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Review Article

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Comparison of Monographs of Indian Pharmacopeia with BP and USP Pharmacopeia

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Abstract

The objective of this study is to emphasis on the importance of the chromatographic testing methods updates to evaluate the quality of drug products and drug substances. Indian pharmacopeial monographs compared with United States pharmacopeia and British pharmacopoeia monographs for the critical testing parameters. The monographs of most commonly prescribed or sold Tablets like Paracetamol, Amoxycillin, Co-amoxiclav, Losartan potassium and its drug substances were selected for this comparative study. The comparison was made to the critical tests like assay and related substances for drug substances; assay, dissolution and related substances tests for drug Products. It has been observed that the Indian pharmacopoeia assay and dissolution tests are comparable with other pharmacopoeias, however related substances methods of analysis need to be updated as per current requirement. The comparative study suggests that Indian Pharmacopoeia need to strengthen testing procedure and specification limits to improve the quality of pharmaceutical products.

Keywords: Paracetamol, Amoxycillin, Co-amoxiclav, Losartan potassium, Monograph, USP, British Pharmacopoeia (BP), Indian Pharmacopoeia (IP).

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1. Introduction

The quality of pharmaceutical medicine is the key for the safety and efficacy of the pharmaceutical drug products. The quality of the medicines is controlled through the specification. Specifications are critical quality standards that are proposed and justified by the manufacturer and approved by regulatory authorities as conditions of approval. Analytical procedures and acceptance criteria for testing drug products are divided into two categories, those that assess general product quality attributes like Identification, Assay and Impurities and those that assess product performance which is a specific quality attribute typically linked to bioavailability and bioequivalence studies like dissolution testing. The standard reference for pharmaceutical drug substance and drug product specifications is Pharmacopeia.

The Pharmacopoeia is an official collection of approved pharmaceutical standards. In addressing anyone who produces, distributes, or controls medicinal products it comprises requirements on the quality of medicinal products and of the substances used to manufacture them. Moreover, it provides quality control methods.

The objective of this study is to evaluate the Indian Pharmacopoeias to United States Pharmacopeia (USP) and British Pharmacopoeia (BP). In this present study some of the IP monographs were selected based on Products that are prescribed mostly. During the selection of monographs both the Drug substance (API) and Drug products (Finished Products) were selected and compared with USP and BP.

1.1. Indian Pharmacopoeia

The history of the Indian Pharmacopoeia (IP) began in 1833, when a committee recommended publication of a pharmacopoeia, which was first completed in 1844 and mainly consisted of commonly used indigenous remedies. A subsequent publication in 1868 included not only the indigenous drugs used in India, but also the drugs of the British Pharmacopoeia. Then in 1885, the BP was made official in India. After independence from Britain, the Indian Pharmacopoeia Commission was

established in 1948, with its main function being the publication of IP as the national pharmacopoeia. The first edition of the modern IP was published in 1955, and the current 8th edition was published in 2018. (1)

Indian Pharmacopoeia (IP) is published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Ministry of Health & Family Welfare, Government of India. IP is recognized as the official book of standards for the drugs being manufactured and/or marketed in India. IP contains a collection of authoritative procedures of analysis and specifications of drugs for their identity, purity and strength. The standards of the IP are authoritative in nature and are enforced by the regulatory authorities for ensuring the quality of drugs in India.

1.2. United States Pharmacopeia

USP has a rich history, dating back to 1820, when 11 physicians met in the Senate Chamber of the U.S. Capitol building to establish a pharmacopeia for the United States. USP Monographs is continuously revised by an exceptional process of public involvement and substantial interaction between USP and its stakeholders, both domestically and internationally. Revisions are presented in the USP–NF three times per year in November, February, and June. Accelerated Revisions [including Errata, Interim Revision Announcements (IRAs), and Revision Bulletins] are published periodically and with greater frequency. (2)

1.3. British Pharmacopoeia

Pharmacopoeias that have legal status within the UK are the British Pharmacopoeia (BP), including the BP (Veterinary), and the European Pharmacopoeia (Ph. Eur.). The BP provides the only comprehensive collection of authoritative official standards for UK pharmaceutical substances and medicinal products. BP is published every year in August, becomes effective on 1 January of the following year, and incorporates all the monographs and texts of the Ph. Eu. (3)

