Chapter 8

CONCLUSION

This chapter attempts to provide a synthesis and forwarding of the different levels of inquiry, embodied in the shifts in the unit of analysis, undertaken in the previous chapters. In this context, it also attempts to triangulate the conceptual aspects borrowed from the constructionist and interpretivist theoretical traditions within Sociology with the methodological protocols deployed and empirical observations forwarded in the thesis.

To recapitulate, the study broadly attempted to examine the discourse of drug quality in the Indian pharmaceutical industry. The discourse of drug quality involves a complex interplay of technical or cognitive, normative and politico-economic dimensions. The technical or cognitive dimensions may be understood in terms of the reification of the drug into a set of physio-chemical parameters or protocols such as purity, efficacy, safety, minimization of error, potency, consistency etc. However, the representations and contestations between different actors in the ‘hybrid group’ like firms, regulatory bodies, health activists etc over such reified attributes of drugs and the transnational drive towards harmonization of these protocols also point to the normative and politico-economic dimensions informing such reification. The notion of qualification (Callon 2002), elaborated in the introductory and methodology chapters, provides us with a point of entry to understand the interplay of these different dimensions, which inform the discourse of drug quality.

The review discussion of the engagements with pharmaceuticals from vantage points as diverse as sociological and anthropological accounts, perspectives from science,
technology and society (STS) studies, the economics of technological change and engagements from within the domain of public health studies attempted to provide a preliminary glimpse into the sheer diversity of issues and range of actors involved in the interplay of these above mentioned dimensions and correspondingly the qualification of drugs. Also, the ‘biographical’ approach (Geest et al 1996), or the understanding of the drug as social or cultural product with a lifecycle of its own, was deployed as a ‘heuristic’ tool and in terms of a frame of analysis in order to understand the socio-technical processes shaping the qualification of drugs.

However, rather than undertake an examination of all the stages of this lifecycle of drugs, a daunting and unfeasible exercise, the study attempted to understand ‘fragments’ of this biography by confining its inquiry to the socio-technical processes driving the qualification of drugs in the pre-clinical stage of research and development and the stage of manufacturing of finished formulations within the sphere of the firm. Outside the ambit of the firm, it attempted to capture such qualification by examining the contestations among the actors located in the hybrid group in relation to a controversial drug and also within the relatively larger terrain of drug regulation.

These shifts in the unit of analysis, in terms of the examination of the qualification of drugs during specific stages within and outside the sphere of the firm, were orchestrated with the objective of unpacking the nuanced, varied and complex nature of the interplay of the afore-mentioned technical, normative and politico-economic dimensions. It must also be emphasized, however, that the ‘biographical’ understanding of drugs, invoked in the above context, does not imply linearity of the qualification process in typical ‘bench to bedside’ fashion but recognizes the dialectical nature of such processes.
The operationalization of concepts deployed to understand such qualification was in itself a daunting task, given that the typical pharmaceutical firm in India, and even the terrain as a whole, is a space, which is a closed-off space, whose inhabitants permit access to researchers interested in studying their activities in a highly restrained and guarded fashion, if at all. In such a situation, the undertaking of a typical ethnographic study involving prolonged interaction and engagement with the activities of the concerned actors can become a near impossible task. Accordingly, and inspite of a departure from conventional ethnographic techniques, the ethnographic component of the study and the related objective of providing an emic perspective into the activities and the negotiations among the concerned actors, with specific reference to the qualification of drugs, was sought to be embodied, at least in part, through in-depth interviews with sixty four respondents. This is not to deny that such techniques have their limitations and the narratives of the respondents may be influenced in ways, which are the product of the interview situation itself. These interviews were sought to be triangulated with relevant secondary material and also notes and observations made by the researcher in the course of attending and participating in several meetings, conferences and workshops organized by civil society bodies like Medicins Sans Frontiers, New Delhi and Centad, New Delhi, WHO, New Delhi, industry bodies like FICCI, New Delhi and government bodies like the National Health Systems Resource Centre, New Delhi on several issues related to patents, Schedule M, financing of health systems, public funded R&D, issues related to access to medicines etc during the period between January 2008 to April 2009. Detailed notes of the proceedings of these meetings, workshops and conferences were taken down. In this context, the researcher also had the opportunity to have short conversations with the participants, who included
individuals representing industry bodies, health activists, regulators in one or two instances and academicians. The researcher was also invited as a resource person and participant in three of these meetings and workshops.

