surfaces but does not necessarily eliminate bacterial spores.

26.2 Moist heat uses saturated steam, acts mainly through protein denaturation and usually uses lower temperature/shorter exposure for suitable loads. Dry heat uses hot air and oxidative damage, generally needs higher temperature/longer exposure and suits materials such as certain oils, powders and glass. Compare agent, action, conditions and suitable materials.

26.3 Use a validated sterilising-grade membrane filtration process, commonly 0.22 micrometre, if compatible; verify filter integrity and aseptically fill into sterile containers/closures in a controlled environment. Filtration does not reliably remove endotoxins or all viruses.

26.4 Consider heat/moisture sensitivity, formulation and container, microbial risk/penetration, and process validation/sterility assurance. Aseptic handling alone is not a sterilisation process.

මතක තබාගන්න Sterile filtration පසු aseptic filling අවශ්‍යයි. Sterile යන්න pyrogen-free යන්නට සමාන නොවේ.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q053 — Quality Assurance, Quality Control and GMP

[20 marks]

Original EduRase SEQ300 number Q053 | Priority B | Quality storage and sterility

53.1 Differentiate between quality assurance (QA) and quality control (QC). [4 marks]

53.2 Define Good Manufacturing Practice (GMP) in relation to pharmaceutical production. [4 marks]

53.3 State four GMP controls that help prevent mix-ups, contamination or inconsistent product quality. [8 marks]

53.4 Explain why a passing finished-product test alone does not prove that an uncontrolled manufacturing process was acceptable. [4 marks]

Model answer and marking points

53.1 QA is the broader planned system that gives confidence in product quality. QC covers sampling, specifications and testing to verify conformance and support disposition/release decisions.

53.2 GMP is the part of QA that ensures medicines are consistently produced and controlled to the standards appropriate to their intended use and authorisation.

53.3 Four examples: trained staff with approved procedures; cleaning and line clearance; controlled materials and equipment calibration; and batch records with in-process checks. Validation and deviation/CAPA systems also matter.

53.4 A sample tests only part of a batch and selected attributes. An uncontrolled process may cause hidden variability, contamination or future instability; quality must be built in and documented.

මතක තබාගන්න QA යනු පුළුල් system එකයි. QC යනු එහි testing සහ specification සම්බන්ධ කොටසයි.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q055 — Cold-Chain Storage and Temperature Excursions [20 marks]

Original EduRase SEQ300 number Q055 | Priority B | Quality storage and sterility

55.1 State four controls needed for reliable storage of medicines that require refrigeration. [8 marks]

55.2 A refrigerator is found at 14°C and the duration of the excursion is uncertain. Describe four actions that should be taken before affected medicines are returned to usable stock. [8 marks]

55.3 State two reasons why appearance alone is insufficient to decide whether a temperature-exposed medicine is safe to use. [4 marks]

Model answer and marking points

55.1 Use a suitable qualified refrigerator; calibrated monitoring with records; correct loading/airflow and protection from freezing; and an excursion/alarm/power-failure procedure. Follow each product's specified range.

55.2 Quarantine the affected medicines. Identify products/batches and establish temperatures/duration. Obtain an authorised manufacturer/product-specific assessment. Document the disposition before returning any stock to use.

55.3 Potency can fall without a visible change. Degradation or aggregation may be clinically important but invisible. Returning the fridge to its normal temperature does not reverse damage already caused.

මතක තබාගන්න Fridge එක ආපසු සාමාන්‍ය උෂ්ණත්වයට ආවත් කලින් වූ හානිය ආපසු හැරෙන බව නොසිතන්න.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q040 — Metered-Dose Inhaler Technique and Device Counselling [20 marks]

Original EduRase SEQ300 number Q040 | Priority B | Medicines devices and safety

40.1 Describe the main steps for correct use of a pressurised metered-dose inhaler (pMDI) without a spacer. [8 marks]

40.2 State three common technique errors that can reduce lung delivery from a pMDI. [6 marks]

40.3 State two situations in which a spacer may be useful. [4 marks]

40.4 State one counselling point after use of an inhaled corticosteroid. [2 marks]

Model answer and marking points

40.1 For the prescribed pMDI, follow its instructions: remove cap/check mouthpiece; shake if required and prime when indicated; sit/stand upright; breathe out away from the device; seal lips; begin a slow deep inhalation and actuate one puff; continue inhaling; hold the breath for up to about 10 seconds as comfortable; breathe out gently. Repeat only as prescribed with the product's interval; replace cap.

