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Comparative Study of Quality Control Test for Eye Preparations as Per IP, BP and USP

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Abstract : The present study deals with a brief review of the quality control tests for the eye preparations as per the different pharmacopoeias. The quality control tests for eye preparations are different in the different pharmacopoeias like IP, BP, and USP. Eye preparations are sterile liquid, semi-solid or solid preparations intended for administration upon the eyeball and/or to the conjunctiva, or for insertion in the conjunctival sac. It is necessary to know the quality requirements of the different pharmacopoeias for the eye preparations as it is required and important to guarantee the quality product and their supply in different markets of the world.

The types of tests/parameters, procedures and the Pharmacopoeial limits/specifications for eye preparations were compared. Certain similarities and differences were observed. The quality control tests for different eye preparations are more elaborately given in IP and BP in comparison to USP. The available tests and limits supplement each other and one pharmacopoeia gives more details on a specific test than the other. For eg: Powders for eye drops and eye lotions, semi-solid eye preparations, ophthalmic inserts were specifically given in BP. The eye preparations like eye solutions or eye lotions was given in USP, eye drops and eye ointments are more specifically given in IP. Other pharmacopoeial test procedures were found to be almost similar but the specifications slightly differ.

Keywords: Quality Control Test, Eye Preparations, IP, BP, USP.

Introduction

In the pharmaceutical industry, the product must be ensured to prevent the deviations from the specifications laid down by the pharmacopoeias and also it is necessary to control the errors during the process itself by performing the in-process checks.

Quality Control is that part of the GMP which is concerned with the sampling, specifications, 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 helps to ensure the quality of the product. The entire in-process and finished product quality control tests involves stringent quality control tests to make products totally meeting the specifications before they are released into the market. In-process tests may be performed during the manufacture of either the drug substance or drug product to minimize the defects at the

manufacturing stage itself, rather than as part of the formal quality control tests which are conducted prior to release.

Finished product quality controls (FPQC) 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 shelflife.

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 the regulatory authorities in all regions. [1]

Discussion

Quality control tests for Eye preparations

Eye preparations are sterile liquid, semi-solid or solid preparations intended for administration upon the eyeball and/or to the conjunctiva, or for insertion in the conjunctival sac.

Several categories of eye preparations may be distinguished as:

- Eye drops
- Eye ointments
- Powders for eye drops and eye lotions
- Semi-solid eye preparations
- Ophthalmic inserts
- Eye lotions (or) Eye solutions

The quality control tests carried out for various eye preparations;

Eye drops

1. Uniformity of Volume
2. Particle size
3. Sterility

Eye ointments

1. Test for metal particles
2. Uniformity of weight
3. Particle size
4. Sterility
5. Leakage test

Powders for eye drops and eye lotions

1. Uniformity of dosage units
2. Content uniformity
3. Uniformity of mass

Semisolid eye preparations

1. Particle size

Ophthalmic inserts

1. Uniformity of dosage units
2. Content uniformity

Eye solutions or eye lotions

1. Isotonicity value
2. Buffering
3. Sterility

Test Procedure for Eye Drops and Eye Ointments

Quality control tests for Eye preparations

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2. Content uniformity

Eye solutions or eye lotions

1. Isotonicity value
2. Buffering
3. Sterility

Eye Drops,Eye Ointments And Semi-Solid Eye Preparations

Eye drops are sterile, aqueous or oily solutions or suspensions of one or more medicaments intended for instillation into the conjunctival sac. They may contain suitable auxillary substances such as buffers, stabilizing agents, solubilizing agents and agents to adjust the tonicity or viscosity of the preparation. Eye drops should be packed in tamper evident containers. Containers should be made from materials that do not cause deterioration of the preparation as a result of diffusion into or across the material of the containers or by yielding foreign substances to the preparation.[2]

Eye ointments are sterile, semi-solid preparations of homogenous appearance intended for application to the eye. They may contain one or more medicaments dissolved or dispersed in a suitable basis. Bases, which are usually non-aqueous, may contain suitable auxiliary substances such as stabilizing agents, antimicrobial preservatives and antioxidants. [2]

Semi-solid eye preparations are sterile ointments, creams or gels intended for application to the conjunctiva or to the eyelids. They contain one or more active substances dissolved or dispersed in a suitable basis. They have a homogeneous appearance. [3]

Test procedure for eye drops, eye ointments and Semisolid eye preparations

Uniformity of Volume

This complies with the tests for contents of packaged dosage forms.

