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Comparative Study of In-process and Finished Products Quality Control Tests of IP, BP & USP for Tablets

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Abstract

Present study deals with a brief overview of the comparative study of quality requirements for in-process and finished products quality control Tests of Indian Pharmacopeia (IP), British Pharmacopeia (BP) & United States Pharmacopeia (USP) for some conventional dosage forms. The concept of total quality control test refers to the process of striving to produce a quality product by a series of measures, requiring an organized effort in order to eliminate errors at every stage in the production. In process product testing is done in order to check the conformance of the final product with the compendial standards as specified in the pharmacopoeias. As the final sample taken for the finished product testing is only a representative of a large batch, a significant difference still remains. The pharmacopoeias have laid down the specified limits within which the value should fall in order to be compliant as per the standards. The official pharmacopoeias in different parts of the world specify the quality requirements for pharmaceutical products. However the parameters and standards differ to some extent from each other. Hence an attempt is being made to compare and bring out the harmonised limits within which a product should fall in order to meet the pharmacopoeial specifications that satisfy quality requirements for many regions. The main aim is to study the quality control tests of Tablets which is the most popular conventional dosage forms and to list down the similarities and differences as per various Pharmacopoeias. The parameters examined for conventional dosage forms as per the Pharmacopoeias were compared and certain similarities and differences were observed. It was noted that except for a few parameters, the quality control tests were broadly similar.

Keywords: Indian Pharmacopeia, British Pharmacopeia, United States Pharmacopeia, Tablet Quality control Tests, Quality control Tests

Introduction

In the pharmaceutical industry, total quality of the product must be ensured in order to prevent the kind of product which does not comply with the specifications laid down by the Pharmacopoeias, and at the same time it is also necessary for controlling the errors during the production process. Quality can be defined as the suitability of the goods or service to the determined qualifications. Quality control emphasizes testing of products for defects and reporting to management who makes the decision to investigate or deny the release. Both the in process and finished product quality control tests help to ensure the total quality of the product. The entire dealing process (In process and finished product quality control tests) involves stringent quality control tests to make products totally flawless before they are released into the market.

In-process tests may be performed during the manufacture of either the drug substance or drug product, rather than as part of the formal battery of tests which are conducted prior to release.

In process controls (IPC) are checks that are carried out before the manufacturing process is completed. The function of in process controls involves monitoring and if necessary, adaptation of the manufacturing process in order to comply with the specifications. This may include control of equipment and environment too.

In process materials should be tested for their physical parameters and its quality attributes which are later approved or rejected by the quality control department based on the results obtained during the manufacturing process. Rejected In process materials should be

identified and controlled under a quarantine system designed to prevent their use in manufacturing.

Standard operating procedures should be established and followed that describe the in process controls and tests. Certain tests conducted during the manufacturing process, where the acceptance criterion is identical to or narrower than the release requirement, (e.g., pH of a solution) which may satisfy requirements when the test is included in the specification.

References to certain procedures are quite similar in pharmacopoeias in each region even though there are minor changes within each of them. Wherever and whichever procedures are appropriate, pharmacopoeial procedures should be utilized. Whereas differences in pharmacopoeial procedures and/or acceptance criteria have existed among the regions, a harmonized specification is possible only if the procedures and acceptance criteria defined are acceptable to regulatory authorities in all regions.

In process controls may be performed at regular intervals during a process or at the end of the process. The objectives of in process control are both quality control and process control. The classic interpretation of the term in process control includes the recording of measured values by members of the in process control group.

Finished product controls (FPC) are checks that are carried out after the manufacturing process is complete with respect to qualitative and quantitative characteristics along with test procedures and their acceptance limits, with which the finished product must comply throughout its valid shelf life.

In order to determine the specifications of the finished product, the quality characteristics related to the manufacturing process should be taken into account. An appropriate specification for each aspect of quality studied during the phase of development and during the validation of the manufacturing process should be determined. At least those aspects considered to be critical should be the object of specifications routinely verified. The specification limits of the finished product at the time of batch release are set by the marketing authorization applicant such that the specifications proposed at the end of shelf life are guaranteed and are established on the basis of a critical detailed review of the data gathered from the batches analysed.