2. Comparison of Monographs of Paracetamol Drug substances

Paracetamol, also known as acetaminophen, is a medication used for fever and mild to moderate pain. Over 200 paracetamol brands are sold in India. In 2017-18, 4.77 lakh tablets worth Rs 1,008 crore were sold in India, according to the data. “The unit sales have seen consistent growth. During covid-19, the sales of Paracetamol Tablets has shown a significant increase in the sales. (4)

Table 1. Comparison of Monograph of Paracetamol Drug substance with USP and BP

Monograph Test Contents	IP 2018 (5)	USP NF 2021(6)	BP 2021 (7)
Assay Limits	99.0 -101.0 %	98.0 -102.0 %	99.0 -101.0 %
Assay	Titrimetric method End point: Visual detection (Yellow colour is produced)	Method: HPLC Column: L7 Packing Detection: UV at 254 nm Quantification: External standard System Suitability: Tailing factor: NMT 2.0 RSD NMT:1.0 %	Titrimetric method End point: Visual detection (Greenish yellow colour is produced)
RS	Method: HPLC Column: C8 Packing Detection: UV at 245 nm System suitability: Resolution: 4.0 S/N ratio: NLT 50 Quantification: External standard peak area comparison. Limits: Chloroacetanilide: 10 ppm 4-aminophenol:50 ppm 4-nitrophenol: 0.05 % Sum of unknowns: 0.1 %	Limit of Free 4-Amino phenol: Method: HPLC Column: L7 Packing Detection: UV at 230 nm System suitability: Quantification: External impurity reference standard, Limit: NMT 0.005 % Organic impurities: Method: HPLC Column: L7 Packing Detection: UV at 254 nm System suitability: Resolution: 2.0 between acetaminophen and acetaminophen related compound B NLT: 1.5 between acetaminophen related compound B and acetaminophen related compound C. Tailing factor: MT 2.0 % RSD for Impurity D and Acetaminophen: NMT 5.0 % Quantification: External impurity	Method: HPLC Column: C18 Packing Detection: UV at 254 nm System suitability: Resolution: minimum 5.0 Quantification: External standard, Impurity K and J: quantified against impurities. Unknowns: Quantified using Paracetamol diluted reference standard. Limits: Imp K: 50 ppm Imp J:10 ppm Unknowns:0.05 % Total imp:0.2 % Note: Other detectable impurities A, B, C, D, E, F, G, H, I, L, M, N

	reference standard quantification (D), response factors for all impurities available. Limits: Related compound B:0.05 % Related compound C:0.05 % Related compound D:0.05 % Related compound J:0.001 % Individual imp:0.05 % Total imp:0.1 %	to be controlled.

In IP, Assay tests are performed by Titrimetric method (by visual identification), which will have low accuracy compared to LC method. Moreover, the assay limits are more stringent compared to USP, due to the titrimetric method, it is expected that out of trend /specification results may be observed.

In IP, related substances are limited by HPLC method, there are three known impurities. Impurities are quantified by comparing their peak response with impurity reference standard peak response.

As per BP, two known impurities are mentioned, and they are quantified using impurity standards. There is an additional statement regarding additional impurities and those need to be controlled by general drug substances monograph.

As per USP, two impurity methods are available, one for 4-nitrophenol and another one method for the other organic impurities. 4-Nitrophenol limited by LC method and quantified using impurity standard. In other organic methods, there are four unknown impurities and those are limited by LC method, quantification performed using impurity quantification method.