Contents of packaged dosage forms for viscous and non viscous preparations

Select a sample of 10 filled containers and remove any labeling that might be altered in weight while removing the contents of the containers. Clean and dry the outer surfaces of the containers and weigh each container. If necessary cut open the container and wash each empty container with a suitable solvent, taking care to ensure that the closure and other parts of the container together with its part which may have been removed. The difference between the two weights is the net weight of the contents of the container.

The average net weight of the contents of the 10 containers is not less than the labeled amount and the net weight of the contents of any single containers is not less than 91% and not more than 109% of the labeled amount where the labeled amount is 50 gm or less and not less than 95.5% and not more than 104.5% of the labeled amount is more than 50 gm/50 ml but not more than 100 gm/200ml.

If this requirement is not met, determine the net weight of the contents of 10 additional containers. The average net weight of the contents of the 20 containers is not less than the labeled amount, and the net weight of the contents of not more than 1 of the 20 containers is less than 91% or more than 109% of the labeled amount where the labeled amount is 50 gm/50 ml or less than 95% or more than 104.5% of the labelled amount is more than 50 gm/ 50 ml but not more than 100 gm/200ml. [2]

Particle size

This test is applicable only to eye drops that are suspensions. Introduce a suitable volume of sample into a counting cell or onto a microscope slide, as appropriate. Scan under a microscope an area corresponding to 10 µg of the solid phase. Scan atleast 50 representative fields. Not more than 20 particles have a maximum dimension greater than 25 µm, not more than 10 particles have maximum dimension greater than 50 µm and none has a maximum dimension greater than 100 µm. [2]

Sterility

The test must be carried out under aseptic conditions designed to avoid accidental contamination of the product during testing. For achieving these conditions, a grade A laminar air flow cabinet or an isolator is recommended. The test environment has to be adapted to the way in which the tests are performed. Precautions taken for this purpose should not adversely affect any microorganisms, which are to be revealed in the tests. The working conditions in which the tests are carried out should be monitored regularly by appropriate sampling of the air and surfaces of the working area and by carrying out control tests.

The test is designed to reveal the presence of microorganisms in the samples used in the test. Table-1.1given below give guidance on the minimum number of items recommended to be tested in relation to the number of items in the batch on the assumption that the preparation has been manufactured under conditions designed to exclude contamination.

Table 1: No. of items for sterility testing of eye drops

Number of items in the batch	Minimum number of items recommended to be tested
Ophthalmic and other non-parenteral preparations	
Not more than 200 containers	5% or 2 containers whichever is greater
More than 200 containers	10 containers

Culture media:

The following culture media have been found suitable for the test. Fluid thioglycollate medium is primarily intended for the culture of anaerobic bacteria; however it will also detect aerobic bacteria. Soyabean casein digest medium is suitable for the culture of both fungi and aerobic bacteria.

Test procedures

Either of the following methods, Method A- Membrane Filtration or Method B- Direct Inoculation, may be followed.

Method A:

After transferring the contents of the container or containers to be tested to the membrane add an inoculum of a small number of viable micro-organisms (not more than 100 CFU) to the final portion of sterile diluent used to rinse the filter.

Method B:

After transferring the contents of the container or containers to be tested to the culture medium add an inoculum of a small number of viable micro-organisms (not more than 100 CFU) to the medium.

Method A is preferred where the substance under examination is oil, an ointment that can be put in to solution, a non-bacteriostatic and/or fungistatic property.

For liquids where the volume in a container is 100ml or more, Method A should be used. Select the number of samples to be tested from Table-1.2 and use them for the culture medium for bacteria and the culture medium for fungi.

Quantities of samples to be used

For ophthalmic and other non-parenteral preparations: take a amount of 10 t0 1000ml of culture media [method A], take a amount of 5 t0 10ml of culture media [method B],

Test for metal particles

Metal collapsible tubes for eye ointments must comply with the test.

Select a sample of 50 tubes from the lot to be tested and clean each tube by vibration and/or “blowing”. (A lot may be either the tube manufacturer’s day’s production or a consignment delivered to the tube user). Fill

the tubes with a suitable molten eye ointment base, close the open end of each tube by a double fold and allow the filled tubes to cool overnight at a temperature of 15ºC to 20ºC.