The logic afforded by grounded theory, which allows for the collection of data in a qualitative non-statistical mode and its insights, was deployed to identify potential respondents, who could provide relevant information to the researcher. Additionally, the nature of the problem necessitated the use of the case study method rather than the recourse to conventional survey-related techniques to understand the processes shaping qualification in the stages selected for inquiry within and outside the ambit of the firm.

Methodologically speaking, in the above-mentioned context, the study also attempted to take recourse to the interpretative tradition within sociology. The issues involved in the qualification of drugs may be located within this theoretical tradition, involving the feeding off a critical social science. This essentially also involved understanding qualification in terms of meanings attached to the drugs by different actors and examining their negotiations in terms of the power exercised by the actors of the hybrid group to shape the qualification of drugs in certain ways. The constructionist tradition was also felt to be significant here in terms of the understanding of the qualification of drugs as a ‘negotiated order’. Power in this sense is construed not as monolithic but as dispersed (Busfield 2006: 301-306) and the key sociological question here is how the balance of power operates between these groups and influences the interplay of the cognitive, normative and politico-economic dimensions in particular ways that shape the qualification of drugs. This is the active sociological dimension that the study attempted to retrieve in its
examination of the discourse of drug quality with reference to the actors in the hybrid group both within and outside the ambit of the firm.

The characteristic features of the Indian pharmaceutical industry that distinguish it from the global pharmaceutical industry were also sought to be examined in this context. The pharmaceutical industry in India is a fragmented and heterogeneous sector consisting of nearly three hundred large and medium scale firms and over ten thousand registered small scale firms, (Gehl, Sampath 2008: 14) with varying capabilities in terms of research and development and manufacturing. The proliferation of these firms, with varying levels of expertise, occurred during the eighties, in the context of the Patent Act of 1970, which recognized only process patents and permitted firms to come up with generic versions of the original drug with alternate processes. These processes were developed both in-house and by the laboratories of the CSIR. (Abrol 2004: 273-294). This also resulted in a gradual building up of competencies and expertise in reverse engineering techniques and led to the production of essential drugs at low costs, which were affordable to poor consumers. However, in the post-product patent regime, the need of large firms to produce lead molecules in the context of discovery research activities to survive the patent game in the long term and the progressive stringency in manufacturing protocols, emphasized by recent regulatory policies, has led to the gradual decline of the small and medium scale sector and also generated apprehensions among health activists about the rise in prices of essential drugs. The post-product patent regime has also thrown up new issues related to the definition of new chemical entities, ethical considerations in clinical trials and issues related to data protection and data exclusivity. (Chaudhuri 2007, Gehl Sampath 2008, Srivastava 2008). However, the production and emergence of new and ostensibly innovative
formulations, which are mostly varied combinations of old drugs, continues unabated in the industry even in the new patent regime. The proliferation of these formulations has largely been in the context of the circumventing of the Drug Price Control Order (DPCO) related policies by the firms. The thrust of the study in this context was to track the shifts in regulatory policies in the context of the various activities carried out by the firms in the sector, both in the process patent and the product patent regime.

The qualification of drugs and the interplay of the cognitive, normative and politico-economic dimensions in the a) pre-clinical stage of R&D and b) the stage of manufacturing of finished formulations within the sphere of the firm and c) the contestations among actors located in the hybrid group in terms of a controversial drug and d) within the larger terrain of drug regulation was sought to be captured and outlined separately in four substantive chapters in the thesis. A rendering of the insights that emerged through these shifts in the unit of analysis becomes pertinent in this context.

In the context of examining the qualification of drugs in the pre-clinical stage of research and development, the study sought to examine the process of fact-making and knowledge production by actors in the hybrid group within a firm located in Hyderabad, Dr Reddy’s Laboratories, through an interrogation of their every day practices and routines. Discovery research at the firm level is generally referred to as pre-clinical testing, involving test-tube level experiments and testing on animals. Fact-making by the actors in the firm occurs in an interdisciplinary context and the hybrid group is largely composed of medicinal chemists, biologists, pharmacologists and management committees who negotiate with each other to transform indeterminate and amorphous problems in the laboratory into concrete entities, which have therapeutic value.
Scientific interests are clearly tailored in this context to the therapeutic demands of the market since it is the management committees within the firm, which arrive at decisions about the nature of the projects to be undertaken, the specific approaches involved and the methods to discover new drugs within the therapeutic areas taken up by the firm. Also, research projects are largely designed to obtain candidate molecules, which are efficacious in a large percentage of the population. This involves using some selectivity or judgement in terms of which compounds to synthesize.