The concept of total quality control test refers to the process of striving to produce a perfect product by a series of measures requiring an organized effort in order to eliminate errors at every stage in the production. In process product testing is required in order to check the conformance of the product with the compendial standards as specified in the pharmacopoeias. The pharmacopoeias have laid down the specified limits within which the value should fall in order to be compliant as per the standards. As the final samples taken for the finished product testing is only a representative of a large batch, a significant difference still remains because of minor variation in the specified limits in different pharmacopoeias. Since the markets have opened up due to globalization it is necessary for a product to comply with the standards of the place where it is to be marketed.

As the official pharmacopoeias are different in different parts of the globe, there is a need for the harmonised limit within which a product should fall in order to meet the pharmacopoeia specifications of that region. The aim of the study is quality control tests for some conventional dosage forms and to list down the similarities and differences as per various Pharmacopoeias.

In-Process and Finished Product Quality Control tests for Tablets

Tablets are solid dosage forms usually prepared with the aid of suitable pharmaceutical excipients. They may vary in size, shape, weight, hardness, thickness, disintegration and dissolution characteristics and in other aspects depending on their intended use and method of manufacture. Most tablets are used in the oral administration of drugs. Many of these are prepared with colorants and coatings of various types. Other tablets, such as those administered sublingually, buccally or vaginally are prepared to have features most applicable to their particular route of administration.

The Tablet quality control **(**TQC**)** tests are

- Uniformity of container contents.
- Content of active ingredients.
- Uniformity of content.
- Uniformity of weight.
- Friability.
- Disintegration test.
- Dissolution test.

Table 1: Test procedures for tablets

Reference code	Test procedure
TQC 1	**Uniformity of container contents:** Select a sample of 10 containers and count the number of tablets in each container. The average number of the contents in the 10 containers is not less than the labelled amount and the number in any single container is not less than 98 percent and not more than 102 percent of the labelled amount. If the requirement is not met, count the number of the contents in 10 additional containers. The average number in the 20 containers is not less than the labelled amount, and number is not less than 98 percent and not more than 102 percent of the labelled amount.

TQC 2

Content of active ingredients:

Determine the amount of active ingredient by the method described in the assay and calculate the amount of active ingredient per tablet. The result lies within the range for the content of active ingredient stated in the monograph. This range is based on the requirement that 20 tablets, or such other number as may be indicated in the monograph, are used in the assay.

Where 20 tablets cannot be obtained, a smaller number, which must not be less than 5, may be used, but to allow for sampling errors the tolerances are widened in accordance with the Table 1(A).

The requirements of the Table 1(A) apply when the stated limits are between 90 and 110 percent. For limits other than 90 to 110 percent, proportionately smaller or larger allowances should be made.

Table 1(A): Limits for content of active ingredients

Weight of active ingredients in each tablet	**Subtract from lower limit for samples of**			**Add to the upper limit for samples of**		
	15	**5**	**10**	**15**	**5**	**10**
0.12 g or less	0.2	0.7	1.6	0.3	0.8	1.8
More than 0.12 g But less than 0.3 g	0.2	0.5	1.2	0.3	0.6	1.5
0.3 g or more	0.1	0.2	0.8	0.2	0.4	1.0

TQC 3

Uniformity of content:

The preparation complies with the test if each individual content is 85 to 115 percent. The preparation fails to comply with the test if more than one individual content is outside these limits or if one individual content is outside the limits of 75 to 125 percent of the average content.

If one individual content is outside the limits of 85 to 115 percent of the average content but within the limits of 75 to 125 percent, repeat the determination using another 20 tablets.

The preparation complies with the test if not more than one of the individual contents of the total sample of 30 tablets is outside 85 to 115 percent of the average content and none is outside the limits of 75 to 125 percent of the average content.

TQC 4

Uniformity of weight:

Weigh individually 20 units selected at random or, for single-dose preparations in individual containers, the contents of 20 units, and calculate the average weight.

Not more than two of the individual weights deviate from the average weight by more than the percentage shown in the Table 1(B) and none deviates by more than twice that percentage.

Table 1(B): Limits for Uniformity of weight

Dosage form	**Average weight**	**Percentage deviation**
Uncoated and film coated tablets	80 mg or less	10
	More than 80 mg but less than 250 mg	7.5
	250 mg or more	5

TQC 5

Disintegration test:

Introduce one tablet into each tube and add a disc to each tube. Suspend the assembly in the beaker containing the specified liquid and operate the apparatus for the specified time. Remove the assembly from the liquid. The tablets pass the test if all of them have disintegrated.