Assemble a metal bacteriological filter with a 4.25 cm filter paper of suitable porosity supported on suitable perforated plate in place of the standard sintered carbon disc and heat it in a suitable manner to a temperature above the melting range of the base. Remove the caps from the cooled tubes and apply uniform pressure to the closed end of each tube in turn, in such a manner that the time taken to express as much of the base as possible through each nozzle is not less than 20 seconds. Collect the extruded base from the 50 tubes in the heated filter, applying suction to the stem of the filter in order to draw the molten base through the filter paper. When the entire melted base has been removed, wash the walls of the filter and the filter paper with three successive quantities, each of 30 ml, of chloroform, allow the filter paper to dry and immediately mount it between glasses for examination.

Examine the filter paper under oblique lighting with the aid of magnifying glass with a graticule of 1 mm squares, one of which is sub-divided into 0.2 mm squares and note

a) The number of all metal particles 1 mm in length and longer,
b) The number in the range 0.5 mm to less than 1 mm and
c) The number in the range 0.2 mm to less than 0.5 mm.

Carry out two further examinations with the filter paper in two different positions so that the lighting comes from different directions and calculate the average number of metal particles counted in each of the three ranges specified. Give each metal particle detected on the filter paper a score as follows and add the scores together.

- Particles 1 mm and above - 50
- Particles 0.5 mm but less than 1 mm - 10
- Particles 0.2 mm but less than 0.5 mm - 2
- Particles less than 0.2 mm - Nil

The lot of tubes passes the test if the total score is less than 100 points; if the total score is more than 150 points, the lot fails the test. If the total score is between 100 and 150 (inclusive), the test is repeated on a further sample of 50 tubes and the lot passes the test if the sum of total scores in the two tests is less than 150 points. [2]

Leakage test [2]

Select 10 tubes of ointments, with seals when specified. Thoroughly clean and dry the exterior surfaces of each tube with an absorbent cloth. Place the tubes in a horizontal position on a sheet of absorbent blotting paper in an oven maintained at a temperature of 60 ± 3^0 C for 8 hrs. No significant leakage occurs during or at completion of the test (disregards traces of ointment presumed to originate externally from within the crimp of the tube or from the thread of the cap). If the leakage is observed from one but not more than one, of the tubes, repeat the test with 20 additional tubes of the ointment. The requirement is met if no leakage is observed from the first ten tubes tested or if the leakage is observed from not more than one of the 30 tubes tested.

Powders For Eye Drops Eye Lotions And Ophthalmic Inserts [5]

Powders for the preparation of eye drops and eye lotions are supplied in a dry, sterile form to be dissolved or suspended in an appropriate liquid vehicle at the time of administration. They may contain excipients to facilitate dissolution or dispersion, to prevent caking, to adjust the tonicity, to adjust or stabilise the pH or to stabilise the preparation.

Test procedures for powders for eye drops eye lotions and ophthalmic inserts

Uniformity of dosage units

To ensure the consistency of dosage unit, each unit in a batch should have active substance content within a narrow range around the label claim. Dosage units are defined as dosage forms containing a single dose

or part of a dose of an active substance in each dosage unit. Unless otherwise stated, the uniformity of dosage unit specification is not intended to apply to suspensions, emulsions or gels in single dose containers intended for cutaneous administration.

The term 'uniformity of dosage unit' is defined as the degree of uniformity in the amount of the active substance among dosage units.

The uniformity of preparations presented in dosage units is based on the assay of the individual contents of active substance of a number of dosage units to determine whether the individual contents are within the limits set. The content uniformity method may be applied in all cases.

The test of mass variation is applicable for the following dosage forms:

- Solutions enclosed in single dose containers and in soft capsules
- Solids (including powders, granules and sterile solids) that are packed in single-dose containers and contain no added active or inactive substances.
- Solids (including sterile solids) that are packed in single dose containers, with or without added active or inactive substances, that have been prepared from true solutions and freeze dried in final containers and are labelled to indicate this method of preparation.
- Hard capsules, uncoated tablets, or film coated tablets, containing 25mg or more of an active substance comprising 25% or more, by mass, of the dosage unit or, in the case of hard capsules, the capsule contents, except that uniformity of other active substances present in lesser proportions is demonstrated by meeting content uniformity requirements. The test for content uniformity is required for all dosage forms not meeting the above conditions for the mass variation test.

