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The Comparative Study of Different Pharmacopoeias: Indian Pharmacopoeia, British Pharmacopoeia, United States Pharmacopoeia

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Abstract

The objective of the study is to ensure Indian pharmacopoeia monographs are on par with United States, British pharmacopoeia standards. A few monographs were selected on random and compared. It has been observed that Indian pharmacopoeia has replaced titrimetrry assay method of analysis to sophisticated chromatographic techniques. As a whole the comparative study reveals that Indian pharmacopoeia is on par with United States, British pharmacopoeia and it is necessary that global countries also recognize Indian pharmacopoeia. General monographs available in Indian pharmacopeia 2014 were compiled and analyzed to identify the number of analytical method employed especially in the assays. HPLC Method of analysis is highest used where ever necessary UV method is made available instead especially for formulation, Indian pharmacopeia Commission is periodically updating indian Pharmacopoeia on par with ICH Q4 pharmaceutical harmonization and has its unique identity over years and being recognized globally.

Keywords: Indian Pharmacopeia; Pharmaceutical Harmonization; United States Pharmacopeia; British Pharmacopeia

Introduction

The Pharmacopeia or pharmacopoeia in its modern sense, is legally binding collection, Prepared by a national or regional authority, of medicine uses that country or region.

A quality specification composed of a set of appropriate tests that will confirm identity and purity of the product Amount active substances and when needed, its performance characteristics reference substances. i.e. Highly – characterized physical specimens, are used in testing to help ensure the quality, such as identity, strength and purity of medicines.

Pharmacopoeia is the role of the mode pharmacopeia to furnish quality specification for active pharmaceutical ingredient FPPs and general requirement.

Ex. Dosage form the existence of such specifications and requirements is necessary for the proper functioning or regulatory control of medicines.

Pharmacopoeia requirements form a base for establishing quality requirements for individual pharmaceutical preparations in their final form according to the information available to the world Health organization.

The 140 independent countries are at present employing some 30 national as well as regional pharmacopoeias, international pharmacopoeia. Compared national and regional pharmacopeia. The international pharmacopeia issued by WHO as recommendation with the aim provide international standards.

Right to health is the fundamental right of a citizen of a country government of countries vest legislation as acts to safeguard health of the countries vest legislation as acts to safeguard health of the citizens. Several countries Maintain own pharmacopoeia where in drugs available in market are to the standards mentioned in monograph manufacture of bulk drugs , Formulation have to end users of medicines are ensured for quality, reliability and safety.

Methodology

The IP 2014, BP 2019, and USP 2018 [1-4] Were analyzed and compare in this study two types of standards monograph is a standard that describes the properties and minimum quality requirement for raw material or drug product A general chapter is standard that provides and minimum quality requirement for information for a test methods technical guideline on drug we analyzed and compared the drug.

The monograph relating API and formulation under category of analgesics and antipyretics and anti-inflammatory drug and Corticosteroids. Drug was selected on random but available in all pharmacopeia.

Hypothesis

The overall Consider that USP is one of the standard official book which is use worldwide as Standard However we going compare Indian Pharmacopeia , United state Pharmacopeia , British Pharmacopeia and to field gap between Indian Pharmacopeia, United state Pharmacopeia and British Pharmacopeia For Quality [5].

Expected Outcomes

To determine whether which pharmacopoeia is superior and to assure the quality of the pharmaceutical product. We Can use this literature survey for further study in future and will be Much helpful as it is described un simple Language and easy Tables 1-10.