40.2 Poor actuation-inhalation coordination, inhaling too fast and failing to exhale first reduce delivery. An empty/blocked device or failure to shake/prime when required can also cause failure.

40.3 A compatible spacer helps people who cannot coordinate a pMDI and can reduce oropharyngeal deposition with an inhaled corticosteroid.

40.4 Rinse/gargle with water and spit it out after an inhaled corticosteroid. Demonstrate technique and ask the patient to demonstrate it back.

මතක තබාගන්න pMDI සඳහා slow deep inhalation වැදගත්. DPI technique එක මෙයට අනුකූලවේන් මිශ්‍ර කරන්න එපා.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q057 — Diabetes Medicines and Hypoglycaemia

Safety [20 marks]

Original EduRase SEQ300 number Q057 | Priority B | Medicines devices and safety

57.1 State the principal mechanism of action of metformin. [4 marks]

57.2 State two common or important adverse effects/precautions associated with metformin. [4 marks]

57.3 State four symptoms or signs that may occur during hypoglycaemia. [4 marks]

57.4 Describe four counselling points for a patient using insulin or another glucose-lowering medicine that can cause hypoglycaemia. [8 marks]

Model answer and marking points

57.1 Metformin mainly decreases hepatic glucose production and improves insulin sensitivity. It does not directly stimulate insulin secretion.

57.2 Examples include gastrointestinal upset and reduced vitamin B12 with prolonged use. Renal impairment/acute illness can require review because of rare lactic-acidosis risk.

57.3 Sweating, shaking, palpitations and hunger are common; confusion, visual disturbance, seizures or unconsciousness can occur.

57.4 Recognise symptoms and monitor glucose; carry rapid-acting carbohydrate and follow the individual treatment/recheck plan; coordinate medicines with meals/activity; and ensure a caregiver emergency plan. If unconscious or unable to swallow, give nothing by mouth and obtain emergency help. Metformin alone usually has a low hypoglycaemia risk.

මතක තබාගන්න Hypoglycaemia ඇති කළ හැකි medicine එක හඳුනාගන්න. සිහි නැති කෙනෙකුගේ කටට ආහාර හෝ දියර දෙන්න එපා.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q058 — Asthma Medicines and Reliever/Controller Use [20 marks]

Original EduRase SEQ300 number Q058 | Priority B | Medicines devices and safety

58.1 Differentiate between a bronchodilator reliever and an inhaled corticosteroid controller in terms of purpose and pharmacological action. [6 marks]

58.2 State three adverse effects or precautions associated with inhaled corticosteroids. [6 marks]

58.3 State two signs that a patient's asthma control may be inadequate and requires review. [4 marks]

58.4 State two reasons why inhaler technique should be checked before assuming that treatment failure is due to an ineffective medicine. [4 marks]

Model answer and marking points

58.1 A bronchodilator reliever relaxes airway smooth muscle to relieve bronchoconstriction. An inhaled corticosteroid (ICS) reduces airway inflammation and exacerbation risk. Some relievers combine ICS with rapid-onset formoterol, so reliever and anti-inflammatory functions can be in one inhaler.

58.2 Oral candidiasis, dysphonia and throat irritation can occur. Use correct technique and rinse/spit after ICS; a compatible spacer can help with a pMDI. Higher/prolonged exposure can cause systemic effects.

58.3 Frequent symptoms/reliever use, night waking or activity limitation require review; recurrent exacerbations also indicate risk.