If 1 or 2 tablets fail to disintegrate, repeat the test on 12 additional tablets; not less than 16 of the total of 18 tablets tested disintegrate.

If the tablets adhere to the disc and the preparation under examination fails to comply, repeat the test omitting the disc. The preparation complies with the test if all the tablets in the repeat test disintegrate.

TQC 6

Friability test:

For tablets with an average weight of 0.65 g or less take a sample of whole tablets corresponding to about 6.5 g and for tablets with an average weight of more than 0.65 g take a sample of 10 whole tablets.

Dedust the tablets carefully and weigh accurately the required number of tablets. Place the tablets in the drum and rotate it 100 times.

Remove the tablets, remove any loose dust from them and weigh them accurately. The test is run only once unless the results are difficult to interpret or if the weight loss is greater than the targeted value, in which case, the test is repeated twice and the mean of the three tests is determined. A maximum loss of weight (from a single test or from the mean of the three tests) not greater than 1.0 per cent is acceptable for most tablets.

If obviously cracked, chipped or broken tablets are present in the sample after tumbling, the sample fails the test.

TQC 7

Dissolution test:

Conventional and prolonged-release tablets:

Place the stated volume of the dissolution medium in the vessel. Assemble the apparatus and warm the dissolution medium to 36.5º to 37.5º C. Place one tablet in the apparatus, taking care to exclude air bubbles from the surface of the tablet.

When paddle type is used, Allow the tablet to sink to the bottom of the vessel prior to the rotation of the paddle. A suitable device such as a wire of glass helix may be used to keep horizontal at the

bottom of the vessel tablets that would otherwise float.

When basket type is used**,** place the tablet in the dry basket at the beginning of each test. Lower the basket into position before rotation. Operate the apparatus immediately at the speed of rotation specified in the individual monograph. Within the time interval specified, or at each of the time stated, withdraw a specimen from a zone midway between the surface of the dissolution medium and the top of the rotating blade or basket, not less than 10 mm from the wall of the vessel. Except in the case of single sampling, add a volume of dissolution medium equal to the volume of the samples withdrawn. Perform the analysis as directed in the individual monographs. Repeat the whole operation 5 times. Where two or more tablets are directed to be placed together in the apparatus, carry out 6 replicate tests.

For each of the tablet tested calculate the amount of dissolved active ingredient in solution as a percentage of the stated amount. where two or more tablets are placed together, determine for each test the amount of active ingredient in solution per tablet and calculate as a percentage of stated amount.

Acceptance criteria

Unless otherwise specified, the requirements are met if the quantities of active substance dissolved from the dosage units conform to the Table 1(C) given below.

If the results do not conform to the requirements at stage S_1 given in the Table 1(C), continue testing with additional dosage units through stages S_2 and S_3 unless the results conform at stage S_2.

Table 1(C): Acceptance criteria for conventional dosage form

Level	Number tested	Acceptance Criteria
S_1	6	Each unit is not less than D* + 5 percent**.
S_2	6	Average of 12 units (S_1 + S_2) is equal to or greater than D and no unit is less than D-15 percent**.
S_3	12	Average of 24 units (S_1 + S_2 + S_3) is equal to or greater than D, not, more than two units are less than D-15 percent**and no unit is less than D- 25 percent**.

*D is the amount of dissolved active ingredient specified in the individual monograph, expressed as a percentage of the labelled content.

**Percentages of the labelled content.

Prolonged release dosage forms:

Unless otherwise specified, the requirements are met if the quantities of the active substance dissolve from the dosage units conform to the Table 1(D). If the results do not confirm to the requirements at stage L_1 given in the Table 1(D), continue testing with additional dosage units through stages L_2 and L_3 unless the results confirm at stage L_2. The limits embrace each value of D, the amount dissolved at each specified dosing interval. Where more than one range is specified the acceptance criteria applied to each range.

