RESEARCH PAPER

A Competency Framework for Selection of Personnel in Pharmaceutical Industry in India: Development and Validation

Smita Jain[1]*, Gomathy Subramanian[2]

[1,2] Department of Pharmaceutical Chemistry, JSS College of Pharmacy, JSS Academy of Higher Education and Research, Ooty, Nilgiris, Tamil Nadu, INDIA.

***Correspondence:** Smita Jain
Email: smitajain181086@gmail.com Mobile No: 9899108526

ABSTRACT

Background: Personnel selection practices in the Indian pharmaceutical industry are heterogeneous and may be vulnerable to subjectivity and bias. A structured, context-relevant competency framework could support more consistent, evidence-informed selection and development of industrial pharmacists. **Objectives:** To develop and validate an India-relevant competency framework and questionnaire for selection and development of industrial pharmacists. **Materials and Methods:** An English, web-based cross-sectional survey instrument grounded in the FIP Global Competency Framework and extended with industrial pharmacy technical domains was developed and deployed (n=75). Content validity was quantified using item-level and scale-level Content Validity Index (CVI) from expert ratings. Internal consistency was evaluated using Cronbach's alpha. Construct validity of the Professional/Personal Competency section was assessed using exploratory factor analysis (EFA) for ordinal Likert data with oblique rotation. Known-groups analyses (experience and education) were conducted as supportive evidence. **Results:** The instrument demonstrated strong content validity (S-CVI/Ave=0.907; average modified k*=0.903) and high internal consistency for the overall Professional/Personal scale (Cronbach's alpha=0.91). EFA supported a parsimonious four-factor structure for the Professional/Personal competency items after item reduction. Technical competency modules showed domain-wise internal consistency. **Conclusion:** A structured competency framework and questionnaire with initial evidence of content validity, internal consistency, and construct validity was developed for industrial pharmacists in India, supporting applications in competency-based selection, training needs assessment, and professional development.

Keywords: Competency Frameworks, Competency Standards, Pharmaceutical Industry, Industrial Pharmacist, Personnel Selection Procedures.

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INTRODUCTION

Pharmacists work across patient-care settings and the pharmaceutical industry, as well as in academia, government/regulatory bodies, and clinical research.

In contrast to the United States, Europe, Canada, and Australia—where pharmacists are largely employed in patient-care settings—the pharmacy workforce in India is predominantly engaged in the pharmaceutical industry. Because competency requirements differ across industry functions, role-aligned training and assessment are needed. Although competency frameworks offer structured approaches to define and assess professional capabilities, many existing frameworks have limited applicability in India because they emphasize patient-facing practice. Only a few regions (e.g., Europe and Saudi Arabia) have reported competency frameworks tailored to industrial pharmacists.

India is a major producer and exporter of medicines, with key export destinations including the United States, the United Kingdom, the European Union, and Canada[1]. While the Pharmacy Council of India (PCI) specifies standards for pharmacy education, guidance for defining and assessing competency for different practice settings remains limited. PCI promotes WHO competency standards for patient-care pharmacists[2]; however, an India-specific competency framework for industrial pharmacists is not available.

Given the critical role of industrial pharmacists and the lack of standardized guidance to support competency-based personnel qualification across industry functions, further work is warranted. Selecting appropriately qualified and trained personnel is central to an effective quality management system and compliance with Good Manufacturing Practices (GMP).

A structured tool to assess competencies across pharmaceutical industry roles may support more consistent selection and targeted training and may contribute to improved inspection readiness and reduced compliance risk. Accordingly, an India-relevant competency framework may help standardize expectations and strengthen personnel selection practices. Additional applications of competency frameworks are summarized in Figure 1.