The problem confronting the scientists, who belong to these different disciplines, in the hybrid group is to come up with a drug, which is analogous or similar to an existing drug or class of drugs and which involves the modification of known compounds. Pre-clinical research in this context also involves the extrapolation of data obtained in in-vitrio research to in-vivo animal tests. However, the problem, perceived with most of these modified compounds, is that the data obtained in most animal models are often poorly extrapolatable to human patients. This is felt to be the reason for the failure of compounds at the stage of clinical trials.

In terms of the qualification of drugs, what is significant here is that while the attributes of the molecule, in terms of parameters such as potency, safety and efficacy are ascribed in quantifiable terms, most of the processes in the human body, which is perceived as a complex jungle of proteins and processes, are still perceived as relatively less known, which renders the prediction of adverse or therapeutic effects of the drug extremely difficult. The qualification of a drug in the pre-clinical stage thus generally involves investing it with quantifiable attributes, related to its distribution and absorption, safety, potency, efficacy and toxicity.
In terms of the norms invoked during this stage, problems related to disciplinary differences between chemists and biologists and the unpredictability in finding therapeutically beneficial candidate drugs are couched in a discourse about the challenging nature of the pharmaceutical discovery enterprise, the level of capabilities entailed “even” in analogue research and the logistics of interdisciplinary team management.

The qualification of drugs in terms of a “negotiated order” here is felt to be facilitated by the evolution of common jargons between chemists and biologists, which in itself is visualized as the result of the shifts in the engagements of biologists from macroscopic processes to microscopic processes operating at the molecular level. This is also perceived as leading to the gradual emergence of shared meanings with respect to attributes of the drug such as potency, efficacy and toxicity. The explanations for the resolution of issues and consensus among the members of the hybrid group are couched in a broad discourse of the “objective” and “factual” nature of experiments and data generated by the team and the privileging of the scientific method as compared to the methods used in social science disciplines, with the caveat of the possibility of different ways of interpreting results to some extent. Again, with respect to the qualification of drugs by the chemists and biologists in the hybrid group, the potential of the drug to be efficacious in a large cross-section of the population, the available scientific expertise in the firm and commercial feasibility are determining factors in resolving disputes among members about the ‘ideal’ candidate drug.

These analogous molecules are also qualified as low risk ventures in comparison to the discovery of a new family of molecules. The task of arriving at these molecules is orchestrated through carefully crafted managerial strategies of deploying the appropriate
merge of academic and industrial expertise in the concerned project within the firm. The other interesting aspect here is that if the candidate drugs, which are qualified in particular ways, do not act predictably, the failure related to such qualification is articulated in terms of the incorrect scientific assumptions pertaining to the function of the active locus or target and the lapses in the scientific competence of the concerned researcher. Qualification in this context implies not only the context of the attributes assigned to the molecule but also in its potential to act in predictable ways.

The side effects of the drugs are qualified by the hybrid groups in the firm as the inevitable ‘penalties’ paid for curing larger medical problems, inevitable because the larger context of scientific beliefs, in which these analogous molecules are crafted, perceives these molecules as ‘alien’ substances, which have curative properties, but which simply by virtue of their ‘alien’ nature are resisted by the animal and human biological system. Articulations about these side effects are also made in the context of different treatment regimens and in terms of being more severe and difficult to predict in the case of chronic diseases in comparison to infectious diseases. Thus different protocols for molecules relating to different diseases are sought to be justified in this context. What this means in effect is that drugs are invested with different attributes or qualified differently, depending upon the disease they seek to address. These perceptions also point to the porosity between discovery related laboratories and clinical spaces and how the stabilization of laboratory related protocols and knowledge regarding drugs occurs through the flow of facts between these different spaces.

The out-licensing episode, which dealt with the episode of the out-licensing of two molecules Balaglitazone and Ragaglitazar by the firm attempts to demonstrate how the
attributes of the drugs were qualified differently by the different groups, including the licensing firm *Novo Nordisk* on the one hand and *DRL* and *Rheosciences* on the other hand, in terms of safety related concerns (technical dimension), norms related to professional judgement and scientific evaluation of the drug (normative dimension) and also in terms of their interests in relation to these molecules (politico-economic dimension).