Table 1(D): Acceptance criteria for Prolonged release dosage form

Level	Number tested	Acceptance Criteria
L_1	6	No individual value lies outside the stated ranges and no individual value is than the stated amount at the final test time.
L_2	6	The average value of the 12 units (L_1+ L_2) lies within each of the stated ranges and is not less than the stated amount at the final test time; none is more than 10 percent of labelled content outside each of the stated ranges; and none is more than 10 percent of labelled amount below the stated amount at the final test time.
L_3	12	The average value of the 24 units (L_1+ L_2+ L_3) lies within each of the stated ranges, and is not less than the stated amount at the final test time; not more than 2 of the 24 units are more than 10% of the labelled content outside each of the stated ranges; not more than 2 of the 24 units are more than 10% of labelled content below the stated amount at the final test time; and none of the units is more than 20% of labelled content outside each of the stated ranges or more than 20% of labelled content below the stated amount at the final test time.

Modified release dosage forms:
Use method A or method B.
Method A
Acid stage:
Place 750 ml of 0.1M Hydrochloric acid in the vessel, and assemble the apparatus. Warm the dissolution medium to 36.5º to 37.5º C. Place one tablet in the apparatus, cover the vessel and operate the apparatus at the specified rate. After two hours of operation in the acid medium, withdraw aliquots of the liquid and proceed immediately as directed under buffer stage. Perform the analysis of the aliquots using a suitable assay method.
Buffer stage:
Complete the operation of adding the buffer and adjusting the pH within 5 minutes. With the apparatus operating at a rate specified, add to the medium in the vessel, 250 ml of 0.2 M solution of trisodium phosphate dodecahydrate that has been warmed to 36.5° to 37.5° C. Adjust if necessary, with 2M Hcl or 2M sodium hydroxide to a pH of 6.8 ±0.05^0.

Method B:
Acid stage:
Place 1000 ml of 0.1 M hydrochloric acid in the vessel and assemble the apparatus. Warm the dissolution medium to 36.5° to 37.5°C. Place one tablet in the apparatus, cover the vessel and operate the apparatus at the specified rate. After 2 hours of operation in the acid medium, withdraw an aliquot of the liquid and proceed immediately as directed under buffer stage. Perform the analysis of the aliquot using a suitable assay method.
Buffer stage:
Use buffer that has previously been warmed to 36.5° to 37.5° C. Drain the acid from the vessel and add 1000 ml of pH 6.8 phosphate buffer, prepared by mixing 3 volumes of 0.1 M hydrochloric acid with 1 volume of 0.2 M solution of trisodium phosphate dodecahydrate and adjusting, if necessary, with 2M hydrochloric acid or 2M Sodium hydroxide to a pH of 6.8 ± 0.05. This may also be done by removing from the apparatus the vessel containing the buffer and transferring the dosage unit to the vessel containing the buffer. Continue to operate the apparatus for 45 minutes, or for the specified time. At the end of this period, withdraw an aliquot of the liquid and perform the analysis using a suitable assay method.

Table 1(E): Acceptance criteria for modified release dosage form

Level	Number tested	Acceptance criteria
A_1	6	No individual value exceeds 10 percent dissolved.
A_2	6	The average value of the 12 units (A_1+A_2) is not more than 10 percent dissolved, and no individual unit is greater than 25 percent dissolved.
A_3	12	The average value of the 24 units (A_1+A_2) is not more than 10 percent dissolved, and no individual unit is greater than 25 percent dissolved.

Buffer stage:
Unless otherwise specified, the requirements of this part of the test are met if the quantities, based on the percentage of the labelled content of active substance dissolved from the units tested conform to Table 1(F). Continue the testing through the 3 levels unless the results of both acid and buffer stages conform at an earlier level. The value of D in Table 1(F) is 75 percent dissolved unless otherwise specified. The quantity D is the specified total amount of active substance dissolved in both the acid and buffer stages, expressed as a percentage of the labelled content.

Table 1(F): Acceptance criteria for modified release dosage form in buffer stage

Level	Number tested	Acceptance criteria
B_1	6	No unit is less than D + 5 percent*
B_2	6	The average value of the 12 units (B1 + B2) is equal to or greater than D, and no unit is less than D – 15 percent*
B_3	12	The average value of the 24 units (B1 + B2) is equal to or greater than D, not more than 2 units are less than D – 15 percent*, and no unit is less than D – 25 percent*