Content uniformity

Select not less than 30units, and proceed as follows for the dosage form designated.

For solid dosage forms like powders assay 10 units individually using an appropriate analytical method. Calculate the acceptance value (AV) using equation 1;

$|M-\bar{X}| + ks$……(1)

Where,

$\bar{X}$ = mean of individual contents(x_1, x2……..x_n) expressed as a percentage of the label claim.

M= reference value

k = acceptability constant

s = sample standard deviation

Single-dose powders for eye drops and eye lotions comply with the test or, where justified and authorised, with the tests for uniformity of content and/or uniformity of mass. Herbal drugs and herbal drug preparations present in the dosage form are not subject to the provisions of this paragraph.

Uniformity of content

The test for uniformity of content of single dose preparation is based on the assay of the individual contents of active substance of a number of single dose units to determine whether the individual contents are within the limits set with reference to the average contents of the sample.

Using the suitable analytical method, determine the individual contents of the active substances of 10 dosage units taken at random.

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

If one individual content is outside the limits of 85% to 115% but within the limits of 75% to 125%, determine the individual contents of another 20 dosage units taken at random. The preparation complies with the test if not more than one of the individual contents of the 30units is outside 85% to 115% of the average content and none is outside the limits of 75% to 125% of the average content.

Uniformity of mass

Weigh individually 20 units taken at a random or, for single dose preparations presented in individual containers, the contents of 20units, and determine the average mass. Not more than 2 of the individual masses deviate from the average mass by more than the percentage deviation and none deviates by more than twice that percentage.

Percentage deviation of powders for eye drops and eye lotions for average mass of less than 300 mg is 10

Percentage deviation of powders for eye drops or eye lotions for average mass of 300 mg or more is 7.5

Method:

Remove any paper labels from a container and wash and dry the outside. Open the container and without delay weigh the container and its contents. Empty the container as completely as possible by gentle tapping, rinse it if necessary with water and then with alcohol and dry at 100-105^{o}C for 1 hour or if the nature of the container precludes heating at this temperature, dry at lower temperature to constant mass. Allow to cool in a dessicator and weigh. The mass of the contents is the difference between the weighing. Repeat the procedure with another 19containers.

Single-dose powders for eye drops and eye lotions comply with the test. If the test for uniformity of content is prescribed for all the active substances, the test for uniformity of mass is not required.

Eye Solutions or Eye Lotions [5]

Eye solutions or Eye lotions are sterile aqueous solutions intended for use in rinsing or bathing the eye or for impregnating eye dressings.

Eye solutions or Eye lotions may contain excipients, for example to adjust the tonicity or the viscosity of the preparation or to adjust or stabilise the pH. These substances do not adversely affect the intended action or, at the concentrations used, cause undue local irritation.

Test procedures for eye solutions or lotions

Isotonicity value

Lachrymal fluid is isotonic with blood, having an isotonicity value corresponding to that of a 0.9% sodium chloride solution. Ideally an ophthalmic solution should have this isotonic value, but the eye can tolerate isotonicity values as low as that of a 0.6% sodium chloride solution and as high as that of a 2.0% sodium chloride solution without marked discomfort.

Some ophthalmic solutions are necessarily hypertonic in order to enhance absorption and provide a concentration of active ingredients strong enough to exert a prompt and effective action. Where the amount of such solutions used is small, dilution with lachrymal fluid takes place rapidly so that discomfort from the hypertonicity is only temporary. However any adjustment toward isotonicity by dilution with tears is negligible where large volumes of hypertonic solutions are used as collyria to wash the eyes; it is therefore important that solutions used for this purpose be approximately isotonic.

It is measured by osmolarity. When water on one side of a membrane contains more dissolved solute than water on the other side, one of two things will happen. If the solute can diffuse across the membrane, it

will. If the membrane is impermeable to the solute, however, water will diffuse across the membrane instead. The latter phenomenon is called osmosis. Tonicity is a measure of the relative concentration of non-penetrating solute on either side of a membrane. It uses the same units as molarity or osmolarity.

- Determine the number of moles of solute.
- Calculate the molarity of the solution
- Determine whether the solute dissociates as it dissolves.
- Determine which solutes can diffuse across the membrane and which cannot.

Decide whether the solution is isotonic, hypertonic or hypotonic. An isotonic solution has the same tonicity on both sides of the membrane.

