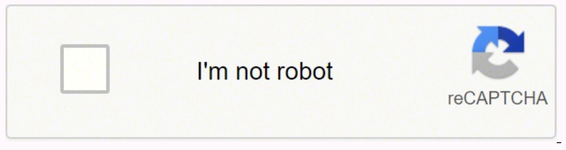

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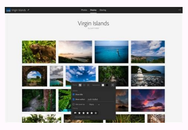
Evaluation of pharmaceutical aerosols pdf



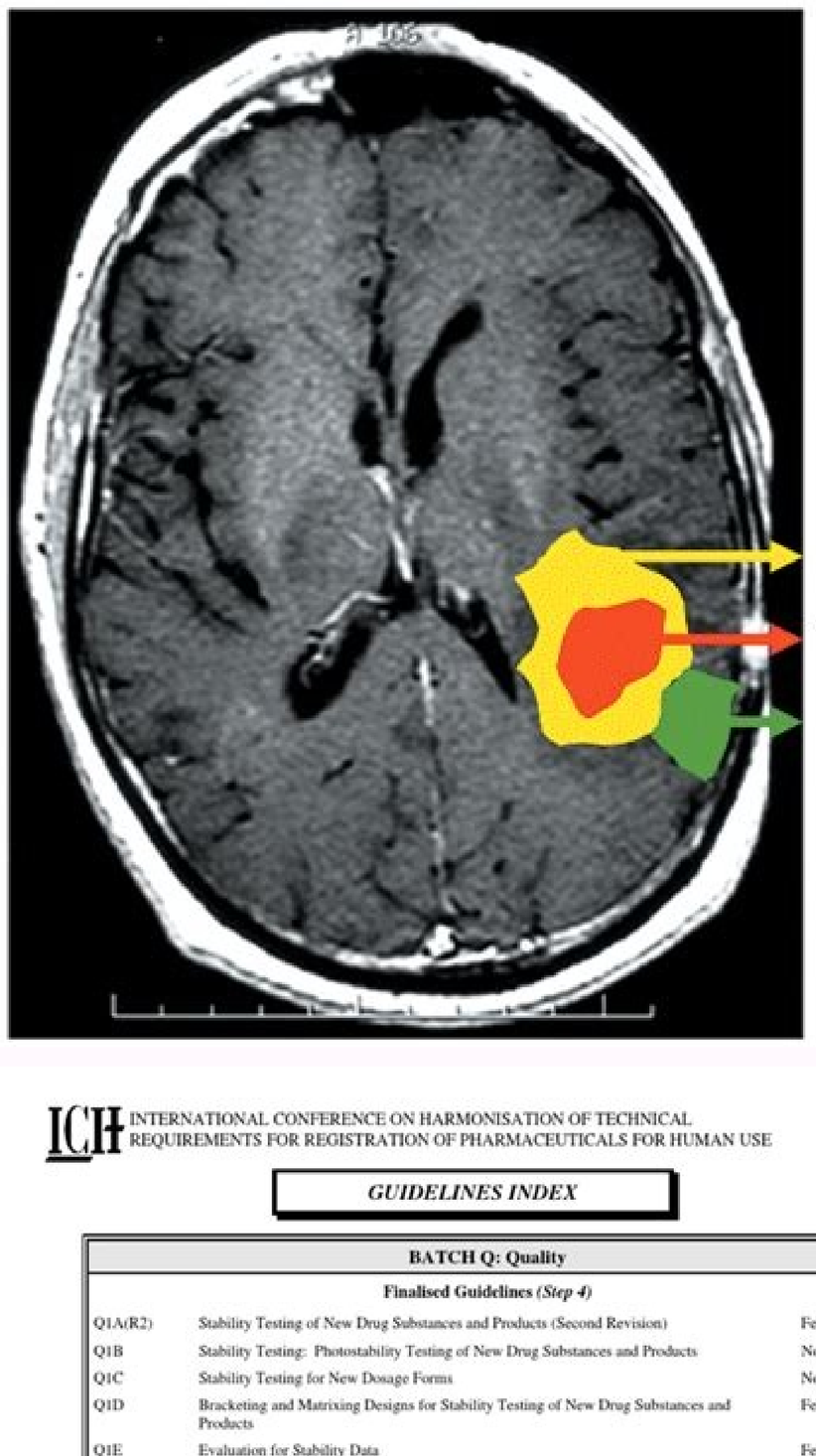
Robert Smith

Senior Research Scientist (Skincare)