Comparison of Monograph

Sr. No	Pharmacopoeia	Identification test	Related Substances Test	Assay & Limit	Other Test	Loss On drying
1	Indian Pharmacopoeia	Id By IR, UV and Chemical Test.	By HPLC **Specifications** – Impurity k maximum 50 ppm Impurity j maximum 10 ppm Unspecified impurity 0.05% Total 0.2% column size 25cm x 4.0mm **Conditions:** Column temp:35 °c Flow rate – 1.5ml/min Detector: 245nm. Injection Volume:20µ	Yes, By Chemical method **Specification** NLT 99.0% NMT 101.1 % (Dried Basis)	Heavy Metal – 20gm Complies with limit Test (Method B 10 PPM)	NMT 0.5 % Determined by 0.1 gm. by drying an oven at 105 °c
2	British Pharmacopoeia	Id By UV and IR	By HPL **Specification:** Impurity k Maximum 50ppm Impurity J Maximum 10 ppm Unspecified Impurities 0.05% Total Impurity Maximum 0.2% **Condition:** Column Size:0.10m,Ø=2.1mm Column Temp:30 °c Flow rate: 0.3 ml/min Detector: 254 nm. Injection Volume: 5 µl	Yes, Chemical Method **Specification** 99.0 % to 101% (Dried basis)	Sulphated Ash – Maximum 01. %	Maximum 0.5 % Determined by 1.000 by drying is an Oven at 105 °c

3	United states Pharmacopoeia	Id By IR	BY HPLC **Specifications-** Acetaminophen Related compound 0.5% Acetaminophen related compound D 0.05% Individual unspecified impurity 0.05% Total impurity 0.1% Column size: 4.6mm x 25-Cm Condition: Column temp: 40°c Flow Rate: 0.9 ml /min Detector- UV- 230nm Injection Volume-5 µl	Yes, **Specification** BY HPLC NLT 98.0 % and NMT 102.0% (Dried Basis)	NA	Analysis Criteria -NMT 0.5% Acceptance Criteria – NMT 0.5 %

Table 1: Paracetmol API.

Sr.No	Pharmacopoeia	Identification Test	Related Substances Test	Assay and Limit	Dissolution Test
1	Indian Pharmacopoeia	Id By UV And chemical test	BY HPLC **Specifications:** Based upon area under peak: The test is not unless the resolution between two principal peak is NLT 4.0 Run times : 12 Time Corresponding peak in reference solution (b): NMT0.1% Reference solution: 10 ppm Any other secondary peak is NMT 0.25% **Condition:** Column Size- 25cm x 4.0mm, Column Temp- 35 °c Flow Rate 1.5ml/min, Detector :245nm Injection Volume – 20 µl	Yes BY UV Specifications NLT 95.0% and NMT 105.0%	Apparatus NO – 1 Medium : 900 ml of Phosphate buffer ph 5.8 speed and time . 50 Rpm and 30 Min
2	United states Pharmacopoeia	Id By TLC	By HPLC **Specifications-** Acetaminophen Related compound 0.5% Acetaminophen related compound D 0.05% Individual unspecified impurity 0.05% Total impurity 0.1% Column size: 4.6mm x 25-Cm Conditions: Column Size- 3.9mm x 15cm, Column Temp- 40 °c Flow Rate 2.0ml/min Detector295 nm, Injection Volume – 20 µl	Yes, BY HPLC Specifications NLT 90.0 and NMT 111.0 %	Apparatus No – 2 For – 50 RPM Time – 30 Min Medium : PH 7.2 phosphate buffer

Table 2: Paracetmol Tablet.

Sr. No	Pharmacopeia	Identification Test	Related Substances Test	Assay and Limit	Loss on drying
1	Indian Pharmacopeia	Id By IR, UV and TLC and chemical Test	BY HPLC **Specification:** Impurity F: By Gc Area of any other peak NMT 0.3% Area of any other Secondary peak NMT 0.3 times. Principal Peak 0.3% and sum area other secondary peak NMT o.7 times Ignore any peak less than 0.1 times **Condition:** Column size: 15cm x4.6 mm Column Temp: Flow Rate:1.5 ml/min Injection volume: 2ml/min Detector:214nm	Yes, HPLC Specification NLT 98.5% and NMT 101.1 % (Dried basis)	**Specification:** NMT – 0.5 %Determined on 1.0 g by drying Over Phosphorus pen oxide at a pressure of 1.5 to 5.5 Kg.
2	British Pharmacopeia	Id By IR , MP (75 °c to 78 °c)& chemical Test	BY HPLC **Specifications:** Impurities A, J,N for each impurity NMT 1.5 times. Unspecified impurity NMT 0.5 times. Total impurity: NMT twice. Disregard Limit: 0.3 times. **Condition:** Column size-0.15m,Ø 4.6nm Column temp: Flow rate:2ml/min Injection Volumes:20µl Detector:214nm	**Yes,** By chemical Method **Specification:** 99.5 % to 101.0 % (Dried Substances)	Maximum 0.5% determined on 1,000 g by drying on vacuo
3	United states Pharmacopoeia	Id by IR and UV	BY HPLC **Specifications:** Ibuprofen Related Compound 1 Relative retention time 0.47 Acceptance criteria 0.7% Ibuprofen Related Compound c Relative retention time 1.62 Acceptance criteria -0.25% Any unspecified Degradation Product Acceptance Total unspecified Degradation Acceptance criteria 1.5% **Condition:** Column size-4mm x15cm Column temp: Flow rate: 2ml/min Injection Volumes: 10µl. Detector:214nm	**Yes,** HPLC **Specification** _ NLT 97.0 % and NMT 103.0 % (Anhydrous basis.)	NA