*Author for Correspondence: smitajain181086@gmail.com

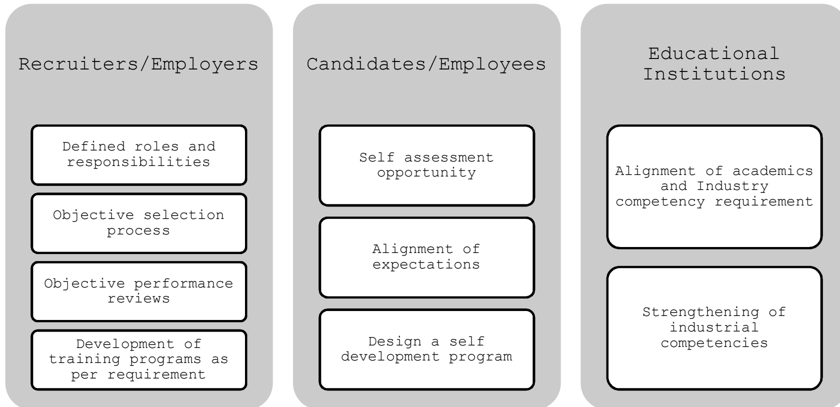

Figure 1: Applications of Competency Frameworks.

Design of competency frameworks for industrial pharmacists in India

Within GMP-oriented quality management approaches (e.g., TQM and the 6Ms), personnel competence is foundational. Without clear guidance on qualification requirements and competency validation, practices may vary across organizations, increasing the risk of inconsistent expectations and bias. Developing guidance to validate personnel qualifications can support more consistent and objective GMP compliance across the industry.

A review of major pharmacist competency frameworks from the United States[3], Europe[4,5], and Canada[6], together with the International Pharmaceutical Federation (FIP) Global Competency Framework (GbCF)[7], highlights the importance of both technical and professional/personal competencies. While professional/personal competencies are broadly transferable across settings, technical competencies are role dependent. In the Indian context, key technical competency areas for industrial pharmacists include:

- Research and development
- Analytical development
- Industrial pharmaceutical production
- Quality control
- Quality assurance
- Quality management
- Legal and regulatory affairs

In addition to technical competencies, professional/personal competencies support consistent performance and quality. The FIP GbCF describes the following domains:

- Communication
- Continuous professional development (CPD)
- Digital literacy
- Interpersonal relations and collaboration
- Leadership and self-regulation
- Professional and ethical practice

In this study, the proposed competency framework for industrial pharmacists in India was mapped to the FIP Global Competency Framework (GbCF) and other commonly used pharmacist competency frameworks. Six professional/personal domains were retained due to their cross-setting relevance, and the framework was extended by specifying role-relevant technical domains (e.g., research and development, analytical development, industrial pharmaceutical production, quality control/quality assurance/quality management, and legal/regulatory practice). Behavioral statements were framed for competency-based personnel selection in pharmaceutical manufacturing and quality systems; patient-care-specific behaviors were outside the scope of this instrument. Accordingly, this work (i) proposes an India-relevant framework integrating transferable professional/personal competencies with role-specific technical domains; (ii) operationalizes the framework as a structured, web-based questionnaire for competency assessment; and (iii) provides initial evidence of content validity, internal consistency, and construct validity to support further use and refinement.

MATERIALS AND METHODS

Research Method

An English, web-based cross-sectional survey based on the proposed competency framework for industrial pharmacists in India was designed to meet the study objectives. The questionnaire was administered electronically using Microsoft Forms and comprised three sections: (1) demographic information, (2) a core Professional/Personal Competency section completed by all respondents (Q1–Q36), and (3) domain-specific Industrial Pharmacy (Technical) Competency modules (Q37–Q120), in which participants completed one module aligned to their experience.

Recruitment, Eligibility, and Participant Characteristics

Participants were recruited from the Indian pharmaceutical industry using convenience sampling. The Microsoft Forms link was shared via professional channels (industry contacts and networks, including professional social media) using standardized invitations describing the study and providing access to the questionnaire. Participation was voluntary; informed consent was obtained electronically; no incentives were offered; and responses were collected anonymously. To broaden representation and to reduce bias, dissemination was not restricted to a single organization, job role, or seniority level, and eligibility criteria were applied consistently.