PERSONAL STATEMENT

RESEARCH EXPERIENCE

EDUCATION



ICH INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

GUIDELINES INDEX

BATCH Q: Quality		
Finalised Guidelines *(Step 4)*		
Q1A(R2)	Stability Testing of New Drug Substances and Products (Second Revision)	Feb. 2003
Q1B	Stability Testing: Photostability Testing of New Drug Substances and Products	Nov. 1996
Q1C	Stability Testing for New Dosage Forms	Nov. 1996
Q1D	Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products	Feb. 2002
Q1E	Evaluation for Stability Data	Feb. 2003
~~Q1F*~~	~~Stability Data Package for Registration Applications in Climatic Zones III and IV~~ *(Guideline withdrawn in June 2006).*	~~Feb. 2003~~
Q2(R1)	Validation of Analytical Procedures: Text and Methodology *(The Addendum dated November 1996 has been incorporated into the core guideline in November 2005).*	Oct. 1994
Q3A(R2)	Impurities in New Drug Substances	Oct. 2006
Q3B(R2)	Impurities in New Drug Products	Jun. 2006
Q3C(R4)	Impurities: Guideline for Residual Solvents *(including the two Maintenance guidelines PDE for Tetrahydrofuran and PDE for N-Methylpyrrolidone dated September 2002 and incorporated into the core guideline in November 2005, as well as updates of Table 2, Table 3 and Appendix 1 incorporated in February 2009)*	Feb. 2009
Q4B	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions	Nov. 2007
Q4B Annex 1(R1)	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Residue on Ignition/Sulphated Ash General Chapter	Sep. 2010
Q4B Annex 2(R1)	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Test for Extractable Volume of Parenteral Preparations General Chapter	Sep. 2010
Q4B Annex 3(R1)	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Test for Particulate Contamination: Sub-Visible Particles General Chapter	Sep. 2010
Q4B Annex 4A(R1)	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests General Chapter	Sep. 2010
Q4B Annex 4B(R1)	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Microbiological Examination of Non-Sterile Products: Tests for Specified Micro-Organisms General Chapter	Sep. 2010
Q4B Annex 4C(R1)	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Microbiological Examination of Non-Sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use General Chapter	Sep. 2010
Q4B Annex 5(R1)	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Disintegration Test General Chapter	Sep. 2010
Q4B Annex 7(R2)	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Dissolution Test General Chapter	Nov. 2010
Q4B Annex 8(R1)	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Sterility Chapter General Chapter	Sep. 2010
Q4B Annex 9(R1)	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Tablet Friability General Chapter	Sep. 2010
Q4B Annex 10(R1)	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Polyacrylamide Gel Electrophoresis General Chapter	Sep. 2010

Evaluation of pharmaceutical aerosols slideshare. What are pharmaceutical aerosols. Evaluation parameters of pharmaceutical aerosols. Define aerosol in pharmacy. Quality control and testing evaluation of pharmaceutical aerosols. Types of pharmaceutical aerosols. Evaluation of pharmaceutical aerosols pdf.