58.4 Poor technique reduces lung deposition. Correcting it and checking adherence may restore benefit before unnecessary escalation. Current asthma care requires ICS-containing treatment; do not teach SABA-only treatment as routine long-term care.

මතක තබාගන්න Reliever එකකින් ICS තිබිය හැකියි. Reliever සහ controller කියන වෙන වෙනම medicine class දෙකක් ලෙස පමණක් මතක තබාගන්න එපා.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q088 — Anticoagulant and Antiplatelet Medicine Safety [20 marks]

Original EduRase SEQ300 number Q088 | Priority B | Medicines devices and safety

88.1 Differentiate between an anticoagulant and an antiplatelet medicine in terms of their principal target in haemostasis. [4 marks]

88.2 State four factors that may increase bleeding risk in a patient taking an anticoagulant or antiplatelet medicine. [8 marks]

88.3 State two counselling points that help reduce avoidable bleeding-related harm. [4 marks]

88.4 State two symptoms or situations that require prompt medical assessment. [4 marks]

Model answer and marking points

88.1 Anticoagulants act mainly on the coagulation cascade/thrombin or clotting factors; antiplatelets reduce platelet activation/aggregation. Both can increase bleeding risk.

88.2 Four factors: additional NSAIDs/antithrombotics; previous bleeding or active ulcer; renal/hepatic impairment; and excessive dose or interacting medicines. Trauma, alcohol misuse and unstable INR with warfarin also matter.

88.3 Check new medicines, including OTC/herbal products, with the pharmacist/prescriber. Follow the dose and any required monitoring; do not stop essential therapy or double a missed dose without medicine-specific advice.

88.4 Urgent assessment is needed for vomiting blood/black stools or prolonged/uncontrolled bleeding. Head injury or a sudden severe headache/neurological change also needs urgent assessment.

මතක තබාගන්න Anticoagulant සහ antiplatelet target වෙනස්. Bleeding risk දෙකේම තිබිය හැකියි.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q029 — Immunity and Infection Prevention [20 marks]

Original EduRase SEQ300 number Q029 | Priority A | Immunity and natural products

29.1 Differentiate between (a) active immunity and (b) passive immunity. [4 marks]

29.2 Differentiate between an antigen and an antibody, and state one role of each in an immune response. [6 marks]

29.3 State three ways in which vaccination contributes to prevention or control of communicable diseases. [6 marks]

29.4 State four infection-prevention practices relevant to the operation of a community pharmacy. [4 marks]

Model answer and marking points

29.1 Active immunity develops through the person's own response to infection or vaccination and can produce memory. Passive immunity supplies preformed antibodies, acts promptly but is temporary and does not itself establish active immune memory.

29.2 An antigen is a structure recognised specifically by immune receptors/antibodies and can be a target of an immune response. An antibody is an immunoglobulin produced by plasma cells that binds an antigen, helping neutralisation or other elimination mechanisms.

29.3 Vaccination can prevent disease, reduce severe illness/complications and, for appropriate infections/vaccines, reduce transmission and provide indirect protection. The size of each effect varies by vaccine/pathogen.

29.4 Hand hygiene; suitable cleaning/disinfection; safe sharps and waste handling; and respiratory precautions/ventilation with appropriate patient workflow.

මතක තබාගන්න Vaccination එකකින් ලැබෙන infection, severity සහ transmission බලපෑම් එකම ප්‍රමාණයක් නොවිය හැකියි.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Q030 — Crude Drugs and Natural Medicinal Products

[20 marks]

Original EduRase SEQ300 number Q030 | Priority A | Immunity and natural products

30.1 Define (a) crude drug and (b) biological source of a crude drug. [4 marks]

30.2 For any four of the following natural medicinal substances, state the biological source and one important pharmacological action or pharmaceutical use: Senna, Digitalis, Atropine, Menthol, Acacia, Cinchona. [8 marks]

30.3 State four factors that may affect the quality of a crude drug between collection and use. [4 marks]

30.4 State four reasons why a pharmacist should not assume that a medicinal product is automatically safe merely because it is of natural or herbal origin. [4 marks]

Model answer and marking points

30.1 A crude drug is a natural medicinal material used raw or with limited processing. Its biological source identifies the organism and relevant part from which it is obtained.