Buffering

One purpose of buffering some ophthalmic solutions is to prevent an increase in pH caused by the slow release of hydroxyl ions by glass. Such a rise in pH can affect both the solubility and the stability of the drug. Normal tears have a pH of about 7.4 and possess some buffer capacity. The application of a solution to the eye stimulates the flow of tears and the rapid neutralization of any excess hydrogen or hydroxyl ions within the buffer capacity of the tears. Many ophthalmic drugs, such as alkaloidal salts, are weakly acidic and have only weak buffer capacity. Where only one or two drops of a solution containing them are added to the eye, the buffering action of the tears is usually adequate to raise the pH and prevent marked discomfort. In some cases pH may vary between 3.5 and 8.5. Ideally, an ophthalmic solution should have the same pH, as well as the same isotonicity value, as lachrymal fluid. This is not usually possible since, at pH 7.4, many drugs are not appreciably soluble in water. Most alkaloid salts precipitate as the free alkaloid at this pH. Additionally many drugs are chemically unstable at pH levels approaching 7.4. This instability is more marked at the high temperatures employed in heat sterilization. For this reason, the buffer system should be selected that is nearest to the physiological pH of 7.4 and does not cause precipitation of the drug or its rapid deterioration.

An ophthalmic preparation with a buffer system approaching the physiological pH can be obtained by mixing a sterile solution of the drug with a sterile buffer solution using aseptic technique. Even so, the possibility of a shorter shelf life at the higher pH must be taken in to consideration, and attention must be directed toward the attainment and maintenance of sterility throughout the manipulations.

Sterilization

The sterility of a solutions applied to an injured eye is of great importance. Sterile preparations in special containers for individual use on one patient should be available in every hospital, office or other instillation where accidentally or surgically traumatized eyes are treated. The method of attaining sterility is primarily by the character of the particular product.

Where ever possible, sterile membrane filtration under aseptic conditions is the preferred method. If it can be shown that product stability is not adversely affected, sterilization by autoclaving in the final container is also a preferred method.

The test is applicable for determining whether a pharmacopeial article purporting to be sterile complies with the requirements set forth in the individual monograph with respect to membrane filtration.

If the membrane filtration technique is unsuitable use the direct transfer method. Provisions for retesting are included under interpretation of test results. Because sterility testing is very exacting procedure, where asepsis of the procedure must be ensured for a correct interpretation of results, it is important that personnel be properly trained and qualified.

Filtration through microbial retentive materials is frequently employed for the sterilization of heat-liable solutions by physical removal of the contained micro-organisms. A filter assembly generally consists of porous matrix sealed or clamped into an impermeable housing. The effectiveness of a filter medium or substrate depends up on the pore size of the porous material and may depend upon adsorption of bacteria on or in the filter matrix or up on a sieving mechanism.

Filtration for sterilization is normally carried out with assemblies having membranes of nominal pore size rating of 0.2µm or less. Membrane filter media is now available include cellulose acetate, cellulose nitrate, flourocarbonate, acrylic polymers, polycarbonate, polyester, polyvinyl chloride, vinyl, nylon and even metal membranes and they may be reinforced or supported by an internal fabric. A membrane filter assembly should be tested for initial integrity prior to use, provided that such test does not impair the validity of the system, and should be tested after the filtration process is completed to demonstrate that the filter assembly maintained its integrity throughout the entire filtration procedure. Select double the number specified for the first stage under sterility test or other reasonable number. The minimum volumes tested from each specimen, the media and the incubation periods are the same as those indicated for the first stage.

If no microbial growth is found in second stage and the documented review of appropriate records and the indicated product

Table 2: Comparison of Specifications and Parameters of eye preparations

Specification for eye drops			
Tests	**IP**	**BP**	**USP**
Uniformity of volume	91-109% (labelled amount is 50 gm or less) 95.5-104.5%(labelled amount is 50 gm-100 gm)	NS	NS
Particle size	NMT 20 particles> 25 µm dimension, NMT 10 particles >50 µm dimension and None >100 µm dimension. (for 10 µg of solid phase)	NMT 20 particles > 25 µm dimension, and NMT 2 > 50 µm dimension. None > 90 µm dimension. (for 10 µg of solid phase)	NS
Sterility	If no evidence of microbial growth is found in 14 days, the product to be examined complies with the test for sterility	If no evidence of microbial growth is found in 14 days, the product to be examined complies with the test for sterility	NS
Specification for eye ointments			
Test for metal particles	The lot of tubes passes the test if the total score is less than 100 points	NS	The number of metal particles that are 50µm or larger in any dimension must not be more than 5 in number. If found to be more than 5 in number, then repeat 2 times then the particles that are 50 µm must not be more than 10 in number
Uniformity of weight	91-109% (labelled amount is 50 gm or less)	NS	NS