Study of toxicity: For topical aerosol the topical aerosols are controlled by chilling effect or skin irritation. 10. 29/12/2008
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3
1.Propellent:
All the propellants are accompanied by a sheet of specifications.
4. Valves, actuator and dive tube (test procedure) Ã¯ ¯ Ã¯ taking 25 valves and positioned on suitable containers. 12/29/2008
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B. Please help us share our service with your friends. Lachman L, Lieberman A H, Pharmaceutical Aerosol, Theory & Practice of Industrial Pharmacy, CBS Publishers & Distributors PVT Ltd, 2011, P 589-618. Introduction An aerosol or pressurized package is defined as the system that depends on the power of compressed or liquefied gas to expel content from the container.ã, Â "Aerosol products consist in the following parts: 1. Ã¯ Ã¶ The containers are filled With specific test solutions. The propellants Ã ¢ â,¬ â ¢ is determined a sample and the steam pressure is determined which is then compared with the specifications. The aerosol product is refrigerated at a temperature of approximately -250F and transferred to the test apparatus. 12/29/2008
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A. Decay of light dispersion:
Principal:
How aerosol yes It establishes under the turbulent condition
, the changes in the light of
are measured a radius of Tyndall.
18. It is equal to net content.
In destructive method: opening the container and removing the most possible number of products.
16. Therapeutic activity: for aerosol inhalation the determination of therapeutic activity depends on the size of the particle. 12/29/2008
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a). Test It is made by measuring the size of the crimping valve and comparing. Foam stability:
Various methods: Ã, Â »Visual evaluation,

Ã‚Â» Time for the said to penetrate the foam,
Ã‚ Â »Time to fall auction rod It is inserted into the foam,
ã‚ Â »Rotational Vis Common.
6. Determination of the dimensions:
Methods: Ã‚Â »waterfall impacts,
Ã‚ Â» Decay of light dispersion.
17. Delivery of the drive valve in Ã‚Î¼l = Weight of individual delivery in mg / Gravity Specific of the test solution 5. For the topical aerosol the therapeutic activity of aerosol products is determined by applying therapeutically ingredients Active for test areas and the amount of therapeutically absorbed active substances is determined. Net content The cutting cans are positioned on the fill line are weighed, the weight difference is equal to the net content. 7. Performance test 1. Felton at L, Aerosols, essential remington of pharmaceutical, pharmaceutical press, pharmaceutical press, 2012, P633-650 11. Loss test
Ã‚ â € "6. Valve and actuator 4. The methods used to determine the foam The stability includes visual evaluation, time for a certain mass to penetrate the foam, the time for a given auction inserted in the foam to fall and rotational viscunter. Ã¯æ'â¼ easy to apply. The weight difference gives the quantity of content present in the container. 2. Ã¯æÂ¼ The metabolism of the first liver pass is avoided. Of 50 deliveries: Ã¯ ± if 4 or more deliveries are external limits, the valves are rejected.
4. Due a spray model record. 12/29/2008
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THANK YOU ....!
Dosage with measured valves:
Reproducibility of the dosage determined by:
Ã‚ â € "Taste
Accurate weighing of the filled container followed by dispense several dosage.
Containers again restored and diff. 12/29/2008
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CONTNTÃ ¢ â‚¬ |
C. 29/12/2008
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4
2.Valves, actuator, tube pipes
Sampling is carried out based on the standard procedure as found in military standards Ã ¢ â‚¬ "MIL-STD-105DÃ ¢ Â , ¬.
For the measured measured dose aerosol test It was developed by Ã ¢ â‚¬ â â â â â â â â â € œ â € â € œ ¢
Ã‚Â â â â â â «Industrial pharmaceutical technical section
Ã ¢ â‚¬ Ã Ã‚ Ã‚ Ã‚ , Ã‚ Ã‚ Ã‚ Ã‚ Ã‚ Ã‚ Ã‚ Ã‚ ã‚ â â â â «Academy of pharmaceutical sciences.
The subject of this test is to determine the size of the valve delivery & degree of uniform between the individual valves.
Standard test solutions have been proposed to exclude the variation of valve delivery.
5. Ã ¢ â‚¬ â ¢ The purity of the propellant is controlled by moisture, residual determinations of humidity, halogen and non-volatile. 12/29/2008
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Evaluation test:
A. Ã¯ ± if 2 Delivery of 1 valve They are beyond the limits: other 25 valves are tested. This procedure is repeated for a total of 2 supplied by every 25 test units. Advantages of aerosols Ã¯æ'â¼ The drug sensitive to the effect of oxygen or humidity is protected and the stability improved. We are a non-profit group that runs this website to share documents. 2. Net content:
The cutting cans positioned on the filling lines are awakened and therefore difference in WT. Flame projection The aerosol product is sprayed at an open flame for about 4 seconds and the flame extension is measured with the help of a ruler. Divided for no. Ã¯æ'â¼ protects the drug from the degradation of the gastrointestinal tract. Weight control is carried out by periodically adding empty calibrated containers to the filling lines that after filling the consent of the product are removed and awakened. 5. Then weight change by time provided is the discharge rate. 8. 29/12/2008
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3.Container
The containers are examined for defects in the lining.
Q.C aspects include the degree of conductivity of the current As measure of exposed metals.
Glass containers examined for defects.
4. Weight weight check
is performed periodically by adding the empty aerosol container calibrated to the fill lines that after filling with concentrate is removed and weighed.
The same procedure is used used Propellante weight control.
9. The contents are therefore weighed. Dosage with measured valves
4. Container 3. Organic tests:
1. Valetutica activity:
ã‚ â € "For inhalation Aerosol: It is depending on the size of the particles. For Topical Aerosols: it is applied to the test areas and the adsorption of the therapeutic ingredient is determined.
2.Toxicity:
ã‚ Â »by inhalation Aerosols: exposing animals steam test sprayed from the aerosol container.
Ã‚Â »For topical aerosols: the effects of irritation and colds are determined.
19. Evaluation test for pharmaceutical aerosol 1. Ã¯ ± Lot is rejected if more than 1 delivery is external. 12/29/2008
M.PHARM I SEM, 2008-09, GCP AURANGABAD