30.2 Any four: senna—*Senna alexandrina* leaflets/pods, stimulant laxative; digitalis—*Digitalis lanata/purpurea* leaves, cardiac glycoside source; atropine—*Atropa belladonna* and related *Solanaceae*, antimuscarinic; menthol—mint oils including *Mentha arvensis*, cooling/flavouring agent; acacia—*Senegalia senegal* or related gum exudate, emulsifier/binder; cinchona—*Cinchona* bark, quinine source.

30.3 Correct species/part, collection and drying, moisture/mould/insects, and storage/container conditions influence quality.

30.4 Natural products may cause toxicity or allergy, interact with medicines, vary in identity/strength/purity and be unsuitable in pregnancy or organ disease. Natural origin alone proves neither safety nor efficacy.

මතක තබාගන්න Source එකේ species සහ භාවිත කරන part එක මතක තබාගන්න. Natural යන්න safe යන්නට සමාන නොවේ.

Attempt date _____ Self-check ____ / 20 Next attempt _____

Timed SEQ practice

Choose one set. Close the model answers and write on separate paper for 30 minutes. Allow about 2 minutes to inspect all five questions, about 5 minutes per response and about 3 minutes to check gaps. This speed drill is a teaching exercise; follow the official examination instructions on the day.

Set	Original questions	Skills tested
A	Q001 Q002 Q012 Q019 Q042	Recall; prescription checks; excipients; paediatric arithmetic; mixing
B	Q272 Q010 Q222 Q018 Q030	Inspection; antibiotic counselling; drying; dilution; natural products

Review the response honestly

Score each bank question out of its practice 20 marks using the model points and the requested depth. This is a learner/lecturer estimate, not an official CMCC mark. If an answer is only a keyword when an explanation is requested, improve the reasoning before awarding yourself full credit.

Question	Estimated mark / 20	One missing point	Repair date
1			
2			
3			
4			
5			

කාලය ඉවර වුණාම නැවත model answer එක නොබලා අඩු වූ subpart එකට උත්තරයක් හදා බලන්න. ඊට පසුව explanation එක කියවා එය නිවැරදි කරන්න.

Exam focus Do not treat Set A or Set B as a forecast of the actual paper. They are balanced combinations for transferring what you learned to a timed response.

Repair log and the final revision plan

A repair action should name a specific gap. “Study law” is too broad; “state the four Regulation 91 sources without notes” is a usable action.

SEQ or rule	My exact gap	What I will do	Recheck

After the seminar

First, revisit the Priority A questions you could not answer independently. Next, correct calculation errors using a fresh written method. Then practise the NMRA comparisons and number-with-context table. Finally, use Priority B to widen coverage and repeat a timed set.

Before the examination

Read the current CMCC admission and answering instructions. Prepare the required identity/signature and other listed documents. Review the original Q numbers you marked for repair. Use short recall attempts and adequate rest; avoid replacing your whole plan with an unverified prediction list.

මෙම ප්‍රශ්න 40 කරලා අවසන් කියන්නේ syllabus එකේ ඉතිරි කොටස් අනවශ්‍යයි කියන අදහස නොවේ. ඉතිරි කාලයේදී තමන්ගේ දුර්වලතා, විෂය ආවරණය සහ නැවත ලිවීමේ හැකියාව අනුව වැඩ තෝරන්න.

Exam focus Completion standard: I can define it, explain the reason, apply it to a case and write the answer without the model.

Why these questions were selected

Selection uses direct topic overlap in three accessible prior SEQ sittings, the published training scope and the importance of common pharmacy decisions. The sample supports study priorities; it is too small to estimate the probability of an October question. Topic overlap is not evidence that the same wording will repeat.