Table 2. Comparison of Monographs of Paracetamol Tablets

Monograph Test Contents	**IP 2018** (5)	**USP NF 2021** (8)	**BP 2021** (9)
Limit	95.0 to 105.0 %	90.0 to 110.0 %	95.0 to 105.0 %
Dissolution	Apparatus: Paddle Medium: phosphate buffer pH: 5.8 900ml. Speed & Time point:50 rpm,30 minutes Release: NLT 80% at Q Method: UV Detection: at 243 nm	Apparatus: Paddle Medium: phosphate buffer pH: 5.8 900ml. Speed & Time point:50 rpm,30 minutes Release: NLT 80% at Q Method: UV Detection: at 243 nm	Apparatus: Paddle Medium: phosphate buffer pH: 5.8 900ml. Speed & Time point:50 rpm Method: UV Detection: at 257 nm
Assay	Method: UV Detection: at 257 nm	Method: HPLC Column: L1 Packing Detection: UV at 243 nm System suitability: Tailing factor: NMT 2.0 RSD: NMT 2.0 % Quantification: External standard.	Method: UV Detection: at 257 nm
RS	Method: HPLC Column: C8 Packing Detection: UV at 245 nm Quantification: External impurity standard peak area comparison. Limits: 4-Chloroacetanilide:10 ppm 4-aminophenol:0.1% ppm Unknown:0.25 % Total impurities: Not mentioned.	Method: HPLC Column: L1 Packing Detection: UV at 272 nm System suitability: S/N Ration: NLT 10 RSD: 5.0 % Quantification: External impurity standard for 4-Aminophenol and Unknowns quantified against diluted reference standard. Limits: 4-Aminophenol-NMT:0.15 % Unknown imp-NMT: 0.15 % Total-0.60 %	Method: HPLC Column: C8 Packing Detection: UV at 245 nm System suitability: Resolution: NLT 4.0 Quantification: External impurity standard peak area comparison. Limits: 4-aminophenol:0.1 % 4-Chloroacetailide :NMT10ppm unknowns:0.25 % Total impurities: missing

The impurity specification levels are low, as per IP impurities are quantified by the area comparison method which may not be the accurate method to evaluate the impurity quantification. Hence, it was suggested to have

the quantitation method rather than peak area comparison.

Assay test was performed by UV method for both IP and BP methods, however as per USP the Assay testing performed by HPLC method by external quantification method. Dissolution tests are comparable to both BP and USP.

For Related substances, the test is comparable to BP. However, in IP in addition to the 4-aminophenol limit specified for Chloroacetanilide. In IP limits for total impurities are missing. The impurity limits are very low (ppm level); hence it is recommended to have the quantitation method rather than peak response comparison.

As per USP the tests are quantified using HPLC and there is only one known impurity available as per USP. Impurity quantified using impurity reference standard method.

3. Amoxycillin Trihydrate Drug substance

Amoxycillin is an antibiotic used to treat bacterial infections including middle ear infection, strep throat, pneumonia, skin infections, and urinary tract infections. The preferred dosage form is Tablet.

Amoxycillin/clavulanic acid is a combination of Amoxycillin and potassium clavulanate, a β-lactamase inhibitor. It is specifically used for otitis media, streptococcal pharyngitis, pneumonia, cellulitis, urinary tract infections, and animal bites.

Table 3. Comparison of Monographs of Amoxycillin Trihydrate Drug substance

Monograph Test Contents	IP 2018 (5)	USP NF 2021 (10)	BP 2021 (11)
Assay Limits	95.0-102.0 %	NLT 900 µg/mg and NMT 1050 µg/mg	95.0 to 102.0 %
Assay	Method: HPLC Column: C18 Packing Detection: UV at 230 nm Quantification: External standard. System Suitability: RSD: 2.0 % Plate counts: NLT1700 Tailing factor: NMT 2.5	Method: HPLC Column: L1 Packing Detection: UV at 230 nm Quantification: External standard System Suitability:RSD:2.0% and Tailing factor: NMT 2.5	Method: HPLC Column: C18 Packing Detection: UV at 254 nm Quantification: External standard. System Suitability: RSD: NMT1.0%
RS	Not listed	Method: HPLC Column: L1 Packing Detection: UV at 210 nm System suitability: Resolution and RSD: 10.0 % Quantification: External diluted reference standard. Limits: Known impurities:1.0 % (There are about 11 known impurities) Unknown imp:1.0 % Total impurities :5.0 %	Method: HPLC Column: C18 Packing Detection: UV at 254 nm System suitability: Resolution: minimum 2.0 Quantification: Area comparison from diluted reference standard. Limits: There are no known impurities. Unknown imp:1%

Assay Method

Assay test performed by LC method by external standard quantification.

Related substances

In IP Related substances testes are not listed, whereas in USP and BP impurity testing is mentioned. Hence, it is suggested to include the RS method in IP.