Sample Size Calculation

The minimum sample size was calculated using the CDC OpenEpi software[8]. A 95% expected frequency was chosen based on the assumption that specialized competencies would be met by practicing industrial pharmacists. Consequently, a minimum sample size of 73 participants was calculated to ensure a 5% margin of error, with a 95% confidence level, a 5% alpha error, and 80% statistical power.

Questionnaire development

The competency assessment questionnaire was developed through a structured, multi-step process to ensure conceptual grounding, relevance to the Indian pharmaceutical industry, and content validity.

(1) Literature mapping and conceptual framework

An initial mapping of existing pharmacist competency frameworks was undertaken to identify accepted domains and behavioral constructs and to assess applicability to industrial pharmacy roles in India. Key sources included the International Pharmaceutical Federation (FIP) Global Competency Framework (GbCF), the European PHAR-QA framework, and national entry-to-practice frameworks (e.g., Canada and the United States). This mapping informed the definition of two competency categories: (i) transferable professional/personal competencies and (ii) role-specific industrial pharmacy (technical) competencies.

Professional/personal competency domains were retained from global frameworks because of their applicability across practice settings (communication, continuous professional development, digital literacy, interpersonal relations and collaboration, leadership and self-regulation, and professional and ethical practice). Technical competency domains were defined to reflect major functional areas of the Indian pharmaceutical industry (research and development, analytical development, pharmaceutical and industrial development, industrial pharmaceutical production, quality assurance and control, quality management, and legal and regulatory practice).

(2) Item generation and response scale design

Behaviour-based items were drafted for each domain to support competency-based assessment and personnel selection. Section 1 captured demographic variables (e.g., age, years of experience, current organization, and domain of work). Section 2 (Professional/Personal Competencies; Q1–Q36) measured the frequency of observable behaviours using a five-point Likert scale (Always, Often, Sometimes, Rarely, Never), scored 5–1; domain-wise and overall scores were computed as sums and averages. Section 3 consisted of optional technical modules aligned to respondents' functional area: Research & Development (Q37–Q45), Pharmaceutical and Industrial Development (Q46–Q60), Analytical Development (Q61–Q67), Industrial Pharmaceutical Production (Q68–Q86), Quality Assurance and Control (Q87–Q98), Quality Management (Q99–Q113), and Legal and Regulatory Practice (Q114–Q120). Respondents completed one technical module and rated confidence on a five-point scale (Very Confident=5, Fairly Confident=4, Slightly confident=3, Not confident at all=2, I don't know/Not applicable=1); module scores were summarized using sums and averages.

(3) Expert review for content and face validity

The draft questionnaire was reviewed by subject-matter experts from the pharmaceutical industry with experience across industrial pharmacy domains, quality systems, and regulatory practice. Experts assessed items for relevance, clarity, domain alignment, and redundancy. Feedback was used to refine wording, remove overlap, and improve interpretability.

(4) Revision and finalization

Based on expert feedback, the questionnaire was revised prior to deployment. Following data collection, item analysis and reliability testing were used to identify redundant items in the Professional/Personal Competency section and to support refinement of the scale, as reported in the Results.

Response rate and final analytic sample

A total of 77 responses were received. Of these, 2 respondents did not provide consent and were excluded. The final analytic sample therefore comprised 75 participants, whose responses were used for reliability and validity analyses.