The larger argument sought to be made in the context of the DRL study is that within the ambit of the firm, in regard to pre-clinical R&D, some kind of ‘partial qualification’ of the ideal candidate molecule is sought to be done by the management committees of the firm in the process of moulding the research strategies of the teams in particular therapeutic areas, the specific approach and methods to be deployed in the crafting of the molecule and judgements about which molecule to synthesize. This ‘partial qualification’ is in terms of a risk-benefit assessment and is determined by technical or cognitive dimensions (the molecule’s specific attributes in terms of purity, efficacy, side effects etc) and aspects relating to its patent-worthiness, the discovery of analogous molecules as a low-risk venture and its commercial viability and use in a large population (politico-economic dimensions).

Such partial qualification of the molecule by the management committee gets ‘factored in’ in the efforts of the other scientists in the hybrid group, mainly chemists and biologists, in their subsequent attempts to further qualify and effect a closure in terms of these attributes. The different interpretations of the attributes of the molecule and the subsequent negotiations between the members of this interdisciplinary team also involve the invoking of norms related to the scientific enterprise and their disciplinary background. Norms relating to disciplinary background are invoked in the context of tensions related to how, while the attributes of the molecule get ascribed in quantifiable terms, the task related
to the role of the chemists in the team; knowledge about most of the processes in the human body and its response to the molecule is still limited, the task relating to the role of the biologists. Norms relating to the ‘scientificity’ of their enterprise are invoked in the context of failure to qualify the molecule in predictable ways and here the articulations are also in terms of scientific lapses committed by individuals in the team. These qualifications are also informed by politico-economic considerations involving the need to take the molecule quickly through the stage of clinical trials and commercial it.

The ‘negotiated order’ is effected here by the chemists and biologists in the context of generating shared meanings about attributes of the molecule relating to potency, efficacy, safety etc. Power obtains here in terms of the ability of the management committees to shape research strategies of scientists and influence their judgements about the potential and viability of candidate molecules in ways that are beneficial to the firm. Thus we see the interplay of cognitive, normative and politico-economic dimensions occurring in a specific way in the context of pre-clinical research.

The qualification of drugs by individuals in the hybrid group during the stage of manufacture of finished formulations was sought to be examined through the everyday routines and practices of an organization, Locost Standard Therapeutics, located in Baroda, Gujarat. In this context, the study specifically attempted to chart the organization’s shift from local GMP-related drug manufacturing and testing protocols to the ostensibly more sophisticated and stringent set of protocols, embodied by Schedule M. The actors in this hybrid group include manufacturing personnel, testing personnel and the local regulators, who interact with the personnel in the organization during inspections. In this sense, the hybrid group here is relatively more fluid as the firm mediates with actors outside its realm.
The notion of drug quality is conventionally associated with and invoked more explicitly in the context of manufacturing and related testing activities by pharmaceutical firms. The articulations about the notion of quality here by firm personnel were in terms of the trope of cost benefit assessment. The discourse of drug quality is informed here by considerations related to whether the costs involved in the purchase of sophisticated instrumentation and infrastructural changes, mandated by the Schedule M protocols, is justified in the context of the marginal or incremental improvement in the therapeutic efficacy of the drug.

The qualification of the manufacturing process or final product by the regulators in terms of detailed documentation, the use of sophisticated instrumentation and automated machinery was also questioned by the personnel in the organization on grounds of the potential for circumvention of these protocols through non-usage of the machinery in everyday manufacturing activities, lack of adequate regulatory expertise to detect such circumvention, skipping of tests and procedures by firms with the expectation that these would not be detected in the final product and the generation of spurious documents.

The problematizing of quality related issues by the personnel in the organization was not done through purely technical criteria but also in relation to other normative aspects like organizational commitment, adequate expertise of the concerned personnel, market pressures etc. The utility of the larger philosophical principles undergirding quality control were critiqued in terms of the practices built around these principles. This is also because the onus of tailoring the copiously laid down protocols, in accordance with local economic and political realties, regulators’ requirements and the requirements of the concerned organization largely rests with the individual firm. The organization’s assertion in this context was also that similar product quality can be obtained and validated, independent of
firm-level differences in aspects like standard operating practices, procedures, methods of documentation and degree of automation. The seemingly routine negotiations over protocols related to infrastructure, instrumentation and manufacturing processes were also perceived by the organization as having larger politico-economic implications in terms of creating entry barriers for small firms.