Prior source	Themes present	Bank links used
January 2026	Recall; legal classification; ethics; prescription authenticity; excipients; incompatibilities; paediatric/base-salt calculations; trituration and mixing	Q001 Q002 Q004 Q006 Q012 Q017 Q019 Q020 Q042
December 2021	Prescription legality; counselling/reconstitution; written information; storage; legal classes; semisolids; procurement; immunity and crude drugs	Q002 Q004 Q009 Q010 Q016 Q025 Q029 Q030 Q083
December 2020	Dilution; buffers; pharmacy licensing/registration; Authorized Officers; fluidised-bed drying; ionisation	Q003 Q018 Q022 Q023 Q092 Q222 Q272

Priority A and B

Priority A contains 24 questions for first attempts, giving emphasis to the retrieved recurring themes and basic transferable skills. Priority B contains 16 additional questions covering safety, quality, devices, governance and applied therapeutics. A/B are teaching priorities in this seminar, not official weightings.

Question and answer provenance

All 40 full question stems and subparts retain the source wording, original Q numbers and practice marks from the EduRase SEQ300 Question and Model Answer Master Q001–Q300 v1.0. The model answers here are reviewed seminar answers, including completed or clarified answers where needed. They are not claimed to be official examination answers.

The NMRA lessons condense the existing EduRase NMRA seminar student tutorial and incorporate the relevant 10 October accuracy-audit corrections. The older module text is not copied forward where it conflicts with those corrections.

Internal sources: SEQ300 master and programme question book; Final QA Release Control Report v1.1; NMRA seminar student tute; NMRA accuracy audit of 10 October 2026; controlled 2020, 2021 and January 2026 SEQ transcriptions.

Official sources and further checking

N1 National Medicines Regulatory Authority Act No 5 of 2015 Statutory anchors used in the audited course copy. Official legislation listing. [Open source](#)

N2 National Medicines Registration and Licensing of Medicine Regulations 2019 Gazette 2145/1, 14 October 2019. Clinical Trials Regulations are the separate Gazette 2145/2. [Open source](#)

N3 NMRA pharmacy and published guidelines Use the live pharmacy page and current guidance for procedures, applications, storage and fees. [Open source](#)

N4 NMRA pharmacovigilance Current reporting information, alerts and linked recall resources. [Open source](#)

N5 WHO quality terminology Distinguishes substandard, unregistered and falsified medical products. [Open source](#)

E1 CMCC October 2026 Instructions for Answering Current five-SEQ and script-collection instructions. [Open source](#)

E2 CMCC External Pharmacist course information Published training and examination regulations and syllabus information. [Open source](#)

M1 GINA 2026 Strategy Report Current asthma framework, including ICS-containing care and reliever distinctions. [Open source](#)

M2 NHS hypoglycaemia information Recognition, prompt treatment and avoiding oral intake when swallowing is unsafe. [Open source](#)

M3 MHRA metformin and vitamin B12 safety update B12 reduction and risk-based monitoring advice. [Open source](#)

M4 NHS Specialist Pharmacy Service anticoagulant interactions Relevant medicine combinations and bleeding-risk precautions. [Open source](#)

Source check 20 October 2026. For real supply, check current product information, NMRA classification/approval and applicable notices. The tutorial does not freeze a changing fee, product price or application process.

Compiled for Lecturer Pradeep Dissanayake and EduRase. Educational patient cases and practice mark allocations are for teaching.

EduRase තුළ ඉගෙනීම විභාග පිළිතුරකට ගෙන යන ආකාරය

මම Pradeep Dissanayake. මගේ External Pharmacy ඉගැන්වීමේ අරමුණ වන්නේ විෂය කරුණු තේරුම්ගෙන, ඒවා නිවැරදිව මතකයෙන් ලබාගෙන, විභාගයේ අසන ආකාරයට පැහැදිලි පිළිතුරක් ලියන්න ඔබට පුහුණුව ලබාදීමයි.