Statistical analysis (validity evidence and reliability)

Survey data were exported from Microsoft Forms for cleaning and analysis. **Content validity** was quantified using expert ratings via item-level and scale-level Content Validity Index (CVI), including S-CVI/Ave and S-CVI/UA, with chance-corrected agreement summarized using modified kappa (k*). **Reliability** was evaluated using Cronbach's alpha for the overall Professional/Personal scale and by domain; technical competency modules were analyzed separately because respondents completed only one module aligned with their primary role. **Construct validity** of the Professional/Personal Competency section (Q1–Q36) was examined using exploratory factor analysis (EFA) appropriate for ordinal Likert-type data (polychoric correlations; oblique rotation), with factorability assessed using the Kaiser–Meyer–Olkin (KMO) measure and Bartlett's test of sphericity. **Known-groups validity** was examined as supportive evidence by comparing scale/factor scores across experience bands and education category (t-tests/one-way ANOVA), with effect sizes reported alongside p-values. Content validity computations were performed in Microsoft Excel; reliability and known-groups analyses were conducted in Minitab® 20.2; and psychometric analyses (polychoric correlations and EFA) were conducted in R using the *psych* package (version 2.6.3).

Technical competency modules were treated as **formative** (i.e., a checklist-like set of role-specific capabilities) rather than reflective indicators of a single latent construct. Accordingly, factor analysis was not forced for the technical modules because items are intended to capture distinct, potentially independent skills within a role and respondents completed only one module aligned to their functional area. Evaluation of the technical modules therefore emphasized (i) content validity (CVI and modified kappa based on expert ratings), (ii) item endorsement/response patterns within each module (descriptive summaries of confidence ratings), (iii) domain-wise internal consistency as a supporting reliability check, and (iv) exploratory known-groups comparisons across experience and training-related characteristics as supportive evidence of validity.

RESULTS

Participant characteristics are summarized in Table 1, including primary technical domain, highest educational qualification, years of experience in the pharmaceutical industry, and education location (India vs outside India). The distribution of respondents across these characteristics is also presented in Figure 2. Figure 3 summarizes average competency scores across participant subgroups. Figures are reported descriptively to show observed patterns in the study sample.

Table 1: Participant characteristics (final analytic sample, n=75).

Characteristic	Category	n	%
Primary technical domain (self-reported)	Research & Development	16	21
	Analytical Development	5	7
	Pharmaceutical and Industrial Development	7	9
	Industrial Pharmaceutical Production	4	5
	Quality Assurance and Control	14	19
	Quality Management	7	9
	Legal and Regulatory Practice	22	29
Highest educational qualification	Bachelor’s	11	15
	Master’s	52	69
	Doctorate	12	16
Years of experience in pharmaceutical industry	0–3 years	20	27
	3-6 years	8	11
	6–10 years	9	12
	11–20 years	21	28
	>20 years	7	9
Education location (highest qualification)	India	70	93
	Outside India	5	7