4. Potassium clavulanate Drug substance

Table 4. Comparison of Monographs of Potassium clavulanate Drug substance

Monograph Test Contents	IP 2018 (5)	USP NF 2021(12)	BP 2021 (13)
Assay Limits	96.5 % -102.0 %	75.5 % - 92.0 %	96.5% -102.0%
Assay	Method: HPLC Column: C18 Packing Detection: UV at 230 nm Quantification: External standard System Suitability: Resolution: NLT 3.5	Method: HPLC Column: L1 Packing Detection: UV at 220 nm Quantification: External standard System Suitability: Resolution NLT:3.5 RSD:2.0% Tailing factor: NMT 1.5	Method: HPLC Column: C18 Packing Detection: UV at 230 nm Quantification: External standard System Suitability: Resolution: minimum 3.5
RS	Method: HPLC	Procedure 1:	Procedure 1:

	Column: C18 Packing Detection: UV at 230 nm System suitability: Resolution: NLT 13 Quantification: External diluted reference standard. Limits: Ind unknown:1.0 % Total unknown :2.0 %	Method: HPLC Column: L1 Packing Detection: UV at 230 nm System suitability: Resolution: NLT 13 Tailing factor: NMT 2.0 RSD: NMT 2.0 % Quantification: External reference standard. Limits: Total impurities :2 % Procedure 2: Limit of Clavam-2-carboxylate potassium. Method: HPLC Column: L1 Packing Detection: UV at 210 nm System suitability: Tailing factor: NMT 1.5 RSD: NMT 5 % Quantification: External diluted reference standard. Limits: NMT:0.01% Procedure 3: Limit of Aliphatic Amines. Method: GC Column: G41 Detection: FID Quantification: External diluted reference standards. Limits: Total of all aliphatic amines NMT:0.2 % Procedure 4: Limit of 2-Ethylhexanoic acid. Method: GC Column: G35 Detection: FID System suitability: Resolution: NLT 2.0 Quantification: External diluted reference standards. Limits: NMT:0.8 %	Method: HPLC Column: C18 Packing Detection: UV at 230 nm System suitability: Resolution: NLT 13 Quantification: External diluted test solution, area comparison. Limits: Ind unknown Imp E:1.0% Imp G:1.0% Ind unknown:0.2 % Total unknown :2.0 % Procedure 2: Limit of Aliphatic Amines. Method: GC Column: Phenyl column Detection: FID Quantification: External diluted reference standards. Limits: Total of all aliphatic amines NMT:0.2 % (H, J, K, L, M) Procedure 3: Limit of Ethyl hexanoic acid. Max:0.8% Procedure 4: Manufacturing control Clavam-2 Carboxylate Limit:0.01 %

Assay Method

Assay test performed by LC method by external standard quantification

Related substances

As per IP, there are no known impurities, only unknown impurities are mentioned. As per USP, there are 4 RS methods available for known and unknown impurities.

5. Amoxycillin + Clavulanate potassium Tablets

Table 5. Comparison of Monographs of Amoxycillin + Clavulanate potassium Tablets

Monograph Test Contents	IP 2018 (5)	USP NF 2021 (14)	BP 2021 (15)
Limit	90.0 -120.0% for both actives.	90.0 - 120.0% for both actives	90.0 - 105.0% for both actives.
Dissolution	Apparatus: Paddle Medium: Water, 900ml. Speed and Time point:75 rpm,30 minutes Release: Amoxycillin: NLT 85% at Q Clavulanate acid: NLT 80% at Q Method: HPLC Column: C18 Packing	Test 1 Apparatus: Paddle Medium: Water, 900ml. Speed and Time point:75 rpm,30 minutes Release: Amoxycillin: NLT 85% at Q Clavulanate acid: NLT 80% at Q	Apparatus: Paddle Medium: Water, 900ml. Speed and Time point:75 rpm,45 minutes Release: Method: HPLC Column: C18 Packing Detection: UV at 220 nm Quantification: External