In the context of manufacturing, there is clearly a fragmenting and digitizing of the notion of quality or the investing of a drug with quantifiable attributes, again related to stability, potency, efficacy, purity, safety, avoidance of contamination, adherence to SOPs etc by the members of the hybrid group (technical dimension). However, the qualification of the drugs in this context is also linked to norms such as regulators’ professional expertise, ‘appropriateness’ of the protocols in terms of augmenting therapeutic efficacy, organizational commitment etc. (normative dimension). Additionally, the qualification of these drugs by the organization is also sought to be understood in terms of the larger and global context of harmonization of protocols and the creation of entry barriers for small firms (politico-economic dimension). The element of ‘negotiated order’ may be understood in this context in terms of how firm personnel arrive at a common understanding of and tailor standard operating practices and procedures in accordance with their requirements.

The ‘negotiated order’ also manifests itself in the interaction between firm personnel and regulators during compliance related audits and regulators’ local and contextual interpretations of these protocols. Power obtains here in terms of the ability of the regulators to shape and enforce certain kinds of compliance but which may be resisted by firms in terms of the skipping of certain procedures with the expectation that these would not be detected or in terms of partial compliance with protocols.
The examination of a controversial drug, Nimesulide, was undertaken in order to obtain an insight into the processes and mechanisms shaping the qualification of drugs outside the realm of the firm. In this context, the present study attempted to understand the mediation of the drug with other agencies outside the realm of the firm in regard to how these agencies attempted to shape its career in the Indian context. The Nimesulide controversy also examined how the terrain of drug regulation is a contested terrain, involving a hybrid group, consisting of heterogeneous actors like firms, regulatory bodies, health activists, scientists, physicians, consumers etc. These actors are all involved in the qualification process, though the extent of their involvement and influence may vary, in terms of claims and counter-claim about the risks and benefits of drugs and in shaping knowledge claims related to their attributes.

In the context of Nimesulide, different actors including the petitioner, who filed a public interest litigation in the Delhi high court urging for its ban in India, on one hand and the Indian regulatory body and the medico-scientific community, on the other hand, presented different versions of the drug’s regulatory status in countries like the United States and the United Kingdom and its legal status in India, in addition to invoking different sets of ‘medical’ facts and ‘scientific’ evidence pertaining to the drug’s efficacy and safety profile. The submissions by these actors to the court were also reflective of the struggles over credibility by these actors. Each group resorted to endorsements by opinion makers to strengthen the ‘scientificity’ of their particular sets of claims. The petition had the support and endorsement of prominent health activists involved with the All India Drug Action Network. The respondents sought the endorsements of prominent physicians in the Indian Association of Pediatrics, the Indian Medical Association and other medico-scientific
professionals. The submissions by the petitioner alleged collusion between the firms, the regulatory body and the medical practitioners in the promotion of the drug. The petition also alleged that commercial rather than therapeutic interests had dictated the continued presence of the drug in the market despite adverse reactions. The respondents on the other hand, invoked norms of professional expertise and scientific evidence to assert the safety of the drug for use in adults and children. Each group alleged bias, that is, the petitioner alleged conflict of financial and professional interests and the respondents alleged prejudice and ‘over dramatic representations’ by the media and health activists without corroborating evidence.

The attributes of Nimesulide were qualified differently by different groups of actors during the course of the litigation. For the petitioner, Nimesulide was clearly an ‘unsafe’ drug, reinvented as therapeutically beneficial by the demands of the market and the ‘machinations’ of the firms and their collusion with regulatory bodies and physicians. The print media and activists largely represented the Nimesulide episode in the broader context of an over liberal and inefficient regulatory regime, which had allowed the Indian market to be flooded with scores of therapeutically irrational and potentially hazardous formulations. The experts involved in the assessment of the drug believed that the drug was largely ‘safe’ and ‘efficacious’ in the absence of evidence to the contrary and also saw the episode as the ‘over-dramatic’ and ‘unscientific’ representation of stray adverse drug reactions by media and health activists. The firms involved in the litigation, particularly Ranbaxy, also represented the drug as safe and therapeutically beneficial and represented the controversy as needless slander of their ‘legitimate’ economic pursuits. The central regulatory body, though it admitted to some lapses on the part of state regulators in the issuing of licenses,
generally represented the controversy as a needless challenge to its ‘expertise’ and ‘scientific’ judgment.