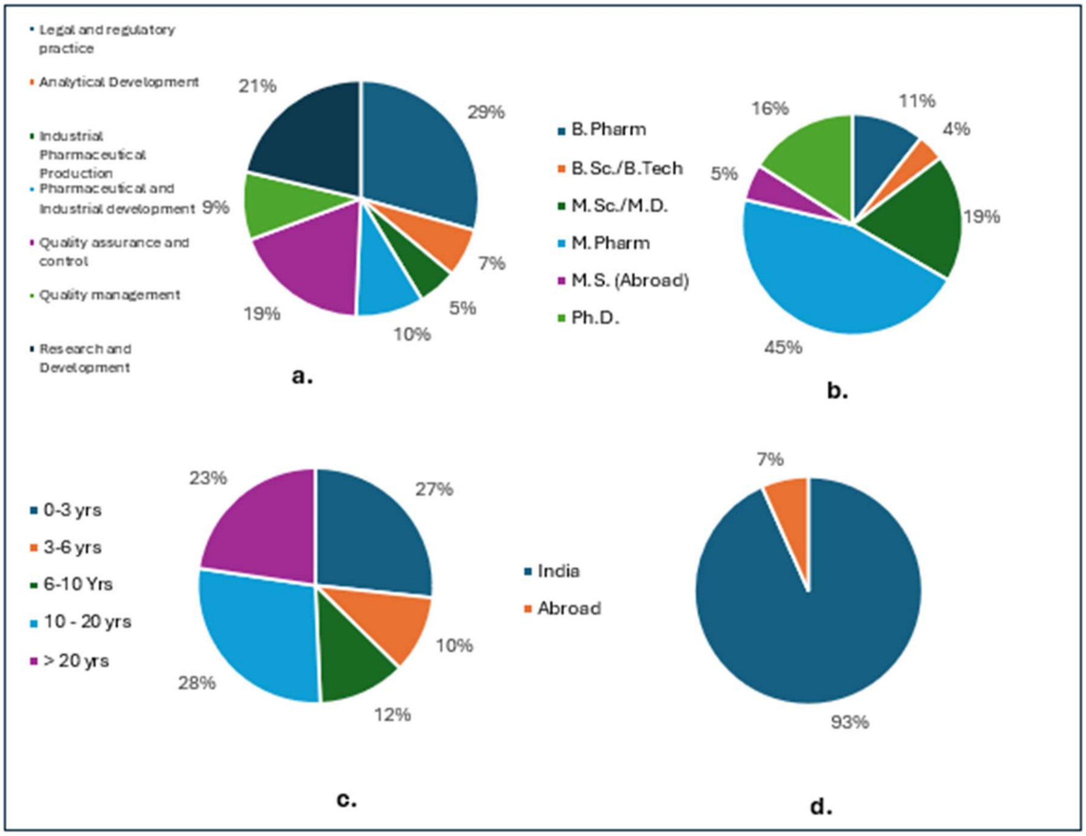

Figure 2: Pie chart depicting graphical distribution of survey participants by a.Pharmaceutical domain b.Highest education c.Number of years of experience d.Highest Education (India vs Outside India)