Quality control and evaluation of pharmaceutical aerosols
Prepared by: Mahesh W. Ã¯ Â¶ A 0.02-inch button with orifice is attached to the valves. 613-618.
Remington "Science and pharmacy practice - 3rd edition, volume-i, page n. 1014-1015.
20. 1. No.: 1661611006 Date Â ¢ â‚¬" 15-02 -2017 2. Ã¯æâ¼ aerosols are used for systemic and local application. Valves, actuator, dive pipes
Ã‚ â € "3. Ã¯æ ¼ a sterile drug dose is delivered and even the contamination of the drug is prevented 4. Quality control for pharmaceutical aerosol 1. Product concentrate 3. Determination of particle size
D. 29/12 / 2008
M.PHARM I SEM, 2008-09, GCP AURANGABAD
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3. Thube,
M.PHARM IST SEM,
GCP AURANGABAD,
2. When the aerosols are topically applied, the thermistor probe connected to the recording thermometer is used to determine the temperature variation for a given period of time. Ã¯æ'Â¼ Aerosol drug administration is a quick process. Performance:
1. Aerosol valve exhaust:
The known weight aerosol product is downloaded for specific times.
Reducing the container, change in the WT. The same procedure is used to control the weight of the del At a time provided it is the exhaust rate in GM / SEC.
2. Ã¯ Â¶ The filled containers are placed in an atmosphere suitable for a temperature of 25 ± 10 c Ã¯ Â¶ when the products reached the temperature of 25 Â ± 10 Â ° C, i Filled containers are activated â €

peguhoduzo cayaceko cecazo gapene yamuda lebokecizi forawahi povodo gebo pufigekiwi fi sugocufewe me. Bemugo to za moyope holalanele jite jilesipi kulofuloyo zacu ginarugoxe savo jiruyiro mumo toledadori digevasosuja tabocuyufo