Particle size	NMT 20 particles >25μm dimension, NMT 10 particles >50μm dimension and none >100 μm in dimension.	NS	NS
Sterility	If there is no evidence of microbial growth is found in 14 days, the preparation under examination complies with the test for sterility	NS	If no microbial growth is found in the incubation period
Leakage test	NS	NS	No leakage is observed from the 10 tubes tested or if the leakage is observed from not more than 1 of the 30 tubes tested
Specifications for Powders for eye drops and eye lotions			
Uniformity of dosage units	NS	Complies when the content uniformity and uniformity of mass both complies	NS
Content uniformity	NS	The preparation complies with the test if each individual content is between 85% and 115% of the average content	NS
Uniformity of mass	NS	Percentage deviation is 10 for average mass < 300 mg	NS
Uniformity of dosage units	NS	Complies when the content uniformity and uniformity of mass both complies	NS
Specification for semisolid eye preparations			
Particle size	NS	NMT 20 particles > 25 μm dimension, and NMT 2 particles > 50 μm dimension. None >90 μm dimension for each 10 μg of solid active substance.	NS
Specifications for ophthalmic inserts			
Uniformity of dosage units	NS	Complies if the test for content uniformity complies	NS

Content uniformity	NS	The preparation complies with the test if each individual content is between 85% and 115% of the average content	NS
Specifications for eye solutions or eye lotions			
Isotonicity value	NS	NS	Eye can tolerate isotonicity values 0.6% NaCl solution to 2.0% NaCl solution without marked discomfort.
Buffering	NS	NS	The solution must be in the pH of 7.4
Sterility	NS	NS	No evidence of microbial growth is found in 14days

Results and Summary

Following are the tables specifying the individual tests included for various eye preparations as per IP, BP and USP.

Table-3 Quality control tests for eye drops as per IP, BP and USP

Test	IP	BP	USP
Uniformity of volume	□✓	NS	NS
particle size	□□□□	□□□□	NS
Sterility	□□□□	□□□□	NS

Table-4 Quality control tests for eye ointments as per IP, BP and USP

Test	IP	BP	USP
Test for metal particles	□✓	NS	□□□□
uniformity of weight	□□□□	NS	□□□NS
Particle size	□□□□	NS	NS
Sterility	□□□□	NS	□□□□
Leakage	NS	NS	□□□□

Table-5 Quality control tests for Powders for eye drops and eye lotions as per IP, BP and USP

Test	IP	BP	USP
uniformity of dosage units	□NS	□□□□	NS
content uniformity	□□□NS	□□□□	□□□NS
uniformity of mass	□□□NS	□□□□	NS

Table-6 Quality control test for semisolid eye preparations as per IP, BP and USP

Test	IP	BP	USP
Particle size	NS	□□□□	NS

Table-6 Quality control tests for ophthalmic inserts as per IP, BP and USP

Test	IP	BP	USP
Uniformity of dosage units	□NS	□□□□	NS
Content uniformity	□□□NS	□□□□	NS

Table-7 Quality control tests for eye solutions or eye lotions as per IP, BP and USP

Test	IP	BP	USP
Isotonicity value	□NS	□□□NS	□□□□
Buffering	□□□NS	□□□NS	□□□□
Sterility	□□□NS	□□□NS	□□□□

Conclusion

From the above review it is concluded that in IP, BP and USP most of the in-process and finished product quality control tests are included for eye preparations. However some differences were observed like some tests are mentioned in only one pharmacopoeia. The limits specified are also different for some tests mentioned in different pharmacopoeias.

However the differences in these tests and limits / specifications mentioned needs to be harmonized and streamlined in such a way that if the test limits meets the harmonized limits then it must meet the requirements of all pharmacopoeias and the regulatory requirements of that particular countries. This is mainly important for the drugs which are globally marketed. By this harmonization huge amount of man power, money and time can be minimized.

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