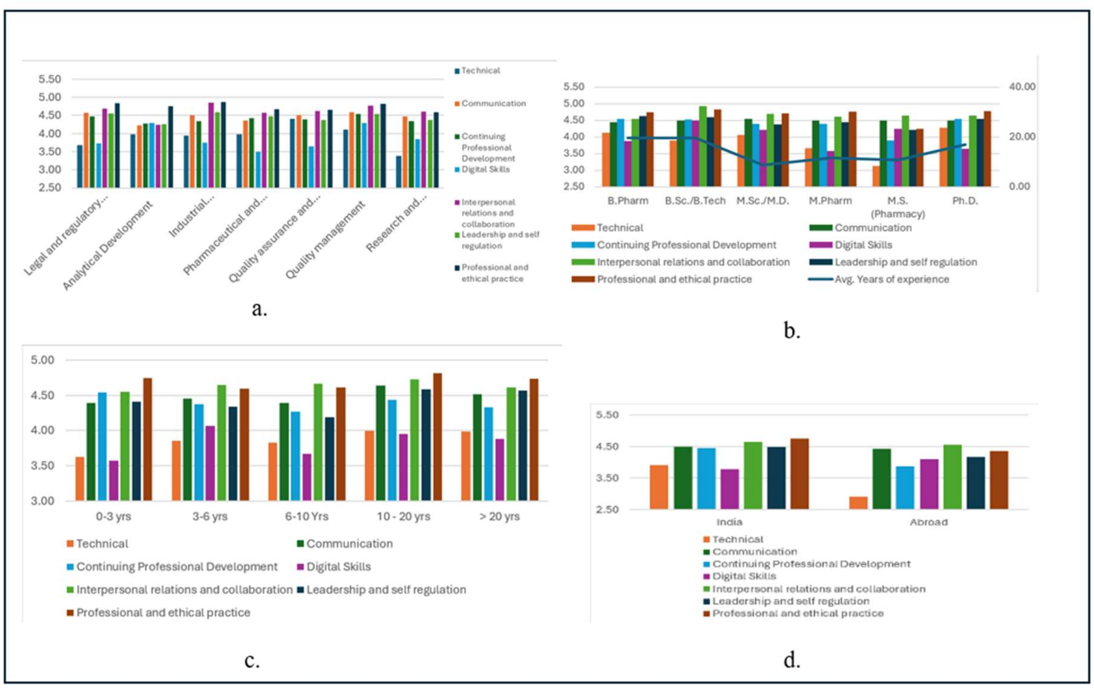

Figure 3: Bar diagram depicting Competency score (technical and professional) distribution of participants against a. Pharmaceutical industry domain b. Educational background (highest degree attained) c. Years of experience d. Education in India or Outside India

Content validity (expert CVI): Expert ratings (10 raters; 4-point relevance scale) indicated excellent content validity for the full instrument (120 items). The scale-level CVI using the average method was high (S-CVI/Ave=0.91), and chance-corrected agreement was also high (average modified k*=0.90). No items fell below common acceptability thresholds (I-CVI<0.78). These findings support that the items are relevant and representative of the intended competency domains (see Table 2).

Construct validity and reliability: The Professional/Personal Competency scale demonstrated high internal consistency reliability (Cronbach's alpha=0.91). Sampling adequacy and factorability diagnostics supported exploratory factor analysis: the overall KMO was 0.70, and Bartlett's test of sphericity was significant (chi-square=1270.42, df=561, p<0.001), indicating that the correlation matrix was suitable for factor extraction. Domain-wise reliability and factorability metrics are summarized in Table 3.

Table 2: Content validity summary (expert CVI; n=10 experts; 120 items).

Metric	Value
Total experts	10
Total items	120
S-CVI/Ave (average I-CVI)	0.91
Average modified kappa (k*)	0.90
Items needing review (I-CVI < 0.78)	0
Items unacceptable (I-CVI < 0.70)	0

Table 3: Exploratory factor analysis (EFA) of Professional/Personal competencies: final 4-factor Promax solution (20 items; n=75).

Item	Factor 1	Factor 2	Factor 3	Factor 4	h^2
Q1	0.76	0.02	0.06	-0.06	0.66
Q16	0.86	0.24	-0.05	-0.06	0.76
Q17	0.86	0.24	0.04	0.07	0.76
Q18	0.86	0.24	0.08	0.05	0.76
Q19	0.86	0.24	-0.04	-0.13	0.77
Q20	0.86	0.24	-0.07	-0.11	0.77
Q21	0.86	0.24	0.01	0.03	0.75
Q22	0.86	0.24	0.25	-0.05	0.82
Q23	0.86	0.24	-0.01	-0.10	0.76
Q24	0.86	0.24	0.01	0.11	0.77
Q25	0.86	0.24	0.06	-0.02	0.76
Q27	0.86	0.24	0.16	0.23	0.83
Q28	0.86	0.24	0.03	0.01	0.75
Q29	0.87	0.24	-0.13	-0.01	0.77
Q31	0.86	0.24	-0.10	0.01	0.76
Q32	0.86	0.24	-0.30	0.27	0.92
Q33	0.86	0.24	0.07	-0.10	0.77
Q34	0.86	0.24	-0.03	-0.05	0.76
Q35	0.86	0.24	-0.17	0.06	0.79
Q36	0.86	0.24	0.05	0.07	0.76

Notes: Promax (oblique) rotation. Values are standardized factor loadings; h^2 indicates communality.

For the technical competency modules, internal consistency varied by domain. Cronbach's alpha values ranged from 0.43 (Analytical Development) to 0.95 (Quality Management), with high reliability observed for several modules including Quality Assurance and Control (0.94), Pharmaceutical and Industrial Development (0.93), and Research and Development (0.85). Given that technical competencies were treated as formative, this reliability estimates are interpreted as supportive checks of item coherence within each module rather than evidence of a single underlying latent construct.