	Detection: UV at 220 nm Quantification: External standard. System Suitability: Plate counts: NLT 550 Tailing factor: MT 1.5 RSD: 2.0 %	Test 2 Apparatus: Paddle Medium: Water, 900ml. Speed & Time point:75 rpm Release: Amoxycillin: 45 min, NLT 85% at Q Clavulanate acid: 30 min, NLT 80% at Q Labelling: If the product complies with this test, the labelling indicates that it meets USP Dissolution Test 2.	standard.
Assay	Method: HPLC Column: C18 Packing Detection: UV at 220 nm Quantification: External standard. System Suitability: Plate counts:550 Tailing factor: NMT 1.5 Resolution: NLT 3.5 RSD: 2.0 % each analyte.	Method: HPLC Column: L1 Packing Detection: UV at 220 nm Quantification: External standard. System Suitability: Resolution: minimum 3.5 Tailing factor: NMT 1.5 RSD: 2.0 % each analyte.	Method: HPLC Column:C18 Packing Detection: UV at 220 nm Quantification: External standard. System Suitability: Resolution; minimum 3.5 Tailing factor: NMT 1.5
Clavulanate polymer and other fluorescent impurities	Not listed	No Not listed	Method: Fluorescence spectrophotometry. Detection: 360 excitation emission 440nm System suitability: Resolution: minimum 2.0 Quantification: fluorescence comparison. Limits: 5% w/w, calculated with respect to the content of clavulanic acid.
RS	Not listed	No Not listed	Method: HPLC Column: C18 Packing Detection: UV at 254 nm System suitability: Resolution Quantification: Area comparison from diluted reference standard. Limits: Amoxicillin dimer: 2% Secondary peak: 1%

Assay and Dissolution testing was performed by LC methods. RS testing was not listed in IP & USP. It is recommended to list RS tests in IP.

Related substance

In IP Related substances testes are not listed and USP the Organic impurities test was not official from 01/11/2021.Whereas, in BP Related substances test is listed and performed by LC Technique. As the Amoxycillin and Clavulanate potassium is combination products and, not having the related substances method to limit the impurities present in each drug substances and impurities rises during the storage conditions, which may pose the risk to patient's safety.

6. Losartan Potassium Drug Substances

Losartan is an Anti-hypertensive drug and also used to lower the risk of strokes in patients with high blood pressure and an enlarged heart.

Table 6. Comparison of Monographs of Losartan Potassium Drug Substances

Monograph Test Contents	IP 2018 (5)	USP NF 2021 (16)	BP 2021 (17)
Assay Limits	98.0-102.0 %	98.5-101.0 %	98.5-101.5 %

Assay	Method: HPLC Column: C18 Packing Detection: UV at 254 nm Stem suitability: Tailing factor: NMT 1.5 Plate counts: NLT 5000 % RSD: NMT 2.0% Quantification: External standard	Method: HPLC Column: L1 Packing Detection: UV at 254 nm Stem suitability: Tailing factor: NMT 1.4 RSD: NMT 0.5% Quantification: External standard	Method: Potentiometric titration
RS	Method: HPLC Column: C18 Packing Detection: UV at 220 nm System suitability: Tailing factor: NMT 2.0 Quantification: External diluted reference standard (peak area comparison). Limits: Single unknown:0.5% Total unknowns:1.0%	Method: HPLC Column: L1 Packing Detection: UV at 220 nm System Suitability: Tailing factor: NMT 1.6 S/N: NLT 10 RSD: NMT 5.0 % Quantification: External diluted reference standard. Limit: Unknown: 0.2% Total imp: 0.5%	Method: HPLC Column: C18 Packing Detection: UV at 220 nm System Suitability: Peak-to -valley ratio: minimum 2.0 (for imp G) System suitability: Resolution Quantification: External impurity standard (For imp D, peak area comparison), for other known and unknowns (Diluted reference standard peak are comparison) Limit: Impurity D:0.15% Imp J, K, L, M:0.15 % (for each imp) Unknown:0.10% Total imp:0.3%

In IP Assay test is comparable to USP. In RS testing limits are double for unknowns compared to USP.

In BP there is specific requirement for the control of NDMA & NDEA," N-Nitroso dimethylamine (NDMA) & N-Nitroso diethylamine (NDEA) are classified as probable human carcinogen, manufacture must ensure that their manufacturing process does not generate such impurities and develop appropriate control".

In USP a new chapter is included for the control of Nitrosamine impurities <1469>, which is official from 01/12/2021.