TQC 8	**Uncoated tablets:** **Disintegration test:** Use water as the liquid. Add a disc to each tube. Operate the apparatus for 15 minutes, unless otherwise stated in the individual monograph. Examine the state of the tablets. If the tablets fail to comply because of adherence to the discs, repeat the test on a further 6 tablets omitting the discs. The tablets comply with the test if all 6 tablets have disintegrated.
TQC 9	**Coated tablets:** **Disintegration test:** Use water as the liquid. Add a disc to each tube. Operate the apparatus for 60 minutes, unless otherwise stated in the individual monograph. Examine the state of the tablets. If any of the tablets has not disintegrated, repeat the test on a further 6 tablets, replacing water with 0.1 M hydrochloric acid. The tablets comply with the test if all 6 tablets have disintegrated in the acid

	medium.
TQC 10	**Dispersible tablets:** **Disintegration test:** Use water as the liquid. Add a disc to each tube. Operate the apparatus for 3 minutes, unless otherwise stated in the individual monograph. Examine the state of the tablets. If any of the tablets has not disintegrated, repeat the test on a further 6 tablets. The tablets comply with the test if all 6 tablets have disintegrated.
TQC 11	**Uniformity of dispersion:** Place 2 tablets in 100 ml of water and stir gently until completely dispersed. A smooth dispersion is obtained which passes through a sieve screen with a nominal mess aperture 710 mm (sieve number 22).
TQC 12	**Effervescent tablets:** **Disintegration test:** Place 1 tablet in a beaker containing 250 ml of water at 20^0-30^0 C; numerous bubbles of gas are evolved. When the evolution of gas around the tablet or its fragments ceases the tablet has disintegrated, being either dissolved or dispersed in the water so that no agglomerates of particles remain. Repeat the operation on 5 other tablets. The tablets comply with the test if each of the 6 tablets used disintegrates in the manner prescribed within 5 min, unless otherwise justified and authorised.
TQC 13	**Soluble tablets:** **Disintegration test:** Soluble tablets disintegrate within 3 minutes. The test is carried out using water at 15° to 25°C.
TQC 14	**Film coated tablets:** **Disintegration test:** Use water as the liquid. Add a disc to each tube. Operate the apparatus for 30 minutes, unless otherwise stated in the individual monograph. Examine the state of the tablets. If any of the tablets has not disintegrated, repeat the test on a further 6 tablets, replacing water with 0.1 M hydrochloric acid. The tablets comply with the test if all 6 tablets have disintegrated in the acid medium. If coated tablets fail to comply because of adherence to the discs, repeat the test on a further 6 tablets omitting the discs. The tablets comply with the test if all 6 tablets have disintegrated.
TQC 15	**Enteric coated tablets:** **Disintegration test:** If the tablet has a soluble external coating, immerse the basket in water at room temperature for 5 minutes. Suspend the assembly in the beaker containing 0.1 M hydrochloric acid and operate without the discs for 2 hours, unless otherwise stated in the individual monograph. Remove the assembly from the liquid. No tablet shows signs of cracks that would allow the escape of the contents of disintegration, apart from fragments of coating. Replace the liquid in the beaker with mixed phosphate buffer pH 6.8, add a disc to each tube and operate the apparatus for a further 60 minutes. Remove the assembly from the liquid. The tablets pass the test if all 6 have disintegrated. **Dissolution test:** Place the stated volume of the dissolution medium. Assemble the apparatus and warm the dissolution medium to 36.5° to 37.5° C. Unless otherwise stated, place 1 tablet in the apparatus. When paddle is used, allow the tablet to sink to the bottom of the vessel prior to the rotation of the paddle. A suitable device such as a wire of glass helix may be used to keep horizontal at the bottom of the vessel tablets that would otherwise float. When basket type is used, place the tablet in a dry basket at the beginning of each test. Lower the basket into position before rotation. Operate the apparatus as specified in the individual monograph. Within the time interval specified, or at each of the times stated, withdraw a specimen from a zone midway between the surface of the dissolution medium and the top of the rotating blade or basket, not less than 10 mm from the wall of the vessel. Add a volume of dissolution medium equal to the volume of the samples withdrawn. Perform the analysis as directed in the individual monograph. Repeat the whole operation 5 times. Where 2 or more tablets are directed to be placed together in the apparatus, carry out 6 replicate tests. For each of the tablet tested, calculate the amount of dissolved active ingredient in solution as a percentage of the stated amount where 2 or more tablets are placed together, determine for each test the amount of active ingredient in solution per tablet and calculate as a percentage of the stated amount.
TQC 16	**Orodispersible tablets:** **Disintegration test:** Use water as the liquid. Add a disc to each tube. Operate the apparatus for 3 minutes, unless otherwise stated in the individual monograph. Examine the state of the tablets. If the tablets fail to comply because of adherence to the discs, repeat the test on a further 6 tablets omitting the discs. The tablets comply with the test if all 6 tablets have disintegrated.
TQC 17	**Gastro – resistant tablets:** **Disintegration test:** For tablets covered with a gastro- resistant coating, carry out the test with the following modifications. Use 0.1 M hydrochloric acid as the liquid. Operate the apparatus for 2 h, or another such time as may be justified and authorised, without the discs and examine the state of the tablets. The time of residence to the acid medium varies according to the formulation of the tablets to be examined. It is typically 2 h to 3 h but even with authorised deviations is not less than 1 h. No tablet shows signs of either disintegration or cracks that would allow the escape of the contents. Replace the acid by phosphate buffer solution pH