For the Professional/Personal Competency items (Q1–Q36; n=75), exploratory factor analysis suitable for ordinal Likert data supported a parsimonious 4-factor structure after item reduction (final 20-item solution with oblique rotation), indicating interpretable latent dimensions within the professional/personal competency construct. The final rotated loading matrix and factor correlations for the refined Professional/Personal Competency scale are presented in Table 4 and Table 5, respectively.

Table 4: Factor correlations (Promax Φ matrix)

	F1	F2	F3	F4
F1	1.00	0.45	0.02	-0.02
F2	0.45	1.00	0.02	-0.02
F3	0.02	0.02	1.00	0.62
F4	-0.02	-0.02	0.62	1.00

Table 5: Reliability and Factorability of Personal Competencies.

Competency	Cronbach's alpha	Kaiser–Meyer–Olkin (KMO) coefficient	Bartlett's test for sphericity
Overall Professional/ Personal competencies	0.91	0.70	highly significant (chi-square = 1270.42, df = 561, $p < 0.001$)
Communication	0.67	0.72	Significant 66.11 ($p<0.05$)
Continuous Professional Development (CPD)	0.67	0.70	significant (chi-square ≈ 50.57, df = 10, $p < 0.001$),
Digital Literacy	0.38	0.5	4.08
Interpersonal relations and Collaboration	0.56	0.53	Significant (chi-square ≈ 38.53, df = 10, p < 0.001
Leadership and self-regulation	0.87	0.81	highly significant (chi-square ≈ 406.83, p-value ≈ 0)
Professional and Ethical practice	0.62	0.60	highly significant (p-value < 0.001)

Candidate solutions extracting three, four, and five factors were examined. Factor retention was guided by eigenvalues, scree-plot inspection, and interpretability of the rotated solution; the four-factor solution was selected as the most parsimonious and interpretable. Items were flagged as weak if their maximum loading was <0.40 and as cross-loading if secondary loadings were ≥0.30. A refined set of 20 items was retained based on strong primary loadings (≥0.60) and limited secondary loadings (<0.40). EFA was re-run on the reduced item set using the same extraction and rotation approach.

Known-groups validity: Known-groups comparisons were conducted to explore whether competency scores differed across participant subgroups defined by years of experience and educational background (pharmacy vs non-pharmacy). Overall, subgroup differences were modest and patterns were interpreted descriptively due to the sample size. As illustrated in Figures 2 and 3, participants with greater industry experience and pharmacy-based education tended to show higher average Professional/Personal competency scores. Formal hypothesis tests were treated as supportive rather than definitive and did not provide consistent evidence of large between-group differences in this sample. The results are presented in Table 6.

Table 6: Known-groups validity (supportive): factor scores across experience and education.

Comparison	Factor	Group statistics	Test	Test value	p	Effect size	Effect size value
A. Years of experience (Low/Medium/High tertiles)							
Experience	Factor 1	Low: 0.209±1.171 (n=24); Medium: 0.011±0.993 (n=24); High: -0.252±0.704 (n=21)	ANOVA	F=1.225	0.300	η^2	0.036
Experience	Factor 2	Low: 0.107±1.191 (n=24); Medium: 0.111±0.811 (n=24); High: -0.183±0.593 (n=21)	ANOVA	F=0.752	0.475	η^2	0.022
Experience	Factor 3	Low: 0.049±0.849 (n=24); Medium: -0.071±0.799 (n=24); High: -0.128±0.896 (n=21)	ANOVA	F=0.260	0.772	η^2	0.008
B. Educational background (Pharmacy vs Non-pharmacy)							
Education	Factor 1	Non-pharmacy: -0.009±0.948 (n=30); Pharmacy: 0.006±1.009 (n=45)	t-test	t=-0.065	0.948	d	-0.015

Education	Factor 2	Non-pharmacy: -0.072±0.842 (n=30); Pharmacy: 0.048±0.933 (n=45)	t-test	t=-0.579	0.565	d	-0.134
Education	Factor 3	Non-pharmacy: -0.045±0.911 (n=30); Pharmacy: 0.030±0.828 (n=45)	t-test	t=-0.359	0.721	d	-0.086

Notes: Factor scores are derived from the final 4-factor EFA solution. Experience bands represent tertiles (low/medium/high). Education was coded as pharmacy vs non-pharmacy. ANOVA results are reported with η^2; t-tests are reported with Cohen's d. Values are rounded to three decimals.