Table 3: Ibuprofen API.

Sr. no	Pharmacopeia	Identification	Related Substances Test	Assay and Limit	Dissolution Test
1.	Indian Pharmacopeia	Id by IR and Chemical Test	NA	**Yes,** By Chemical method **Specification** - NLT 95.0 % and NMT 105.0 % (The tablet are coated)	**Apparatus No – 1** Medium :900 ml of phosphate buffer PH 7.2 Speed – 100 RPM Time – 30 Min
2	United states Pharmacopoeia	Id by UV & chemical Test	NA	**Yes,** HPLC **Specification-**NLT 90.0 % and NMT 110.0 % (Dried Basis)	**Apparatus No – 2** Conditions : Medium – pH 7.2 phosphate buffer , 900 ml Speed – 50 RPM Time – 60 Min

Table 4: Ibuprofen and Pseudoephedrine Hydrochloride tablets.

Sr. No	Pharmacopeia	Identification Test	Related Substances Test	Assay and limit	Other Test	Loss on drying
1	Indian Pharmacopeia	Id By IR &MP UV	BY HPLC **Specification**: Impurity K and naproxen is NLT 2.2 Impurity L and naproxen 1.4 Impurity L NMT 0.1% **Conditions:** Column size: 10cmx4.0mm Column Temp: 50°c Flow Rate:1.5ml/Min Injection volume:20µl Detector: 230nm	Yes, By Chemical methods. **Specifications** NLT 99.0% and 101.0 % (Dried Basis)	Heavy Metal _ 10 gm Complies with the limit .test for Heavy Metal (method B 10 PPM) n	NMT 0.5% determined 1.0 gm by drying in oven 105 (For 3 hrs)
2	British Pharmacopoeia	Id By MP , UV , IR and chemical test	BY HPLC **Specification:** Impurity O NMT 1.5 times Impurity L NMT 1.5 Total Impurity NMT 3 times **Conditions:** Column size: 0.10 m Ø= 40mm Column Temp: 50°c Flow Rate: 1.5/min Injection volume: 20µl Detector:230nm	Yes, By Chemical. **Specifications:** 99.0% to 101.0% (Dried substances)	Sulphated Ash – Maximum 0.1% Determined 0.1gm	Maximum 0.5 % Determined on 1.000 By drying in on oven at 105 °c°c For 3 hrs
3	United states Pharmacopoeia	Id by IR and UV	NA	Yes, By Chemical methods. Specifications NLT 98.5% and 101.5 % (Dried basis)	Not available	Dry at 105 °c and 3 hrs. of loss NMT 0.5% of its weight

Table 5: Naproxen API.

Sr.No	Pharmacopeia	Identification Test	Related Substances Test	Assay and Limit	Dissolution test
1	Indian Pharmacopeia	Id By IR and UV	By TLC	Yes, BY UV. NLT 95.0% & NMT 105. %	Yes Medium 900ml pH 7.4 phosphate buffer By Apparatus no – 1 Time: 45min Rpm: 50rpm
2	United states Pharmacopoeia	Yes Id By UV and Chemical |Method	By HPLC **Specification:** Naproxen Related Compound Acceptance criteria NMT 0.10 % **Condition:** Column size: 4.6mmx15cm Column Temp: 40°c Flow Rate:10 ml/,min Injection volume: 10µl Detector: 236nm	Yes. By HPLC. NLT 90.0% and NMT 110.0%	Yes Medium: buffer 900ml pH 7.4 phosphate buffer By Apparatus No -2 Time: 45min Rpm: 50rpm

Table 6: Naproxen Tablet.