	6.8 and add a disc to each tube. Operate the apparatus for 60 min and examine the state of the tablets. If the tablets fail to comply because of adherence to the discs, the results are invalid. Repeat the test on a further 6 tablets omitting the discs. **Dissolution test:** Similar as that of TQC 7.
TQC 18	**Prolonged release tablets:** **Dissolution test:** Similar as that of TQC 7

Comparison of Specifications and Parameters

Table 2: The comparative study of Quality control parameters and specifications for tablets as per IP, BP and USP are as follows.

Tests	Reference code	IP	BP	USP
Uniformity of container contents	TQC 1	98-102%	NS	NS
Content of active ingredients	TQC 2	90-110%	NS	NS
Uniformity of content	TQC 3	85-115%	85-115%	85-115%
Uniformity of weight	TQC 4	< 10%	< 10%	< 10%
Friability	TQC 5	< 1%	< 1%	< 1%
Disintegration test	TQC 6	**Disintegration time**		
Uncoated tablet		< 15 min	< 15 min	< 15 min
Plain coated		< 60 min	< 60 min	< 60 min
Enteric coated		3 hrs	NS	NS
Dispersible		3 min	3 min	NS
Effervescent		< 3 min	< 3 min	NS
Orodispersible		NS	3 min	NS
Gastro resistant		NS	3 hrs	NS
Dissolution test	TQC 7	>70%	>70%	>70%

SUMMARY

The available QC tests from various pharmacopoeias supplement each other and each pharmacopoeia gives more details on a special issue than the other. Each pharmacopeia has its own specifications for each test.

Table 3: Quality control tests for Tablets as per IP, BP and USP.

Tests	IP	BP	USP
Uniformity of container contents	✓	✓	NS
Content of active ingredients	✓	✓	✓
Uniformity of content	✓	✓	✓
Uniformity of weight	✓	✓	✓
Disintegration test	✓	✓	✓
Dissolution test	✓	✓	✓
Friability test	✓	✓	✓
Uncoated tablets Disintegration test	✓	✓	✓
Coated tablets Disintegration test	✓	✓	✓
Film coated tablets Disintegration test	✓	NS	NS
Dispersible tablets ▪ Disintegration test ▪ uniformity of dispersion	✓	✓	✓
Effervescent tablets Disintegration test	✓	✓	NS
Enteric coated tablets ▪ Disintegration test ▪ Dissolution test	✓	NS	✓
Prolonged release tablets Dissolution test	✓	✓	NS
Soluble tablets Disintegration test	✓	✓	NS
Orodispersible tablets Disintegration test	NS	✓	✓
Gastro-resistant tablets ▪ Disintegration test ▪ Dissolution test	NS	✓	NS

Conclusion

From the above review, it can be concluded that though IP, BP and USP included most of the in process and finished products QC tests for some conventional dosage forms. However some difference was observed. Some of the tests are available only in some pharmacopoeia. The differences in the tests and their limits as specified in the different pharmacopoeias needs to be harmonized and streamlined in such a way that if the test meets the specified limit as per harmonized one, it meets all the requirements of all the pharmacopoeias and later the regulatory requirements of that particular country. This is important for the products which are marketed globally. Because of this a huge amount of time, money and man power can be minimized.

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AUTHORS' CONTRIBUTIONS

Authors contributed equally to all aspects of the study.

PEER REVIEW

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CONFLICTS OF INTEREST

The authors declare that they have no competing interests