අපේ ඉගෙනුම් වැඩ	එයින් පුහුණු වන හැකියාව
Past paper සාකච්ඡා	ප්‍රශ්නය ඉල්ලන දේ, command words සහ පිළිතුරේ අවශ්‍ය කරුණු හඳුනාගැනීම
SEQ 300 ප්‍රශ්න බැහැරව	මාතෘකා ගණනාවක් පිළිබඳ structured answers ලිවීම සහ තම දුර්වලතා හඳුනාගැනීම
MCQ සහ MTF explanations	True හෝ False තීරණයට හේතුව කියා, වැරදි statement එක නිවැරදි කිරීම
Calculations සහ compounding	Formula එක, units, පියවර සහ අවසාන පිළිතුර සාධාරණය යන්න පරීක්ෂා කිරීම
NMRA case discussions	නීතිමය rule එකක් pharmacy සිද්ධියකට යොදාගැනීම
Visual lessons සහ ප්‍රශ්න අනුව explanations	අමාරු සංකල්ප කොටස් කර තේරුම්ගෙන නැවත මතක් කිරීම

විධියේව බැලීමෙන් පසු කළ යුතු වැඩ

පිළිතුර වැසි ඇති විට මුලින් ඔබේ පිළිතුර ලියන්න. Model answer එක සමඟ සසඳා අඩු වූ නිශ්චිත point එක සටහන් කරන්න. එය නැවත පාඩම් කර වෙනත් දිනයක නැවත ලියන්න. Moodle තුළ ලබාදෙන අන්තර්ගතය ඔබට අදාළ course access කාලය තුළ නැවත භාවිත කරන්න.

හරි උත්තරය දුටු විට “මේක මට තේරුණා” කියන හැඟීම සහ එය නොබලා ලියන්න පුළුවන් වීම එකම දෙයක් නොවේ. අපේ පුහුණුවෙන් ඔබ කළ යුතු ප්‍රධාන වැඩ වන්නේ උත්තර දීම, වැරදි හඳුනාගැනීම සහ නැවත උත්සාහ කිරීමයි.

Exam focus පාඨමාලාව ඔබට ඉගෙනුම් මාර්ගය සහ පුහුණු ද්‍රව්‍ය ලබාදෙනවා. ප්‍රතිඵලය සඳහා ඔබේ සක්‍රීය පුහුණුව සහ නිරන්තර වැඩ කිරීමත් අවශ්‍යයි.

ඔබට ගැළපෙන පාඨමාලා මාර්ගය

ඔබේ අවශ්‍යතාව	විමසිය හැකි මාර්ගය	ඉගෙනුම් අවධානය
මූලික දැනුම ක්‍රමානුකූලව ගොඩනගා ගැනීම	මාස 12 Theory	විෂය සංකල්ප, පැහැදිලි කිරීම් සහ ක්‍රමවත් අභ්‍යාස
ඉගෙනගත් කරුණු නැවත සංවිධානය කිරීම	මාස 6 Revision	වැදගත් මාතෘකා, past paper ප්‍රශ්න සහ දුර්වල කොටස් නැවත පුහුණුව
Written exam ප්‍රශ්න රටාවට පුහුණු වීම	Past Paper Revision	ප්‍රශ්න සාකච්ඡාව, explanations සහ නැවත උත්සාහ
Structured පිළිතුරු ලිවීමේ පුහුණුව	SEQ වැඩසටහන්	මුල් ප්‍රශ්නය, subparts, model answers සහ ලිවීමේ ක්‍රම
සම්පූර්ණ paper පුහුණුව	Model Papers	ප්‍රශ්න කට්ටලයක් මත කාලය කළමනාකරණය සහ self review

අලුත් කණ්ඩායම ගැන විමසන විට

ඔබ ලියන්න බලාපොරොත්තු වන විභාගය, දැනට තිබෙන දැනුම, වැඩිපුර අමාරු කොටස් සහ සතියකට ඉගෙනීමට වෙන්කළ හැකි කාලය සඳහන් කරන්න. එවිට Theory, Revision හෝ විශේෂ පුහුණුවකින් ඔබට ගැළපෙන මාර්ගය තෝරාගැනීම පහසු වේ.