Sr. No	Pharmacopeia	Identification Test	Related substances Test	Assay and limit	Other Test	Loss on Drying
1	Indian Pharmacopeia	Id By IR, TLC, UV and chemical Test.	By HPLC **Specifications:** Based upon area under peak: The area peak any peak other than the principal peal is not greater than 0.5 times. Ignore any peak due to blank and any peak less than 0.05 times. Condition: Column size-25cm x 4.6mm Column temp: 45°c Flow rate: 2ml/min Injection Volumes:20µl Detector: 254nm Run time:	Yes, By UV Specifications NLT 96.0% and NMT 104.0 % (Dried basis)	Heavy Metal-Sulphated Ash – NMT 0.1 %	NMT 0.5% Determined on 1gm by drying on oven at 105°c
2	British Pharmacopoeia	Id by IR, TLC Uv and chemical Test.	By HPLC **Specifications:** Based upon area under peak: The area peak any peak other than the principal peal is not greater than 0.5 times. Ignore any peak due to blank and any peak less than 0.05 times. Condition: Column size-25cm x 4.6mm Column temp: 45°c Flow rate: 2ml/min Injection Volumes:20µl Detector: 254nm Run time	Yes, By UV **Specifications** NLT 96.0% and NMT 104.0 % (Dried basis)	Sulphated Ash -Maximum 0.1 % demined on 1.o g	Maximum 0.5 % determined on 1.000 g by drying in oven at 105°c
3	United states Pharmacopoeia	Id By IR And UV	NA	Yes,By HPLC **Specifications** NLT 97.0% and NMT 102.0% (Dried Basis)	Residue on ignition – NMT 0.2 %	Dry at 105°cfor 3 hrs it loses NMT 0.5%

Table 7: Dexamethasone API.

Sr.No	Pharmacopeia	Identification test	Related substance test	Assay and limit	Dissolution Test.
1	Indian pharmacopeia	Id BY IR, TLC, UV &chemical Methods	By HPLC **Specifications:** Based upon area under peak: Ignore any Peak less than 0.05 times **Conditions:** Column size-25cm x 4.6mm Column temp: 45°c Flow rate: 2ml/min Injection Volumes:20µl Detector: 254nm	BY HPLC. NLT 90.0 % and NMT 110 % On Dried Basis.	Medium 500 ml RPM- 100 Time – 45 Min
2	United states [pharmacopeia	Id BY TLC	-	Yes, BY HPLC NLT 90 % and NMT 110.0% Dried Basis	Medium – Dilute HCL (1 in 100) Appartus-1 Rpm-100 Time – 45 Min

Table 8: Dexamethasone Tablet.

Sr. No	Pharmacopeia	Identification Test	Related substances Test	Assay and Limit	Other Test	Loss On drying
1	Indian Pharmacopeia	Id By IR and chemical Test	BY HPLC **Specification:** Ignore any peaks0.25% **Conditions:** Column size: 25cm x4.6mm Column Temp: Flow Rate: 1ml/min Injection volume: 20µl Detector:236 nm	Yes. BY Chemical methods **Specifications** NLT 98.5% and NMT 101.0% (Dried basis)	Heavy Metal – 2.0 g Complies with limit for heavy Metal (Method B 10 PPM)	NMT 0.5 % determined On 1.0 gm by drying in Oven at 105°c For 3 hrs
2	British Pharmacopoeia	Id By IR , TLC and Chemical Test	BY HPLC **Specifications:** Impurity A maximum 0.2% Impurity F maximum 0.15% Unspecified impurities 0.10% Total impurities 0.4% **Conditions:** Column size- 0.25m /Ø 46mm Column temp:254	Yes By chemical methods. **Specifications** 99.o % to 101.0 % (Dried substances)	NA	Maximum 0.5 % determined on 1.0000g by drying in an oven at 105°c
3	United states Pharmacopoeia	Id By IR	BY HPLC **Specifications:** Acceptance criteria: Diclofenac related compound A NMT 0.2% each individual impurity NMT 0.2% Total impurity NMT 0.5% Column size-4.6mm x 25cm **Conditions:** Column temp: Flow rate: 1ml Injection Volumes:10µl Detector: 254nm Run time:2.5 times	Yes, BY chemical Methods. **Specifications** NLT 99.0% and NMT 101.0% (Dried basis)	Diclofenac Related Compound A: NMT 0.2% Each other individual **Impurity:** NMT 0.2 % Total Impurities: NMT 0.5%	Analysis: Dry /AT 105°c t- 110°c For 3 hrs Acceptance Criteria NMT: 0.5 %