7. Losartan Potassium Tablets

Table 7. Comparison of Monographs of Losartan Potassium Tablets

Monograph Test Contents	**IP 2018** (5)	**USP NF 2021** (18)	**BP 2021** (19)
Assay Limits	90.0-110.0 %	95.0-105.0 %	95.0-105.0 %
Assay	Method: HPLC Column: C8 Packing (Lithosphere RP8e) Detection: UV at 237 nm System suitability: Tailing factor: NMT 2.0 Plate counts: NLT 5000 RSD: NMT 2% Quantification: External standard.	Method: HPLC Column: L7 Packing Detection: UV at 250 nm System suitability: Tailing factor: NMT 2.0 Plate counts: NLT 3000 Resolution: NLT 2.0 RSD 2.0% Quantification: External standard.	Method: HPLC Column: L1 Packing Detection: UV at 250 nm System suitability: Appendix IID Quantification: External standard.
RS	Method: HPLC Column: C8 Packing (Lithosphere RP8e) Detection: UV at 235 nm System suitability: Tailing factor: NMT 3.0 Plate counts: NLT 1000 Quantification: External diluted reference standard. (Peak are comparison)	Method: HPLC Column: L7 Packing Detection: UV at 250 nm System suitability: Tailing factor: NMT 2.0, Plate counts: NLT 3000 Resolution: NLT 2.0 S/N: NLT 10 and RSD NMT 5.0% Quantification: External diluted reference standard. 1H-Dimer:0.5% 2H-Dimer:0.5% Total imp:1.0%	Method: HPLC Column: C8 Packing (Symmetry C8) Detection: UV at 250 nm System suitability: Resolution: NLT 2.0 Quantification: External diluted reference standard. (Peak area comparison) Limits:

	Unknown:1.0% Total unknowns:2.0%		Imp M:0.5% Imp L:0.5% Unknown:0.2% Total imp:1.0%
Dissolution	Test 1: Apparatus: Paddle Medium: water, 900ml. Speed and Time point:50 rpm,45 minutes Release: NLT 75% at Q Method: UV Detection: at 250 nm	Test 1: Apparatus: Paddle Medium: Water,900ml. Speed and Time point:50 rpm,30 minutes Release: NLT 75% at Q Method: UV Detection: at 254 nm Method: HPLC Column: L1 Packing Detection: at 254 nm System suitability: Tailing factor NMT 2.0 RSD 2.0% Quantification: External standard Test 2: If the product complies with this test, the labeling indicates that the product meets USP Dissolution test 2 Apparatus: Paddle Medium: Water, 900ml. Speed and Time point:75 rpm,30 minutes Release: NLT 75% at Q Method: UV Detection: at 265 nm Method: HPLC Column: L10 Packing Detection: at 254 nm System suitability: Tailing factor NMT 2.0 RSD 2.0% Quantification: External standard Test 3: If the product complies with this test, the labeling indicates that the product meets USP Dissolution test 3 Apparatus: Paddle Medium: Water, 900ml. Speed and Time point:50 rpm,30 minutes for 25mg,50mg and 45 min for 100mg Release: NLT 75% at Q for 25 and 50mg NLT 80% at Q for 100mg Method: HPLC Column: L7 Packing Detection: UV at 220 nm System suitability: Tailing factor NMT 2.0 RSD 2.0% Quantification: External standard	Apparatus: Paddle Medium: Water, 900ml. Speed and Time point:75 rpm,30 minutes Release: NLT 70% at Q Method: UV Detection: at 250 nm

Assay and Dissolution testing are comparable in IP compared to BP and USP.

Related substances

As per IP no known impurities are list, however according to BP and USP known impurities are listed and also the limit for total impurities is more stringent in BP and USP compared to IP.

8. Conclusion

In this comparative study, drug substances and drug products were selected on the most prescribed/widely used therapeutic range and comparison was made only to the Assay, Purity and Dissolution analysis. Assay and dissolution tests are in most of the cases in-line with other pharmacopoeias. However, it is recommended change to the Liquid Chromatography methods rather than titrimetric methods for Assay testing. In Related substances tests, impurity level, Quantification

procedure needs to be updated as per current requirements. In some of the monograph procedures, it was observed that related substances tests are not listed. The related substances methods are very important for the quality and safety of the patient health. Hence, Indian Pharmacopeia needs consider for inclusion of the Related Substances methods.

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Conflict of Interest

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