නව කණ්ඩායමේ ආරම්භක දිනය, කාලසටහන, online හෝ physical arrangement, ප්‍රවේශ කාලය, ගාස්තු සහ ගෙවීම් විකල්ප අදාළ කණ්ඩායම සඳහා විමසා තහවුරු කරගන්න. එක් course එකක payment හෝ access කොන්දේසි අනෙක් සියල්ලටම එකසේ අදාළ නොවේ.

දැනට EduRase student කෙනෙකු නම් ඒ බව මුලින් කියන්න. ඔබේ දැනට ඇති ගිණුම සහ course access විස්තර භාවිත කර අවශ්‍ය නව පාඨමාලාව ගැන විමසන්න.

විමසීමට සරල පණිවිඩයක්

“මම External Pharmacy විභාගයට සූදානම් වෙනවා. මට වැඩිපුර අමාරු කොටස් වන්නේ _____. මාස 6 Revision / මාස 12 Theory / SEQ / Model Papers ගැන දැනට තිබෙන විස්තර එවන්න.”

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අදාළ කණ්ඩායමේ නිල විස්තර ලබාගෙන ඔබේ ඉගෙනුම් සැලැස්ම තෝරාගන්න.

සම්බන්ධ වන්න සහ නොමිලේ පාඩම් සොයාගන්න

Pradeep Dissanayake EduRase

External Pharmacy Examination සඳහා පැහැදිලි විෂය ඉගැන්වීම සහ විභාග පුහුණුව.

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WhatsApp



EduRase website

YouTube පාඩම් භාවිත කරන ක්‍රමය

YouTube තුළ “Pradeep Dissanayake EduRase” ලෙස සොයා ඔබේ ගුරුවරයාගේ channel එක තෝරන්න. Pharmacy සහ pharmacology පාඩම්, MCQ ප්‍රශ්න හා කෙටි explanations ඔබේ revision එකට යොදාගන්න. Subscribe කර අවශ්‍ය පාඩම් ඔබේ revision list එකට එක්කරගන්න.

Short එකක ප්‍රශ්නයට පිළිතුර පෙන්වීමට පෙර විචියෝව නවතා උත්තර දෙන්න. වැරදුණොත් හේතුව කෙටි සටහනකට ලියාගෙන, ඊළඟ දවසේ නැවත උත්සාහ කරන්න. නොතේරුණු සංකල්පය සම්පූර්ණ පාඩමකින් නැවත ඉගෙනගන්න.

ඔක්තෝබර් Past Paper Revision විශේෂ ප්‍රවේශය

එක්වර ගාස්තුව රු 2,500. Course access 2026 ඔක්තෝබර් 24 රාත්‍රී 11:59 දක්වායි. විස්තර සඳහා WhatsApp වෙත PP2500 ලෙස එවන්න. මෙය SEQ සහ NMRA seminar එකෙන් වෙන් වූ course එකකි; seminar ගාස්තුවට ස්වයංක්‍රීයව ඇතුළත් නොවේ. සෙමිනාරයෙන් පසු ඔබට ලැබෙන ප්‍රධාන ප්‍රයෝජනය තමයි දැන් සිටින මට්ටම හඳුනාගෙන ඊළඟ පුහුණුව තෝරාගැනීමට හැකි වීම. මේ ටියුට් එකේ repair log එක පුරවා දුර්වල කොටස්වලින්ම ඊළඟ revision එක අරඹන්න.

පාඨමාලා හා සම්බන්ධතා විස්තර 2026 ඔක්තෝබර් 20 දිනට. October offer details: approved 19 October campaign record. New-intake details are obtained separately.