Table 9: Diclofenac sodium API.

Sr.No	Pharmacopeia	Identification Test	Related substances Test	Assay and Limit	Dissolution test
1	Indian Pharmacopeia 1.Diclofenac Gastro -Resistant Tablet	Id by TLC	BY HPLC **Specifications:** Impurity A NLT 6.5 Retention time of Diclofenac 25 min **Conditions:** Column size- 25cm x 4.6 Column temp: Flow rate:1 ml/min Injection Volumes:20µl Detector:254nm Run time:	Yes, BY HPLC NLT – 99.0 % and NMT 110.0% By the enteric – coating tablet	NA
2	United states Pharmacopoeia Diclofenac sodium Delayed-Release Tablet	Id BY UV and Assay	By UV **Specifications:** Diclofenac related Compound D : Relative Retention time:1.04 Diclofenac related Compound Relative Retention time:1.48 Acceptances Criteria 0.5% Any individual Un specified Impurity : 0.5% Total Impurities: 1.5% **Conditions:** Column size-10cm x 2.0nm Column temp: 35° Flow rate:0.3ml/min Injection Volumes: 1µl Detector:280nm Run time:	Yes, BY HPLC 90.0% and NMT 110.0 %	Yes, Apparatus No-2 Paddles constructed of coated with polylef being used.

Table 10: Diclofenac sodium Tablet.

Comparisons of Paracetmol API

- **Identification Test:** The identification test is Commonly Found in IP & BP but USP only IR test is included.
- **Assay Limit:** The observed that drug content limits of assay are within same ranges in IP and BP While the Rang is higher in USP.
- **Assay Method:** The assay method perform by chemical Method in IP, BP While USP Prefer in HPLC Method.
- **Related substances Test:** Common Test inn IP, BP, and USP.
- **Other test:** Heavy metal, Impurities are same in IP and USP. Suphated ash Form NMT 0.1 % in the BP.
- **Loss on drying:** The Moisture are at same rages in IP, BP, USP.

Comparisons of Paracetmol Tablet

- **Identification Test:** When Comparisons of made with respect to Paracetmol tablet identification test are UV.& Chemical Test in IP & USP refer TLC technique.
- **Related substances test:** The Common test in IP, BP and USP.
- **Assay limit & method:** Assay limits drug Paracetmol tablet at narrow range in IP and higher rang in USP.
- **Dissoulation Test:** IP prefer the apparatus no -1as per IP and apparatus no -2 USP as per USP.

Comparison of Ibuprofen API

- **Identification Test:** The identification Test IR and UV are Commonly Found in IP, BP, and USP but TLC method in IP & MP method in BP.

- **Assay limits and Assay Method:** The Assay limit of at narrow ranges in IP, BP while the higher range in USP and assay method by HPLC in IP, USP But chemical Test in BP.
- **Related substance Test:** The related substance test is commonly found by HPLC techniques.
- **Other test:** Impurities are not available in IP, BP and USP.
- **Loss on Drying:** The LOD is the same rang in the IP, BP, and USP.

Comparisons of Ibuprofen Pseudoephedrine Tablet

- **Identifications Test:** The identification test IP prefers IR and chemical test and USP prefer only Uv.
- **Assay limits and Methods:** Assay limits drug Paracetmol tablet at narrow range in IP and higher rang in USP and assay method IP prefers chemical test and USP prefer HPLC.
- **Related substances test:** IP, TLC method and USP HPLC.
- **Dissolution Test:** IP prefer the apparatus no -1as per IP and apparatus no -2 USP as per USP.