DISCUSSION

This study developed and provided initial validation evidence for an India-relevant competency framework and questionnaire to support competency-based selection and development of personnel in the pharmaceutical industry. Overall findings indicate strong content validity (expert CVI), high internal consistency for the Professional/Personal competency scale, and an interpretable four-factor structure for the refined Professional/Personal items, supporting use of the tool as a structured, context-relevant assessment approach.

Comparison with existing competency frameworks

The framework is conceptually aligned with widely used models such as the FIP Global Competency Framework (GbCF), PHAR-QA, and national entry-to-practice frameworks by retaining transferable professional/personal domains (e.g., communication, CPD, leadership/self-regulation, and professional/ethical practice). However, because many global frameworks are oriented toward patient-facing practice, their direct applicability to industrial roles is limited. The present work extends these models by explicitly incorporating role-relevant technical competency modules reflecting common pharmaceutical industry functions in India (e.g., research and development, production, quality systems, and regulatory practice) and by operationalizing competencies as behavior-based items that can be used in selection and workforce development.

Interpretation of validity evidence

The content validity results indicate strong expert agreement that the included items are relevant for the intended competency domains. For the Professional/Personal competencies, the combination of high internal consistency and adequate factorability supported exploratory factor analysis and yielded an interpretable, parsimonious four-factor structure after item reduction. In contrast, technical competency modules were designed and analyzed as formative (checklist-like) role-specific capability sets rather than reflective indicators of a single latent construct; therefore, construct validation for technical modules focused on content validity, item response patterns, and supportive domain-wise reliability rather than factor analysis.

Implications for implementation

In practice, the framework can support more structured and transparent personnel selection by linking role requirements to explicit professional/personal and technical competency expectations (e.g., informing interview guides, assessment rubrics, and onboarding plans). It can also be used to identify competency gaps and prioritize targeted training and continuing professional development. From a quality and compliance perspective, competency documentation aligned to GMP expectations may strengthen qualification and training records for inspections and internal audits.

Limitations and future directions

This study is limited by convenience sampling and modest sample size, which may reduce generalizability and the stability of subgroup comparisons. In addition, respondents completed only one technical module aligned to their role, limiting cross-domain psychometric evaluation. Future work should validate the Professional/Personal factor structure in larger samples and assess predictive/criterion validity against external performance outcomes (e.g., supervisor ratings, training completion, quality metrics). For technical modules, larger domain-specific samples would support refinement based on item endorsement patterns and role-specific performance criteria.

CONCLUSION

This study proposes an India-relevant competency framework and questionnaire that integrates transferable professional/personal competencies with role-specific technical competency modules for the pharmaceutical industry workforce. Initial evidence supports strong content validity and good psychometric performance for the Professional/Personal competency scale. The tool may support competency-based selection, targeted training, and more consistent personnel qualification documentation within GMP-oriented quality systems.

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ABBREVIATIONS:

PCI: Pharmacy Council of India; WHO: World Health Organization; GMP: Good Manufacturing Practices; FIP: International Pharmaceutical Federation; GbCF: Global Competency Framework; CPD: Continuous Professional Development; CDC: Centers for Disease

Control and Prevention; EFA: Exploratory Factor Analysis; KMO: Kaiser–Meyer–Olkin Coefficient; TQM: Total Quality Management; CVI: Content Validity Index.

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