Needless to say, the complex interplay of technical, normative and politico-economic dimensions involved in the qualification of the controversial drug is reflected adequately in the insights brought out in the foregoing paragraphs. Though closure of the controversy was sought to be effected through litigation, the outcome of the litigation was also shaped by the negotiations between the concerned firms, regulatory bodies and prominent members of the medico-scientific community in India over the safety related issues pertaining to the drug. There is thus a ‘negotiated order’ at work here too, although clearly of a different sort from that witnessed in the earlier two case studies. Additionally, the Nimesulide controversy also indicated how firms, in collusion with regulatory bodies and medical practitioners, may have relative power to qualify drugs as ‘safe’ and ‘effacious’ and shape its therapeutic attributes in comparison with other actors in the hybrid group.

The study also sought to examine the ways in which the discourse of the firms, in relation to the qualification of drugs, is received and shaped by the individuals located in the hybrid group in the terrain of drug regulation, such as health activists, regulatory bodies, academicians, physicians and representatives of industry bodies in the context of different regulatory issues, such as the generation of patents, R&D activities, licensing of medicines, the conduct of clinical trials, compliance with manufacturing protocols, marketing practices, monitoring of adverse drug reactions and policy issues. The study also attempted to understand the negotiations among these actors with respect to such qualification. In this sense, the qualification of drugs was sought to be understood within a relatively larger and denser canvas.
What was common about the contestations on these various issues or sites in the terrain of drug regulation was that they originated largely from technical or cognitive issues relating to how the attributes of the drugs were qualified. In the context of patents, the technical dimension of the contestations pertained to the qualification of the new chemical entity and definitions about what constituted incremental therapeutic efficacy. In the context of clinical trials, the contestations emanated from the different representations of the safety and efficacy related data of the concerned drugs. These very same technical dimensions were the source of contestations in the case of combination drugs, the issues related to licensing of medicines and marketing issues. However, these differences over the technical aspects related to the drugs were represented in normative terms or by the invocation of different sets of norms by the actors. In normative terms the qualification of drugs by firms, was largely in terms of ‘innovative effort’ and ‘scientific progress’. However, politico-economic considerations related to commercial viability and profit also shaped the ways in which these in these drugs were represented in different sites of contestation. The norms invoked by health activists in relation to the qualification of these drugs in different contested sites were in terms of ‘therapeutic worth’, ‘access to medicines for the poor’, ‘rationality’ and ‘appropriateness.’ The norms invoked by the regulators and their qualification of these drugs, however, were relatively ambiguous and fluid and attempted to strike a balance between public health concerns and promoting innovative effort and growth in the industry. Regulators’ qualifications of attributes and protocols related to drugs were also equally informed by the larger politico-economic context of harmonization.

There are variations in terms of how the “negotiated order” obtains in each of these sites of contestation. With reference to patent related issues, there is a convergence of norms
and interests among domestic firms, health activists and regulators and the ‘negotiated order’ obtains in a relatively straightforward manner there. However, with reference to issues related to clinical trials, combination drugs and marketing practices, the ‘negotiated order’ is redolent of issues involving the relative power of different actors and is effected largely through the collusion of firms and regulatory bodies.

To sum up and revert to the principal arguments of the thesis, the reification of drugs in terms of its technical attributes is a trope, which is common to the qualification of drugs in the Indian pharmaceutical industry, whether in the stages of pre-clinical R&D or manufacturing, in the case of a controversial drug or in different sites of contestation in the terrain of drug regulation. However, the norms invoked to justify such reification may vary, not only in terms of different sets of norms being invoked by actors in the hybrid group but also in terms of the same actor, for instance the firm, invoking different norms in various stages that a drug undergoes or in various contested sites. While the qualification of drugs is primarily in terms of a trope of ‘risk-benefit’ assessment in the pre-clinical stage, it is informed by considerations about ‘cost-benefit’ during the stage of manufacturing, within the ambit of the firm. Again, different kinds of politico-economic considerations may inform actors’ qualifications of these drugs. The discourse of drug quality, in this sense, is thus informed by a complex interplay of technical or cognitive, normative and politico-economic dimensions.

Limitations of the study

The present study largely attempted to capture certain fragments of the biography of drugs. The culture of industrial research and testing in the industry are ethnographically unknown areas, especially in the Indian context. Such studies require a sustained
ethnographic engagement with the field, which was not possible in the current context due to the difficulties experienced in obtaining access to personnel from the Indian pharmaceutical industry and regulators, even though the ethnographic content was partly sought to be embodied through in-depth interviews and participation in numerous conferences, seminars and workshops, organized by health activists, scientists/academicians and industry bodies, on the issues related to the study over a period of time. Issues for future research could be in terms of capturing the non-linear nature of this lifecycle that drugs undergo, especially in the stages related to clinical testing and marketing.