Comparisons of Naproxen API

- **Identification Test:** The Comparison of Identification test IR, UV and MP, Commonly Found in IP, and BP While USP prefer UV and IR.
- **Assay limit and assay method:** Assay limit is almost same ranges in IP, BP, and USP. Assay method is commonly found in IP and BP.
- **Related substances Test:** Commonly found HPLC Methods.
- **Other test:** Suphated ash form limited do not more than 0.1% in BP. IP and USP are not available.
- **Loss on Drying:** The Moisture Content are same ranges In IP, BP and USP.

Comparisons of Naproxen Tablet

- **Identification Test:** The identification test is UV is commonly found but IP also refer IR.
- **Assay limits and Methods:** Assay limits drug Paracetmol tablet at narrow range in IP and higher rang in USP and assay method IP prefer chemical and USP prefer HPLC.
- **Related substances test:** IP TLC method and USP HPLC.
- **Dissolution Test:** IP prefer the apparatus no -1as per IP and apparatus no -2 USP as per USP.

Comparison of Dexamethasone API

- **Identification test:** In IP and BP same identification test and USP prefer IR and UV.
- **Assay limit and Method:** The assay limit is some ranges on the Dried basis. And assay methods are same in IP and BP USP prefer HPLC Method. Related substances Test are same In IP and USP.
- **Other test:** Heavy metal NMT 0.1 % in IP, Suphated ash NMT 0.1 % in BP and USP 0.2%
- **Loss on Drying:** The moisture content is same ranges [6].

Comparison of Dexamethasone Tablet

- **Identification Test:** Identification Test IR, TLC, UV, and chemical test and USP only prefer TLC.
- **Assay limit and method:** Assay limit and assay method both are same in IP and USP.
- **Related substances:** Related substances test are same.
- **Dissoulation Test:** IP prefer the apparatus no -1as per IP and apparatus no -2 USP as per USP.

Comparison of Diclofenac

- **Identification Test:** The identification test IR, Chemical test method are Common in IP, and whereas TLC method in BP and USP prefer only IR Methods.
- **Assay limit and method:** Assay limit is almost same and assay method also same.
- **Other test:** Heavy metal in IP and Diclofenac Related impurity are 0.2 % and Total NMT 0.5%
- **Loss on drying:** The Moisture content are same ranges in IP, BP and USP.

Discussion

An analytical technique is adopted based on the nature of drug formulation drug combination pharmaceutical aids presents in a formulations, pharmacopoeia analytical methods are established after confirming precision accuracy instrumental titration techniques and other tests that are available in the pharmacopeia are proved for their sensitivity, repeatability and reproducibility.

The standard ranges established are statically significant after` establishing the sampling procedures form a populations. When a comparison among pharmacopoeia is made, the range of drug content, impurities as limits fixed by different countries varies.

Traditional techniques like visible colour reaction, titrations with indicators were used for majority of the drugs earlier. Advanced instrumental techniques using melting point, pH meter, HPLC, GC, NMR, X- ray crystallography etc.In several monograph TLC technique is used for related substances and such test is sensitive at very low

concentrations when there may not be necessary for an HPLC method however due to lack of availability of standard impurities and other reasons , several companies practice HPLC technique instead of TLC technique.Exporting a pharmaceutical product should comply with pharmaceutical standards of destination country and where such pharmacopoeia is not available such country authorities refer to pharmacopoeia standards of their interest i.e. BP, USP, international pharm [7].

All pharmacopeias were referred for analysis and compare of including IP,BP and USP it was found that USP much more updated compendia among all.

Conclusion

The whole comparative study the observed several updated methods and technique are available in the USP.

The sophistication of methods of analysis or identification test in the very burdensome and older technique available in Bp and IP some older technique are not sensitive result. For ex. Paracetmol identification test performed by UV& IR chemical Test in BP while USP only performed in IR Test.

Future Prospect

The comparison data produced by this study are expected to be used to develop strategies for future revisions of pharmacopoeias around the world.

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